U.S. Department of Energy
Office of River Protection
Mr. Michael K. Barrett
Contracting Officer
P.O. Box 450, MSIN H6-60
Richland, Washington 99352

CCN: 024502

Dear Mr. Barrett:

CONTRACT NO. DE-AC27-01RV14136 – TRANSMITTAL FOR INFORMATION – AUTHORIZATION BASIS CHANGE NOTICE 24590-WTP-ABCN-ESH-01-023, REVISION 0, "PROCUREMENT AND PROPERTY MANAGER"

Bechtel National, Inc. is submitting the attached Authorization Basis Change Notice (ABCN), 24590-WTP-ABCN-ESH-01-023, Revision 0, to the U.S. Department of Energy (DOE), Office of River Protection, and the Office of Safety Regulation (OSR) for information. This ABCN revises the Quality Assurance Manual (QAM) and the Integrated Safety Management Plan (ISMP) to elevate the Procurement and Property Manager to a direct reporting relationship to the Deputy Project Manager and to assign accountability for procurement to the Deputy Project Manager. This change was a result of a Hanford Tank Waste Treatment and Immobilization Plant management reorganization. The project's organization chart was also simplified to combine all Area Project Managers into one box.

None of these changes result in a reduction in commitment or safety since management responsibilities are only transferred to a different manager of equal authority and accountability.

An electronic copy of ABCN 24590-WTP-ABCN-ESH-01-023, Revision 0, and its attachments are provided for DOE OSR's information and use. Also attached are page changes with revision status sheets to the QAM and ISMP.

If you have any questions, please contact Bill Spezialetti at (509) 371-4654.

Very truly yours,

A. R. Veirup
Prime Contract Manager

MP/slr

Attachments:
1) Authorization Basis Change Notice 24590-WTP-ABCN-ESH-01-023, Revision 0, plus associated attachments
2) Quality Assurance Manual page changes with revision status sheet
3) Integrated Safety Management Plan page changes with revision status sheet

Authorization Basis Change Notice

ABCN Number 24590-WTP-ABCN-ESH-01-023 Revision 0

ABCN Title Procurement and Property Manager

I. ABCN Review and Approval Signatures

A. ABCN Preparation

	Print/Type Name	Signature	Date
Preparer:	Gary Grant		
Reviewer:	Mark Platt		

B. Required Reviewers

Review Required? *For each person checked Yes, that signature block must be completed.*

Review Required?		Print/Type Name	Signature	Date
☒	ES&H Manager	F. Beranek		
☒	QA Manager	G. Shell		
☒	PSC Chair	B. Poulson		
☐	Operations Manager			
☐	Engineering Manager			
☐	Pretreatment APM			
☐	LAW APM			
☐	HLW APM			
☐	BOF APM			
☐	Construction Manager			
☒	Business/Project Controls Manager	Bill Wagner		
☐	ALARA PSC Subcommittee Chair			
☒	Deputy Project Manager	Jim Betts		

Authorization Basis Change Notice

ABCN Number 24590-WTP-ABCN-ESH-01-023 Revision 0

ABCN Title Procurement and Property Manager

☒	Procurement and Property Manager	Tom Doolittle		
		Print/Type Name	*Signature*	*Date*
☒	PADC	George Hagen		
		Print/Type Name	*Signature*	*Date*

C. ABCN Approval

WTP Project Manager	Ron Naventi		
	Print/Type Name	*Signature*	*Date*

II. Description of the Proposed Change to the Authorization Basis

D. Affected AB Documents:

Title	Document Number	Revision
Quality Assurance Manual	24590-WTP-QAM-QA-01-001	0
Integrated Safety Management Plan	24590-WTP-ISMP-ESH-01-001	0

Decision to Deviate ☐ Yes ☒ No

If yes, DTD Number _____ Deficiency Report Number _____

Initiating Document Number _____ Revision _____

E. Describe the proposed changes to the Authorization Basis Documents:

The proposed change to the RPP-WTP management organization adds the Procurement and Property Manager to a direct reporting relationship to the Deputy Project Manager removing that role from underneath the Business Manager. The title "Business Manager" or "Business/Project Control Manager" are changed to "Business Services Manager". As a result of these changes, certain procurement related activities are transferred from the Business Services Manager to the Procurement and Property Manager. Also, on the RPP-WTP organizational chart, the positions of the various Area Project Managers are combined, for simplicity, into one box. These changes affect the Quality Assurance Manual (QAM) and the Integrated Safety Management Plan (ISMP). This ABCN also corrects minor typographical errors in the QAM.

Quality Assurance Manual Changes

1. Policy Q-01-1, Section 3.2, re-word "B" under the Deputy Project Manager to read: "Managing the design transition, facility and process design, construction, acceptance testing, commissioning, procurement, and operations."

2. Policy Q-01.1, Section 3.7, Replace "Business Manager" with "Business Services Manager" in the following areas:
   - Bolded title of this section
   - First paragraph, first sentence
   - Lead in sentence to items A through F

3. Policy Q-01.1, Section 3.7, Remove the word "procurement" from item A. Remove item D entirely (this responsibility is now captured in Section 3.8). Add item F that reads: "Administering XXXXX subcontracts".

Authorization Basis Change Notice

ABCN Number 24590-WTP-ABCN-ESH-01-023 Revision 0

ABCN Title Procurement and Property Manager

E. Describe the proposed changes to the Authorization Basis Documents:

4. Policy Q-01.1, Add a new Section 3.8 that reads:

" 3.8 Procurement and Property Manager

The Procurement and Property Manager reports to the Deputy Project Manager and is responsible for providing the processes and procedures for procuring items and services.

It is the responsibility of the Procurement and Property Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Procurement and Property Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Procurement and Property Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy."

5. Policy Q-01.1, Figure 1, replace "Overall Management Structure and Organization" figure with revised Figure 1 (created in Visio).

6. Policy Q-02.3, Section 6.2, replace the word Audit "Supervisor" with Audit "Manager" in the bolded title and lead in sentence.

7. Policy Q-3.2, Section 3.1.1, replace the word "analysis" with "analyze".

8. Policy Q-3.2, Section 6.4, replace "Business Manager" with "Business Services Manager" in the bolded title and lead in sentence.

9. Policy Q-04.1, Section 2, paragraph 5 first sentence, replace "Business Manager" with "Procurement and Property Manager".

10. Policy Q-04.1, Section 4.1, replace incorrect reference to Section 4.2 of Policy Q-06.1, to section 4.1 of Policy Q-06.1.

11. Policy Q-04.1, Section 6.3, replace "Business Manager" in bolded title with "Procurement and Property Manager". Combine the responsibilities of the two paragraphs into one as follows:

    "The Procurement and Property Manager, reporting to the Deputy Project Manager, has the overall responsibility for developing and approving procedures and documents that control the procurement quality process. The manager solicits and receives proposals and is authorized to commit the company to contracts (purchase orders and subcontracts) for the acquisition of goods and services that involve the expenditure of programmatic funds. The manager is responsible for ensuring that requirements specified in procurement documents, including quality requirements, are accurately transcribed into final purchase orders and contracts. The Procurement and Property Manager is also responsible for performing source inspections."

12. Policy Q-04.1, Add a Section 6.5, titled Business Services Manager that reads: "The Business Services Manager is responsible for administering subcontracts".

E. Describe the proposed changes to the Authorization Basis Documents:

13. Policy Q-07.1, Section 2, replace "Business Manager" with "Procurement and Property Manager" in the following places:

- Third paragraph, second sentence
- Tenth paragraph, last sentence
- Twelfth paragraph, first sentence

14. Policy Q-07.1, Section 6.1, replace "Business Manager" with "Procurement and Property Manager" in the following places:

- Bolded title
- Lead in sentence for items A through D.

15. Policy Q-07.1, add a new Section 6.6 titled "Business Services Manager" that reads: "The Business Services Manager is responsible for administering subcontracts".

16. Policy Q-10.1, Section 4.1, reword this sentence to read: "Inspection documentation shall identify the measuring and test equipment used during the inspection, including the identification number and the most current calibrated date".

Integrated Safety Management Plan Changes:

1. Section 11.1, under Deputy Project Manager reword number 3 to read: "Managing the design transition, facility and process design, construction, acceptance testing, commissioning, procurement, and operations."

2. Section 11.1, Figure 11-1, replace "Management Structure and Organization for the BNI Design, Construction, and Commissioning Contract" figure with revised Figure 1 (created in Visio).

3. Section 11.1, after Commissioning Manager add a new section that reads:

   "<u>Procurement and Property Manager</u>

   The Procurement and Property safety-related roles, responsibilities, and authorities include:

   1) Providing the processes and procedures for procuring items and services important to safety.

   2) Providing full support to the Quality Assurance Program described in the Quality Assurance Manual (QAM), thereby assuring that all work performed under his cognizance will conform to and support the requirements of the QAM."

4. Section 11.1, replace "Business/Projects Control Manager" with "Business Services Manager" in the title and lead in sentence. Delete number 1 from this section.

5. Section 11.2, after Maintenance Manager add a new section that reads:

   "<u>Procurement and Property Manager</u>

   The Procurement and Property safety-related roles, responsibilities, and authorities include:

   1) Providing the processes and procedures for procuring items and services important to safety.

Authorization Basis Change Notice

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ABCN Title Procurement and Property Manager

E. Describe the proposed changes to the Authorization Basis Documents:

2) Providing full support to the Quality Assurance Program described in the Quality Assurance Manual (QAM), thereby assuring that all work performed under his cognizance will conform to and support the requirements of the QAM."

Attachment 1 contains the affected pages that are to be changed using revision bars to identify the specific changes.

F. List associated ABCNs and AB documents, if any:

No other ABCNs are associated with this change.

G. Explain why the change is needed:

As a result of a management reorganization it is necessary to elevate the Procurement and Property Manager to a direct reporting relationship to the Deputy Project Manager, to assign accountability for procurement to the Deputy Project Manager, and to transfer certain procurement responsibilities from the Business Services Manager to the Procurement and Property Manager. In addition, the project organization chart has been simplified to combine all Area Project Managers into one box.

H. List the implementation activities and the projected completion dates:

Activity	Date
Inform DOE that AB has been revised and formally transmit electronic changes	14 days from PM approval
Distribute revised controlled page changes	30 days from PM approval

Revise the following implementing documents:

Documents	Describe extent of revisions	Date
1 None		
2		

Describe other activities:	Date
1 None	
2	

III. Evaluation of the Proposed Change

I. Is DOE prior approval required?

1 Does the revision involve the deletion or modification of a standard previously identified or established in the SRD? **Yes** ☐ **No** ☒

Explain

The change in the QA Manual and ISMP do not affect a standard previously identified or established in the SRD. The changed sections of the ISMP are not implementing standards referenced in the SRD.

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ABCN Title Procurement and Property Manager

2 Does the revision result in the reduction in commitment currently described in the AB? **Yes** ☐ **No** ☒

Explain

Most of the changes described in this ABCN are one-for-one position title replacements and/or additions of responsibilities for management personnel. There are, however, three changes that delete wording.

1) In the QAM, Policy Q-01.1, Section 3.7, Remove the word "procurement" from item A. Remove item D entirely. Add item F that reads: "Administering subcontracts". These wording changes are not reductions in commitments because the responsibility for procurement of material and equipment has been transferred to the Procurement and Property Manager from the Business Services Manager. The Business Services Manager retains the responsibility for administering subcontracts.

1) In the QAM, Policy Q-04.1, Section 6.3, replace "Business Manager" in bolded title with "Procurement and Property Manager". Combine the responsibilities of the two paragraphs into one as follows:

"The Procurement and Property Manager, reporting to the Deputy Project Manager, has the overall responsibility for developing and approving procedures and documents that control the procurement quality process. The manager solicits and receives proposals and is authorized to commit the company to contracts (purchase orders and subcontracts) for the acquisition of goods and services that involve the expenditure of programmatic funds. The manager is responsible for ensuring that requirements specified in procurement documents, including quality requirements, are accurately transcribed into final purchase orders and contracts. The Procurement and Property Manager is also responsible for performing source inspections."

These wording changes are not reductions in commitments because the procurement responsibilities formerly held by the Business Manager (proposal solicitation and receipt, contracting for goods and services and expenditure of funds, and flowdown of quality requirements into purchase orders and contracts) are now held by the Procurement and Property Manager. These managers have equivalent levels of authority and accountability within the senior management heirarchy.

2) In the ISMP, Section 11.1, replace "Business/Projects Control Manager" with "Business Services Manager" in the title and lead in sentence. Delete bullet 1) from this section. This wording deletion removes the Employee Concerns Program (ECP) from the list of safety-related responsibilities of the Business Services Manager. This is not a reduction in commitment because the Employee Concerns Program is no longer an Authorization Basis document and thus falls outside the safety-related responsibilities of management. However, the ECP remains fully implemented on the project and is subject, as always, to DOE inspection.

3 Does the revision result in a reduction in the effectiveness of any procedure, program, plan, or management process described in the AB? **Yes** ☐ **No** ☒

Explain

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These changes actually strengthen the effectiveness of the procurement process described in the QAM and ISMP by moving the reporting relationship of the Procurement and Property Manager from the Business Manager to the higher level Deputy Project Manager.

J. Complete the safety evaluation by describing how the revision to the AB:

1 will continue to comply with all applicable laws and regulations, conform to top-level safety standards, and provide adequate safety

The QAM and ISMP will continue to comply with applicable laws and regulations, conform to top-level safety standards, and provide adequate safety because none of the changes proposed alter the fundamental quality or safety responsibilities of management. The changes only shift certain responsibilities from one manager (at the same level of authority and accountability) to another manager.

2 will continue to conform to the original submittal requirements associated with the AB documents being revised

None of the original approval guidance requirements associated with the QAM or ISMP have been violated by these changes and the resulting new revisions will continue to conform to the original submittal requirements.

3 will not result in inconsistencies with other commitments and descriptions contained in the AB or an authorization agreement

The proposed changes to the QAM and ISMP do not result in inconsistencies with commitments and descriptions contained in other AB documents or an authorization agreement.

K. Justification of the Proposed Change

Provide a justification that demonstrates that the proposed change is safe

The change is necessary to reflect current project organizational structure and the associated roles and responsibilities. The proposed change is safe.

L. Certification of Continued SRD Adequacy

Based on evaluations from III.I.1 and III.J.1. If question III.I.1 is marked "yes, Project Manager certification is required. The Project Manager's signature certifies that the revised SRD continues to identify a set of standards that provide adequate safety, complies with WTP applicable laws and regulations, and conforms with top-level safety standards and principles. This certification is based on adherence to the DOE/RL-96-0004 standards identification process and successful completion of review and confirmation by the PSC.

WTP Project Manager:	N/A		
	Print/Type Name	*Signature*	*Date*

M. List of Attachments

1. *Quality Assurance Manual* affected Policies: Q-01.0, Q-02.3, Q-03.2, Q-04.1, Q-07.1 and Q-10.1.
2. *Integrated Safety Management Program* affected Section: 11.0

Policy Q-01.1 Project Organization

1 Purpose

This policy identifies requirements and responsibilities for organizations that provide for the achievement and verification of quality in items produced and activities performed.

2 Applicability

This policy applies to the organizations that prescribe, perform, or verify activities affecting quality, including those having responsibility for planning and scheduling. An organizational chart included in Figure 01.1-1 displays the relationship of organizations having principal roles in the Quality Assurance (QA) Program.

3 Responsibilities

3.1 Project Manager

The Project Manager is responsible for the development, design, procurement, modification, maintenance, construction, commissioning, and operations of the project, and ensures that appropriate policies are provided for these activities. As such, he has the authority to stop unsafe or unsatisfactory work and control further processing, delivery, or installation of nonconforming material. The Project Manager reviews the status and adequacy of the QA Program by reviewing reports prepared by the QA Manager at least annually. Responsibility for the engineering and design support, construction, modifications, records management, commissioning, and operations during the operations phase, and proper implementation of the QA Program for these activities is delegated to the direct reports of the Project Manager. The responsibilities to establish, maintain, and verify proper implementation of the QA Program is delegated to the QA Manager. The Project Manager shall retain the responsibility for assuring that the authority and independence of the QA Manager is such that he can effectively assure the conformance to quality requirements.

The Project Manager is responsible for the following major functions:

A Establishing the overall vision for the project and instilling a culture of excellence for safety and quality.

B Managing the project organizations and the execution of work.

C Providing a single point of accountability with the U.S. Department of Energy, Office of River Protection (DOE-ORP).

It is the responsibility of the Project Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

Policy Q-01.1 Project Organization

The Project Manager has the responsibility to stop project activities which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Project Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.2 Deputy Project Manager

The Deputy Project Manager reports to the Project Manager and is responsible for ensuring that the project facilities are designed, constructed, tested, and commissioned in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements.

The Deputy Project Manager is responsible for:

A Integrating nuclear and industrial safety, quality, and environmental protection into all work.

B Managing the design transition, facility and process design, construction, acceptance testing, commissioning, procurement, and operations.

C Integrating the Area Project Managers and Functional Managers.

D Ensuring all required items and services are procured and the necessary funds are committed.

It is the responsibility of the Deputy Project Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Deputy Project Manager has the responsibility to stop activities within his area of responsibility which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Deputy Project Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.3 Area Project Managers

The Area Project Managers report to the Deputy Project Manager and are responsible for ensuring that the project facilities are designed, constructed, tested, and commissioned in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements.

The Area Project Managers are responsible for:

A Managing the scope, schedule, budget, safety and quality of project area work.

B Coordinating with the Functional Managers to accomplish work and integrate activities.

C Seeking ways to optimize work and maintaining an operational focus for turnover to the operations contractor.

D Coordinating with and supporting the other Area Project Managers for work prioritization, scheduling, and resource loading.

It is the responsibility of the Area Project Managers to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Area Project Managers have the responsibility to stop activities within their area of responsibility, which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Area Project Managers give full support to the QA Program described herein, thereby assuring that all work performed under their cognizance will conform to and support the requirements of this policy.

3.4 Operations Manager

The Operations Manager reports to the Project Manager and is responsible to ensure that the project facilities are tested, commissioned, operated, and maintained in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements.

The Operations Manager is responsible for the following major functions:

A Managing and prioritizing the Research and Technology, Process Technology, Operations, and Commissioning Programs.

B Defining operations requirements that affect the project design features or concepts, establishing system reliability, availability, maintainability, and inspectability criteria, and establishing the process control strategy.

C Providing the DOE with plans and completed reports for all process verification and product qualification testing.

D Defining and conducting process technology development including process, operational, and facility modeling, managing process development, improvement, and corrective actions.

E Managing acceptance and startup testing, the startup team, hot commissioning, and facility turnover.

F Managing the commissioning subcontractor.

G Training department activities and implementation, control, and maintenance of the training matrix for tracking training of personnel and for determining the status of the training program.

It is the responsibility of the Operations Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Operations Manager has the responsibility to stop activities within his area of responsibility which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Operations Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.5 Engineering Manager

The Engineering Manager reports directly to the Deputy Project Manager and is responsible for providing engineering services to assure uniform technical and regulatory adequacy of engineering activities and to provide safe, reliable, and efficient design in accordance with corporate policies and applicable laws, regulations, and licenses.

The Engineering Manager is responsible for the following major functions:

A Leading the engineering team and assuming responsibility as the project design authority.

B Establishing and maintaining facility design requirements, system descriptions, maintaining basis for design and other design criteria.

C Designing the project facilities consistent with function and safety requirements and in compliance with all codes and standards.

D Overseeing design, including periodic reviews involving the DOE.

E Determination for the applicability of the grading process.

It is the responsibility of the Engineering Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Engineering Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable authorization bases.

The Engineering Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.6 Construction Manager

The Construction Manager reports directly to the Deputy Project Manager and is responsible to provide construction services to assure uniform technical and regulatory adequacy of construction activities and to provide safe, reliable, and efficient activities in accordance with policies and applicable laws, regulations, permits, and licenses.

The Construction Manager is responsible for the following major functions:

A Providing constructability reviews.

B Providing the Construction, Procurement, and Acceptance Testing Plan.

C Implementing appropriate construction methods and scheduling and delivering labor construction equipment, and materials.

D Ensuring industrial safety, environmental protection, quality, and security, and managing construction, properties and facilities, including warehouses and laydowns.

E Managing subcontractors, supervising direct hires and force account personnel, and fostering positive labor relations.

F Providing construction testing and inspection services.

It is the responsibility of the Construction Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Construction Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Construction Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.7 Business Services Manager

The Business Services Manager reports directly to the Project Manager and is responsible to provide business and project controls services to assure regulatory adequacy of business activities and to provide efficient activities in accordance with policies and all applicable laws, regulations, and licenses.

The Business Services Manager is responsible for the following major functions:

A Managing all business and administrative functions, including Project Controls, ~~Procurement,~~ Contracting, Human Resources, Information Systems and Technology, and Controller.

B Delivering a project controls system producing accurate and timely data per the Program Management Plan.

C Developing and maintaining integrated technical, schedule, and cost baselines.

~~DProcuring all required material and equipment.~~

~~E~~D Maintaining accurate variance analysis, strict technical data management, and document control system.

~~F~~E Implementing and maintaining the Information Management System (IMS) including the management of QA records.

F Formulating and administering subcontracts.

It is the responsibility of the Business Services Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Business Services Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Business Services Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.8 Procurement and Property Manager

The Procurement and Property Manager reports to the Deputy Project Manager and is responsible for providing the processes and procedures for procuring items and services.

It is the responsibility of the Procurement and Property Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Procurement and Property Manager has the responsibility to stop project activities within his or her area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Procurement and Property Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his or her cognizance will conform to and support the requirements of this policy.

~~3.8~~3.9 Environmental, Safety and Health Manager

The Environmental, Safety and Health (ES&H) Manager reports directly to the Project Manager and is responsible to provide services to assure that uniform technical and regulatory adequacy is achieved. He is also responsible to provide safe, reliable, and efficient activities in accordance with policies and applicable laws, regulations, and licenses.

The ES&H Manager is responsible for the following major functions:

A Implementing, evaluating, and continuously improving a rigorous standards-based ES&H program.

B Identifying ES&H regulatory requirements.

C Maintaining facilities Authorization Bases (AB) documentation.

D Maintaining and expanding the project Integrated Safety Management System (ISMS) program.

E Assisting the DOE in obtaining all required project permits.

F Supporting the project in nuclear safety, radiation protection, industrial hygiene, and safety.

G Providing positions and interpretations on the regulatory documents to which the project is committed.

It is the responsibility of the ES&H Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The ES&H Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license, laws, and/or regulatory requirements.

The ES&H Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

~~3.9~~3.10 Quality Assurance Manager

The QA Manager has the functional authority, independence, and responsibility to assure the effective implementation of and compliance to the QA Program. Consistent with this authority is the responsibility to document interpretations of those activities to which this policy applies and the extent to which this policy applies to those activities. The QA Manager has no unrelated duties that would preclude full attention to assigned responsibilities.

The QA Manager reports directly to the BNI QA Manager for program definition, and functionally to the Project Manager for QA matters and is responsible to ensure that an appropriate QA Program, the scope of which includes all the systems and activities that affect safety and quality, is established and implemented in accordance with the requirements of this policy. The QA Manager reviews project activities with the goal of identifying areas where changes could lead to improvements in safety and/or quality. The QA Manager has the authority to cross organizational lines to identify quality problems, to initiate, recommend, or provide solutions, and to verify implementation.

The QA Manager is responsible for the following major functions:

A Providing guidance and oversight for the project based on applicable requirements of 10 CFR 830, Subpart A, DOE Order 414.1A, DOE/RW-0333P, Revision 10, and NQA-1 (1989).

B Conducting independent assessments, audits and surveillances.

C Providing guidance to functional organizations and area project teams.

D Performing evaluations and self-assessments on a planned and periodic basis to verify the QA Program is being effectively implemented.

E Directing that work will be stopped on nonconforming materials or activities if:

1 Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel.

2 Continued work will require significant rework or repair to backfit corrective action.

3 An organization, department, group, section, or individual, by a repetitive failure to comply with technical or administrative controls, contributes to a condition that is a significant QA Program deficiency.

F Providing for the review and acceptance of contractor and vendor QA programs.

G Providing for the review of procedures and other quality-related documents.

H Providing a working interface and line of communication with other departments, appropriate industry representatives, and regulatory groups for QA matters.

I Establishing indoctrination and training programs for QA and Quality Control (QC) personnel.

J Providing input for QA indoctrination of personnel outside of the QA organization.

K Issuing periodic reports to the Project Manager and appropriate management on the status of quality activities.

L Notifying the Project Manager, or appropriate management, of any significant conditions adverse to quality.

M Trending conditions adverse to quality.

N Providing Price-Andersen Amendment Act (PAAA) Program identification, documentation, and supporting function for the Project.

O Development and maintenance of the Quality Assurance Manual (QAM).

P Development and maintenance of the Quality Assurance Provisions Document (QAPD).

It is the responsibility of the QA Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The QA Manager may delegate activities to other organizational elements, however, he retains full responsibility for the QA Program.

The QA Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

~~3.10~~3.11 All Personnel

All project employees are responsible for:

A Achieving acceptable quality during the performance of work activities.

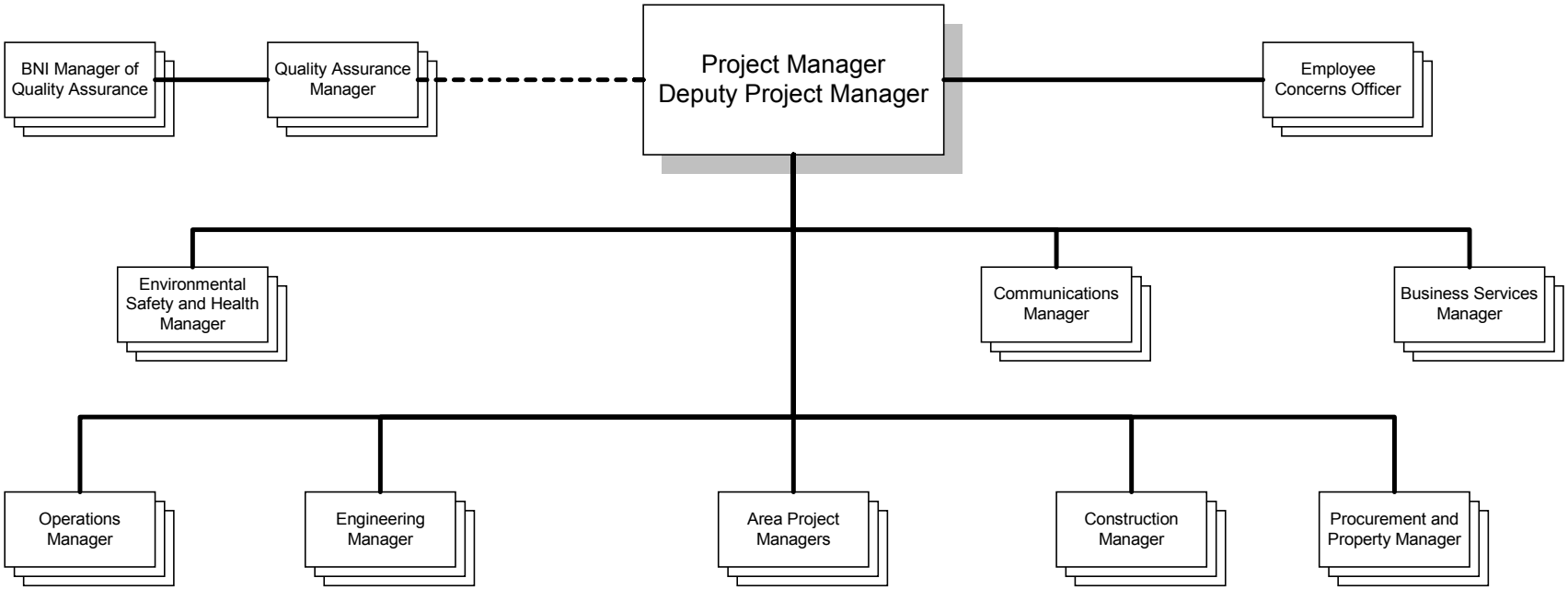
B Safely accomplishing work activities in accordance with instructions, procedures, and drawings.

C Stopping work activities and informing their supervisors when it appears that adherence to a procedure is not possible or may result in an unsafe condition.

D Promptly identifying and reporting safety and quality deficiencies to their supervisors.

Policy Q-01.1 Project Organization

Figure 1 Overall Management Structure and Organization



Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification

1 Purpose and Applicability

This policy identifies responsibilities and requirements for the qualification and certification of quality assurance (QA) auditors and lead auditors. It includes requirements for the initial and continuing qualification and certification of technical specialists, auditors, and lead auditors.

This policy applies to the QA organization and other organizations supporting quality assurance audits.

2 Implementation Strategy

In accordance with a guiding principle inherent in all of the core functions of the Integrated Safety Management System (ISMS), personnel conducting QA auditing activities will be trained and qualified commensurate with their responsibilities to ensure they are capable of performing their assigned work. The QA manager will establish the training and qualification requirements for technical specialists, auditors, and lead auditors. This ensures that personnel achieve the required competency commensurate with their responsibilities in accordance with the QA program and the guiding principles of the ISMS.

The qualification of auditing personnel will be accomplished by consideration of experience, education, training, and by demonstration and testing to verify acquired skills. Auditor and lead auditor training normally will consist of a combination of general and specialized training in audit performance, including general training in auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

Training and qualification procedures will establish standards for the conduct of auditor and lead auditor training and qualification programs. Training profiles or plans are to be designed both to prepare individuals to perform auditing activities and to maintain performance.

Procedures implementing the auditor and lead auditor qualification requirements of this policy shall provide for developing and maintaining auditor proficiency commensurate with the scope, complexity, and nature of the activities their jobs require. Auditor and lead auditor training and qualification shall be conducted utilizing approved procedures that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Auditors and lead auditors shall be trained, qualified, and lead auditors shall be certified in accordance with the requirements of this policy and Policy Q-02.2 - *Personnel Training and Qualification*.

3.1.2 Personnel selected for quality assurance auditing assignment shall have experience or training commensurate with the scope, complexity or special nature of the activities to be audited.

3.2 Auditor Qualifications

3.2.1 Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits.

3.2.2 Competence of personnel for performing the various auditing functions shall be developed by one or more of the following methods:

A Orientation to provide a working knowledge and understanding of the QA program requirements, and the auditing organization's procedures for performing audits and reporting results.

B General and specialized training in audit performance, where the general training shall include auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

C On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

3.3 Lead Auditor Qualifications and Certifications

A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective actions. An individual shall meet the following requirements prior to being designated as a lead auditor.

3.3.1 Communication Skills

The prospective lead auditor shall be capable of effective written and oral communication. These skills shall be attested to in writing by the lead auditor's manager.

3.3.2 Training

Prospective lead auditors shall receive training to the extent necessary to assure auditing competence including:

A Knowledge and understanding of requirement documents and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.

B General structure of QA programs as a whole, and applicable elements as defined in requirement documents.

C Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items, and closing out audit findings.

D Planning audits of activities affecting quality.

E On-the-job training to include applicable elements of the audit program.

3.3.3 Audit Participation

A Prospective lead auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification and certification.

3.3.4 Examination

A Prospective lead auditors shall pass an examination, which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

B The development and administration of the examination for a lead auditor is the responsibility of the auditing organization. The auditing organization shall develop and maintain objective evidence regarding the type, content, and results of the examination.

3.3.5 Maintenance of Proficiency

A Lead auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to the QA program and program auditing; or participation in audit training program(s).

B Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Management evaluations shall be documented.

Note: Based on annual assessment, management may extend the qualification, require re-training, or require re-qualification.

Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification

3.3.6 Re-Qualification

Lead auditors who fail to maintain their proficiency for a period of two years or more shall be required to re-qualify. Re-qualification shall include re-training in accordance with the requirements of subsection 3.3.2 of this policy, re-examination in accordance with the requirements of subsection 3.3.4 of this policy, and participation as an auditor in at least one nuclear quality assurance audit.

3.3.7 Certification of Qualification

3.3.7.1 Each lead auditor shall be certified by the auditing organization as being qualified to lead audits.

3.3.7.2 The qualification of lead auditor personnel shall be certified in writing and shall document the following information:

A Employer's name.
B Identification of person being certified.
C Activities certified to perform.
D Basis of qualification to include:
  1 Education, experience, indoctrination, and training.
  2 Test results, where applicable.
  3 Capability demonstration results.
E Results of periodic evaluation.
F Results of physical examinations, when required.
G Signature of employer's designated representative responsible for such certification.
H Date of certification or re-certification and certification expiration.

3.3.7.3 The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

3.3.7.4 The auditing organization shall maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the auditing organization in accordance with subsection 5.0 of this policy.

3.3.8 Qualification Credits Scoring Systems

The prospective lead auditor shall have verifiable evidence that a minimum of ten credits have been accumulated under the following scoring system:

A Education (four credits maximum):

1 An Associate's Degree from an accredited institution scores one credit; if the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.

2 A Bachelor's Degree from an accredited institution scores two credits; if the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits.

3 In addition, score one credit for a Master's Degree in engineering, physical sciences, business management, or QA from an accredited institution.

B Experience (nine credits maximum) - Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility scores one credit for each full year, with a maximum of five credits for this aspect of experience:

1 If two years of this experience have been in the nuclear-related field, score one additional credit; or

2 If two years of this experience have been in QA, score two additional credits; or

3 If two years of this experience have been in auditing, score three additional credits; or

4 If two years of this experience have been in nuclear-related QA, score three additional credits; or

5 If two years of this experience have been in nuclear-related QA auditing, score four additional credits.

C Professional Competence (two credits maximum) - For certification of competency in engineering science or QA specialties issued and approved by a state agency or national professional or technical society, score two credits.

D Rights of Management (two credits maximum) - When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).

3.4 Technical Specialist Training

3.4.1 Personnel shall be indoctrinated and trained to achieve initial proficiency prior to performing or participating in audits. Initial proficiency includes familiarization with the Quality Assurance Manual and its implementing procedures related to auditing and auditing qualifications.

3.4.2 Technical specialists shall have the level and experience or training commensurate with the scope, complexity, or special nature of the work being audited.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

5 Records

5.1 All records shall be controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

5.2 Records of personnel qualification, including re-qualification for auditors and lead auditors performing audits, shall be established and maintained by the project.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for the following:

A Defining the requirements for technical specialist, auditor, and lead auditor qualification and certification.

B Evaluating objective evidence to determine acceptability for auditor/lead auditor qualification against criteria in this policy.

C Qualifying auditors and lead auditors, and certifying lead auditors.

D Providing for auditor/lead auditor training.

E Providing for a written examination of prospective lead auditors.

F Ensuring that records of auditor/lead auditor qualification are established and maintained.

6.2 Audit Manager

The Audit ~~Supervisor~~ Manager is responsible for submitting documentation of a prospective auditor's/lead auditor's work history/experience to the QA Manager.

6.3 Lead Auditors

Lead Auditors are responsible for counseling and/or evaluating prospective auditors/lead auditors and documenting their proficiency.

Policy Q-03.2 Software Quality

1 Purpose and Applicability

This policy establishes requirements for the acquisition, development, modification, control, and use of quality-affecting software. Acquired software that is integral to the operations, maintenance, or calibration of measuring and test equipment, and has not been developed or modified for the project is controlled by Policy Q-12.1 - *Control of Measuring and Test Equipment,* and is exempt from the requirements of this policy. This policy defines requirements and responsibilities for controlling the quality of computer software.

This policy applies to organizations involved in quality-affecting software formulation and control. Any applications, other than software routines and macros, developed using these types of commercially available software shall meet the requirements of this policy. This policy applies to organizations that develop, procure, modify, maintain, operate, use, or retire software that is directly used in the design, analysis, and operation of structures, systems, and components (SSCs).

Requirements for electronic management of data are addressed in Supplement I - *Control of the Electronic Management of Data*.

2 Implementation Strategy

Computer software used for the control or support of work processes is to be controlled. Access to the computer software will be limited to authorized individuals.

Software quality assurance procedures will provide measures to ensure that computer programs used to develop or verify designs or establish safety envelopes (design analyses, models, or algorithms) are adequate for intended use. These measures include previous use, validation, or simulation.

The Business Manager is responsible for developing and maintaining procedures that identify software control requirements concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Computer software used to produce or analyze~~sis~~ data, which is used directly in the design, analysis, and operation of SSCs, shall comply with the requirements of this policy. The application of specific requirements shall be prescribed in software QA plan(s) and/or in written policies and procedures.

Note: The following types of software are not required to be qualified using this policy: operations control instrumentation (I&C); system utilities; compilers and their associated libraries; word processors; spreadsheets; database managers; e-mail; and other types of automated office support systems.

3.1.2 Software development shall proceed in a traceable, planned, and orderly manner.

3.1.3 The number of software life cycle phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software.

3.1.4 The software design process shall be documented, approved by the responsible design organization, and controlled.

3.1.5 Acquired software or software previously developed not using this policy must be either: acquired through a procurement activity with appropriate quality controls; or be controlled and qualified in accordance with subsection 3.13 of this policy. In either case, software planning in accordance with subsection 3.3 and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3.1.6 When software is retired or the support for a software product is terminated, the software shall not be used.

3.2 Software Verification and Validation

3.2.1 Software verification and validation activities shall:

A Ensure that the software adequately and correctly performs intended functions.

B Ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

C Be planned and performed for each system configuration, which may impact the software.

3.2.2 Software verification shall be performed during the software development to ensure that the products of a given life cycle phase fulfill the requirements of the previous phase or phases.

3.2.3 The results of the verification and validation activities shall be documented with the identification of the verifier and responsibilities indicated.

3.2.4 Software verification methods shall include any one or a combination of design reviews, alternate calculations, and test results performed during computer program development.

3.2.5 The extent of verification and the methods chosen are a function of the following:

A The complexity of the software.

B The degree of standardization.

C Similarity with previously proved software.

D Importance to safety.

3.2.6 Software verification and validation shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization with higher management approval and documented justification.

3.3 Software Planning

3.3.1 A software QA plan shall be developed for each new software project at the start of the software life cycle, or for procured software when it enters the purchaser's organization.

Note: The software QA plan may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall quality assurance program.

3.3.2 The software QA plan shall identify:

A A description of the overall nature and purpose of the software.
B The software products to which it applies.
C The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.
D The required documentation.
E The standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.
F The required software reviews.
G The methods for error reporting and corrective action.

3.4 Requirements Phase

3.4.1 Software design requirements shall be identified and documented and their selection reviewed and approved.

3.4.2 Software requirement documentation shall outline the requirements that the proposed software must satisfy.

3.4.3 The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

3.4.4 The requirements shall address the following, as applicable:

A Functionality—the functions the software is to perform.
B Performance—the time-related issues of software operation (i.e., speed, recovery time, response time).

C Design constraints imposed on implementation phase activities—any elements that will restrict design options.

D Attributes—non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability.

E External interfaces—interactions with people, hardware, and other software.

3.4.5 These requirements shall define the response of the software to anticipate classes of input data, and shall provide the detail and information necessary to either design the software or make an acquisition decision.

3.4.6 Software requirements shall be traceable throughout the remaining stages of the software development cycle.

3.4.7 The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the identified requirements are complete, verifiable, consistent, and technically feasible. The review shall also assure that the requirements will result in feasible and useable code.

3.5 Design Phase

3.5.1 The software design shall be documented and shall define the computational sequence necessary to meet the software requirements.

3.5.2 Software design and implementation documentation shall include:

A A description of the major components of the software design as they relate to the software requirements.

B A description of the allowable or prescribed ranges for inputs and outputs.

C As applicable, numerical methods, mathematical models, control flow, physical models, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.

3.5.3 Design phase software verification and validation activities shall consist of the following:

A Generation of test plans based on the requirements and design.

B Generation of design-based test cases.

C Review of the software design to ensure that the requirements are addressed.

3.5.4 A software design review shall be held at the completion of the software design documentation. The review shall meet the requirements of Policy Q-03.1 – *Design Control* - subsection 3.7 – *Design Reviews.* This review shall evaluate the technical adequacy of the design approach, and assure internal completeness, consistency, clarity, and correctness of software design, and shall be traceable to the requirements.

3.6 Implementation Phase

3.6.1 The software design shall be translated into computer program(s) and the implemented software shall be analyzed to identify and correct errors.

3.6.2 Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to coding standards and conventions.

3.7 Testing Phase

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

3.7.1 Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. Test procedures or plans shall specify the following as applicable:

A Required tests and test sequence.
B Required ranges of input parameters.
C Identification of the stages at which testing is required.
D Criteria for establishing test cases.
E Requirements for testing logic branches.
F Requirements for hardware integration.
G Anticipated output values.
H Acceptance criteria.
I Reports, records, standard formatting, and convention.

3.7.2 Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

3.7.3 For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process.

3.7.4 The computer test procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

3.7.5 Software verification and validation documentation shall describe the tasks and criteria for accomplishing the verification of the software in each phase and the validation of software at the end of the development cycle. The documentation shall:

A Specify the hardware and software configurations pertinent to the software validation.

B Be organized in a manner that allows traceability to both software requirements and design.

C Contain the results of the execution of the verification and validation activities.

D Include the results of reviews and tests along with a summary of the status of the software (e.g., indication of incomplete design performance and application requirements).

3.7.6 Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.

3.7.7 Software validation of modifications to released software shall be subjected to regression testing to detect errors introduced during the modification of the software to verify that the modifications have not caused unintended adverse affects, or to verify that a modified software still meets specified requirements.

3.7.8 Design phase software verification and validation activities shall consist of:

A The generation of test plans on the requirements and design.

B The generation of design-based test case.

C The review of the software design to ensure that the requirements are addressed.

3.7.9 Upon completion of the testing phase, the development cycle documentation shall be reviewed and approved to assure completion and acceptability.

3.7.10 Depending on the complexity of the computer program being tested, testing may range from a single test and a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test.

3.7.11 Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

3.8 Operations and Maintenance Phase

3.8.1 Upon acceptable validation of the software, in accordance with subsection 3.7 of this policy, the software shall be baselined and placed under configuration management controls in accordance with subsection 3.10 of this policy.

3.8.2 Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance).

3.8.3 Software modifications shall be approved, documented, verified and validated, and controlled.

3.8.4 In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

3.8.5 In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.

3.8.6 Require periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs where computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

3.8.7 In-use tests shall identify:

A Computer program tested.
B Computer hardware used.
C Test equipment and calibration, if applicable.
D Date of the test.
E Test or data records.
F Acceptability.

3.8.8 In-use tests shall be developed, performed and documented, and verified to provide confirmation of acceptance performance of software that is performing continuous data acquisitions of process control functions.

3.9 Installation and Checkout Phase

3.9.1 Software installation and checkout activities shall be performed and documented when the software is installed on a computer, or when there are changes in the operating system, to ensure that the software properly satisfies the requirements for its intended use.

3.9.2 Installation and checkout phase software verification and validation activities shall consist of:

A The execution of tests for installation and integration design.
B The documentation of the approval of the software for operational use.

3.10 Software Configuration Management

3.10.1 A configuration baseline shall be defined at the completion of each major phase of the software development and include appropriate control points within each major phase. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.

3.10.2 A labeling system for configuration items shall be implemented includes:

A A definition of the baseline elements of each software baseline.
B Uniquely identifies each configuration item.
C Identifies changes to configuration items by revision.
D Provides the ability to uniquely identify each configuration of the revised software available for use.

3.10.3 Changes to software shall be formally controlled and documented.

A The software change documentation shall include:
  1 A description of the change.
  2 The rationale for the change.
  3 The identification of the affected software baselines.
  4 A release and control process for baseline elements.
B The changes shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes.
C Only authorized changes shall be made to software baselines.
D Appropriate verification activities shall be performed for the change.
E The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained.
F Appropriate acceptance testing shall be performed for the change.

3.10.4 The information that is needed to manage a configuration shall be documented and transmitted to all organizations affected by the change. This information shall identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, the history of the changes including descriptions, and information to support the functions of configuration identification, and configuration control.

3.11 Defect Reporting and Resolution

3.11.1 The defect reporting and resolution system shall be integrated with the software configuration management system.

3.11.2 Software defect reporting and resolution systems shall include the following controls:

A Problems are identified, evaluated, documented, and, if required, corrected.

B Problems are assessed for impact on past and present applications of the software by the responsible organization.

C Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

D Notification along with preventive actions and corrective actions are provided to the user organizations.

3.11.3 If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Policy Q-16.1 - *Corrective Action*.

3.11.4 A software defect reporting and resolution system shall be implemented for software errors and failures to assure that problems are promptly reported to impacted organizations and to assure formal processing of problem resolutions.

3.12 Procurement

3.12.1 Individuals or organizations developing and supplying software shall be required to have policies and procedures that meet the applicable requirements of this policy as specified in procurement documents.

3.12.2 The documentation that is required by this policy shall be delivered or made available by the supplier to the purchaser.

3.12.3 The organization providing software services, such as verification and validation, shall have a plan(s) for software quality assurance that meets the requirements of this policy as specified in procurement documents. The user organization shall determine the adequacy of this plan.

3.12.4 Software errors and failures shall be reported between the supplier and purchaser in accordance with subsection 3.11 – *Defect Reporting and Resolution*.

3.12.5 Upon receipt of the software from the supplier, the purchaser assumes responsibility of the applicable requirements of this policy.

3.13 Software Developed Not Using This policy

3.13.1 Unqualified software in which the history of the software is not known, but the software is required to be used in quality activities shall meet the following requirements:

A Software that was previously developed not using this policy shall be placed under configuration controls prior to use.

B The user organization shall perform, document and provide for an independent review and evaluation to:

1 Determine its adequacy to support software operation and maintenance.

2 Identify the activities to be performed and documents required in order for the software to be placed under configuration management as a minimum, these activities include:

a User application requirements.

b Test plans and test cases required to validate the software for acceptability.

c User documentation required in accordance with subsection 3.15 of this policy.

d Upon independent review and approval of the above activities, the software shall be placed under configuration control in accordance with subsection 3.10 of this policy.

3.14 Access Control

3.14.1 To the extent appropriate, controls shall be established to permit authorized access and prevent unauthorized access to a computer system.

3.15 User Documentation

User documentation, as a minimum, shall include:

A User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software.

B Input and output specifications.

C Input and output formats.

D A description of systems limitations.

E A description of anticipated errors and how the user can respond.

F Information for obtaining user and maintenance support.

4 Specific Requirements for DOE/RW-0333P QARD Requirements

4.1 Implementation Phase

4.1.1 The design shall be translated into source code and resulting executables necessary to perform the functions required.

4.1.2 The source code and resulting executables shall adhere to the design specifications.

4.1.3 User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

A Instructions that contain an introduction, description of the user's interaction with the software, and a description of any required training necessary to use the software.
B Input and output specifications.
C Data files, input and output data, defaults, and file formats.
D A description of the allowable and tolerable ranges for inputs and outputs.
E Anticipated errors and how the user can respond.
F The hardware and software environments.
G Available sample problems.
H Installation procedures.

4.2 Software routines or macros that are documented in each product in which they are used and independently verified by visual inspection or hand calculation, without recourse to the original, shall have limited requirements applied as follows:

A Identification, including version of the software routine or macro.
B Documentation that includes inputs, computer program-generated correct results for a specified range of input parameters, computer program-generated evidence of the programmed algorithms or equations (e.g., computer program listings and spreadsheet cell contents), and verification results.
C Identification, including version of the commercially available software used to develop the routine and macro.

4.3 Software shall be placed under configuration management control as each baseline element is approved. Software shall not be used in quality-affecting activities unless it is obtained and limited to received copies from software configuration management.

4.4 Control of the Use of Software

4.4.1 Quality-affecting software shall be controlled and documented, and the use of released software items such that comparable results can be obtained, with any difficulties explained, through independent replication of the process.

4.4.2 Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

4.4.3 If the use of software items falls outside the range of validation as baselined, changes shall be made to the appropriate baseline elements prior to use.

4.4.4 Documentation for the receipt of software obtained from software configuration management in accordance with this policy shall be provided and maintained for all software in operation or use.

5 Records

5.1 Record copies of required documentation shall be retained with other project records as required by codes, standards, specifications, plans, or procedures.

5.2 Records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

5.3 Verification test records shall identify:

A Computer program tested.
B Computer hardware used.
C Test equipment and calibration, where applicable.
D Date of test.
E Tester or data recorder.
F Simulation models used, if applicable.
G Test problems.
H Results and acceptability.
I Action taken in connection with any deviations.
J Person evaluating the test results.

6 Responsibilities

6.1 Functional Manager

The Functional Managers are responsible for:

A Establishing procedures to implement the software QA program.

6.2 Quality Assurance Manager

The QA Manager is responsible for:

A Identifying quality assurance requirements and policies.
B Assuring that QA procedures and processes are developed and maintained.
C Providing technical assistance/guidance to directors, managers, and staff in meeting QA requirements.
D Providing independent oversight of activities to ensure compliance with applicable regulations and requirements.

6.3 Project Manager

The Project Manager is responsible for:

A Ensuring that a software QA program and software configuration management is established, documented, and implemented in accordance with the requirements of this policy and applicable DOE orders.

B Designating individuals or organizations responsible for implementing this policy (e.g., technical support organization) and defining the interfaces with external organizations.

6.4 Business Services Manager

The Business Services Manager is responsible for:

A Development and maintenance of a program for the control of project software in accordance with all applicable laws, regulations, and requirements.

B Ensuring that the program implemented for control of software includes all phases of software life cycle, including, but not limited to, procurement, verification and validation, and use.

C Mediating and resolving software QA program issues that have not been resolved at subordinate levels.

6.5 Operations Manager

The Operations Manager is responsible for developing and implementing procedures for the control of process modeling software.

Policy Q-04.1 Procurement Document Control

1 Purpose and Applicability

This policy identifies requirements and responsibilities to ensure that procurement documents, and changes thereto, contain appropriate technical and quality assurance requirements.

This policy applies to organizations and employees involved in the processing of documents for the procurement of quality affecting items and services.

2 Implementation Strategy

Technical, administrative, and quality requirements applicable to items or services being procured are to be identified and specified in procurement documents. These requirements include applicable codes, regulations and industry standards, tests and inspections, traceability, and special procedures or instructions. Procurement documents are to identify acceptance methods and criteria for acceptance or rejection of items or services.

Procedures will provide specific requirements and guidelines to initiate purchase requisitions, procurement specifications, and other procurement documents. These procedures will define appropriate controls for the selection, suitability determination, evaluation, and receipt of items or services being procured as well as controls that prevent the introduction of suspect or counterfeit items onto the project.

Procurement procedures will include a process for procurement of off-the-shelf commercial grade items and dedicating these items for safety-related applications. Engineering will initiate dedication by defining the critical characteristics of the item and associated verification requirements. These items will be subjected to specific inspections (Policy Q-10.1 - *Inspection*), tests (Policy Q-11.1 - *Test Control*), and/or evaluations to ensure that these items will perform properly in the safety-related application.

The procurement processes are part of the core function of Develop/Implement Controls of the Integrated Safety Management.

The ~~Business~~ Procurement and Property Manager is responsible for developing and implementing the procedures that provide a detailed methodology for preparing, reviewing and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures are to ensure procured items and services meet established requirements and perform as specified. Procurement documents are to be developed utilizing approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.

3.1.2 To the extent necessary, procurement documents shall require suppliers to have a documented QA program consistent with the applicable requirements of this policy.

3.1.3 When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another affected organization's QA program provided the work is adequately addressed. In these cases, procurement documents shall specify that the purchaser's or another organization's implementing documents are applicable to the supplier, and that the purchaser shall provide these applicable documents to them.

3.1.4 Procurement processes and controls shall include provisions for preventing the procurement of suspect and counterfeit items.

3.2 Procurement Document Contents

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the purchaser, and identify the revision level or change status on each document.

3.2.1 Procurement documents shall include a statement of the scope of work to be performed by the supplier.

3.2.2 Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished.

3.2.3 The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

3.2.4 QA program requirements shall be specified in procurement documents. These requirements shall be consistent with the importance and/or or complexity of the item or service being procured.

3.2.5 The procurement documents shall require the supplier to incorporate the appropriate QA requirements in subtier procurement documents.

3.2.6 QA requirements shall include provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.

3.2.7 The procurement documents shall provide for access to the supplier's and subtier supplier's facilities and records for surveillance, inspection, or audit by the purchaser, its designated representative, or others authorized by the purchaser.

3.2.8 The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. The time of submittal shall also be established.

3.2.9 When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

3.2.10 The procurement documents shall specify the purchaser's requirements for the supplier's reporting of nonconformances and the purchaser approval of the disposition of nonconformances.

3.2.11 The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies, special tools required, and the related technical and quality assurance data required for ordering these parts, tools and assemblies.

3.2.12 Tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.

3.3 Procurement Document Review and Approval

3.3.1 A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective supplier(s) include all appropriate technical and QA provisions to assure that items or services will meet the specified requirements.

3.3.2 Technical or QA program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents.

3.3.3 Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

3.3.4 Procurement document reviewers for Quality Level items and activities shall include representatives from the technical and QA organizations.

3.3.5 Procurement document reviews shall be performed and documented in accordance with Policy Q-06.1 - *Document Control*, prior to issuance of the procurement documents to the supplier.

3.3.6 Procurement documents shall be approved by the originating organization.

3.4 Procurement Document Changes

3.4.1 Changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformances, hold points, and lists of spare and replacement parts delineated in procurement documents shall be subject to the same degree of control as used in the preparation of the original documents.

3.4.2 Evaluation of procurement document changes as a result of proposal/bid evaluation or negotiations and the resulting impact shall be completed before the contract is awarded.

This evaluation shall consider the following:

A The appropriate requirements as specified in this section.
B Additional or modified design criteria.
C Analysis of exceptions or changes requested or specified by the supplier and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Procurement document reviews shall be performed and documented in accordance with Policy Q-06.1 - *Document Control*, subsections 3.7 and 4.~~2~~1, prior to issuance of the procurement documents to the supplier.

5 Records

5.1 No additional records requirements are applicable to this policy.

6 Responsibilities

6.1 Functional Organization

The designated Functional Organization is responsible for:

A Reviewing and approving the technical provisions of quality-significant [Quality Level (QLs)] purchase requisitions.
B Assuring that appropriate technical requirements and administrative controls for the specified items or services have been properly specified.

6.2 Requesting Organization

Organizations requesting procurement of Quality Level (QLs) items or services are responsible for documenting the requirements for the specified items or services by providing requisite ordering information, and ensuring adequacy of the documentation used to initiate a procurement and any subsequent changes. The manager of the requesting organization has the responsibility to verify that any requisitions and any

attached documents have been properly reviewed and approved and meet the requirements specified in this policy for initiating procurement.

6.3 ~~Business~~ Procurement and Property Manager

~~The Business Manager is responsible for solicitation and receipt of proposals and the only organization authorized to commit the company to contracts (purchase orders or subcontracts) for the acquisition of goods and services that involve the expenditure of programmatic funds. The Business Manager is responsible for assuring that quality requirements are correctly translated from procurement requisitions to purchase orders and contracts.~~

The Procurement and Property Manager, reporting to the ~~Business~~ Deputy Project Manager, has the overall responsibility for developing and approving procedures and documents that control the procurement quality process. The Procurement and Property ~~m~~Manager is responsible for solicitation and receipt of proposals and ensuring that requirements specified in the procurement documents, including quality requirements, are accurately transcribed into the final purchase documents. The Procurement and Property Manager is also responsible for performing source inspections.

6.4 Quality Assurance Manager

The QA Manager is responsible for:

A Evaluating and qualifying of suppliers.

B Performing receipt inspection of designated quality-affecting items.

C Performing supplier audits.

D Reviewing and approving the quality provisions of Quality Level (QLs) requisitions.

E Assuring that appropriate quality requirements and administrative controls for the specified items or services have been properly specified in procurement requisitions.

6.5 Business Services Manager

The Business Services Manager, reporting to the Project Manager, has the overall responsibility for the contract administration process, including formulating and administering subcontracts, and approving procedures and documents that control the contract administration process. The Business Services Manager is responsible for ensuring that requirements specified in the procurement documents, including quality requirements, are accurately transcribed into the subcontract documents.

Policy Q-07.1 Control of Purchased Items and Services

1 Purpose and Applicability

This policy identifies requirements and responsibilities for planning and executing procurement of items and services to assure conformance with specified requirements.

This policy applies to organizations responsible for planning and executing procurements to ensure that Quality Level (QL) purchased items and services meet specified requirements.

2 Implementation Strategy

Procurement procedures provide a detailed methodology for preparing, reviewing and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures ensure procured items and services meet established requirements and perform as specified.

The procurement process is part of the Integrated Safety Management System (ISMS) core function of Develop/Implement Controls.

Prospective suppliers will be identified early in the design and procurement process. The ~~Business Service~~Procurement and Property Manager is responsible for evaluating prospective suppliers, with assistance from the Engineering and quality assurance (QA) organizations. Supplier selection and evaluation will apply to the procurement of items and services in a manner consistent with their importance and a graded approach.

Prospective suppliers will be evaluated and selected on the basis of specified criteria published in procurement procedures and the procurement package. Evaluations are conducted by qualified assessors and supported by technical specialists when warranted by the nature of the procurement action. Items or services are to be procured from suppliers whose qualification results satisfy the requirements of the project quality assurance program. Those suppliers will be listed on an Approved Suppliers List (ASL) maintained by the QA organization.

Reviews of the suppliers' documentation and in-house assessment of the suppliers' capabilities are typically used for supplier selection based on the nature and application of items or services being procured. In addition, requalification and supplemental audits are performed on selected suppliers to verify compliance with the procurement requirements as indicated in Policy Q-18.1 - *Independent Assessment/Audit*.

The quality of purchased items and services is verified at intervals during various phases of the procurement process. Frequency or necessity of verification are determined by requirements of the procurement documents, applicable specification, codes and standards, uniqueness, complexity, application of the item, quantity and frequency of the procurement, and previous quality-related performance of the supplier. Processes are established for monitoring suppliers to ensure compliance with QA and technical requirements.

Purchased items or services are accepted using approved procedures and method(s) specified by the requisitioning organization. Items are accepted by one or more of the following methods: source verification, receiving inspection, or post-delivery testing. In addition, a certificate of conformance with the appropriate receipt inspection may be used for acceptance of certain standard items. The certificate of conformance and inspection documentation is to be traceable to the item and identify the specific requirements met by the purchased item.

Procured services may be accepted by the review and technical verification of data/reports produced, performance, or by surveillance/audit of the activity. Performance of source verification and receiving inspection activities utilize procurement documents reviewed by the QA organization. Purchased items are examined for potential suspect/counterfeit part characteristics. If identified as a potential suspect/counterfeit part, they are evaluated by engineering and, as appropriate, dispositioned as nonconforming items.

Processes to ensure that approved suppliers continue to provide acceptable items and services are to be established and implemented. Surveillances (Policy Q-18.2 - *Quality Assurance Surveillance*) will be conducted at supplier facilities by qualified personnel to verify compliance to requirements, as needs dictate. These surveillances will consist of inspections and tests, including witness and hold points, and document verification as specified in procurement documents. Surveillance of subtier suppliers will also be performed as applicable.

Procured items are put into service only when the acceptance requirements (Policy Q-10.1 - *Inspection*) of the procurement documents have been satisfied. Nonconforming items and deficiencies will be recorded on a nonconformance (Policy Q-15.1 - *Control of Nonconforming Items*) or a deficiency report (Policy Q-16.1- *Corrective Action*) respectively. Identified deficiencies will be dispositioned and corrective action taken and verified prior to the use of the item. Information from nonconformance and deficiency reports is reviewed as part of the trend analysis process to identify supplier performance trends and problems (Policy Q- 16.1 - *Corrective Action*). Adverse trends and problems are reported to the ~~Business Service~~Procurement and Property Manager and other responsible organizations.

Post-installation, functional, or pre-operational testing is to be performed after installation of procured items when specified (Policy Q-11.1 - *Test Control*). These tests will verify actual performance of the item against established criteria for the item and the system. Tests and in-service inspections will monitor the performance of the procured item against established criteria.

The ~~Business~~ Procurement and Property Manager is responsible for developing procedures for the procurement of items and services concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by

the supplier, source inspection, audit, and examination of items or services upon delivery or completion.

3.2 Procurement Planning

Procurement planning shall:

A Identify procurement methods and organizational responsibilities.

B Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.

C Identify and document the sequence of actions and milestones needed to effectively complete the procurement.

D Provide for the integration of the following activities:

1 Procurement document preparation, review, and change control according to the requirements of Policy Q-04.1 - *Procurement Document Control.*

2 Selection of procurement sources.

3 Proposal/bid evaluation and award.

4 Evaluation of supplier performance.

5 Verifications including any hold and witness point notifications.

6 Control of non-conformances.

7 Corrective action.

8 Acceptance of the item or service.

9 Identification of QA records per Policy Q-06.1 – *Document Control.*

E Be accomplished as early as possible and no later than at the start of those procurement activities that are required to be controlled.

F Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.

G Include the involvement of the QA organization.

3.3 Source Evaluation and Selection

3.3.1 Prior to awarding a contract, the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results shall be documented and shall include one or more of the criteria listed below:

A Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability.

B Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.

C Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and implementation of the supplier's QA program.

3.3.2 Source verification shall be performed by personnel qualified in accordance with Policy Q-02.2 - *Personnel Training and Qualification*.

3.3.3 Subcontractors or suppliers qualified by Bechtel National Inc. (BNI) or the Washington Group International (WGI) may be selected without further evaluation as delineated above, provided the subcontractors or suppliers are qualified for the intended services. Before initiation of work, supplier's QA programs will be evaluated against project quality assurance requirements.

3.3.4 The organizational responsibilities for source evaluation and selection shall be identified, including provisions for input from the QA organization.

3.3.5 When sources are qualified by other the Department of Energy (DOE) contractors, the qualification documentation shall be obtained and retained in files. As a minimum, they will be evaluated against project quality assurance requirements.

3.4 Proposal Bid Evaluation

3.4.1 The proposal/bid evaluation process shall include a determination of both the extent of conformance to the procurement document requirements, and the supplier's capability to conform to the technical and QA requirements.

3.4.2 The proposal/bid evaluation shall be performed by designated, technically qualified organizations including the QA organization.

3.4.3 The proposal/bid evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:

A Technical considerations.
B QA program requirements.
C Supplier personnel.
D Supplier production capability.
E Supplier past performance.
F Alternatives.
G Exceptions.

3.4.4 Prior to award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable technical and QA conditions resulting from the bid evaluation.

3.4.5 Supplier QA programs shall be evaluated before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to this QA manual.

3.4.6 Supplier QA programs shall be accepted by the purchaser before the supplier starts work.

3.5 Control of Supplier Generated Documents

Controls shall be implemented to assure that the submittal, evaluation, acceptance, and control of supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the QA, technical, inspection, and test documentation or data against established criteria.

3.6 Control of Changes in Items or Services

The purchaser and supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented, and are in accordance with applicable quality assurance requirements.

3.7 Supplier Performance Evaluation

3.7.1 The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance. The measures shall include:

A Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents.

B Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.

C Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements.

D Identifying and processing necessary change information.

E Establishing the method to be used to document information exchanges between purchaser and supplier.

F Establishing the extent of source surveillance and inspection.

3.7.2 The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.

3.7.3 Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement.

3.7.4 Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's QA program.

3.8 Acceptance of Items or Services

3.8.1 Prior to offering the item or service for acceptance, the supplier shall assure that the item or service being furnished complies with the procurement requirements.

3.8.2 The supplier shall provide the purchaser with objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.

3.8.3 Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:

A Evaluating the supplier Certificate of Conformance.

B Performing one or a combination of source verification, receiving inspection, or post-installation test.

C Technical verification of the item or service.

D Surveillance or audit of the work.

E Review of objective evidence (i.e., certifications, stress reports, or personnel qualifications) for conformance to the procurement requirements.

3.9 Certificate of Conformance

When a Certificate of Conformance is used to accept an item or service the following requirements must be met:

3.9.1 The certificate shall identify the purchased material or equipment, such as by the purchase order number.

3.9.2 The certificate shall identify the specific procurement requirements met by the purchased material, equipment, or service, (i.e., codes, standards, and other specifications).

Note: This may be accomplished by either including a list of the specific requirements, or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, along with a suitable certificate.

3.9.3 The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material, equipment, or service.

3.9.4 The certificate shall identify any procurement requirements that have not been met, along with an explanation and the means for resolving the nonconformance

3.9.5 The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

3.9.6 The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the purchaser or supplier's QA program.

3.9.7 Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the

supplier or independent inspection or test of items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

3.10 Source Verification

3.10.1 When source verification is used, it shall be performed at intervals consistent with:

A The supplier's planned inspections, examinations, or tests at predetermined points.

B The importance and complexity of the item or service. Source inspection shall include monitoring, witnessing, or observed selected activities.

3.10.2 Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points.

3.10.3 Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

3.11 Receiving Inspection

3.11.1 When receiving inspection is used to accept an item, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier.

3.11.2 Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.

3.11.3 The inspection shall be planned and executed according to the requirements of Policy Q-10.1 - *Inspection*.

3.11.4 Receiving inspection shall be coordinated with a review for adequacy and completeness of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

3.11.5 The inspection shall be performed in accordance with established inspection implementing documents.

3.12 Post-Installation Testing

3.12.1 When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.

3.12.2 The test shall be in accordance with the requirements of Policy Q-11.1 - *Test Control*.

3.13 Acceptance of Services Only

In cases involving procurement of services only, such as third party inspection; engineering and consulting service; auditing; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any of the following methods:

A Technical verification of data produced.

B Surveillance or audit of the work.

C Review of objective evidence (i.e., certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.

3.14 Control of Supplier Nonconformances

Methods for control and disposition of supplier nonconformances for items and services that do not meet procurement documentation requirements shall include the following:

A Evaluation of nonconforming items in accordance with Policy Q-15.1 - *Control of Nonconformances*.

B Submittal of nonconformance notice to the purchaser by supplier as directed by the purchaser. These submittals shall include supplier-recommended disposition (e.g., use as-is or repair) and technical justification.

C Nonconformances to the procurement requirements or purchaser approved documents which consist of one or more of the following, shall be submitted to the purchaser for approval of the recommended disposition:

1 Technical or material requirement is violated.

2 Requirement in supplier documents, which have been approved by the purchaser is violated.

3 Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.

4 The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

D Purchaser disposition of the supplier's recommendation.

E Verification of the implementation of the disposition by the purchaser.

F Maintenance of records of supplier-submitted nonconformances.

3.15 Commercial Grade Items

Where the design uses commercial grade items, the purchaser can use the following requirements as an acceptable alternative to other requirements of this section for procuring and accepting items.

A The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.

B Source evaluation and selection, when deemed necessary by the purchaser based on complexity and importance to safety, shall be in accordance with subsection 3.3 - *Source Evaluation and Selection*, of this document.

C Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., catalog number).

D Prior to acceptance of a commercial grade item, the purchaser shall determine that:

1 The item did not sustain damage during shipment.

2 The item received was the item ordered, and the item satisfied the specified acceptance criteria.

3 Inspection or testing is accomplished to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.

4 Specified documentation, applicable to the item, was received and is acceptable.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in Section 3 - *Policy*.

5 Records

5.1 No additional record requirements are applicable to this policy.

6 Responsibilities

6.1 ~~Business~~ Procurement and Property Manager

The ~~Business~~ Procurement and Property Manager is responsible for the following:

A Developing and maintaining implementing procedures for the procurement process.

B Implementing this process for procured items and services within the scope of this document from receipt of the requisition from the originator through the acceptance of the item or service by the purchaser.

C Maintaining quality history records on suppliers who have demonstrated their ability to provide quality materials, equipment, or services or whose capability has been established by survey or audit.

D Establish and implement a source inspection program to assure supplier compliance with procurement document requirements.

6.2 Construction Manager

The Construction Manager is responsible for the following:

A Carrying out requirements contained in this document through use of implementing documents. Specifically implementing this process for items and activities within the scope of this document at all facilities under construction.

B Disposition of supplier and contractor nonconformance when that responsibility has been assigned to Field Engineering by Design Engineering.

C Disposition of supplier and contractor nonconformance for field engineered designed items.

D Track supplier/subcontractor nonconformance, which require action at the site and assure that appropriate action is taken to resolve such nonconformance.

6.3 Engineering Manager

The Engineering Manager is responsible for the following:

A Reviewing of supplier and subcontractor engineering documents.

B Reviewing supplier reported design nonconformance.

C Supporting the supplier selection process.

D Developing procurement specifications.

E Reviewing bids for technical adequacy, as required.

6.4 Operations Manager

The Operations Manager is responsible for the following:

A Reviewing supplier and subcontractor operations-related documents.

B Reviewing supplier reported operations-related nonconformances.

C Supporting the supplier selection process.

D Developing operations-related procurement specifications.

6.5 Quality Assurance Manager

The QA Manager is responsible for the following:

A Concur with supplier QA Programs to the extent required in the procurement documents.

B Establish and implement a program of surveillance and audit, to assure supplier compliance with procurement document requirements.

C Review procurement documents to assure that quality requirements are correctly stated, inspectable, and controllable; that there are adequate acceptance/rejection criteria; that source surveillance or receipt inspection is specified; that minimum documentation to be supplied is specified; and that the procurement documents have been processed in accordance with established requirements.

D Establish and maintain an ASL which documents those suppliers qualified per specific project procurement requirements.

E Concurring in the selection of the source for field procurement not requiring submittal of a quality program, to assure that the source has been qualified in accordance with the requirements of this policy.

F Reviewing supplier quality verification documentation for items that have not been inspected at the source.

G Identify as nonconforming discrepant material received at the site for which a supplier's completed nonconformance report has not been received.

H Receiving inspection of designated quality-affecting items.

I Verification of field subcontractor's activities.

6.6 Business Services Manager

The Business Services Manager is responsible for formulating and administering subcontracts.

Policy Q-10.1 Inspection

1. Purpose and Applicability

This policy identifies requirements and responsibilities for specifying, planning, performing, and reporting inspections used to verify the acceptance of items or activities. The inspection process is designed to prevent the inadvertent acceptance and use of nonconforming items.

This policy applies to organizations involved with the evaluation of conformance to specified requirements and acceptability of items and activities by inspection. Independent inspections performed by the Quality Control (QC) organization shall not relieve any organization performing work from their responsibility to provide items and services that meet quality requirements.

2. Implementation Strategy

Inspection of specified items, services, and processes is to be conducted using established acceptance and performance criteria. Examples of inspections include source, in-process, final, receipt, maintenance, and in-service. Administrative controls, including the use of status indicators, are to be used to preclude inadvertent bypassing of required inspections and inadvertent operation of nonconforming or indeterminate items or processes.

Inspections will be planned, controlled, and documented in accordance with established requirements (e.g., hold/witness points) and consistent with the results of the graded approach. Trained personnel will perform inspections using approved procedures. The engineering organization will establish level, extent, and acceptance criteria for inspections based on the critical characteristics of the item.

Inspection planning will ensure that inspection requirements are properly incorporated into inspection documents. Organizations performing inspections will be responsible for the planning of those inspections consistent with the owner/user needs. Inspection planning will include, as a minimum, item and process characteristics to be inspected; inspection techniques to be used; acceptance criteria (including tolerances); hold and witness points; and identification of the organization performing these inspections.

Inspection personnel will have the freedom to communicate inspection results to the appropriate level of management. Nonconforming items and processes being inspected will be controlled in accordance with the Policy Q-15.1 – *Control of Nonconforming Items.* After verification of corrective action implementation, the item or process will be re-inspected to the original or approved alternative acceptance criteria prior to being used or returned to service.

The Engineering and QA Managers are responsible for developing the necessary procedures that contain the requirements of this policy.

3. Policy

3.1 General

3.1.1 Inspections required to verify conformance of an item or activity to specified requirements or the continued acceptability of items in service shall be planned and executed.

3.1.2 Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented.

3.1.3 Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected. These personnel shall not report directly to the immediate supervisor responsible for the item being examined.

Note: Data recorders, equipment operators, or other inspection team members who are supervised by a qualified inspector are not required to be qualified inspectors.

3.1.4 When sampling procedures are used, they shall be based on valid statistical methods.

3.2 Inspection Requirements

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

3.3 Inspection Hold Points

If mandatory QC independent inspection hold points are required beyond which work shall not proceed without specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents.

Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

3.4 Planning

3.4.1 Required in-service inspection or surveillance of structures, systems, or components (SSCs) shall be planned and executed by, or for, the organization responsible for operation.

3.4.2 Inspection planning shall be performed, documented, and include the following:

A Identification of each work operation where inspection is necessary to ensure quality and implementing documents that will be used to perform the inspections.

B Identification of characteristics to be inspected; methods of inspection; acceptance criteria; process monitoring methods to be employed; and when during the work process the inspections are to be made.

C Identification of the functional qualification level (i.e., Level I, II, or III Qualification Level) of personnel performing inspections.

D Identification of acceptance criteria.

E Identification of sampling requirements.

F Methods to record inspection results.

G Selection and identification of the measuring and test equipment to be used to perform the inspection to ensure that the equipment is calibrated and is of the proper type, range accuracy, and tolerance to accomplish the intended function.

H The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

3.5 In-Process Inspection and Monitoring

3.5.1 Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality.

3.5.2 If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

3.5.3 Both inspection and process monitoring shall be provided when control is inadequate without both.

3.5.4 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process, and the quality of the item are met throughout the duration of the process.

3.5.5 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

3.6 Final Inspections

3.6.1 Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance to the specific requirements.

3.6.2 The acceptance of an item shall be documented and approved by qualified and authorized personnel.

3.6.3 The inspection status of an item shall be identified according to Policy Q-14.1 - *Inspection, Test, and Operating Status*.

3.6.4 Final inspections shall include a record review of the results and resolution of nonconformances identified by prior inspections.

3.6.5 Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

3.6.6 Inspection documentation shall identify:

A The item inspected.
B The date of inspection.
C The name of the inspector, or the inspector's unique identifier, who documented, evaluated, and determined acceptability.
D The name of the data recorder, as applicable.
E The type of observation or method of inspection.
F The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance.
G Results indicating acceptability of characteristics inspected.
H Reference to information on actions taken in connection with nonconformances.
I Measuring and test equipment used during the inspection, including the identification number and the most current calibrated date and/or the calibration due date.

3.6.7 Documentation not previously examined prior to final inspection shall be examined for adequacy and completeness.

3.7 Qualifications of Inspection and Test Personnel

3.7.1 Personnel performing quality control independent inspections to verify conformance of an item to specified acceptance criteria or as described in this section and personnel performing tests as described in Policy Q-11.1 - *Test Control*, shall be qualified and certified according to the indoctrination, training, education, experience, and physical requirements of this policy and Policy Q-02.2 - *Personnel Training and Qualification*.

Note: See Policy Q-11.1 - *Test Control*, subsection 3.8, for the qualification requirements of personnel who operate systems/subsystems during testing and the qualification requirements for test engineers and others who prepare and direct testing activities.

3.7.2 The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The evaluation shall be performed to the requirements of the applicable functional level, and education and experience requirements of this document.

3.8 Indoctrination and Training Qualification Requirements

3.8.1 Inspection and test personnel shall be indoctrinated to the technical objective and requirements of the applicable codes and standards, and the QA program requirements that are to be employed in executing their responsibilities.

3.8.2 Indoctrination and training shall be commensurate with scope; complexity; importance of the activities; special nature of the inspections or tests; and the education, experience, and proficiency of the person.

3.8.3 The need for a formal training program shall be determined. Training shall be provided as required to qualify personnel for performing inspections and tests.

3.8.4 On-the-job training, with emphasis on hands-on experience gained through actual performance of inspections and test, shall be included in the training program.

3.8.5 On-the-job training for personnel qualification shall be performed under the direct observation and supervision of a qualified person.

3.8.6 The documented verification of conformance shall be performed by the qualified person and not by the person being administered on-the-job training.

3.9 Functional Qualification Levels of Inspection and Test Personnel

Three levels of functional qualification (Levels I, II, and III) shall be used depending on the complexity of the functions involved. The criteria for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional work.

3.9.1 Level I Personnel Capabilities—Level I personnel shall be capable of performing and documenting the results of designated inspections or tests.

3.9.2 Level II Personnel Capabilities—Level II personnel shall have Level I capabilities for the corresponding category or class. Additionally, Level II personnel shall have demonstrated capabilities in:

A Inspection or test planning.
B Advanced preparation, including the preparation and setup of related equipment, as appropriate.
C Supervising or monitoring the inspections or tests.
D Supervising and certifying lower-level personnel.
E Evaluating the validity and acceptability of results.

3.9.3 Level III Personnel Capabilities—Level III personnel shall have Level II capabilities for the corresponding category or class. In addition, Level III personnel shall also be capable of evaluating the adequacy of specific programs used to train, qualify, and certify the personnel.

3.10 Education and Experience Qualification Requirements

The requirements for education and experience shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspections or tests affect the assurance that a person can competently perform a

particular task. Other factors that demonstrate capability in a given job and the basis for their equivalency shall be documented.

3.10.1 Level I inspection personnel shall meet the following education and experience requirements:

A Two years of related experience in equivalent inspections or tests; or

B High school graduation or general equivalency diploma (GED) and six months of related experience in equivalent inspections or tests; or

C Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspections or tests.

3.10.2 Level II inspection personnel shall meet the following education and experience requirements:

A One year of satisfactory performance as a Level I in the corresponding category or class; or

B High school graduation or GED plus three years of related experience in equivalent inspections or tests; or

C Completion of college-level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspections or tests; or

D Graduation from a four-year college plus six months of related experience in equivalent inspections or tests.

3.10.3 Level III inspection personnel shall meet the following education and experience requirements:

A Six years of satisfactory performance as a Level II in the corresponding category or class; or

B High school graduation plus ten years of related experience in equivalent inspections or tests; or high school graduation plus eight years of experience in equivalent inspections or tests with at least two years as a Level II and with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or

C Completion of college-level work leading to an associate degree and seven years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or

D Graduation from a four-year college plus five years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility.

3.11 Maintaining Qualification Documentation for Inspection and Test Personnel

3.11.1 Records of qualification, including re-qualification for inspection and test personnel, shall be established and maintained by the employer and for indoctrination and training.

Note: Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

3.11.2 Inspection and test personnel qualification documentation shall contain the information required for the initial qualification and the maintenance of qualification.

3.11.3 Documentation for each person shall be maintained and updated according to the following requirements:

A Removal of a person from performing in an area of certification when the responsible organization determines that the capabilities of the individual are not in accordance with the qualification requirements specified for the job as described in this section. This shall be documented at the time of removal.

B Reinstatement of certifications for the qualified area when the required capability has been demonstrated as described in this section. This shall be documented at the time of reinstatement.

C Continued performance in each certified area or re-determination of required capability as described in this section for each certified area shall be updated annually.

D Re-evaluation of job performance by evidence of continued satisfactory performance or re-determination of capability as described in this section. This shall be updated every three years.

3.11.4 Integrity of examinations shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examination. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be maintained by the employer in accordance with the requirements of Policy Q-02.2 - *Personnel Training and Qualification*.

3.12 Physical Qualification Requirements

The responsible organization shall identify any special physical characteristics needed in the performance of each activity including the need for initial and subsequent visual acuity and other physical examinations.

3.13 Certification of Qualifications

The qualification of inspection and test personnel shall be certified in writing by the responsible organization and document the following information:

A Employer's name.

B Identification of the person being certified.

C Activities, qualified inspection and test categories or class the individual is certified to perform.

D Basis of qualification, such as:

1 Education, experience, indoctrination, and training.

2 Test results, where applicable.

3 Capability demonstration results.

4 Results of periodic evaluations.

E Results of visual acuity and other physical examinations, when required.

F Signature of the employer's designated representative who is responsible for such certification.

G Date of certification or recertification and certification expiration.

4. Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Inspection documentation shall identify the ~~M~~measuring and test equipment used during the inspection, including the identification number and the most current calibrated date.

5. Records

5.1 Records of personnel qualification shall be established and maintained in accordance with Policy Q-17.1 - *Quality Assurance Records*. These records will include the certification of qualifications.

6. Responsibilities

6.1 Engineering Manager

The Engineering Manager is responsible for the identification of and selective application of appropriate acceptance criteria in implementing documents and specifications.

6.2 Quality Assurance Manager

The QA Manager is responsible for:

A The preparation and/or review of quality-affecting documents that establish inspection requirements.

B Planning, performing, documenting and reporting inspection and tests.

C Qualification and training of inspection personnel, and ensuring that appropriate inspections and tests are scheduled and performed.

Project Manager

The Project Manager safety-related roles, responsibilities, and authorities include:

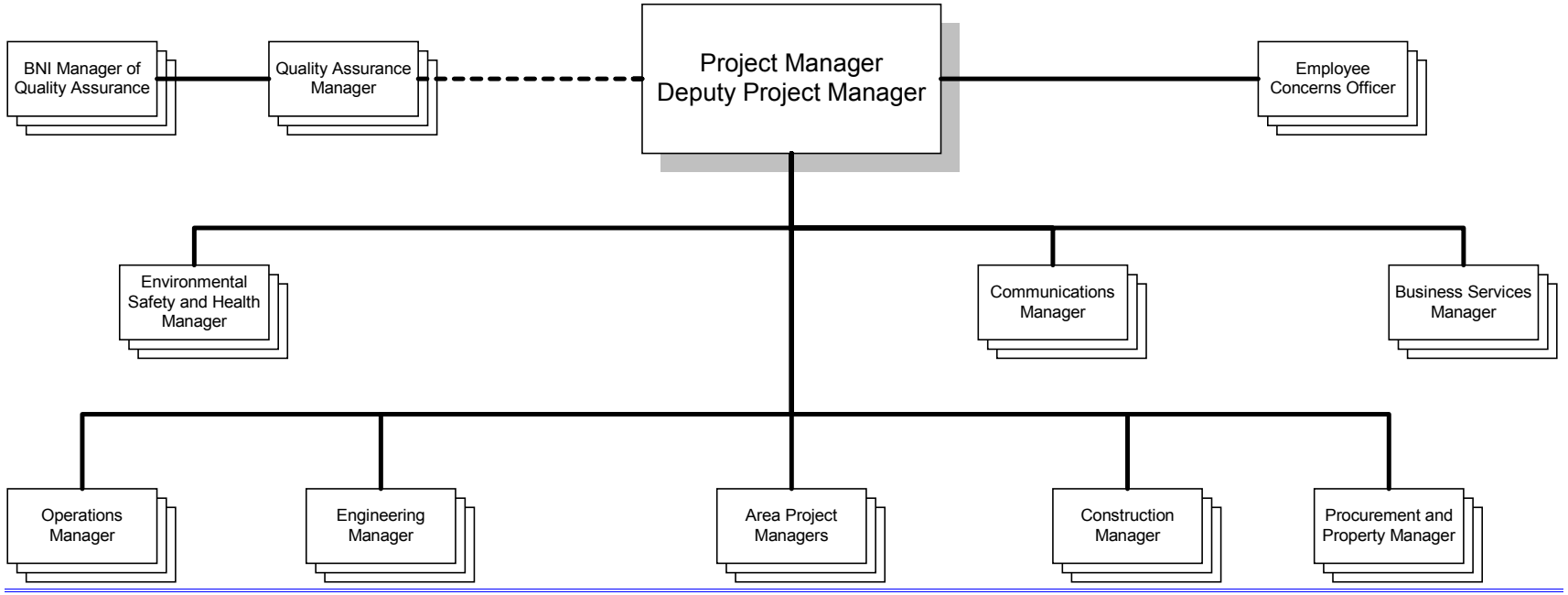
1) Responsibility for RPP-WTP safety
2) Defining safety policy, objectives, and interfaces
3) Assigning roles and responsibilities for safety-related activities
4) Setting performance expectations
5) Developing management assessment policies
6) Signatory on permit applications for construction of the Facility
7) Serving as a member of the Executive Committee
8) Ensuring implementation of the Quality Assurance Program (QAP)

Deputy Project Manager

The Deputy Project Manager safety-related roles, responsibilities, and authorities include:

1) Ensuring that the RPP-WTP is designed, constructed, tested, commissioned, operated, and maintained in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements
2) Integrating nuclear and industrial safety, quality, and environmental protection into all work
3) Managing the design transition, facility and process design, construction, acceptance testing, ~~and~~ commissioning, procurement, and operations
4) Integrating the Area Project Managers and functional managers
5) Creating an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels
6) Stopping activities within his area of responsibility, which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements

Figure 11-1 Management Structure and Organization for the BNI Design, Construction, and Commissioning Contract



4) Providing information from the startup program to the operations, training, and procedures groups, and maintenance for verification and validation of operating administrative controls

Procurement and Property Manager

The Procurement and Property Manager safety-related roles, responsibilities, and authorities include:

1) Providing the processes and procedures for procuring items and services important to safety.
2) Providing full support to the Quality Assurance Program described in the *Quality Assurance Manual* (QAM), thereby assuring that all work performed under his cognizance will conform to and support the requirements of the QAM.

Business~~/Projects Control~~ Services Manager

The safety-related roles, responsibilities, and authorities of the Business~~/Projects Control~~ Services Manager include:

~~1)Implementing the Employee Concerns Program~~
~~2)~~1) Implementing an employee feedback program
~~3)~~2) Controlling the facility policy manual (containing the Project Manager safety policy) and all procedures
~~4)~~3) Developing and maintaining the records management program (See Table 8-1)

11.2 Operations Contractor Organization Roles, Responsibilities, and Authorities

The envisioned safety-related roles, responsibilities, and authorities for the Operations phase of the operation, as assigned to individuals and organizations within the Operations Contract, are discussed below.

Facility Manager

Responsibilities and roles of the Facility Manager include the following:

1) Ensuring the development and implementation of facility controls to protect the health and safety of the public, and workers and to protect the environment from hazardous situations associated with the chemical and radiological hazards of the facility
2) Ensuring that operational activities are properly staffed and controlled
3) Managing operation of the facility to obtain the defined work activity while maintaining the authorization basis for the facility
4) Approving Facility activities, including modifications to Safety Design Class and Safety Design Significant SSCs
5) Ensuring that work is performed in conformance with procedures, policies, and safety requirements

6) Implementing the contractor requirements of 10 CFR 820, "Procedural Rules for DOE Nuclear Activities"
7) Serving as the Emergency Director during events categorized as emergencies
8) Assigning roles and responsibilities for activities related to safety including operations, performance improvements, safety improvements, and deactivation of the facility

Engineering Manager

The Engineering Manager a member of the PSC. Roles of the Engineering organization include the following:

1) Evaluating startup test results and comparing the results to acceptance criteria
2) Developing and evaluating proposed design improvements and changes to engineered features
3) Supporting resolution of production problems
4) Developing the surveillance and maintenance criteria for facility operations
5) Identifying measures that minimize hazards associated with treating and storing radioactive waste, and for the safe handling of fissionable materials
6) Performing a job hazard analysis and participating with ES&H to update HAR
7) Updating the process hazards analysis (PHA) to support permit and authorization basis updates
8) Preparing and implementing a deactivation management plan that includes:
   - updating the HAR
   - defining surveillance and maintenance criteria for deactivation and safe storage
   - developing facility modifications to facilitate performance of surveillance tests
   - implementing measures that minimize hazards associated with treating and storing radioactive materials

Maintenance Manager

The Maintenance Manager oversees the activities of the Maintenance organization. Roles of the Maintenance organization include:

1) Defining and implementing a maintenance program that includes preventive, predictive, and corrective maintenance practices and incorporates vendor-recommended maintenance activities and equipment history
2) Performing TSR surveillances assigned to maintenance and supporting those TSR surveillances assigned to operations
3) Implementing facility modifications
4) Developing and modifying operating and maintenance instructions for post-deactivation operational equipment
5) Writing maintenance procedures
6) Collecting and processing baseline data for system and component performance monitoring and maintenance planning

Procurement and Property Manager

The Procurement and Property Manager's safety related roles, responsibilities, and authorities include:

1) Providing the processes and procedures for procuring items and services important to safety.
2) Providing full support to the Quality Assurance Program described in the *Quality Assurance Manual* (QAM), thereby assuring that all work performed under his or her cognizance will conform to and support the requirements of the QAM.

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History Sheet

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0	31 Aug 2001	Document approved for issuance per DOE Letter 01-OSR-0285	G. Grant
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Revision Status Sheet

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Policy Q-01.1	Project Organization	0a	7 Nov 2001	8 Nov 2001	9
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Policy Q-02.2	Personnel Training and Qualification	0	2 Aug 2001	31 Aug 2001	6
Policy Q-02.3	Auditor/Lead Auditor Qualification and Certification	0a	7 Nov 2001	8 Nov 2001	6
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Policy Q-09.1	Control of Special Processes	0	2 Aug 2001	31 Aug 2001	3
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Policy Q-13.1	Handling, Storage, and Shipping	0	2 Aug 2001	31 Aug 2001	3
Policy Q-14.1	Inspection, Test and Operating Status	0	2 Aug 2001	31 Aug 2001	2
Policy Q-15.1	Control of Nonconforming Items	0	2 Aug 2001	31 Aug 2001	5
Policy Q-16.1	Corrective Action	0	2 Aug 2001	31 Aug 2001	5
Policy Q-16.2	Stop Work	0	2 Aug 2001	31 Aug 2001	2
Policy Q-17.1	Quality Assurance Records	0	2 Aug 2001	31 Aug 2001	7
Policy Q-18.1	Independent Assessment (Audit)	0	2 Aug 2001	31 Aug 2001	7
Policy Q-18.2	Quality Assurance Surveillance	0	2 Aug 2001	31 Aug 2001	3
Policy Q-18.3	Management Assessment	0	2 Aug 2001	31 Aug 2001	3
Supplement I	Control of the Electronic Management of Data	0	2 Aug 2001	31 Aug 2001	2
Supplement II	Sample Control	0	2 Aug 2001	31 Aug 2001	3
Supplement III	Scientific Investigation	0	2 Aug 2001	31 Aug 2001	4
Appendix A	Quality Assurance Manual Acronyms	0	2 Aug 2001	31 Aug 2001	2

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Appendices

Appendix A **Quality Assurance Manual Acronyms**

IHLW Supplements

Supplement I **Control of the Electronic Management of Data**

Supplement II **Sample Control**

Supplement III **Scientific Investigation**

Foreword

The Quality Assurance (QA) Policies in this manual establish the quality assurance requirements for Bechtel National, Inc. (BNI) at the Waste Treatment Plant (WTP) Project. They meet the requirements specified in the following sources:

1 US Code of Federal Regulations (CFR) 10 CFR 830, Subpart A, Quality Assurance Requirements.

2 US Department of Energy (DOE) Order 414.1A, Quality Assurance.

3 American National Standard, ASME NQA-1-1989 (NQA-1), Quality Assurance Program Requirements for Nuclear Facilities.

4 Office of Civilian Radioactive Waste Management, DOE/RW-0333P (Rev. 10), Quality Assurance Requirements and Description (QARD).

This manual contains policies that are applicable to the facilities and services being designed, constructed, commissioned, operated, managed, or provided under BNI's contract with the US Department of Energy, Office of River Protection (DOE-ORP). It applies to work that takes place at or for the WTP Project (project) and to suppliers and subcontractors, such as design, manufacturing, or analytical laboratory services. In addition, these policies apply to spare/replacement part procurement; repair; modifications; maintenance; in-service and/or non-destructive examinations, inspections, or testing; technical analysis and support; and other quality-affecting activities.

The requirements found in each policy reflect the integration of applicable requirements from the above referenced sources. The requirements are either consensus requirements, specific requirements, or project-imposed requirements. A consensus requirement is a requirement that serves as a baseline requirement for the project. A baseline requirement represents a single requirement that meets the intent of the individual requirements identified from each source. Specific requirements have only narrow scope application and are not applied across the project. Project-imposed requirements are those that reflect good management practice.

This integration of requirements allows the development of one project quality assurance program composed of the quality assurance manual policies and the necessary implementing documents (i.e., procedures) for the project. This concept of developing a single-project quality assurance program simplifies compliance by simultaneously satisfying requirements from multiple requirements sources. This concept also allows implementing documents to be developed from the quality assurance policies rather than referring to the individual source requirements.

Overview

The project QA program (defined by the QA manual and associated implementing documents) directs the achievement and verification of quality. The project quality assurance manager is responsible for the overall QA program—its development, maintenance, verification, and continuing improvement—and is the approval authority for matters pertaining to its interpretation and implementation. Line organizations are responsible for implementing and meeting the requirements of the QA program. Each individual is

responsible for the quality of his or her work. Line management is ultimately responsible to see that quality is achieved.

The project QA program provides an important function in implementing the Integrated Safety Management System (ISMS). The QA program is an integral part of all the processes by which (a) work is prioritized, (b) clear roles and responsibilities are established, (c) individuals performing work have competence commensurate with their responsibilities, (d) hazards are analyzed, (e) standards and controls are identified and applied, (f) work is performed, and (g) performance is evaluated and improved.

The project QA program establishes controls within its implementing documents that are consistent with the risks associated with the activity, and that take into account the work to be performed and the associated hazards. Effective implementation of the quality assurance program will also provide processes and tools to support principles and functions of the Safety Management System Policy (DOE P 450.4) and related portions of the DOE Acquisition Regulation (DEAR, 48 CFR 970.5204-2).

Policy Statement

One of the fundamental aspects of any quality assurance (QA) program is that the individuals performing the work determine the quality that is to be achieved. Though plans, procedures, and instructions are a basic part of any quality program, it should be recognized that people make quality happen. Each individual, when properly trained and motivated, must achieve the highest quality of performance of which he or she is capable.

It is the policy of Bechtel National, Inc. (BNI) to design, construct, and commission the Waste Treatment and Immobilization Plant (WTP) so that it can be maintained and operated in such a manner as to ensure the health and safety of the public, the personnel onsite, and protect the environment. One way to accomplish this critical objective is to have an aggressive and comprehensive quality assurance program in place for those activities which can impact safety and quality.

The Project Manager has directed the establishment of a formal and comprehensive QA program for the project. This program places accountability for quality on each person working on the project. In addition, it emphasizes the creation of an atmosphere in the workplace where the reporting and the resolution of conditions adverse to quality are encouraged and expected at all levels.

The QA program identifies those requirements that shall be implemented to satisfy the contractual requirements. The QA program includes the associated procedures and instructions which implement the program requirements.

Quality assurance objectives shall not be subordinate to cost or schedule objectives. To ensure compliance with the QA program requirements, independent verifications and assessments shall be conducted to provide management a measure of the program's effectiveness and adequacy in meeting the requirements of the QA program and its implementing procedures and instructions.

Conflicts involving implementation of the requirements of the QA program shall be resolved by the QA Manager or, if deemed necessary, the BNI Corporate QA Manager. In those instances when BNI has imposed implementation of parts of the QA program to suppliers and/or subcontractors, BNI retains responsibility to ensure the adequacy of their respective program.

_____
R Naventi
Project Manager

Policy Q-01.1 Project Organization

1 Purpose

This policy identifies requirements and responsibilities for organizations that provide for the achievement and verification of quality in items produced and activities performed.

2 Applicability

This policy applies to the organizations that prescribe, perform, or verify activities affecting quality, including those having responsibility for planning and scheduling. An organizational chart included in Figure 01.1-1 displays the relationship of organizations having principal roles in the Quality Assurance (QA) Program.

3 Responsibilities

3.1 Project Manager

The Project Manager is responsible for the development, design, procurement, modification, maintenance, construction, commissioning, and operations of the project, and ensures that appropriate policies are provided for these activities. As such, he has the authority to stop unsafe or unsatisfactory work and control further processing, delivery, or installation of nonconforming material. The Project Manager reviews the status and adequacy of the QA Program by reviewing reports prepared by the QA Manager at least annually. Responsibility for the engineering and design support, construction, modifications, records management, commissioning, and operations during the operations phase, and proper implementation of the QA Program for these activities is delegated to the direct reports of the Project Manager. The responsibilities to establish, maintain, and verify proper implementation of the QA Program is delegated to the QA Manager. The Project Manager shall retain the responsibility for assuring that the authority and independence of the QA Manager is such that he can effectively assure the conformance to quality requirements.

The Project Manager is responsible for the following major functions:

A Establishing the overall vision for the project and instilling a culture of excellence for safety and quality.

B Managing the project organizations and the execution of work.

C Providing a single point of accountability with the U.S. Department of Energy, Office of River Protection (DOE-ORP).

It is the responsibility of the Project Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Project Manager has the responsibility to stop project activities which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Project Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.2 Deputy Project Manager

The Deputy Project Manager reports to the Project Manager and is responsible for ensuring that the project facilities are designed, constructed, tested, and commissioned in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements.

The Deputy Project Manager is responsible for:

A Integrating nuclear and industrial safety, quality, and environmental protection into all work.

B Managing the design transition, facility and process design, construction, acceptance testing, commissioning, procurement, and operations.

C Integrating the Area Project Managers and Functional Managers.

D Ensuring all required items and services are procured and the necessary funds are committed.

It is the responsibility of the Deputy Project Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Deputy Project Manager has the responsibility to stop activities within his area of responsibility which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Deputy Project Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.3 Area Project Managers

The Area Project Managers report to the Deputy Project Manager and are responsible for ensuring that the project facilities are designed, constructed, tested, and commissioned in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements.

The Area Project Managers are responsible for:

A Managing the scope, schedule, budget, safety and quality of project area work.

B Coordinating with the Functional Managers to accomplish work and integrate activities.

C Seeking ways to optimize work and maintaining an operational focus for turnover to the operations contractor.

D Coordinating with and supporting the other Area Project Managers for work prioritization, scheduling, and resource loading.

It is the responsibility of the Area Project Managers to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Area Project Managers have the responsibility to stop activities within their area of responsibility, which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Area Project Managers give full support to the QA Program described herein, thereby assuring that all work performed under their cognizance will conform to and support the requirements of this policy.

3.4 Operations Manager

The Operations Manager reports to the Project Manager and is responsible to ensure that the project facilities are tested, commissioned, operated, and maintained in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements.

The Operations Manager is responsible for the following major functions:

A Managing and prioritizing the Research and Technology, Process Technology, Operations, and Commissioning Programs.

B Defining operations requirements that affect the project design features or concepts, establishing system reliability, availability, maintainability, and inspectability criteria, and establishing the process control strategy.

C Providing the DOE with plans and completed reports for all process verification and product qualification testing.

D Defining and conducting process technology development including process, operational, and facility modeling, managing process development, improvement, and corrective actions.

E Managing acceptance and startup testing, the startup team, hot commissioning, and facility turnover.

F Managing the commissioning subcontractor.

G Training department activities and implementation, control, and maintenance of the training matrix for tracking training of personnel and for determining the status of the training program.

It is the responsibility of the Operations Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Operations Manager has the responsibility to stop activities within his area of responsibility which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements.

The Operations Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.5 Engineering Manager

The Engineering Manager reports directly to the Deputy Project Manager and is responsible for providing engineering services to assure uniform technical and regulatory adequacy of engineering activities and to provide safe, reliable, and efficient design in accordance with corporate policies and applicable laws, regulations, and licenses.

The Engineering Manager is responsible for the following major functions:

A Leading the engineering team and assuming responsibility as the project design authority.

B Establishing and maintaining facility design requirements, system descriptions, maintaining basis for design and other design criteria.

C Designing the project facilities consistent with function and safety requirements and in compliance with all codes and standards.

D Overseeing design, including periodic reviews involving the DOE.

E Determination for the applicability of the grading process.

It is the responsibility of the Engineering Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Engineering Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable authorization bases.

The Engineering Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.6 Construction Manager

The Construction Manager reports directly to the Deputy Project Manager and is responsible to provide construction services to assure uniform technical and regulatory adequacy of construction activities and to provide safe, reliable, and efficient activities in accordance with policies and applicable laws, regulations, permits, and licenses.

The Construction Manager is responsible for the following major functions:

A Providing constructability reviews.

B Providing the Construction, Procurement, and Acceptance Testing Plan.

C Implementing appropriate construction methods and scheduling and delivering labor construction equipment, and materials.

D Ensuring industrial safety, environmental protection, quality, and security, and managing construction, properties and facilities, including warehouses and laydowns.

E Managing subcontractors, supervising direct hires and force account personnel, and fostering positive labor relations.

F Providing construction testing and inspection services.

It is the responsibility of the Construction Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Construction Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Construction Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.7 Business Services Manager

The Business Services Manager reports directly to the Project Manager and is responsible to provide business and project controls services to assure regulatory adequacy of business activities and to provide efficient activities in accordance with policies and all applicable laws, regulations, and licenses.

The Business Services Manager is responsible for the following major functions:

A Managing all business and administrative functions, including Project Controls, Contracting, Human Resources, Information Systems and Technology, and Controller.

B Delivering a project controls system producing accurate and timely data per the Program Management Plan.

C Developing and maintaining integrated technical, schedule, and cost baselines.

D Maintaining accurate variance analysis, strict technical data management, and document control system.

E Implementing and maintaining the Information Management System (IMS) including the management of QA records.

F Formulating and administering subcontracts.

It is the responsibility of the Business Services Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Business Services Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Business Services Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.8 Procurement and Property Manager

The Procurement and Property Manager reports to the Deputy Project Manager and is responsible for providing the processes and procedures for procuring items and services.

It is the responsibility of the Procurement and Property Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The Procurement and Property Manager has the responsibility to stop project activities within his or her area of responsibility which are not accomplished in compliance with applicable license and/or regulatory requirements.

The Procurement and Property Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his or her cognizance will conform to and support the requirements of this policy.

3.9 Environmental, Safety and Health Manager

The Environmental, Safety and Health (ES&H) Manager reports directly to the Project Manager and is responsible to provide services to assure that uniform technical and regulatory adequacy is achieved. He is also responsible to provide safe, reliable, and efficient activities in accordance with policies and applicable laws, regulations, and licenses.

The ES&H Manager is responsible for the following major functions:

A Implementing, evaluating, and continuously improving a rigorous standards-based ES&H program.

B Identifying ES&H regulatory requirements.

C Maintaining facilities Authorization Bases (AB) documentation.

D Maintaining and expanding the project Integrated Safety Management System (ISMS) program.

E Assisting the DOE in obtaining all required project permits.

F Supporting the project in nuclear safety, radiation protection, industrial hygiene, and safety.

G Providing positions and interpretations on the regulatory documents to which the project is committed.

It is the responsibility of the ES&H Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The ES&H Manager has the responsibility to stop project activities within his area of responsibility which are not accomplished in compliance with applicable license, laws, and/or regulatory requirements.

The ES&H Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.10 Quality Assurance Manager

The QA Manager has the functional authority, independence, and responsibility to assure the effective implementation of and compliance to the QA Program. Consistent with this authority is the responsibility to document interpretations of those activities to which this policy applies and the extent to which this policy applies to those activities. The QA Manager has no unrelated duties that would preclude full attention to assigned responsibilities.

The QA Manager reports directly to the BNI QA Manager for program definition, and functionally to the Project Manager for QA matters and is responsible to ensure that an appropriate QA Program, the scope of which includes all the systems and activities that affect safety and quality, is established and implemented in accordance with the requirements of this policy. The QA Manager reviews project activities with the goal of identifying areas where changes could lead to improvements in safety and/or quality. The QA Manager has the authority to cross organizational lines to identify quality problems, to initiate, recommend, or provide solutions, and to verify implementation.

The QA Manager is responsible for the following major functions:

A Providing guidance and oversight for the project based on applicable requirements of 10 CFR 830, Subpart A, DOE Order 414.1A, DOE/RW-0333P, Revision 10, and NQA-1 (1989).

B Conducting independent assessments, audits and surveillances.

C Providing guidance to functional organizations and area project teams.

D Performing evaluations and self-assessments on a planned and periodic basis to verify the QA Program is being effectively implemented.

E Directing that work will be stopped on nonconforming materials or activities if:

1 Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel.

2 Continued work will require significant rework or repair to backfit corrective action.

3 An organization, department, group, section, or individual, by a repetitive failure to comply with technical or administrative controls, contributes to a condition that is a significant QA Program deficiency.

F Providing for the review and acceptance of contractor and vendor QA programs.

G Providing for the review of procedures and other quality-related documents.

H Providing a working interface and line of communication with other departments, appropriate industry representatives, and regulatory groups for QA matters.

I Establishing indoctrination and training programs for QA and Quality Control (QC) personnel.

J Providing input for QA indoctrination of personnel outside of the QA organization.

K Issuing periodic reports to the Project Manager and appropriate management on the status of quality activities.

L Notifying the Project Manager, or appropriate management, of any significant conditions adverse to quality.

M Trending conditions adverse to quality.

N Providing Price-Andersen Amendment Act (PAAA) Program identification, documentation, and supporting function for the Project.

O Development and maintenance of the Quality Assurance Manual (QAM).

P Development and maintenance of the Quality Assurance Provisions Document (QAPD).

It is the responsibility of the QA Manager to create an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

The QA Manager may delegate activities to other organizational elements, however, he retains full responsibility for the QA Program.

The QA Manager gives full support to the QA Program described herein, thereby assuring that all work performed under his cognizance will conform to and support the requirements of this policy.

3.11 All Personnel

All project employees are responsible for:

A Achieving acceptable quality during the performance of work activities.

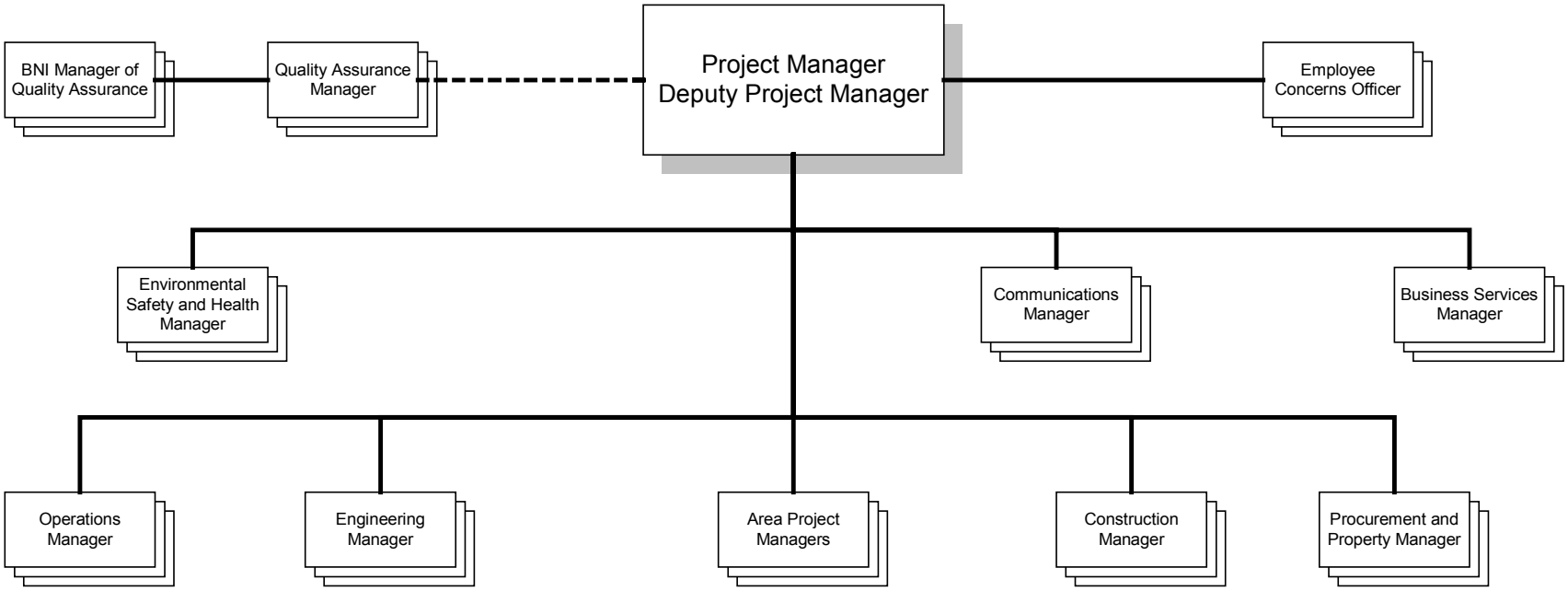
B Safely accomplishing work activities in accordance with instructions, procedures, and drawings.

C Stopping work activities and informing their supervisors when it appears that adherence to a procedure is not possible or may result in an unsafe condition.

D Promptly identifying and reporting safety and quality deficiencies to their supervisors.

Policy Q-01.1 Project Organization

Figure 1 Overall Management Structure and Organization



Policy Q-02.1 Quality Assurance Program

1.0 Quality Assurance Program

1.1 General

The Bechtel National, Inc. (BNI) Quality Assurance (QA) program has been established to control the activities performed within the scope of designing, constructing, and pre-operational testing the Waste Treatment Plant (hereafter referred to as the project). The key elements of the QA program include a defined work scope, a planned methodology of quality management, clear work control elements, a process for documenting nonconformances and corrective actions, an indoctrination and training program, and provisions for independent and management assessments.

The QA program is a management system designed to promote the effective and efficient achievement of performance objectives through:

A Planning and documenting requirements for items, processes, and services.

B Controlling activities affecting the quality of those items, processes, and services.

C Demonstrating adequacy of work and verifying the achievement of required quality.

D Analyzing and correcting conditions adverse to quality in a continuing process of self-improvement.

E Ensuring personnel have adequate training to ensure competence commensurate with responsibility.

The QA program is binding on all project personnel, including those responsible for planning and scheduling activities and external organizations working under the direct control of BNI. Management will ensure, through a formal, documented indoctrination and training program, that project personnel understand the basic QA program. Additional, in-depth training will be provided as appropriate to meet project-specific needs.

QA program implementation and maintenance will be verified through a two-tiered field assessment program. The first tier consists of on-going management assessments, described in Policy Q-18.3 – *Management Assessment*, that are performed by all levels of management to determine the level of program compliance, promote continuous improvement, and enhance project performance. The second tier consists of ongoing independent audits and surveillances performed by the QA organization in accordance with Policies Q-18.1 - *Independent Assessment (Audit)* and Q-18.2 - *Independent Assessment Surveillance*, to verify program implementation, maintenance, and the effectiveness of the management assessment process.

Policy Q-02.1 Quality Assurance Program

The QA program is the management system that addresses the major elements of the U.S. Department of Energy (DOE) QA Order (DOE-O 414.1A) and the Nuclear Quality Assurance Rule (10 CFR 830, Subpart A): managing, performing, and assessing the adequacy of work. The QA program includes the QA Manual (hereafter referred to as the manual) any special QA plans, the implementing procedures, and other documents. The QA Manual serves as the "umbrella" for defining the QA program. Additional QA plans, in the form of Quality Assurance Project Plans, may be required and developed for specific project activities subject to environmental regulation. Specifically, Quality Assurance Project Plans (QAPjPs) are written to address how Washington Administrative Codes or Environmental Protection Agency requirements are applied to project operations.

The QA Manual is structured to capture and integrate into a single cohesive QA program, the requirements that apply to the project as stated in the Contract (DE-AC27-01RV14136) and reflects the 18 criteria structure of NQA-1-1989 and DOE/RW-0333P, Revision 10. Each of the 18-plus policies that comprise the manual reflects the NQA-1 criteria structure. The policies, as appropriate, contain purpose and applicability statements, implementation strategy, discrete requirements or policy, and responsibilities of management and personnel for effective implementation of requirements. The QA Manager is responsible for the resources for developing and maintaining the manual. The Project Manager retains the responsibility for authorizing the manual and assuring that the authority and independence of the QA Manager is such that he can effectively assure the conformance to quality requirements.

The implementation strategy and policy are the two important elements that comprise each policy used in constructing the manual. The implementation strategy element is structured to describe appropriate methods and guidance for implementing the policy requirements to achieve implementation of a quality assurance program that surpasses minimum requirements and promotes project excellence. The policy element defines the contract requirements based on comparisons that have been made between the two major QA requirement documents that define operation of the project at large: NQA-1-1989 and DOE/RW-0333P, Revision 10, including the required supplements of each. Where requirements are equivalent, one statement has been selected as the requirement for the project. Where requirements are not equivalent, separate requirements were established and their applicability specified (i.e., applicable to the project at large or limited to Immobilized High Level Waste [IHLW] applications).

Requirements of this manual are to be contained in project procedures. These procedures can be supplemented by other lower-tier instructions and other implementing documents, where applicable, to provide the detail necessary for proper flowdown and implementation of QA requirements. The QA program documentation constitutes a significant portion of the project’s Integrated Safety Management System (ISMS), which ensures that work is performed safely and in compliance with requirements. Current implementing documents can be found in the Quality Assurance Provisions Document (24590-WTP-QPD-QA-01-001). Documents will be added, deleted, or modified as necessary to reflect the requirements stated in this manual.

1.2 Quality Assurance Scope

The scope of the manual includes, but is not limited to, items and activities related to safe plant operation, and protection of personnel and the public. To ensure consistency in identifying quality-affecting items and activities, a classification process has been developed and is controlled through engineering procedures. This process relies on the use of the terms "Quality Level (QL)-1 (Safety Design Class), QL-2 (Safety Design Significant), other QLs as identified, and non-quality related." This QA manual shall be applied to all QL items and activities as described below:

A The program applies to radiological and nuclear process safety items and activities.

B This program applies to items and activities that affect product quality of the Immobilized Low-Activity Waste (ILAW), including but not limited to, entrained solids, waste form development, qualification, characterization, production process control, and certification. Research and technology activities used for waste form development, qualification, production, and acceptance shall be conducted in accordance with this policy as appropriate to the importance to safety and quality impact.

C This program applies to items and activities that affect the IHLW product quality, including but not limited to, waste form development, qualification, characterization, production process control, and certification. IHLW research and technology activities used for waste form development, qualification, production, and acceptance shall also be conducted in accordance with this manual.

D Permitting activities shall be conducted in accordance with the applicable requirements of this manual and all applicable laws and regulations.

E The requirements of this manual shall be applied to other project items and activities, including balance of facilities and pretreatment activities, based on their importance to safety and quality.

1.2.1 Items

Items to which this manual applies are designated as QL. The classification process for items is controlled through engineering procedures. This classification process produces an items list, which identifies the permanent plant structures, systems, and components that are within the scope of this manual and their specific classifications.

The classification of parts, materials, and consumable items and the technical and quality requirements shall be specified, documented, and approved as part of the engineering process.

Items affecting ILAW and IHLW shall be designated as such in accordance with engineering procedures.

1.3 Graded Approach

The scope, depth, and rigor of the application of quality assurance requirements to a specific item or activity should be determined by the use of a grading process. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the project. Grading is encouraged if a single or uniform method of applying a requirement across an item or activity does not add value or reduce risk. The grading process provides the flexibility to design controls that best suit the item or activity. The grading process is not used to obtain exemptions from the requirements of this manual.

The extent to which the requirements of this manual and its implementing documents are applied to an item or activity shall be based upon the following:

A Function or end use of the item.

B Consequence of failure (risk) of the item.

C Importance of the data being collected or analyzed.

D Complexity of design or fabrication of the item or design or implementation of the activity.

E Reliability of the process.

F Reproducibility of the results.

G Uniqueness of the item or degree of standardization.

H History of the item or service quality.

I Necessity for special controls or processes.

J Degree to which functional compliance can be demonstrated through inspection or test.

The extent to which the requirements of this policy apply to an item shall be based on an evaluation of the above factors as well as other regulatory commitments as may have been made associated with the item. Such other plans or regulatory commitments include, but are not limited to, those associated with emergency planning, physical plant security, safeguard contingency planning, radiological controls, environmental controls, fire protection, in-service inspection, in-service testing, operator qualification and re-qualification, process control, and offsite dose calculation.

The varying degrees of the controls applied should be dependent upon function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations. Risk is a fundamental consideration in determining to what extent controls should be applied. Risk is a quantitative or qualitative expression of possible impacts or loss (e.g., project, financial, safety) that considers both the probability of an event causing harm or loss and the consequences of the event. Determination (or estimation) of the probability or likelihood of the occurrence should be a part of the risk expression. For example, procurement of QL 1 items would require more rigorous supplier controls to meet procurement requirements than that needed for facility area lighting fixtures. Estimates and qualitative expressions are useful for management issues

where quantitative data is unavailable. Process systems, repetitive activities, and hardware are typically suitable for quantitative expressions of risk.

Application of the graded approach shall be accomplished in accordance with procedures concurred with by the QA organization. The procedures shall include the provision to ensure that the application of the graded approach is consistently applied. Application of quality requirements to items shall be the responsibility of the Engineering Manager.

1.4 Work Planning

Work planning ensures work is accomplished under suitably controlled conditions, and is a fundamental concept of Integrated Safety Management. Planning elements shall include, as appropriate:

A Definition of the work scope, objectives, and a listing of the primary tasks involved.

B Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work.

C Identification of applicable standards and criteria.

D Identification and application, or development, of appropriate implementing documents.

E Identification of field and laboratory testing equipment or other equipment.

F Identification of, or provisions for the identification of required records and the recording of objective evidence of the results of the work performed.

G Identification of QA program verifications of the work performed.

H Identification of prerequisites, special controls environmental conditions, processes, or skills.

I Identification of computer software.

J Identification of applicable hazards, hazard mitigation, and the incorporation of applicable and relevant feedback to improve the work process and work activity.

1.5 Control of the Quality Assurance Program

The QA Manager shall, for each revision to the manual, determine if the proposed change affects the program description previously accepted by the DOE.

Revisions to the manual that do not reduce the commitments in the program description previously accepted by the DOE shall be concurred with by affected Senior Management, the Project Safety Committee (PSC), and approved by the QA Manager. Revisions of this type do not require approval by the DOE prior to issuance, but must be submitted to the DOE at least annually in accordance with the requirements of Section (b)(3) of 10 CFR Part 830, Subpart A, *"Quality Assurance Requirements."* The QA Manager shall approve all revisions to this manual.

Revisions to the manual that reduce the commitments in the program description previously accepted by the DOE shall be concurred with by affected Senior Management,

the QA Manager, and approved by the Project Manager. They must be submitted to the DOE for approval prior to implementation. Such revisions shall be submitted to the DOE for approval and regarded as approved 90 days after submittal, unless it is approved or rejected by the DOE at an earlier date. The submittal of a revision to the manual shall identify the changes, all pages affected by that change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the contract requirements and to provide a suitable level of control. Changes made to correct spelling, punctuation, or other editorial items do not require explanation. Annually, changes to the DOE approved manual shall be submitted to the DOE for approval. The submittal shall include a justification for why the changes continue to satisfy the quality assurance requirements.

1.6 Effective Date of Implementation

Changes to implementing procedures resulting from changes to this manual shall be incorporated within 90 days of the manual change approval date unless an interim action plan is defined and approved by the QA Manager.

1.7 Regulatory Commitments

The Environmental, Safety, and Health (ES&H) Manager is responsible for providing the BNI positions and interpretations on the regulatory documents to which BNI is committed. Changes to these commitments shall be accomplished in accordance with regulatory requirements. The QA Manager shall concur with changes to the positions and interpretations affecting this QA Manual.

1.8 Quality Assurance Program Review

The effectiveness of the QA program and its implementation is periodically reviewed at the department level and the results of these reviews are documented in reports to the Project Manager and Senior Management for evaluation and corrective action as required. The effectiveness of the QA program is also evaluated and reported by the QA organization through the inspection, review, monitoring, auditing, and assessment functions. In addition, the QA organization at a minimum, annually, prepares evaluation reports on program effectiveness.

In addition to the reviews and evaluations performed above, the Project Manager shall have an independent assessment of the QA program implementation performed at least annually. This assessment may be performed utilizing an independent consultant, representatives from other DOE locations, corporate representatives and/or senior staff representatives. Any corrective action which may be deemed necessary as a result of these assessments shall be formally identified and tracked through resolution.

1.9 Quality Classification

The quality classifications for items and activities within the scope of the QA program shall be established using approved engineering procedures concurred with by QA. Systems and components shall be identified as either QL or non-quality related in

accordance with procedures. Subsection 1.3 provides the basis for grading which is the extent of application of the requirements of this policy.

1.10 External Organizations

Suppliers who provide items, parts, materials, consumables, and/or services that are within the scope of this program shall perform work to an appropriate QA program and implementing procedures. The supplier's QA program shall be subject to review and concurrence by QA. The extent to which the supplier's QA program shall be applied shall be specified by procurement documents.

1.11 Resolution of Differences and Escalations

Differences of opinion involving QA program requirements shall, if possible, be resolved at the level at which they occur. If this is not possible, the differences shall be escalated through supervisory/management levels until resolution is achieved.

The QA Manager shall be the arbiter on matters concerning the applicability and interpretation of the manual.

1.12 Integrated Safety Management System

Effective implementation of the QA requirements will also provide processes and tools to support principles and functions of the Safety Management System Policy (DOE P 450.4) and related portions of the DOE Acquisition Regulation (DEAR, 48 CFR 970.5204-2). The DOE Safety Management System Policy expresses a fundamental expectation that all work be performed safely. Project management's fundamental quality assurance expectation is that all work meets established requirements. In this regard, management ensures compliance with the approved standards set, so that the expectation for safe work within controls is met. This also ensures workers, the environment, and the public are reasonably protected from harm. The project's quality and safety requirements share a management systems approach to achieving their objectives. As such, compliance to established processes (e.g., procedures and instructions) satisfies quality and safety requirements.

Shared attributes of Quality and Safety Management Systems include:

A Expectations for implementation (DEAR 970.5204-2 (c)).
B Documentation of the Management System (ISMS Principle 7).
C Clear roles and responsibilities (ISMS Principle 2).
D Balanced priorities (resources) (ISMS Principle 4).
E Feedback and improvement (ISMS Core Function 5).
F Line management responsibility (ISMS Principle 1).
G Competence and qualifications (ISMS Principle 3).
H Standards and controls for work (ISMS Principle 5 and Core Function 4).
I Graded and tailored controls (ISMS Principle 6).

1.13 Flowdown of QA Program Requirements

In accordance with the principles of Integrated Safety Management, requirements must flow from their source down into working level documents. The project QA program applies, with appropriate grading of controls to the scope of work defined in BNI's contract with DOE, and is implemented through a variety of documents. This QA Manual serves to reflect the quality assurance requirements imposed by regulation and by contract (DE-AC27-01RV14136) and to provide the basis for their flowdown and implementation via implementing level documents. The following figure illustrates the requirements flow down from the various requirement sources to the implementing level documents.

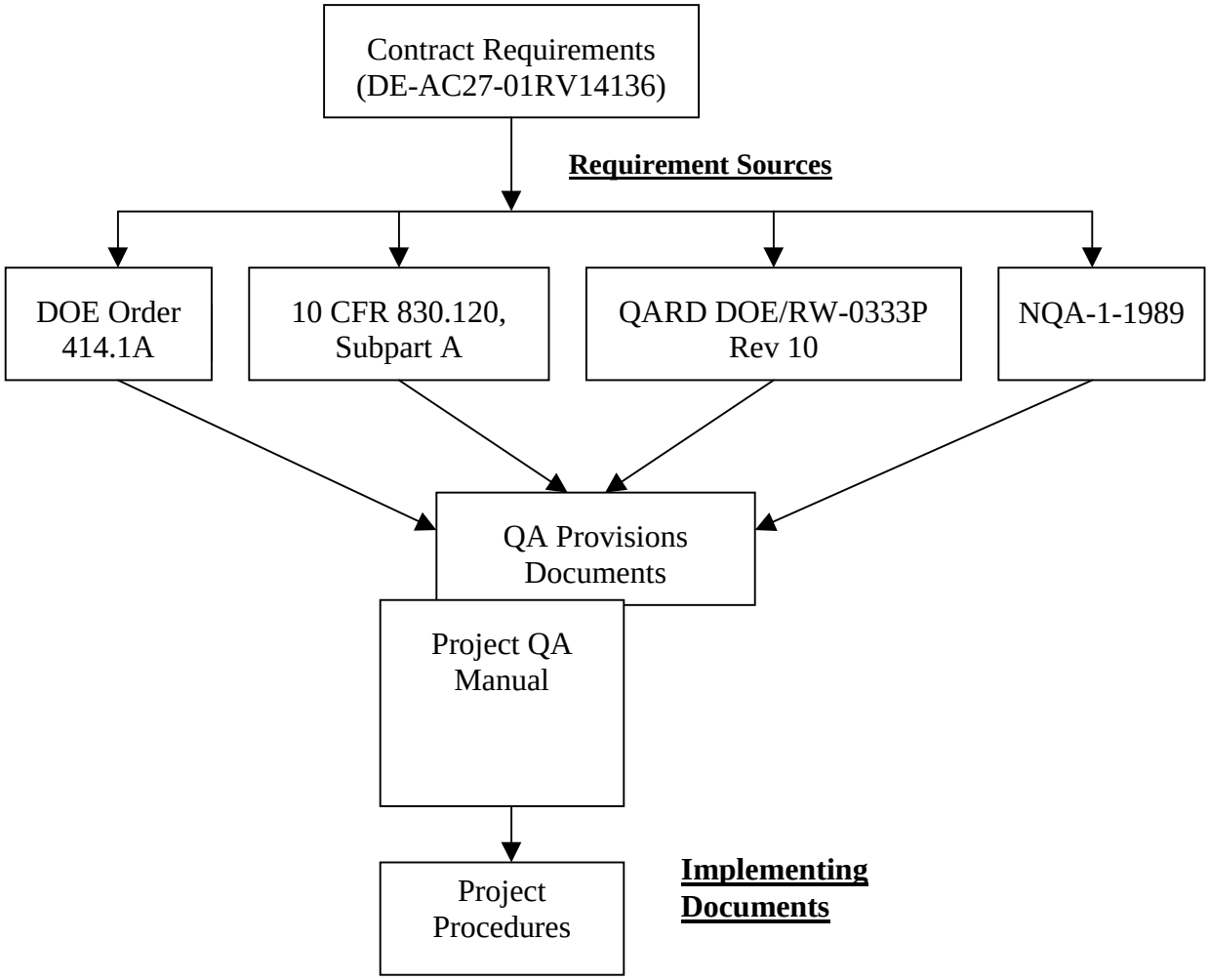


Figure 2. QA Program Requirements Flowdown

Policy Q-02.2 Personnel Training and Qualification

1 Purpose and Applicability

This policy identifies responsibilities and requirements for the indoctrination, training, and qualification of personnel performing or managing activities affecting quality. It includes requirements for the training or indoctrination of personnel as to the technical objectives and requirements of the applicable codes and standards, and the applicable quality assurance requirements to be used on the project, and to ensure that appropriate continuing training is provided to maintain proficiency.

This policy applies to organizations and personnel performing activities that affect quality.

2 Implementation Strategy

In accordance with a guiding principle inherent in the core functions of Integrated Safety Management System (ISMS), project personnel will be trained and qualified commensurate with their responsibilities. Management will establish initial and continuing training and qualification requirements and processes for specific job categories. This ensures that personnel achieve the required competency commensurate with their responsibilities in accordance with the quality assurance (QA) program and the guiding principles of the ISMS.

The qualification of personnel performing activities affecting quality will be accomplished by consideration of experience, education, training, and may include demonstration and testing. Training programs are to consist of a combination of classroom and on-the-job training, and include other training as it applies to the position. Classroom training includes lectures, seminars, computer-based training, and structured self-study activities.

All training and qualification programs for the project will be developed and implemented in a manner consistent with the hazards and the risks associated with the activity performed. Initial training programs will be established for personnel for indoctrination on project-specific requirements. These programs will be structured commensurate with specific position needs. Examinations and/or operational evaluations on material included in the training programs are to be administered and documented as appropriate. Each organization is responsible for training and qualification of their personnel. Organizational interfaces with the training organization will be addressed in implementing procedures. The role of the training organization will be defined in project procedures that include training program scope commensurate with personnel responsibilities.

Continuing training will be established to maintain and enhance the knowledge and skills of personnel commensurate with specific position needs. Continuing training will include, at a minimum, training in significant applicable procedure changes, applicable industry operating experience, selected fundamentals with emphasis on knowledge and skills necessary to assure safety, and other training as needed to correct identified performance problems.

Policy Q-02.2 Personnel Training and Qualification

Training and qualification procedures will establish processes that are used by project personnel for the conduct of training and qualification programs. Training profiles or plans are to be designed both to prepare individuals to perform a job and to maintain performance while in a job. Training profiles or plans may also be used to identify improvement opportunities for those in a job.

Instructors should engage in performance-based training and be appropriately qualified for the specific training tasks. Classroom instructors will be qualified by the project training organization. Instructor training is to be based, in part, on the results of instructor evaluations and the need for training on new methods and equipment. Classroom instructors should possess the technical knowledge, experience, and development and instructional skills commensurate with the subject material and the level of instruction.

Procedures implementing the Personnel Training and Qualification requirements of this policy shall provide for developing worker competence commensurate with the scope, complexity, and nature of the activities their jobs require. Personnel training and qualification shall be conducted utilizing approved procedures that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Each organization shall provide for indoctrination, training, and formal qualification, as necessary, of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.

3.1.2 Management may delegate formal qualification examination activities to an independent certifying agency, but shall retain responsibility for the examination and its administration.

3.2 Indoctrination and Training

3.2.1 Indoctrination and training shall be commensurate with the scope, complexity, and importance of the activities, and the education, experience, and proficiency of the personnel.

3.2.2 Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority, general criteria, including applicable codes and standards, company procedures, and quality assurance program requirements, before performing quality-affecting work.

3.2.3 The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

3.3 Formal Qualification Requirements

3.3.1 The responsible organization shall designate those activities that require formal qualification of personnel and the minimum requirements for such personnel.

3.3.2 The responsible organization shall establish written procedures for the formal qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform the activities identified in 3.3.1.

3.3.3 Qualification requirements for personnel performing nondestructive examination (NDE), inspection and tests to verify quality, and auditing are as follows:

A Personnel who perform NDE including radiographic (RT), magnetic particle (MT), ultrasonic, (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiography (NR), leak testing (LT), and acoustic emission (AE), to verify conformance to specified requirements shall be qualified to procedures that meet the requirements of the *American Society of Nondestructive Testing Recommended Practice* No. SNT-TC-1A, June 1980 Edition, and its applicable supplements. In lieu of the three year certification interval specified in SNT-TC-1A, June 1980 Edition, Level III Nondestructive Examination personnel may be recertified on a five-year interval. When required by the implementing code, visual testing (VT) will be subject to these same requirements.

B Inspection and test personnel qualification requirements will be included in specific procedures.

C Inspection and test personnel shall be qualified as required by specific procedures.

D The initial capabilities of an inspection and test candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.

E Re-evaluation of independent inspection and test personnel job performance shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of this policy. If, during this evaluation, or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Work performed by the individual during the time they were not qualified, shall be evaluated by a qualified individual for acceptance. The evaluation shall be documented.

F Any person who has not performed independent inspection or testing activities in the qualified area for a period of one year shall be re-evaluated.

G Qualification/certification requirements for QA auditors/lead auditors and technical specialists shall be as identified in Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 For personnel who perform or manage design, scientific investigations, software development activities, and for personnel who verify or manage the verification of design, scientific investigation, software development activities, or items, affected organizations shall ensure that:

A Descriptions are established for the positions these personnel occupy.

B Minimum education and experience requirements are established for each position commensurate with the scope, complexity, and nature of the work.

C Personnel have experience and education commensurate with the minimum requirements established. Documented justification is provided for persons that do not meet minimum education and experience requirements.

D Minimum education and experience are verified or, when minimum education and experience cannot be verified, documented justification is provided for the personnel assignment.

5 Records

5.1 Qualification and training records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

5.2 Records of personnel training and/or qualification for activities affecting quality shall be established and maintained by the project.

Note: Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

6 Responsibilities

6.1 All Managers

Are responsible for:

A Developing job specific training and minimum education and experience requirements.

B Establishing training requirements for project personnel.

C Committing resources to provide training to personnel performing activities that affect quality within their organizations.

D Ensuring that personnel within their organization comply with requirements for indoctrination, training, qualification, and that suitable proficiency is achieved and maintained.

E Reviewing job responsibilities and scope-of-work assignments to ensure that the training program is maintained current with work assignments and is updated to improve overall work performance.

F Ensuring indoctrination and training is completed prior to performing work.

G Ensuring that when work must be performed by an individual prior to completion of indoctrination and training, or completion of qualification requirements,the individual will be supervised and all work products will be reviewed and approved for use by a qualified individual.

6.2 The Operations Manager

Is responsible for:

A Training department activities and implementation, control, and maintenance of the training matrix for tracking training of personnel and for determining the status of the training program.

B Control and maintenance of training and certification records as required until turnover to the project records management system.

6.3 The Construction Manager

Is responsible for:

A Construction training activities and implementation, control, and maintenance of the training matrix for tracking training of construction personnel and for determining the status of their training.

B Control and maintenance of construction-related training and certification records as required until turnover to the project records management system.

6.4 The Business Manager

Is responsible for:

A Providing support for the hiring of qualified personnel to meet position requirements, when required.

B Documenting and providing evidence of education and experience as required by the position description.

C Issuing and controlling implementing procedures for the training and indoctrination process.

6.5 The Quality Assurance Manager

Is responsible for:

A Periodically assessing the status and effectiveness of the indoctrination and training programs to ensure that they continue to reflect the current systems, procedures, and policies applicable to each position. Assessments of the training program conducted by the QA Manager shall be coordinated with the Project Manager and shall be scheduled and conducted at least annually.

B Control and maintenance of QA training and certification records as required until turnover to the project records management system.

6.6 All Personnel

Are responsible for:

A Complying with the indoctrination, training, and qualification requirements applicable to their job assignment, and maintaining their job proficiency.

Policy Q-02.3 Auditor/Lead Auditor Qualification and Certification

1 Purpose and Applicability

This policy identifies responsibilities and requirements for the qualification and certification of quality assurance (QA) auditors and lead auditors. It includes requirements for the initial and continuing qualification and certification of technical specialists, auditors, and lead auditors.

This policy applies to the QA organization and other organizations supporting quality assurance audits.

2 Implementation Strategy

In accordance with a guiding principle inherent in all of the core functions of the Integrated Safety Management System (ISMS), personnel conducting QA auditing activities will be trained and qualified commensurate with their responsibilities to ensure they are capable of performing their assigned work. The QA manager will establish the training and qualification requirements for technical specialists, auditors, and lead auditors. This ensures that personnel achieve the required competency commensurate with their responsibilities in accordance with the QA program and the guiding principles of the ISMS.

The qualification of auditing personnel will be accomplished by consideration of experience, education, training, and by demonstration and testing to verify acquired skills. Auditor and lead auditor training normally will consist of a combination of general and specialized training in audit performance, including general training in auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

Training and qualification procedures will establish standards for the conduct of auditor and lead auditor training and qualification programs. Training profiles or plans are to be designed both to prepare individuals to perform auditing activities and to maintain performance.

Procedures implementing the auditor and lead auditor qualification requirements of this policy shall provide for developing and maintaining auditor proficiency commensurate with the scope, complexity, and nature of the activities their jobs require. Auditor and lead auditor training and qualification shall be conducted utilizing approved procedures that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Auditors and lead auditors shall be trained, qualified, and lead auditors shall be certified in accordance with the requirements of this policy and Policy Q-02.2 - *Personnel Training and Qualification*.

3.1.2 Personnel selected for quality assurance auditing assignment shall have experience or training commensurate with the scope, complexity or special nature of the activities to be audited.

3.2 Auditor Qualifications

3.2.1 Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits.

3.2.2 Competence of personnel for performing the various auditing functions shall be developed by one or more of the following methods:

A Orientation to provide a working knowledge and understanding of the QA program requirements, and the auditing organization's procedures for performing audits and reporting results.

B General and specialized training in audit performance, where the general training shall include auditing fundamentals such as objectives, characteristics, organization, performance, and reporting results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

C On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

3.3 Lead Auditor Qualifications and Certifications

A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective actions. An individual shall meet the following requirements prior to being designated as a lead auditor.

3.3.1 Communication Skills

The prospective lead auditor shall be capable of effective written and oral communication. These skills shall be attested to in writing by the lead auditor's manager.

3.3.2 Training

Prospective lead auditors shall receive training to the extent necessary to assure auditing competence including:

A Knowledge and understanding of requirement documents and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.

B General structure of QA programs as a whole, and applicable elements as defined in requirement documents.

C Auditing techniques of examining, questioning, evaluating, and reporting, methods of identifying and following up on corrective action items, and closing out audit findings.

D Planning audits of activities affecting quality.

E On-the-job training to include applicable elements of the audit program.

3.3.3 Audit Participation

A Prospective lead auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification and certification.

3.3.4 Examination

A Prospective lead auditors shall pass an examination, which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

B The development and administration of the examination for a lead auditor is the responsibility of the auditing organization. The auditing organization shall develop and maintain objective evidence regarding the type, content, and results of the examination.

3.3.5 Maintenance of Proficiency

A Lead auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to the QA program and program auditing; or participation in audit training program(s).

B Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Management evaluations shall be documented.

Note: Based on annual assessment, management may extend the qualification, require re-training, or require re-qualification.

3.3.6 Re-Qualification

Lead auditors who fail to maintain their proficiency for a period of two years or more shall be required to re-qualify. Re-qualification shall include re-training in accordance with the requirements of subsection 3.3.2 of this policy, re-examination in accordance with the requirements of subsection 3.3.4 of this policy, and participation as an auditor in at least one nuclear quality assurance audit.

3.3.7 Certification of Qualification

3.3.7.1 Each lead auditor shall be certified by the auditing organization as being qualified to lead audits.

3.3.7.2 The qualification of lead auditor personnel shall be certified in writing and shall document the following information:

A Employer's name.
B Identification of person being certified.
C Activities certified to perform.
D Basis of qualification to include:
  1 Education, experience, indoctrination, and training.
  2 Test results, where applicable.
  3 Capability demonstration results.
E Results of periodic evaluation.
F Results of physical examinations, when required.
G Signature of employer's designated representative responsible for such certification.
H Date of certification or re-certification and certification expiration.

3.3.7.3 The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

3.3.7.4 The auditing organization shall maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the auditing organization in accordance with subsection 5.0 of this policy.

3.3.8 Qualification Credits Scoring Systems

The prospective lead auditor shall have verifiable evidence that a minimum of ten credits have been accumulated under the following scoring system:

A Education (four credits maximum):

1 An Associate's Degree from an accredited institution scores one credit; if the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.

2 A Bachelor's Degree from an accredited institution scores two credits; if the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits.

3 In addition, score one credit for a Master's Degree in engineering, physical sciences, business management, or QA from an accredited institution.

B Experience (nine credits maximum) - Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility scores one credit for each full year, with a maximum of five credits for this aspect of experience:

1 If two years of this experience have been in the nuclear-related field, score one additional credit; or

2 If two years of this experience have been in QA, score two additional credits; or

3 If two years of this experience have been in auditing, score three additional credits; or

4 If two years of this experience have been in nuclear-related QA, score three additional credits; or

5 If two years of this experience have been in nuclear-related QA auditing, score four additional credits.

C Professional Competence (two credits maximum) - For certification of competency in engineering science or QA specialties issued and approved by a state agency or national professional or technical society, score two credits.

D Rights of Management (two credits maximum) - When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).

3.4 Technical Specialist Training

3.4.1 Personnel shall be indoctrinated and trained to achieve initial proficiency prior to performing or participating in audits. Initial proficiency includes familiarization with the Quality Assurance Manual and its implementing procedures related to auditing and auditing qualifications.

3.4.2 Technical specialists shall have the level and experience or training commensurate with the scope, complexity, or special nature of the work being audited.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in subsection 3 – *Policy*.

5 Records

5.1 All records shall be controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

5.2 Records of personnel qualification, including re-qualification for auditors and lead auditors performing audits, shall be established and maintained by the project.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for the following:

A Defining the requirements for technical specialist, auditor, and lead auditor qualification and certification.

B Evaluating objective evidence to determine acceptability for auditor/lead auditor qualification against criteria in this policy.

C Qualifying auditors and lead auditors, and certifying lead auditors.

D Providing for auditor/lead auditor training.

E Providing for a written examination of prospective lead auditors.

F Ensuring that records of auditor/lead auditor qualification are established and maintained.

6.2 Audit Manager

The Audit Manager is responsible for submitting documentation of a prospective auditor's/lead auditor's work history/experience to the QA Manager.

6.3 Lead Auditors

Lead Auditors are responsible for counseling and/or evaluating prospective auditors/lead auditors and documenting their proficiency.

Policy Q-02.4 Special Reviews

1 Purpose and Applicability

This policy identifies additional requirements from the Quality Assurance Requirements Document (QARD) (DOE/RW-0333P) which are specific to the project for ensuring that readiness and peer reviews are identified, planned, and implemented where needed.

This policy applies to project organizations performing readiness and peer reviews.

2 Implementing Strategy

Peer reviews are conducted for work that the adequacy of information or the suitability of implementing documents and methods to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards or practices. Peer reviews are performed by one or more individuals who have technical expertise collectively at least equivalent to those who performed the original work. The peer review is an in-depth critique of assumptions, documents, calculations, extrapolations, alternative interpretations, methodology acceptance criteria, conclusions, and material or data that require interpretation or judgement to verify or validate them.

Requirements for Operational Readiness Reviews (ORR) are also to be established and documented. When required by the established criteria, an ORR will be performed prior to major scheduled or planned facility restarts. ORRs are to be performed at the request of the management responsible for the activity under review to ensure a technically competent assessment.

ORRs will be independent of other management activities to the extent necessary to provide an unbiased perspective. ORRs will include, as a minimum, verification of the following characteristics:

A Work prerequisites are satisfied.

B Detailed technical and quality assurance (QA) procedures, applicable to the work to be performed, are reviewed for adequacy and appropriateness.

C Personnel are suitably trained and qualified.

D Proper equipment, material, and resources are available.

Peer reviews and ORRs are part of the feedback and improvement function of the Integrated Safety Management System (ISMS).

The Engineering Manager and Operations Manager are responsible for developing the implementing procedures for conducting peer reviews and operational readiness reviews that are concurred with by the QA organization that contain the requirements of this policy.

3 Policy

3.1 Readiness Reviews

3.1.1 Line management shall plan, schedule, and conduct readiness reviews at significant transitional events both leading up to and during waste form production.

3.1.2 Line management shall establish measures for controlling technical modifications to the waste form production process. Technical modifications subject to control shall include:

A Waste form and canistered waste form.

B Process control plans and other implementing documents.

C Waste Acceptance Product Specifications, Waste Form Compliance Plans, and Waste Form Qualification Reports.

3.1.3 The need for readiness reviews shall be identified by affected organization management for major scheduled or planned work to ensure program objectives are met.

3.1.4 Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that:

A Work prerequisites have been satisfied.

B Personnel have been suitably trained and qualified.

C Detailed implementing documents and management controls are available and approved.

3.2 Peer Reviews

Peer reviews shall be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.

3.2.1 The following conditions are situations for which a peer review shall be considered:

A Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

B Decisions or interpretations having significant impact on performance assessment results will be made.

C Novel or beyond the state-of-the-art testing, plans and procedures, or analyses will be utilized.

D Detailed technical criteria or standard industry procedures are not available.

E Results of tests are not reproducible or repeatable.

F Data or interpretations are ambiguous.

G Data adequacy is questionable (e.g., the data may not have been collected in conformance with an established QA program).

3.2.2 Management shall determine the need for and, as appropriate, shall initiate peer reviews when the adequacy of a critical body of information can be established by alternate means, but there is significant disagreement regarding the applicability or appropriateness of the alternate means. In conducting a peer review, management shall ensure that the:

A Number of the peer reviewers is commensurate with the complexity of work to be reviewed, its importance to project objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review.

B Collective technical expertise and qualifications of the peer reviewers span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought.

C Technical areas central to the work to be reviewed receive appropriate proportional representation among the peer reviewers.

D Potential for technical or organizational partiality is minimized.

E Peer review group chairperson is identified.

3.2.3 Peer reviews shall be performed by individuals that have:

A Technical qualifications in the review area at least equivalent to that needed for the work under review.

B Technical credentials that are recognized and verifiable.

C Independence from the work under review. Independence means that the individual was not involved as a participant, supervisor, technical reviewer or advisor in the work under review and is, to the extent practical, free from any funding considerations.

Note: In those cases where total independence cannot be met, the rationale as to why someone of equivalent technical qualification and greater independence was not selected shall be documented in the peer review report.

3.2.4 Initiation of the peer review shall require the development of a planning document that:

A Specifies the work to be reviewed.

B Identifies the size and spectrum of the peer review group.

C Describes the expected method and reporting schedule.

D Establishes review criteria that shall include, as appropriate:

1 Validity of the assumptions.

2 Alternate interpretations.

3 Adequacy of requirements and criteria.

4 Appropriateness and limitations of the methods and implementing documents used to complete the work under review.
5 Adequacy of application.
6 Accuracy of calculations.
7 Validity of conclusions.
8 Uncertainty of results and impact if wrong.

3.2.5 The peer review chairperson shall provide a report that:

A Is signed by each peer reviewer or contains information detailing which peer reviewers have chosen not to sign and why.
B States the work or issue that was reviewed and the conclusions of the review.
C Includes individual statements by the peer reviewers reflecting dissenting views or additional comments, as appropriate.
D Includes a listing of the peer reviewers and a statement that the qualifications and experience of each reviewer have been evaluated and are acceptable.

4 Records

4.1 The results of readiness reviews shall be documented and controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

4.2 Final Reports issued by the peer review chairman shall be controlled in accordance with Policy Q-17.1 – *Quality Assurance Records*.

5 Responsibilities

5.1 Operations Manager

The Operations Manager is responsible for the following:

A Identifying the need for readiness reviews.
B Ensuring that readiness reviews are conducted in accordance with the requirements of this policy.
C Developing and approving the necessary implementing documents for conducting readiness reviews.
D Participating in peer reviews as required.

5.2 Engineering Manager

The Engineering Manager is responsible for the following:

A Identifying the need for and initiating peer reviews as appropriate.

B Ensuring that peer reviews are conducted in accordance with the requirements of this policy.

C Participating in readiness reviews as required.

5.3 Quality Assurance Manager

The QA Manager is responsible for reviewing and concurring with the procedures that implement the requirements of this policy and participating in readiness reviews as required.

Policy Q-03.1 Design Control

1 Purpose and Applicability

This policy identifies requirements and responsibilities for ensuring that designs are defined, controlled, and verified.

This policy applies to quality-affecting design activities for the project.

2 Implementation Strategy

Design control processes are part of the Integrated Safety Management System (ISMS) core functions of Define Scope of Work, Analyze Hazards, and Develop/Implement Controls. Items and systems/processes will be designed using sound engineering/scientific principles, and appropriate standards. Engineering practices and procedures will be established and implemented to perform and control design, including design requirements, inputs, processes, outputs, changes, records, and organizational interfaces. Controls are to apply to software and experiments if part of the design process and consequential safety, environment, health, or programmatic risks are identified. The Engineering Manager is responsible for ensuring that the graded approach for the application of appropriate design controls is performed commensurate with the quality levels as described in Policy Q-02.1 – *Quality Assurance Program* - subsection 1.9 - *Quality Classification.* Various elements of the quality assurance (QA) program and administrative controls will be applied in accordance with these quality levels throughout the life of the design. Design control measures will correctly translate appropriate codes, standards and quality requirements to ensure structures, systems, or components (SSC) meet their specified design requirements.

Design work, including changes, will incorporate applicable requirements and design bases. The design control procedure(s) will specify a number of design basis elements that must be considered during development of design input documents. Requirements for determining design bases include basic function and performance requirements; computer systems and applicable software programs; design and environmental conditions; material requirements; interface requirements; operational, maintenance, constructability, and redundancy requirements; and fire protection, safety, quality, and reliability requirements. Requirements are to typically be contained in functional performance requirements and functional design criteria documents.

Design control processes will ensure that design input requirements are correctly translated into design output documents, such as drawings and design/procurement specifications. Design input/output alignment, including drawings, calculations/analyses, computer codes, and supporting documentation, will be an integral part of the design verification process performed during various phases of design development to ensure that the applicable requirements are properly incorporated throughout the design activities.

The Engineering Manager is responsible for developing and maintaining engineering procedures that identify design requirements and technical standards, and establishes engineering process, roles and responsibilities, and engineering personnel qualification requirements. Procedures are

developed to implement engineering processes and meet the requirements of this policy. Designs shall be defined, controlled, and verified utilizing approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 The design shall be defined, controlled, and verified.

3.1.2 Design interfaces shall be identified and controlled.

3.1.3 Individuals other than those who designed the item or computer program shall verify design adequacy.

3.1.4 Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.

3.1.5 Where appropriate, drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

3.1.6 Computer software used to perform design analyses shall be developed or qualified, and used according to the requirements of Policy Q-03.2 - *Software Control*.

3.2 Design Input

3.2.1 Applicable design inputs shall be identified and documented and their selection reviewed and approved by those responsible for the design.

3.2.2 The design input shall be specified and approved on a timely basis to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

3.2.3 Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

3.2.4 Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.

3.3 Interface Control

3.3.1 Design efforts shall be coordinated among participating organizations and groups.

3.3.2 Design information transmitted across interfaces shall be documented and controlled. The controls shall identify the status of the design information or document provided, and identify designs or portions of designs that require further development, analysis, review, or approval.

3.3.3 Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

3.3.4 Interface controls shall include the assignment of responsibility and the establishments of controls among participating organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

3.4 Design Process

3.4.1 The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements.

3.4.2 Design documents shall adequately support facility design, construction, commissioning, and operation.

3.4.3 Appropriate standards shall be identified and documented, and their selection reviewed and approved. Changes from specified standards, including the reasons for the changes, shall be identified, approved, documented, and controlled.

3.4.4 The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.

3.4.5 Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

3.4.6 The final design, including approved design output documents and approved changes shall:

A Relate to the design input through documentation in sufficient detail to permit design verification.

B Specify the minimum acceptance requirements.

C Identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.

3.4.7 The final design shall identify assemblies or components that are part of the item being designed. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.

3.5 Design Analyses

3.5.1 Design analyses shall be planned, controlled, and documented.

3.5.2 Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

3.5.3 Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.

3.5.4 Calculations shall be controlled and identified by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are retrievable.

3.5.5 Documentation of design analyses shall include:

A Definition of the objective of the analyses.

B Design inputs and their sources.

C Results of literature searches or other applicable background data.

D Identification of assumptions and those that must be verified as the design proceeds.

E Identification of any computer calculation, including: identification of the computer type, computer program name, and revision; inputs; outputs; evidence of or reference to computer program verification; and the basis (or reference thereto) supporting application of the computer program to the specific physical problem.

F Identification of the originator, reviewer, and approver.

3.5.6 To the extent required in subsection 3.5.7 of this policy, computer program acceptability shall be pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs shall be controlled in accordance with the requirements of this policy.

3.5.7 The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

3.6 Design Verification

3.6.1 Design verification shall be performed to determine the adequacy of the design. Acceptable verification methods include, but are not limited to, any one or a combination of design reviews, alternate calculations, and qualification testing.

3.6.2 The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs.

3.6.3 Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or release to another organization for other design activities except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be clearly identified and controlled. In all cases the design verification shall be completed prior to relying upon SSCs, or computer programs to perform its safety function and before installation becomes irreversible.

3.6.4 Where the design has been subjected to a verification in accordance with this policy, the verification process need not be duplicated for identical designs. However:

A The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.

B Known problems affecting the standard or previously proven designs and their effects on other features shall be considered.

C The original design and associated verification documentation shall be adequately documented and referenced in records of subsequent application of the design.

3.6.5 Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design, and on any design analysis upon which the design is based, that are affected by the change to previously verified design.

3.6.6 Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization.

3.6.7 Design verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach, or rule out certain design considerations, and did not establish the design inputs used or, provided the supervisor is the only individual competent to perform the verification.

Note: Cursory supervisory reviews do not satisfy the intent of this policy.

3.6.8 The responsible design organization shall identify and document the particular design verification method(s) used.

3.6.9 The results of design verification shall be documented with the identification of the verifier clearly indicated.

3.7 Design Reviews

3.7.1 Design reviews shall be controlled per approved procedures and performed to ensure that:

A The design inputs were correctly selected and incorporated into the design.

B Assumptions necessary to perform the design activity are adequately described and reasonable.

C Where necessary, the assumptions are identified for subsequent re-verifications when the detailed design activities are completed.

D Appropriate design methods and computer programs, when applicable, were used.

E The design output is reasonable compared to design inputs.

F The necessary design inputs and verification requirements are specified in the design documents or in supporting procedures or instructions.

3.8 Alternate Calculations

Alternate calculations shall use alternate methods to verify the correctness of original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program, software, or other calculation method used shall also be reviewed.

3.9 Qualification Tests

3.9.1 If design adequacy is to be verified by qualification tests, the tests shall be in accordance with Policy Q-11.1 - *Test Control*.

3.9.2 Qualification tests shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.

3.9.3 Required tests shall be controlled under appropriate operating modes and environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and test criteria.

3.9.4 Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed.

3.9.5 Test results shall be documented and evaluated to assure that they satisfy test requirements and conform with acceptance criteria. The evaluation shall be documented and include identification of the individual performing the evaluation.

3.9.6 When tests are being performed on models or mockups, scaling laws shall be established, reviewed, and approved.

3.9.7 The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

3.9.8 If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

3.10 Design Change Control

3.10.1 Design changes shall be controlled according to the following requirements

A Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use as-is or repair, shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

B These design control measures shall include provisions to evaluate the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid.

C Changes shall be approved by the same affected groups or organizations that approved the original design documents.

D If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.

E The design organization approving the design shall have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design.

F When a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary. These design deficiencies shall be documented in accordance with Policy Q-16.1 - *Corrective Action.* Additionally, if the incorrect design causes constructed or partially constructed SSCs to be nonconforming, the affected items shall be controlled in accordance with Policy Q-15.1 - *Control of Nonconforming Items*.

G Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design change control measures commensurate with those applied to the original design. Required as-built records shall reflect the use as-is or repair condition.

H Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected documents.

I Design changes that impact related implementing documents or training programs shall be communicated to organizations affected by the change.

3.11 Software Design Control

3.11.1 The software design process shall be documented, approved by the responsible design organization, and controlled.

3.11.2 The requirements of Policy Q-03.2 - *Software Quality*, shall apply to quality affecting computer software design.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Interface control shall include the assignment of responsibility among participating design organizations and groups for the development, review, approval, release, distribution, and revision of documents involving design interfaces.

4.2 Design Verification

A In addition to reviewing completed design analyses and design output in accordance with Policy Q-06.1 - *Document Control*, and the design verification requirements identified in subsection 3.6 above, the specific design control requirements in this section shall be applied.

B The particular design verification method shall be identified and its use justified.

C Design verification shall be performed by competent individuals or groups other than those who performed the original design, but may be from the same organization. If necessary, this verification may be performed by the originator's supervisor provided:

1 The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification.

2 The verification is not hastily and superficially done.

3 The determination to use the supervisor is documented and approved, in advance, with concurrence of the QA organization.

D Changes in previously verified designs shall require re-verification. Such verification shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analysis upon which the design is based.

5 Records

5.1 Design documentation and records shall include not only final design documents, such as drawings and specifications and revisions to those documents, but also documentation which identifies the important steps in the design process, including sources of design inputs that support the final design.

6 Responsibility

6.1 Engineering Manager

The Engineering Manager is responsible for the following:

A Establishing engineering organization policies and procedures for controlling design, engineering, configuration management, and regulatory positions.

B Ensuring that engineering activities are executed in accordance with the requirements of this policy.

C Implementing appropriate corrective actions, up to and including stop work, when work is not in compliance with the applicable design control requirements.

D Determining the need for and controlling facility design and modifications.

E Assuring design input documents are developed.

F Evaluating design-related environmental and safety impacts.

G Reviewing design change documents, as required.

H Participating in peer/technical reviews, as required.

I Assuring design output documents are consistent with design inputs and authorization basis documents.

6.2 Quality Assurance Manager

The QA Manager is responsible for establishing the QA program requirements for design control, and reviewing engineering procedures that implement the stated requirements.

Policy Q-03.2 Software Quality

1 Purpose and Applicability

This policy establishes requirements for the acquisition, development, modification, control, and use of quality-affecting software. Acquired software that is integral to the operations, maintenance, or calibration of measuring and test equipment, and has not been developed or modified for the project is controlled by Policy Q-12.1 - *Control of Measuring and Test Equipment,* and is exempt from the requirements of this policy. This policy defines requirements and responsibilities for controlling the quality of computer software.

This policy applies to organizations involved in quality-affecting software formulation and control. Any applications, other than software routines and macros, developed using these types of commercially available software shall meet the requirements of this policy. This policy applies to organizations that develop, procure, modify, maintain, operate, use, or retire software that is directly used in the design, analysis, and operation of structures, systems, and components (SSCs).

Requirements for electronic management of data are addressed in Supplement I - *Control of the Electronic Management of Data*.

2 Implementation Strategy

Computer software used for the control or support of work processes is to be controlled. Access to the computer software will be limited to authorized individuals.

Software quality assurance procedures will provide measures to ensure that computer programs used to develop or verify designs or establish safety envelopes (design analyses, models, or algorithms) are adequate for intended use. These measures include previous use, validation, or simulation.

The Business Manager is responsible for developing and maintaining procedures that identify software control requirements concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Computer software used to produce or analyze data, which is used directly in the design, analysis, and operation of SSCs, shall comply with the requirements of this policy. The application of specific requirements shall be prescribed in software QA plan(s) and/or in written policies and procedures.

Note: The following types of software are not required to be qualified using this policy: operations control instrumentation (I&C); system utilities; compilers and their associated libraries; word processors; spreadsheets; database managers; e-mail; and other types of automated office support systems.

3.1.2 Software development shall proceed in a traceable, planned, and orderly manner.

3.1.3 The number of software life cycle phases and relative emphasis placed on each phase of software development will depend on the nature and complexity of the software.

3.1.4 The software design process shall be documented, approved by the responsible design organization, and controlled.

3.1.5 Acquired software or software previously developed not using this policy must be either: acquired through a procurement activity with appropriate quality controls; or be controlled and qualified in accordance with subsection 3.13 of this policy. In either case, software planning in accordance with subsection 3.3 and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3.1.6 When software is retired or the support for a software product is terminated, the software shall not be used.

3.2 Software Verification and Validation

3.2.1 Software verification and validation activities shall:

A Ensure that the software adequately and correctly performs intended functions.

B Ensure that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

C Be planned and performed for each system configuration, which may impact the software.

3.2.2 Software verification shall be performed during the software development to ensure that the products of a given life cycle phase fulfill the requirements of the previous phase or phases.

3.2.3 The results of the verification and validation activities shall be documented with the identification of the verifier and responsibilities indicated.

3.2.4 Software verification methods shall include any one or a combination of design reviews, alternate calculations, and test results performed during computer program development.

3.2.5 The extent of verification and the methods chosen are a function of the following:

A The complexity of the software.

B The degree of standardization.

C Similarity with previously proved software.

D Importance to safety.

3.2.6 Software verification and validation shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization with higher management approval and documented justification.

3.3 Software Planning

3.3.1 A software QA plan shall be developed for each new software project at the start of the software life cycle, or for procured software when it enters the purchaser's organization.

Note: The software QA plan may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall quality assurance program.

3.3.2 The software QA plan shall identify:

A A description of the overall nature and purpose of the software.
B The software products to which it applies.
C The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.
D The required documentation.
E The standards, conventions, techniques, or methodologies which shall guide the software development, as well as methods to assure compliance to the same.
F The required software reviews.
G The methods for error reporting and corrective action.

3.4 Requirements Phase

3.4.1 Software design requirements shall be identified and documented and their selection reviewed and approved.

3.4.2 Software requirement documentation shall outline the requirements that the proposed software must satisfy.

3.4.3 The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.

3.4.4 The requirements shall address the following, as applicable:

A Functionality—the functions the software is to perform.
B Performance—the time-related issues of software operation (i.e., speed, recovery time, response time).

C Design constraints imposed on implementation phase activities—any elements that will restrict design options.

D Attributes—non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability.

E External interfaces—interactions with people, hardware, and other software.

3.4.5 These requirements shall define the response of the software to anticipate classes of input data, and shall provide the detail and information necessary to either design the software or make an acquisition decision.

3.4.6 Software requirements shall be traceable throughout the remaining stages of the software development cycle.

3.4.7 The review of software requirements shall be performed at the completion of the software requirements documentation. This review shall assure that the identified requirements are complete, verifiable, consistent, and technically feasible. The review shall also assure that the requirements will result in feasible and useable code.

3.5 Design Phase

3.5.1 The software design shall be documented and shall define the computational sequence necessary to meet the software requirements.

3.5.2 Software design and implementation documentation shall include:

A A description of the major components of the software design as they relate to the software requirements.

B A description of the allowable or prescribed ranges for inputs and outputs.

C As applicable, numerical methods, mathematical models, control flow, physical models, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements or the computer program listings resulting from implementation of the software design.

3.5.3 Design phase software verification and validation activities shall consist of the following:

A Generation of test plans based on the requirements and design.

B Generation of design-based test cases.

C Review of the software design to ensure that the requirements are addressed.

3.5.4 A software design review shall be held at the completion of the software design documentation. The review shall meet the requirements of Policy Q-03.1 – *Design Control* - subsection 3.7 – *Design Reviews.* This review shall evaluate the technical adequacy of the design approach, and assure internal completeness, consistency, clarity, and correctness of software design, and shall be traceable to the requirements.

3.6 Implementation Phase

3.6.1 The software design shall be translated into computer program(s) and the implemented software shall be analyzed to identify and correct errors.

3.6.2 Implementation phase software verification activities shall consist of the examination of source code listings to assure adherence to coding standards and conventions.

3.7 Testing Phase

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design or use of the program to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents.

3.7.1 Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. Test procedures or plans shall specify the following as applicable:

A Required tests and test sequence.
B Required ranges of input parameters.
C Identification of the stages at which testing is required.
D Criteria for establishing test cases.
E Requirements for testing logic branches.
F Requirements for hardware integration.
G Anticipated output values.
H Acceptance criteria.
I Reports, records, standard formatting, and convention.

3.7.2 Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied.

3.7.3 For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process.

3.7.4 The computer test procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

3.7.5 Software verification and validation documentation shall describe the tasks and criteria for accomplishing the verification of the software in each phase and the validation of software at the end of the development cycle. The documentation shall:

A Specify the hardware and software configurations pertinent to the software validation.

B Be organized in a manner that allows traceability to both software requirements and design.

C Contain the results of the execution of the verification and validation activities.

D Include the results of reviews and tests along with a summary of the status of the software (e.g., indication of incomplete design performance and application requirements).

3.7.6 Failure to successfully execute the test cases shall be reviewed to determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.

3.7.7 Software validation of modifications to released software shall be subjected to regression testing to detect errors introduced during the modification of the software to verify that the modifications have not caused unintended adverse affects, or to verify that a modified software still meets specified requirements.

3.7.8 Design phase software verification and validation activities shall consist of:

A The generation of test plans on the requirements and design.

B The generation of design-based test case.

C The review of the software design to ensure that the requirements are addressed.

3.7.9 Upon completion of the testing phase, the development cycle documentation shall be reviewed and approved to assure completion and acceptability.

3.7.10 Depending on the complexity of the computer program being tested, testing may range from a single test and a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test.

3.7.11 Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function.

3.8 Operations and Maintenance Phase

3.8.1 Upon acceptable validation of the software, in accordance with subsection 3.7 of this policy, the software shall be baselined and placed under configuration management controls in accordance with subsection 3.10 of this policy.

3.8.2 Further activity shall consist of maintenance of the software to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance).

3.8.3 Software modifications shall be approved, documented, verified and validated, and controlled.

3.8.4 In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.

3.8.5 In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.

3.8.6 Require periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs where computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

3.8.7 In-use tests shall identify:

A Computer program tested.
B Computer hardware used.
C Test equipment and calibration, if applicable.
D Date of the test.
E Test or data records.
F Acceptability.

3.8.8 In-use tests shall be developed, performed and documented, and verified to provide confirmation of acceptance performance of software that is performing continuous data acquisitions of process control functions.

3.9 Installation and Checkout Phase

3.9.1 Software installation and checkout activities shall be performed and documented when the software is installed on a computer, or when there are changes in the operating system, to ensure that the software properly satisfies the requirements for its intended use.

3.9.2 Installation and checkout phase software verification and validation activities shall consist of:

A The execution of tests for installation and integration design.
B The documentation of the approval of the software for operational use.

3.10 Software Configuration Management

3.10.1 A configuration baseline shall be defined at the completion of each major phase of the software development and include appropriate control points within each major phase. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.

3.10.2 A labeling system for configuration items shall be implemented includes:

A A definition of the baseline elements of each software baseline.

B Uniquely identifies each configuration item.

C Identifies changes to configuration items by revision.

D Provides the ability to uniquely identify each configuration of the revised software available for use.

3.10.3 Changes to software shall be formally controlled and documented.

A The software change documentation shall include:

1 A description of the change.

2 The rationale for the change.

3 The identification of the affected software baselines.

4 A release and control process for baseline elements.

B The changes shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes.

C Only authorized changes shall be made to software baselines.

D Appropriate verification activities shall be performed for the change.

E The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained.

F Appropriate acceptance testing shall be performed for the change.

3.10.4 The information that is needed to manage a configuration shall be documented and transmitted to all organizations affected by the change. This information shall identify the approved configuration, the status of proposed changes to the configuration, the status of approved changes, the history of the changes including descriptions, and information to support the functions of configuration identification, and configuration control.

3.11 Defect Reporting and Resolution

3.11.1 The defect reporting and resolution system shall be integrated with the software configuration management system.

3.11.2 Software defect reporting and resolution systems shall include the following controls:

A Problems are identified, evaluated, documented, and, if required, corrected.

B Problems are assessed for impact on past and present applications of the software by the responsible organization.

C Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

D Notification along with preventive actions and corrective actions are provided to the user organizations.

3.11.3 If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Policy Q-16.1 - *Corrective Action*.

3.11.4 A software defect reporting and resolution system shall be implemented for software errors and failures to assure that problems are promptly reported to impacted organizations and to assure formal processing of problem resolutions.

3.12 Procurement

3.12.1 Individuals or organizations developing and supplying software shall be required to have policies and procedures that meet the applicable requirements of this policy as specified in procurement documents.

3.12.2 The documentation that is required by this policy shall be delivered or made available by the supplier to the purchaser.

3.12.3 The organization providing software services, such as verification and validation, shall have a plan(s) for software quality assurance that meets the requirements of this policy as specified in procurement documents. The user organization shall determine the adequacy of this plan.

3.12.4 Software errors and failures shall be reported between the supplier and purchaser in accordance with subsection 3.11 – *Defect Reporting and Resolution*.

3.12.5 Upon receipt of the software from the supplier, the purchaser assumes responsibility of the applicable requirements of this policy.

3.13 Software Developed Not Using This policy

3.13.1 Unqualified software in which the history of the software is not known, but the software is required to be used in quality activities shall meet the following requirements:

A Software that was previously developed not using this policy shall be placed under configuration controls prior to use.

B The user organization shall perform, document and provide for an independent review and evaluation to:

1 Determine its adequacy to support software operation and maintenance.

2 Identify the activities to be performed and documents required in order for the software to be placed under configuration management as a minimum, these activities include:

a User application requirements.

b Test plans and test cases required to validate the software for acceptability.

c User documentation required in accordance with subsection 3.15 of this policy.

d Upon independent review and approval of the above activities, the software shall be placed under configuration control in accordance with subsection 3.10 of this policy.

3.14 Access Control

3.14.1 To the extent appropriate, controls shall be established to permit authorized access and prevent unauthorized access to a computer system.

3.15 User Documentation

User documentation, as a minimum, shall include:

A User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software.

B Input and output specifications.

C Input and output formats.

D A description of systems limitations.

E A description of anticipated errors and how the user can respond.

F Information for obtaining user and maintenance support.

4 Specific Requirements for DOE/RW-0333P QARD Requirements

4.1 Implementation Phase

4.1.1 The design shall be translated into source code and resulting executables necessary to perform the functions required.

4.1.2 The source code and resulting executables shall adhere to the design specifications.

4.1.3 User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

A Instructions that contain an introduction, description of the user's interaction with the software, and a description of any required training necessary to use the software.
B Input and output specifications.
C Data files, input and output data, defaults, and file formats.
D A description of the allowable and tolerable ranges for inputs and outputs.
E Anticipated errors and how the user can respond.
F The hardware and software environments.
G Available sample problems.
H Installation procedures.

4.2 Software routines or macros that are documented in each product in which they are used and independently verified by visual inspection or hand calculation, without recourse to the original, shall have limited requirements applied as follows:

A Identification, including version of the software routine or macro.
B Documentation that includes inputs, computer program-generated correct results for a specified range of input parameters, computer program-generated evidence of the programmed algorithms or equations (e.g., computer program listings and spreadsheet cell contents), and verification results.
C Identification, including version of the commercially available software used to develop the routine and macro.

4.3 Software shall be placed under configuration management control as each baseline element is approved. Software shall not be used in quality-affecting activities unless it is obtained and limited to received copies from software configuration management.

4.4 Control of the Use of Software

4.4.1 Quality-affecting software shall be controlled and documented, and the use of released software items such that comparable results can be obtained, with any difficulties explained, through independent replication of the process.

4.4.2 Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

4.4.3 If the use of software items falls outside the range of validation as baselined, changes shall be made to the appropriate baseline elements prior to use.

4.4.4 Documentation for the receipt of software obtained from software configuration management in accordance with this policy shall be provided and maintained for all software in operation or use.

5 Records

5.1 Record copies of required documentation shall be retained with other project records as required by codes, standards, specifications, plans, or procedures.

5.2 Records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

5.3 Verification test records shall identify:

A Computer program tested.
B Computer hardware used.
C Test equipment and calibration, where applicable.
D Date of test.
E Tester or data recorder.
F Simulation models used, if applicable.
G Test problems.
H Results and acceptability.
I Action taken in connection with any deviations.
J Person evaluating the test results.

6 Responsibilities

6.1 Functional Manager

The Functional Managers are responsible for:

A Establishing procedures to implement the software QA program.

6.2 Quality Assurance Manager

The QA Manager is responsible for:

A Identifying quality assurance requirements and policies.
B Assuring that QA procedures and processes are developed and maintained.
C Providing technical assistance/guidance to directors, managers, and staff in meeting QA requirements.
D Providing independent oversight of activities to ensure compliance with applicable regulations and requirements.

6.3 Project Manager

The Project Manager is responsible for:

A Ensuring that a software QA program and software configuration management is established, documented, and implemented in accordance with the requirements of this policy and applicable DOE orders.

B Designating individuals or organizations responsible for implementing this policy (e.g., technical support organization) and defining the interfaces with external organizations.

6.4 Business Services Manager

The Business Services Manager is responsible for:

A Development and maintenance of a program for the control of project software in accordance with all applicable laws, regulations, and requirements.

B Ensuring that the program implemented for control of software includes all phases of software life cycle, including, but not limited to, procurement, verification and validation, and use.

C Mediating and resolving software QA program issues that have not been resolved at subordinate levels.

6.5 Operations Manager

The Operations Manager is responsible for developing and implementing procedures for the control of process modeling software.

Policy Q-04.1 Procurement Document Control

1 Purpose and Applicability

This policy identifies requirements and responsibilities to ensure that procurement documents, and changes thereto, contain appropriate technical and quality assurance requirements.

This policy applies to organizations and employees involved in the processing of documents for the procurement of quality affecting items and services.

2 Implementation Strategy

Technical, administrative, and quality requirements applicable to items or services being procured are to be identified and specified in procurement documents. These requirements include applicable codes, regulations and industry standards, tests and inspections, traceability, and special procedures or instructions. Procurement documents are to identify acceptance methods and criteria for acceptance or rejection of items or services.

Procedures will provide specific requirements and guidelines to initiate purchase requisitions, procurement specifications, and other procurement documents. These procedures will define appropriate controls for the selection, suitability determination, evaluation, and receipt of items or services being procured as well as controls that prevent the introduction of suspect or counterfeit items onto the project.

Procurement procedures will include a process for procurement of off-the-shelf commercial grade items and dedicating these items for safety-related applications. Engineering will initiate dedication by defining the critical characteristics of the item and associated verification requirements. These items will be subjected to specific inspections (Policy Q-10.1 - *Inspection*), tests (Policy Q-11.1 - *Test Control*), and/or evaluations to ensure that these items will perform properly in the safety-related application.

The procurement processes are part of the core function of Develop/Implement Controls of the Integrated Safety Management.

The Procurement and Property Manager is responsible for developing and implementing the procedures that provide a detailed methodology for preparing, reviewing and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures are to ensure procured items and services meet established requirements and perform as specified. Procurement documents are to be developed utilizing approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.

3.1.2 To the extent necessary, procurement documents shall require suppliers to have a documented QA program consistent with the applicable requirements of this policy.

3.1.3 When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another affected organization's QA program provided the work is adequately addressed. In these cases, procurement documents shall specify that the purchaser's or another organization's implementing documents are applicable to the supplier, and that the purchaser shall provide these applicable documents to them.

3.1.4 Procurement processes and controls shall include provisions for preventing the procurement of suspect and counterfeit items.

3.2 Procurement Document Contents

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the purchaser, and identify the revision level or change status on each document.

3.2.1 Procurement documents shall include a statement of the scope of work to be performed by the supplier.

3.2.2 Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished.

3.2.3 The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

3.2.4 QA program requirements shall be specified in procurement documents. These requirements shall be consistent with the importance and/or or complexity of the item or service being procured.

3.2.5 The procurement documents shall require the supplier to incorporate the appropriate QA requirements in subtier procurement documents.

3.2.6 QA requirements shall include provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.

3.2.7 The procurement documents shall provide for access to the supplier's and subtier supplier's facilities and records for surveillance, inspection, or audit by the purchaser, its designated representative, or others authorized by the purchaser.

3.2.8 The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. The time of submittal shall also be established.

3.2.9 When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

3.2.10 The procurement documents shall specify the purchaser's requirements for the supplier's reporting of nonconformances and the purchaser approval of the disposition of nonconformances.

3.2.11 The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies, special tools required, and the related technical and quality assurance data required for ordering these parts, tools and assemblies.

3.2.12 Tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.

3.3 Procurement Document Review and Approval

3.3.1 A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective supplier(s) include all appropriate technical and QA provisions to assure that items or services will meet the specified requirements.

3.3.2 Technical or QA program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents.

3.3.3 Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

3.3.4 Procurement document reviewers for Quality Level items and activities shall include representatives from the technical and QA organizations.

3.3.5 Procurement document reviews shall be performed and documented in accordance with Policy Q-06.1 - *Document Control*, prior to issuance of the procurement documents to the supplier.

3.3.6 Procurement documents shall be approved by the originating organization.

3.4 Procurement Document Changes

3.4.1 Changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformances, hold points, and lists of spare and replacement parts delineated in procurement documents shall be subject to the same degree of control as used in the preparation of the original documents.

3.4.2 Evaluation of procurement document changes as a result of proposal/bid evaluation or negotiations and the resulting impact shall be completed before the contract is awarded.

This evaluation shall consider the following:

A The appropriate requirements as specified in this section.
B Additional or modified design criteria.
C Analysis of exceptions or changes requested or specified by the supplier and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Procurement document reviews shall be performed and documented in accordance with Policy Q-06.1 - *Document Control*, subsections 3.7 and 4.1, prior to issuance of the procurement documents to the supplier.

5 Records

5.1 No additional records requirements are applicable to this policy.

6 Responsibilities

6.1 Functional Organization

The designated Functional Organization is responsible for:

A Reviewing and approving the technical provisions of quality-significant [Quality Level (QLs)] purchase requisitions.
B Assuring that appropriate technical requirements and administrative controls for the specified items or services have been properly specified.

6.2 Requesting Organization

Organizations requesting procurement of Quality Level (QLs) items or services are responsible for documenting the requirements for the specified items or services by providing requisite ordering information, and ensuring adequacy of the documentation used to initiate a procurement and any subsequent changes. The manager of the requesting organization has the responsibility to verify that any requisitions and any

attached documents have been properly reviewed and approved and meet the requirements specified in this policy for initiating procurement.

6.3 Procurement and Property Manager

The Procurement and Property Manager, reporting to the Deputy Project Manager, has the overall responsibility for developing and approving procedures and documents that control the procurement quality process. The Procurement and Property Manager is responsible for solicitation and receipt of proposals and ensuring that requirements specified in the procurement documents, including quality requirements, are accurately transcribed into the final purchase documents. The Procurement and Property Manager is also responsible for performing source inspections.

6.4 Quality Assurance Manager

The QA Manager is responsible for:

A Evaluating and qualifying of suppliers.

B Performing receipt inspection of designated quality-affecting items.

C Performing supplier audits.

D Reviewing and approving the quality provisions of Quality Level (QLs) requisitions.

E Assuring that appropriate quality requirements and administrative controls for the specified items or services have been properly specified in procurement requisitions.

6.5 Business Services Manager

The Business Services Manager, reporting to the Project Manager, has the overall responsibility for the contract process, including formulating and administering subcontracts, and approving procedures and documents that control the contract administration process. The Business Services Manager is responsible for ensuring that requirements specified in the procurement documents, including quality requirements, are accurately transcribed into the subcontract documents.

Policy Q-05.1 Instructions, Procedures, and Drawings

1 Purpose and Applicability

This policy identifies requirements and responsibilities to ensure that quality-affecting activities are prescribed by and performed in accordance with instructions, procedures, and drawings of the type appropriate to the circumstances. In addition, instructions, procedures and drawings shall include, as appropriate, reference to the necessary quantitative or qualitative acceptance criteria for determining that the prescribed results have been satisfactorily attained.

This policy applies to project organizations responsible for the development, review, approval, maintenance, use, and cancellation of new and revised instructions, procedures, and drawings for activities affecting quality. This policy is designed to ensure that personnel take responsibility for the quality of their own work and that they follow prescribed standards, procedures, instructions to accomplish work.

2 Implementation Strategy

The objective of the Integrated Safety Management System (ISMS) is to do work safely. To achieve that objective, work is to be performed to established technical standards and administrative controls, using approved instructions, procedures, or other appropriate mechanisms that are easily accessible to the worker. Work control procedures will be developed and implemented for management of work; to ensure compliance with applicable engineering, health, safety, environmental, construction, operational, and quality standards and technical requirements; and to enhance worker safety at all organizational levels.

These procedures will require personnel performing work to be responsible for the safety and quality of their work. This will be achieved by providing people with the necessary training and maintenance of their qualifications to assure competence commensurate with responsibilities of the job. This training will provide necessary knowledge of requirements for the work they perform and an understanding of the capability of the tools and processes they use. Working to established standards and controls will be consistent with expectations of the Integrated Safety Management core functions to develop/implement controls and perform work.

The project management system is designed to ensure that the following are clearly identified and conveyed to workers before beginning work based on the nature, hazards, or complexity:

A Customer and data requirements for the work and final product (ISMS Core Function 1).
B Acceptance criteria applicable to work and final product (ISMS Core Function 1).
C Hazards associated with the work (ISMS Core Function 2).
D Roles and responsibilities, authorities and interfaces (ISMS Principle 2).
E Technical standards applicable to work and final product (ISMS Core Function 1 and 3).

F Safety, administrative, technical, and environmental controls to be employed during the work (ISMS Core Function 3).

Management should ensure that those under their supervision have the skills (including knowledge and understanding of the capabilities of the processes being used), equipment, work process documents, and resources needed to accomplish their work.

Procedures, work instructions, or other means used to define work processes should be documented. The scope and detail of documentation should be commensurate with the complexity and importance of the work, the skills required to perform the work, and the hazards and risks or consequences of quality problems in the product, process, or service (ISMS Guiding Principle 6). Control of processes, skills, hazards, and equipment should be clearly specified, understood, and fully documented (ISMS Guiding Principle 5, Core Function 3). Procedures, instructions, and drawings must comply with the requirements of applicable technical standards, Safety Analysis Reports, codes, specifications, and other technical requirement documents. These procedures and instructions define the requirements for reviews by engineering, quality, operations, construction, health protection, safety and other affected organizations before approval. Personnel reviewing these procedures and instructions are to be assigned by their organization based on qualification, knowledge, experience, and competency in their area of responsibility.

Instructions, procedures and drawings are controlled in accordance with Policy Q-06.1 - *Document Control.*

Instructions, procedures and drawings are to be developed and concurred with by the quality assurance (QA) organization utilizing the requirements of this policy.

3 Policy

3.1 General

3.1.1 Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, and drawings of the type appropriate to the circumstances that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

3.1.2 Activities affecting quality shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.

3.1.3 The need for and the level of detail in written procedures or instructions shall be determined based on the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (i.e., education, training, experience).

3.2 Types of Implementing Documents

3.2.1 Implementing documents include documents such as, instructions, procedures and drawings, with the exception of drawings governed by Policy Q-03-1-*Design Control.*

3.2.2 The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed.

3.3 Review and Approval of Implementing Documents

Implementing documents shall be reviewed, approved, and controlled in accordance with Policy Q-06.1 - *Document Control*.

3.4 Compliance with Implementing Documents

All individuals at the project shall comply with the implementing documents. However, when work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an unsafe condition or undesirable situation, the work shall not proceed. Work shall not be resumed until the implementing document is changed in accordance with the appropriate procedures to reflect safe and correct work practices.

3.5 Contents of Implementing Documents

3.5.1 Implementing documents shall include the following information as appropriate to the work to be performed:

A Responsibilities and organizational interfaces of the organizations affected by the document.

B Where work must be performed in a given sequence a description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations shall be established. The organization responsible for preparing the document shall determine the appropriate level of detail.

C Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished, where necessary for work acceptance.

D Prerequisites, limits, precautions, process parameters, and environmental conditions, for testing and operational activities.

E Quality verification and hold points where appropriate.

F Methods for demonstrating that the work was performed as required (such as provisions for recording inspections and test results, checkoff lists, or signoff blocks).

G Identification of QA records generated by the implementing document.

H Identification of associated items and activities, where appropriate and applicable.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Contents of Implementing Documents

4.1.1 Implementing documents shall include the following information as appropriate to the work to be performed:

A A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations. The organization responsible for preparing the document shall determine the appropriate level of detail.

5 Records

5.1 No additional record requirements are applicable to this policy.

6 Responsibilities

6.1 Managers

Managers are responsible for:

A Ensuring that activities within their area of responsibility are performed in accordance with documented instructions, procedures, and drawings.

B Ensuring that personnel are trained in the use of instructions, procedures, and drawings to achieve and maintain proficiency in their assigned tasks.

6.2 Quality Assurance Manager

The QA Manager is responsible for:

A Reviewing administrative and technical procedures, which implement requirements of the QA Manual.

B Reviewing procedures, which incorporate independent inspection.

6.3 Personnel

All personnel are responsible for:

A Following prescribed instructions, procedures, and drawings in the performance of their assigned tasks for activities that affect quality.

B Reporting errors or deficiencies in instructions, procedures, and drawings to their immediate management.

C Identifying conditions or activities for which instructions, procedures, and drawings are needed.

D Working to the most current document revision.

E Stopping work activities and informing their supervisors when it appears that adherence to a procedure is not possible or may result in an unsafe condition.

Policy Q-06.1 Document Control

1 Purpose and Applicability

This policy identifies requirements and responsibilities to ensure that specified documents, either in hard copy or electronic media, including latest changes thereto, are controlled, reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed.

This policy applies to organizations involved in development, review, approval, revision, distribution, or use of controlled documents.

2 Implementation Strategy

Documents are written, recorded, electronic media or pictorial information that describe, define, specify, report, or certify activities, requirements, procedures, results, or plant conditions. Documents are to be prepared, reviewed, approved, issued, used, and revised and maintained to prescribe processes, specify requirements, or establish design.

The Business Manager is responsible for developing and implementing the project procedure(s) that will require documents to be controlled, maintained, stored, protected, and capable of being retrieved in a timely manner. Record copies of documents are to be retained for their specified retention period. Documents will be prepared and, when specified, reviewed by cognizant individuals or organizations in accordance with a graded approach. Individuals or groups responsible for developing, reviewing, approving, issuing, and revising documents are to be identified in procedures. Guidelines for the distribution and effective dates of new or revised documents will be established.

Revisions are to be reviewed and approved by the same organizations that reviewed and approved the original document. Alternative organizations may be designated to review and approve documents based on their technical competence and capability in the required functional areas. The revision process will provide for minor editorial changes and urgent changes to be processed expeditiously. Measures are to be provided to assure that approved changes are included in documents before implementation.

Controlled copies of approved documents are to be distributed manually or electronically and made available to the individuals responsible for performing the assigned tasks. Document control activities will include provisions for a master index and/or table of contents to identify the current revisions of controlled documents. Superseded/cancelled documents will be controlled to preclude their use and to ensure the use of correct revisions. Controls are to be established to ensure that the current revisions of approved procedures are identified and posted. Typical documents that will be controlled include project procedures, project instructions, special test procedures, and construction drawings.

The Business Manager is responsible for developing the document control procedures that are concurred with the quality assurance (QA) organization that contain the requirements of this policy.

3 Policy

3.1 General

3.1.1 The preparation, issue, and change of documents that specify technical requirements, quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed.

3.1.2 Documents defined in 3.1.1 above, including changes thereto, shall be reviewed for adequacy and approved for issue by authorized personnel.

3.1.3 The organizations and individuals responsible for the preparation, review, document approval, approval for release, distribution, and maintenance of controlled documents shall be assigned.

3.2 Distribution and Use of Documents

3.2.1 The distribution and use of documents, including changes and editorial corrections to documents, shall include the following controls:

A The documents to be controlled shall be identified.

B Controlled documents will be reviewed for completeness and approved prior to distribution.

C A method shall be established to ensure the correct controlled documents, either in hardcopy or electronic media, are distributed to, or made available to, and used at, the work location.

D Effective dates shall be established for approved implementing documents.

E A method shall be established to ensure the disposition of obsolete or superseded documents so they are controlled and not used to perform work.

F A method shall be established to identify the current status of each document that is required to be controlled.

3.3 Major Document Changes

3.3.1 Changes to documents, except minor changes, shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.

3.3.2 The individuals reviewing document changes shall have access to pertinent document background data or information upon which to base their review and approval.

3.4 Minor Document Changes

3.4.1 Minor changes to documents, such as editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. The following are considered editorial changes:

A Correcting grammar or spelling.

B Re-numbering sections or attachments that do not affect the sequence of work.

C Changing the title or number of the document.

D Updating organizational titles.

Note: A change in an organizational title accompanied by a change in responsibilities is **not** considered an editorial correction.

3.4.2 The organizational position responsible for approving the document for release shall approve editorial corrections.

3.5 Incorporating Changes

3.5.1 Implementing documents shall define the method used to incorporate changes.

3.5.2 Implementing documents shall require that a history of changes to quality-affecting documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

3.5.3 If the defined method for incorporating change is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.

3.6 Expedited Document Changes

3.6.1 If an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays, then an expedited change may be made at the work location by responsible management.

3.6.2 After the expedited change has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the documents being changed.

3.6.3 Implementing documents shall describe the process to control expedited changes according to the following requirements:

A The level of management with the authority to make expedited changes shall be identified.

B The time limits for processing expedited changes through the normal change process shall be specified.

C An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change.

3.7 Document Review

Implementing documents and other documents that specify technical or quality requirements, including changes, shall be reviewed to the following requirements:

A Pertinent background information or data shall be made available to the reviewers.

B The review shall be performed by those other than the preparer.

C Reviewers shall be technically competent for the subject area of the document.

D The scope of the review shall consider all aspects of the document.

1 Each organization or technical discipline affected by the document shall review the document including subsequent changes.

2 The QA organization shall review all documents which directly implement the QAM requirements, including changes.

E Mandatory comments resulting from the review shall be documented and resolved before approving the document.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Document Review

Implementing documents and other documents that specify technical or quality requirements shall be reviewed to the following requirements:

A Review criteria shall be established before performing the review. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.

B The QA organization shall review all quality affecting documents including changes.

C Each organization or technical discipline affected by the document shall review the document according to the established review criteria. Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change.

5 Records

5.1 No additional record requirements are applicable to this policy.

6 Responsibilities

6.1 Business Manager

The Business Manager is responsible for establishing and implementing the document control program. The Project Administration and Document Control Manager is responsible for managing documents in accordance with the requirements of this policy.

6.2 All Personnel

Personnel who prepare, process, or use-controlled documents for activities affecting quality are responsible for complying with the requirements of this policy as defined in the implementing documents.

Policy Q-07.1 Control of Purchased Items and Services

1 Purpose and Applicability

This policy identifies requirements and responsibilities for planning and executing procurement of items and services to assure conformance with specified requirements.

This policy applies to organizations responsible for planning and executing procurements to ensure that Quality Level (QL) purchased items and services meet specified requirements.

2 Implementation Strategy

Procurement procedures provide a detailed methodology for preparing, reviewing and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. These procedures ensure procured items and services meet established requirements and perform as specified.

The procurement process is part of the Integrated Safety Management System (ISMS) core function of Develop/Implement Controls.

Prospective suppliers will be identified early in the design and procurement process. The Procurement and Property Manager is responsible for evaluating prospective suppliers, with assistance from the Engineering and quality assurance (QA) organizations. Supplier selection and evaluation will apply to the procurement of items and services in a manner consistent with their importance and a graded approach.

Prospective suppliers will be evaluated and selected on the basis of specified criteria published in procurement procedures and the procurement package. Evaluations are conducted by qualified assessors and supported by technical specialists when warranted by the nature of the procurement action. Items or services are to be procured from suppliers whose qualification results satisfy the requirements of the project quality assurance program. Those suppliers will be listed on an Approved Suppliers List (ASL) maintained by the QA organization.

Reviews of the suppliers' documentation and in-house assessment of the suppliers' capabilities are typically used for supplier selection based on the nature and application of items or services being procured. In addition, requalification and supplemental audits are performed on selected suppliers to verify compliance with the procurement requirements as indicated in Policy Q-18.1 - *Independent Assessment/Audit*.

The quality of purchased items and services is verified at intervals during various phases of the procurement process. Frequency or necessity of verification are determined by requirements of the procurement documents, applicable specification, codes and standards, uniqueness, complexity, application of the item, quantity and frequency of the procurement, and previous quality-related performance of the supplier. Processes are established for monitoring suppliers to ensure compliance with QA and technical requirements.

Purchased items or services are accepted using approved procedures and method(s) specified by the requisitioning organization. Items are accepted by one or more of the following methods: source verification, receiving inspection, or post-delivery testing. In addition, a certificate of conformance with the appropriate receipt inspection may be used for acceptance of certain standard items. The certificate of conformance and inspection documentation is to be traceable to the item and identify the specific requirements met by the purchased item.

Procured services may be accepted by the review and technical verification of data/reports produced, performance, or by surveillance/audit of the activity. Performance of source verification and receiving inspection activities utilize procurement documents reviewed by the QA organization. Purchased items are examined for potential suspect/counterfeit part characteristics. If identified as a potential suspect/counterfeit part, they are evaluated by engineering and, as appropriate, dispositioned as nonconforming items.

Processes to ensure that approved suppliers continue to provide acceptable items and services are to be established and implemented. Surveillances (Policy Q-18.2 - *Quality Assurance Surveillance*) will be conducted at supplier facilities by qualified personnel to verify compliance to requirements, as needs dictate. These surveillances will consist of inspections and tests, including witness and hold points, and document verification as specified in procurement documents. Surveillance of subtier suppliers will also be performed as applicable.

Procured items are put into service only when the acceptance requirements (Policy Q-10.1 - *Inspection*) of the procurement documents have been satisfied. Nonconforming items and deficiencies will be recorded on a nonconformance (Policy Q-15.1 - *Control of Nonconforming Items*) or a deficiency report (Policy Q-16.1- *Corrective Action*) respectively. Identified deficiencies will be dispositioned and corrective action taken and verified prior to the use of the item. Information from nonconformance and deficiency reports is reviewed as part of the trend analysis process to identify supplier performance trends and problems (Policy Q- 16.1 - *Corrective Action*). Adverse trends and problems are reported to the Procurement and Property Manager and other responsible organizations.

Post-installation, functional, or pre-operational testing is to be performed after installation of procured items when specified (Policy Q-11.1 - *Test Control*). These tests will verify actual performance of the item against established criteria for the item and the system. Tests and in-service inspections will monitor the performance of the procured item against established criteria.

The Procurement and Property Manager is responsible for developing procedures for the procurement of items and services concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by

the supplier, source inspection, audit, and examination of items or services upon delivery or completion.

3.2 Procurement Planning

Procurement planning shall:

A Identify procurement methods and organizational responsibilities.

B Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.

C Identify and document the sequence of actions and milestones needed to effectively complete the procurement.

D Provide for the integration of the following activities:

1 Procurement document preparation, review, and change control according to the requirements of Policy Q-04.1 - *Procurement Document Control.*

2 Selection of procurement sources.

3 Proposal/bid evaluation and award.

4 Evaluation of supplier performance.

5 Verifications including any hold and witness point notifications.

6 Control of non-conformances.

7 Corrective action.

8 Acceptance of the item or service.

9 Identification of QA records per Policy Q-06.1 – *Document Control.*

E Be accomplished as early as possible and no later than at the start of those procurement activities that are required to be controlled.

F Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.

G Include the involvement of the QA organization.

3.3 Source Evaluation and Selection

3.3.1 Prior to awarding a contract, the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results shall be documented and shall include one or more of the criteria listed below:

A Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability.

B Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.

C Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and implementation of the supplier's QA program.

3.3.2 Source verification shall be performed by personnel qualified in accordance with Policy Q-02.2 - *Personnel Training and Qualification*.

3.3.3 Subcontractors or suppliers qualified by Bechtel National Inc. (BNI) or the Washington Group International (WGI) may be selected without further evaluation as delineated above, provided the subcontractors or suppliers are qualified for the intended services. Before initiation of work, supplier's QA programs will be evaluated against project quality assurance requirements.

3.3.4 The organizational responsibilities for source evaluation and selection shall be identified, including provisions for input from the QA organization.

3.3.5 When sources are qualified by other the Department of Energy (DOE) contractors, the qualification documentation shall be obtained and retained in files. As a minimum, they will be evaluated against project quality assurance requirements.

3.4 Proposal Bid Evaluation

3.4.1 The proposal/bid evaluation process shall include a determination of both the extent of conformance to the procurement document requirements, and the supplier's capability to conform to the technical and QA requirements.

3.4.2 The proposal/bid evaluation shall be performed by designated, technically qualified organizations including the QA organization.

3.4.3 The proposal/bid evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:

A Technical considerations.
B QA program requirements.
C Supplier personnel.
D Supplier production capability.
E Supplier past performance.
F Alternatives.
G Exceptions.

3.4.4 Prior to award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable technical and QA conditions resulting from the bid evaluation.

3.4.5 Supplier QA programs shall be evaluated before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to this QA manual.

3.4.6 Supplier QA programs shall be accepted by the purchaser before the supplier starts work.

3.5 Control of Supplier Generated Documents

Controls shall be implemented to assure that the submittal, evaluation, acceptance, and control of supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the QA, technical, inspection, and test documentation or data against established criteria.

3.6 Control of Changes in Items or Services

The purchaser and supplier shall assure that measures to control changes in procurement documents are established, implemented, and documented, and are in accordance with applicable quality assurance requirements.

3.7 Supplier Performance Evaluation

3.7.1 The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance. The measures shall include:

A Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents.

B Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.

C Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements.

D Identifying and processing necessary change information.

E Establishing the method to be used to document information exchanges between purchaser and supplier.

F Establishing the extent of source surveillance and inspection.

3.7.2 The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.

3.7.3 Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement.

3.7.4 Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's QA program.

3.8 Acceptance of Items or Services

3.8.1 Prior to offering the item or service for acceptance, the supplier shall assure that the item or service being furnished complies with the procurement requirements.

3.8.2 The supplier shall provide the purchaser with objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.

3.8.3 Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:

A Evaluating the supplier Certificate of Conformance.

B Performing one or a combination of source verification, receiving inspection, or post-installation test.

C Technical verification of the item or service.

D Surveillance or audit of the work.

E Review of objective evidence (i.e., certifications, stress reports, or personnel qualifications) for conformance to the procurement requirements.

3.9 Certificate of Conformance

When a Certificate of Conformance is used to accept an item or service the following requirements must be met:

3.9.1 The certificate shall identify the purchased material or equipment, such as by the purchase order number.

3.9.2 The certificate shall identify the specific procurement requirements met by the purchased material, equipment, or service, (i.e., codes, standards, and other specifications).

Note: This may be accomplished by either including a list of the specific requirements, or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, along with a suitable certificate.

3.9.3 The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material, equipment, or service.

3.9.4 The certificate shall identify any procurement requirements that have not been met, along with an explanation and the means for resolving the nonconformance

3.9.5 The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the purchaser's or supplier's QA program.

3.9.6 The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the purchaser or supplier's QA program.

3.9.7 Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the

supplier or independent inspection or test of items. Such verification shall be conducted by the purchaser at intervals commensurate with the supplier's past quality performance.

3.10 Source Verification

3.10.1 When source verification is used, it shall be performed at intervals consistent with:

A The supplier's planned inspections, examinations, or tests at predetermined points.

B The importance and complexity of the item or service. Source inspection shall include monitoring, witnessing, or observed selected activities.

3.10.2 Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points.

3.10.3 Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

3.11 Receiving Inspection

3.11.1 When receiving inspection is used to accept an item, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier.

3.11.2 Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.

3.11.3 The inspection shall be planned and executed according to the requirements of Policy Q-10.1 - *Inspection*.

3.11.4 Receiving inspection shall be coordinated with a review for adequacy and completeness of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

3.11.5 The inspection shall be performed in accordance with established inspection implementing documents.

3.12 Post-Installation Testing

3.12.1 When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.

3.12.2 The test shall be in accordance with the requirements of Policy Q-11.1 - *Test Control*.

3.13 Acceptance of Services Only

In cases involving procurement of services only, such as third party inspection; engineering and consulting service; auditing; and installation, repair, overhaul, or maintenance work, the purchaser shall accept the service by any of the following methods:

A Technical verification of data produced.

B Surveillance or audit of the work.

C Review of objective evidence (i.e., certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.

3.14 Control of Supplier Nonconformances

Methods for control and disposition of supplier nonconformances for items and services that do not meet procurement documentation requirements shall include the following:

A Evaluation of nonconforming items in accordance with Policy Q-15.1 - *Control of Nonconformances*.

B Submittal of nonconformance notice to the purchaser by supplier as directed by the purchaser. These submittals shall include supplier-recommended disposition (e.g., use as-is or repair) and technical justification.

C Nonconformances to the procurement requirements or purchaser approved documents which consist of one or more of the following, shall be submitted to the purchaser for approval of the recommended disposition:

1 Technical or material requirement is violated.

2 Requirement in supplier documents, which have been approved by the purchaser is violated.

3 Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.

4 The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

D Purchaser disposition of the supplier's recommendation.

E Verification of the implementation of the disposition by the purchaser.

F Maintenance of records of supplier-submitted nonconformances.

3.15 Commercial Grade Items

Where the design uses commercial grade items, the purchaser can use the following requirements as an acceptable alternative to other requirements of this section for procuring and accepting items.

A The commercial grade item is identified in an approved design output document. An alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.

B Source evaluation and selection, when deemed necessary by the purchaser based on complexity and importance to safety, shall be in accordance with subsection 3.3 - *Source Evaluation and Selection*, of this document.

C Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., catalog number).

D Prior to acceptance of a commercial grade item, the purchaser shall determine that:

1 The item did not sustain damage during shipment.

2 The item received was the item ordered, and the item satisfied the specified acceptance criteria.

3 Inspection or testing is accomplished to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.

4 Specified documentation, applicable to the item, was received and is acceptable.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in Section 3 - *Policy*.

5 Records

5.1 No additional record requirements are applicable to this policy.

6 Responsibilities

6.1 Procurement and Property Manager

The Procurement and Property Manager is responsible for the following:

A Developing and maintaining implementing procedures for the procurement process.

B Implementing this process for procured items and services within the scope of this document from receipt of the requisition from the originator through the acceptance of the item or service by the purchaser.

C Maintaining quality history records on suppliers who have demonstrated their ability to provide quality materials, equipment, or services or whose capability has been established by survey or audit.

D Establish and implement a source inspection program to assure supplier compliance with procurement document requirements.

6.2 Construction Manager

The Construction Manager is responsible for the following:

A Carrying out requirements contained in this document through use of implementing documents. Specifically implementing this process for items and activities within the scope of this document at all facilities under construction.

B Disposition of supplier and contractor nonconformance when that responsibility has been assigned to Field Engineering by Design Engineering.

C Disposition of supplier and contractor nonconformance for field engineered designed items.

D Track supplier/subcontractor nonconformance, which require action at the site and assure that appropriate action is taken to resolve such nonconformance.

6.3 Engineering Manager

The Engineering Manager is responsible for the following:

A Reviewing of supplier and subcontractor engineering documents.

B Reviewing supplier reported design nonconformance.

C Supporting the supplier selection process.

D Developing procurement specifications.

E Reviewing bids for technical adequacy, as required.

6.4 Operations Manager

The Operations Manager is responsible for the following:

A Reviewing supplier and subcontractor operations-related documents.

B Reviewing supplier reported operations-related nonconformances.

C Supporting the supplier selection process.

D Developing operations-related procurement specifications.

6.5 Quality Assurance Manager

The QA Manager is responsible for the following:

A Concur with supplier QA Programs to the extent required in the procurement documents.

B Establish and implement a program of surveillance and audit, to assure supplier compliance with procurement document requirements.

C Review procurement documents to assure that quality requirements are correctly stated, inspectable, and controllable; that there are adequate acceptance/rejection criteria; that source surveillance or receipt inspection is specified; that minimum documentation to be supplied is specified; and that the procurement documents have been processed in accordance with established requirements.

D Establish and maintain an ASL which documents those suppliers qualified per specific project procurement requirements.

E Concurring in the selection of the source for field procurement not requiring submittal of a quality program, to assure that the source has been qualified in accordance with the requirements of this policy.

F Reviewing supplier quality verification documentation for items that have not been inspected at the source.

G Identify as nonconforming discrepant material received at the site for which a supplier's completed nonconformance report has not been received.

H Receiving inspection of designated quality-affecting items.

I Verification of field subcontractor's activities.

6.6 Business Services Manager

The Business Services Manager is responsible for formulating and administering subcontracts.

Policy Q-08.1 Identification and Control of Items

1 Purpose and Applicability

This policy identifies requirements and responsibilities for identifying and controlling items to assure that only correct and accepted items are used or installed.

This policy applies to organizations involved in identifying and controlling items during research and development, design, procurement, construction, fabrication, commissioning, operation and maintenance phases of facilities for which Bechtel National, Inc. (BNI) has responsibility.

2 Implementation Strategy

Items including software and electronic information are to be identified and controlled in accordance with a graded approach to ensure their proper use. Items will be maintained to prevent their damage, loss, or deterioration. Items include materials, equipment, components, appurtenances, assemblies, modules, parts, structures, subsystem units, subassemblies, and systems. Material identification and traceability requirements will be based on the specificity of the material identification requirements, its end use, and the consequences of failure.

Identification of items is to be maintained either on the item or in documentation traceable to the item. When required, items are to be identified from initial receipt or fabrication up to and including installation or use. Procedures will be established and used by workers to ensure that, when items having identification or traceability requirements are subdivided or sampled, identification will be transferred to each part, container of parts, or sample at the time of subdividing or sampling.

Controls will be established and implemented for workers to ensure that only correct and accepted items are used and installed. Where specified, items having limited shelf life, operating life or cycles are to be controlled to preclude use when such limits have been exceeded.

The requirements and responsibilities for handling, storing, and maintaining items are specified in Policy Q-13.1 - *Handling, Storage and Shipping*.

Project management is responsible for developing the necessary item identification and control procedures that are concurred with the quality assurance organization that contain the requirements of this policy.

3 Policy

3.1 General

Controls shall be established to assure that only correct and accepted items are used or installed.

3.2 Identification

3.2.1 Identification shall be maintained on the items or in documents traceable to the items, or in a manner, which assures that identification is established and maintained.

3.2.2 Items shall be identified from the initial receipt and fabrication of items up to and including installation or use. This identification shall relate an item to an applicable design or other pertinent specifying document.

3.3 Physical Identification

3.3.1 Physical identification shall be used to the maximum extent possible.

3.3.2 If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels, or tags attached to containers, or procedural control.)

3.3.3 When used, identification markings shall be applied using materials and methods, which provide a clear and legible identification and do not degrade the function or service life of the item.

3.3.4 When used, markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

3.4 Traceability

3.4.1 When codes, standards, or specifications include specific identification or traceability requirements (i.e., identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability control.

3.5 Limited Life Items

Items having a limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

3.6 Maintaining Identification of Stored Items

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as:

A Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging.

B Protection of identifications on items subject to excessive deterioration due to environmental exposure.

C Provisions for updating existing plant records or related documentation.

4 Specific Requirements For DOE/RW-0333P QARD Applications

4.1 Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents.

4.2 Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.

4.3 If codes or standards do not include specific identification or traceability requirements, specifications shall specify identification and traceability methods appropriate to the item.

5 Records

5.1 No additional record requirements are applicable to this policy**.**

6 Responsibilities

6.1 Construction

Construction organizations that originate, use, store, and/or receive items are responsible for identifying and controlling the items in accordance with the requirements contained in this policy.

Warehouse personnel are responsible for acceptance of items in accordance with the requirements of this document.

6.2 Operations Manager

Operations organizations that originate, use, store, and/or receive items are responsible for identifying and controlling the items in accordance with the requirements contained in this policy.

6.3 Business Manager

Business organizations that originate, use, store, and/or receive items are responsible for identifying and controlling the items in accordance with the requirements contained in this policy.

6.4 Quality Assurance Manager

The QA Manager is responsible for establishing and maintaining a system for identifying the quality status of items that encompasses, but is not limited to, acceptance, rejection, hold for inspection, and conditional use.

6.5 All Personnel

Each person performing project work is responsible for ensuring they only use and install the proper item and control the item appropriately as defined by project procedures.

Policy Q-09.1 Control of Special Processes

1 Purpose and Applicability

This policy identifies requirements and responsibilities for controlling special processes, which affect the quality of items and services.

This policy applies to organizations performing special processes for product acceptance or continued service. These include processes such as welding, heat treating, brazing, chemical cleaning, soldering, bonding, and nondestructive examination.

2 Implementation Strategy

The objective of the Integrated Safety Management System (ISMS) is to do work safely. To achieve that objective, special process work is to be performed to established technical standards and administrative controls, using approved instructions, procedures, or other appropriate mechanisms. Procedures will be developed and implemented for control of special processes; to ensure compliance with applicable engineering, health, safety, environmental, security, and quality standards and technical requirements. These procedures will require organizations and personnel performing the special process to be responsible for the safety and quality of their work. This will be achieved by providing people with the necessary training and maintenance of their qualifications to assure competence commensurate with responsibilities of the job. This training will provide necessary knowledge of requirements for the work they perform and the capability of the tools and processes they use. Working to established standards and controls will be consistent with expectations of the Integrated Safety Management core functions of identifying hazards, developing controls, and working to prescribed processes.

Special process will be controlled through the use of approved procedures concurred with by the quality assurance organization that implement the requirements of this policy.

3 Policy

3.1 General

3.1.1 Special processes that control or verify quality, such as those used in welding, weld overlay, heat treating, chemical cleaning, and nondestructive examination, shall be performed by qualified personnel using approved procedures in accordance with specified requirements.

3.1.2 Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained.

3.1.3 Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements.

3.1.4 Conditions necessary for accomplishment of the process shall likewise be included or referenced in special process instructions. These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.

3.1.5 The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions.

3.1.6 For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

3.1.7 The organization performing the special process shall adhere to the approved procedures or processes. Qualification of personnel, procedures, and equipment shall comply with specified requirements.

3.1.8 Nondestructive examination includes visual, radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, and leak testing.

3.1.9 The affected organization shall establish implementing documents for the control and administration for the training, examination, and certification of nondestructive examination personnel that shall be in accordance with Policy Q-02.2 - *Personnel Training and Qualification.*

4 Specific Requirements for DOE.RW-0333P QARD Applications

4.1 Processes to be controlled as special processes shall meet the following criteria**:**

A The results are highly dependent upon the control of the process; or

B The results are highly dependent upon the skill of the operator; and

C The quality of the results cannot be readily determined by inspection or test of the item.

4.2 Based on the criteria in subsection 4.1 above, a list of the special processes that each affected organization will perform, or be responsible for performing, shall be established and maintained.

4.3 Special process implementing documents shall include or reference the conditions necessary for accomplishing the special process, including traceability between the item or product and individual performing the special process.

5 Records

5.1 Records shall be maintained for qualified personnel, processes, and equipment of each special process.

5.2 All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

6 Responsibilities

6.1 Performing Organization

The organizations that perform special processes are responsible for ensuring that specific procedures or instructions for special processes are developed, reviewed, and approved by qualified personnel as required by applicable codes and standards.

6.2 Quality Assurance Manager

The QA Manager is responsible for reviewing special process procedures and work control documents that specify use of special processes to ensure the quality assurance requirements of this policy have been appropriately incorporated.

Policy Q-10.1 Inspection

1. Purpose and Applicability

This policy identifies requirements and responsibilities for specifying, planning, performing, and reporting inspections used to verify the acceptance of items or activities. The inspection process is designed to prevent the inadvertent acceptance and use of nonconforming items.

This policy applies to organizations involved with the evaluation of conformance to specified requirements and acceptability of items and activities by inspection. Independent inspections performed by the Quality Control (QC) organization shall not relieve any organization performing work from their responsibility to provide items and services that meet quality requirements.

2. Implementation Strategy

Inspection of specified items, services, and processes is to be conducted using established acceptance and performance criteria. Examples of inspections include source, in-process, final, receipt, maintenance, and in-service. Administrative controls, including the use of status indicators, are to be used to preclude inadvertent bypassing of required inspections and inadvertent operation of nonconforming or indeterminate items or processes.

Inspections will be planned, controlled, and documented in accordance with established requirements (e.g., hold/witness points) and consistent with the results of the graded approach. Trained personnel will perform inspections using approved procedures. The engineering organization will establish level, extent, and acceptance criteria for inspections based on the critical characteristics of the item.

Inspection planning will ensure that inspection requirements are properly incorporated into inspection documents. Organizations performing inspections will be responsible for the planning of those inspections consistent with the owner/user needs. Inspection planning will include, as a minimum, item and process characteristics to be inspected; inspection techniques to be used; acceptance criteria (including tolerances); hold and witness points; and identification of the organization performing these inspections.

Inspection personnel will have the freedom to communicate inspection results to the appropriate level of management. Nonconforming items and processes being inspected will be controlled in accordance with the Policy Q-15.1 – *Control of Nonconforming Items.* After verification of corrective action implementation, the item or process will be re-inspected to the original or approved alternative acceptance criteria prior to being used or returned to service.

The Engineering and QA Managers are responsible for developing the necessary procedures that contain the requirements of this policy.

3. Policy

3.1 General

3.1.1 Inspections required to verify conformance of an item or activity to specified requirements or the continued acceptability of items in service shall be planned and executed.

3.1.2 Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented.

3.1.3 Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected. These personnel shall not report directly to the immediate supervisor responsible for the item being examined.

Note: Data recorders, equipment operators, or other inspection team members who are supervised by a qualified inspector are not required to be qualified inspectors.

3.1.4 When sampling procedures are used, they shall be based on valid statistical methods.

3.2 Inspection Requirements

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

3.3 Inspection Hold Points

If mandatory QC independent inspection hold points are required beyond which work shall not proceed without specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents.

Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

3.4 Planning

3.4.1 Required in-service inspection or surveillance of structures, systems, or components (SSCs) shall be planned and executed by, or for, the organization responsible for operation.

3.4.2 Inspection planning shall be performed, documented, and include the following:

A Identification of each work operation where inspection is necessary to ensure quality and implementing documents that will be used to perform the inspections.

B Identification of characteristics to be inspected; methods of inspection; acceptance criteria; process monitoring methods to be employed; and when during the work process the inspections are to be made.

C Identification of the functional qualification level (i.e., Level I, II, or III Qualification Level) of personnel performing inspections.

D Identification of acceptance criteria.

E Identification of sampling requirements.

F Methods to record inspection results.

G Selection and identification of the measuring and test equipment to be used to perform the inspection to ensure that the equipment is calibrated and is of the proper type, range accuracy, and tolerance to accomplish the intended function.

H The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

3.5 In-Process Inspection and Monitoring

3.5.1 Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality.

3.5.2 If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

3.5.3 Both inspection and process monitoring shall be provided when control is inadequate without both.

3.5.4 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process, and the quality of the item are met throughout the duration of the process.

3.5.5 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

3.6 Final Inspections

3.6.1 Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance to the specific requirements.

3.6.2 The acceptance of an item shall be documented and approved by qualified and authorized personnel.

3.6.3 The inspection status of an item shall be identified according to Policy Q-14.1 - *Inspection, Test, and Operating Status*.

3.6.4 Final inspections shall include a record review of the results and resolution of nonconformances identified by prior inspections.

3.6.5 Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

3.6.6 Inspection documentation shall identify:

A The item inspected.
B The date of inspection.
C The name of the inspector, or the inspector's unique identifier, who documented, evaluated, and determined acceptability.
D The name of the data recorder, as applicable.
E The type of observation or method of inspection.
F The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance.
G Results indicating acceptability of characteristics inspected.
H Reference to information on actions taken in connection with nonconformances.
I Measuring and test equipment used during the inspection, including the identification number and the most current calibrated date and/or the calibration due date.

3.6.7 Documentation not previously examined prior to final inspection shall be examined for adequacy and completeness.

3.7 Qualifications of Inspection and Test Personnel

3.7.1 Personnel performing quality control independent inspections to verify conformance of an item to specified acceptance criteria or as described in this section and personnel performing tests as described in Policy Q-11.1 - *Test Control*, shall be qualified and certified according to the indoctrination, training, education, experience, and physical requirements of this policy and Policy Q-02.2 - *Personnel Training and Qualification*.

Note: See Policy Q-11.1 - *Test Control*, subsection 3.8, for the qualification requirements of personnel who operate systems/subsystems during testing and the qualification requirements for test engineers and others who prepare and direct testing activities.

3.7.2 The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The evaluation shall be performed to the requirements of the applicable functional level, and education and experience requirements of this document.

3.8 Indoctrination and Training Qualification Requirements

3.8.1 Inspection and test personnel shall be indoctrinated to the technical objective and requirements of the applicable codes and standards, and the QA program requirements that are to be employed in executing their responsibilities.

3.8.2 Indoctrination and training shall be commensurate with scope; complexity; importance of the activities; special nature of the inspections or tests; and the education, experience, and proficiency of the person.

3.8.3 The need for a formal training program shall be determined. Training shall be provided as required to qualify personnel for performing inspections and tests.

3.8.4 On-the-job training, with emphasis on hands-on experience gained through actual performance of inspections and test, shall be included in the training program.

3.8.5 On-the-job training for personnel qualification shall be performed under the direct observation and supervision of a qualified person.

3.8.6 The documented verification of conformance shall be performed by the qualified person and not by the person being administered on-the-job training.

3.9 Functional Qualification Levels of Inspection and Test Personnel

Three levels of functional qualification (Levels I, II, and III) shall be used depending on the complexity of the functions involved. The criteria for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional work.

3.9.1 Level I Personnel Capabilities—Level I personnel shall be capable of performing and documenting the results of designated inspections or tests.

3.9.2 Level II Personnel Capabilities—Level II personnel shall have Level I capabilities for the corresponding category or class. Additionally, Level II personnel shall have demonstrated capabilities in:

A Inspection or test planning.
B Advanced preparation, including the preparation and setup of related equipment, as appropriate.
C Supervising or monitoring the inspections or tests.
D Supervising and certifying lower-level personnel.
E Evaluating the validity and acceptability of results.

3.9.3 Level III Personnel Capabilities—Level III personnel shall have Level II capabilities for the corresponding category or class. In addition, Level III personnel shall also be capable of evaluating the adequacy of specific programs used to train, qualify, and certify the personnel.

3.10 Education and Experience Qualification Requirements

The requirements for education and experience shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspections or tests affect the assurance that a person can competently perform a

particular task. Other factors that demonstrate capability in a given job and the basis for their equivalency shall be documented.

3.10.1 Level I inspection personnel shall meet the following education and experience requirements:

A Two years of related experience in equivalent inspections or tests; or

B High school graduation or general equivalency diploma (GED) and six months of related experience in equivalent inspections or tests; or

C Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspections or tests.

3.10.2 Level II inspection personnel shall meet the following education and experience requirements:

A One year of satisfactory performance as a Level I in the corresponding category or class; or

B High school graduation or GED plus three years of related experience in equivalent inspections or tests; or

C Completion of college-level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspections or tests; or

D Graduation from a four-year college plus six months of related experience in equivalent inspections or tests.

3.10.3 Level III inspection personnel shall meet the following education and experience requirements:

A Six years of satisfactory performance as a Level II in the corresponding category or class; or

B High school graduation plus ten years of related experience in equivalent inspections or tests; or high school graduation plus eight years of experience in equivalent inspections or tests with at least two years as a Level II and with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or

C Completion of college-level work leading to an associate degree and seven years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or

D Graduation from a four-year college plus five years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility.

3.11 Maintaining Qualification Documentation for Inspection and Test Personnel

3.11.1 Records of qualification, including re-qualification for inspection and test personnel, shall be established and maintained by the employer and for indoctrination and training.

Note: Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

3.11.2 Inspection and test personnel qualification documentation shall contain the information required for the initial qualification and the maintenance of qualification.

3.11.3 Documentation for each person shall be maintained and updated according to the following requirements:

A Removal of a person from performing in an area of certification when the responsible organization determines that the capabilities of the individual are not in accordance with the qualification requirements specified for the job as described in this section. This shall be documented at the time of removal.

B Reinstatement of certifications for the qualified area when the required capability has been demonstrated as described in this section. This shall be documented at the time of reinstatement.

C Continued performance in each certified area or re-determination of required capability as described in this section for each certified area shall be updated annually.

D Re-evaluation of job performance by evidence of continued satisfactory performance or re-determination of capability as described in this section. This shall be updated every three years.

3.11.4 Integrity of examinations shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examination. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be maintained by the employer in accordance with the requirements of Policy Q-02.2 - *Personnel Training and Qualification*.

3.12 Physical Qualification Requirements

The responsible organization shall identify any special physical characteristics needed in the performance of each activity including the need for initial and subsequent visual acuity and other physical examinations.

3.13 Certification of Qualifications

The qualification of inspection and test personnel shall be certified in writing by the responsible organization and document the following information:

A Employer's name.

B Identification of the person being certified.

C Activities, qualified inspection and test categories or class the individual is certified to perform.

D Basis of qualification, such as:

1 Education, experience, indoctrination, and training.

2 Test results, where applicable.

3 Capability demonstration results.

4 Results of periodic evaluations.

E Results of visual acuity and other physical examinations, when required.

F Signature of the employer's designated representative who is responsible for such certification.

G Date of certification or recertification and certification expiration.

4. Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Inspection documentation shall identify the measuring and test equipment used during the inspection, including the identification number and the most current calibrated date.

5. Records

5.1 Records of personnel qualification shall be established and maintained in accordance with Policy Q-17.1 - *Quality Assurance Records*. These records will include the certification of qualifications**.**

6. Responsibilities

6.1 Engineering Manager

The Engineering Manager is responsible for the identification of and selective application of appropriate acceptance criteria in implementing documents and specifications.

6.2 Quality Assurance Manager

The QA Manager is responsible for:

A The preparation and/or review of quality-affecting documents that establish inspection requirements.

B Planning, performing, documenting and reporting inspection and tests.

C Qualification and training of inspection personnel, and ensuring that appropriate inspections and tests are scheduled and performed.

Policy Q-11.1 Test Control

1 Purpose and Applicability

This policy identifies requirements and responsibilities for planning and executing tests that are used to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service. The test control process is designed to prevent the use of failed or untested items.

This policy applies to organizations involved in performing tests such as prototype qualification tests, production tests, proof tests, construction tests, operational and pre-operational tests, factory and site acceptance tests, and in-use tests.

Computer program test requirements are identified in Policy Q-03.2 - *Software Control*. Activities required to collect data (such as for siting or design input) are performed in accordance with Supplement III – *Scientific Investigation.*

2 Implementation Strategy

Testing of specified items and processes will be conducted using established acceptance and performance criteria. Establishment and implementation of the test procedures will include the use of testing methods to demonstrate that items and processes perform as intended. These procedures are to be structured to clearly distinguish between tests that verify design requirements and tests that verify operation within safety limits and requirements. Test procedures will be implemented by trained personnel.

Item and process test requirements, including specified acceptance criteria, will be provided or approved by the organization responsible for design. Engineering has the primary responsibility for establishing and approving test requirements and associated acceptance criteria. Designated operations personnel will review the test packages for impact on and interface with operating systems, and confirm that proposed testing will provide adequate verification that the equipment being tested will perform its design functions.

Administrative controls and status indicators will be used to preclude inadvertent bypassing or non-completion of required tests or operation of untested items or processes as required by Policy Q-14.1- *Inspection, Test and Operating Status.*

When items and processes do not meet documented test acceptance criteria, test personnel have the freedom to communicate these deficiencies to management, and the deficiencies are to be documented and dispositioned as required by Policy 15.1- *Control of Nonconforming Items*.

Inspection and acceptance testing processes are to be part of the mechanisms that confirm readiness to perform safely in the project's integrated safety management system. The testing results will also serve the feedback and improvement process of Integrated Safety Management.

Test controls will include the development, approval, and use of test procedures. These procedures will include the requirements of this policy.

3 Policy

3.1 General

3.1.1 Tests required to collect data, to verify conformance of an item or computer program to specified requirements, and to demonstrate satisfactory performance for service shall be planned and executed.

3.1.2 Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, operational tests, computer program tests such as software design verifications, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled.

3.2 Test Requirements

3.2.1 Test requirements and acceptance criteria shall be provided or approved by the responsible design organization.

3.2.2 Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide requirements.

3.2.3 If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority and the organization responsible for the facility is required prior to performing the test.

3.2.4 The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

3.3 Test Planning

3.3.1 Required tests shall be performed and documented in accordance with approved written procedures, work packages, or data sheets.

3.3.2 Test procedure reviews shall be documented and comments dispositioned and resolved prior to final review and approval by the responsible organization(s). The organization responsible for performing the test shall be responsible for obtaining the approval of test procedures for a test activity.

3.3.3 The type and extent of test controls is based on the functional classification, and design, technical, or operational requirements assigned to the structure, system, or component.

3.4 Use of Other Testing Documents

3.4.1 As an alternative to subsection 3.3 above, appropriate sections of related documents such as American Society for Testing and Materials (ASTM) methods, supplier manuals, or related documents containing acceptance criteria may be used instead of preparing special test -implementing documents. If used, they shall incorporate the information directly into the approved test-implementing document, or shall be incorporated by reference in the approved test-implementing document.

3.4.2 Implementing documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.

3.5 Implementing Documents

Tests shall be performed in accordance with implementing documents that address the following requirements as applicable:

A Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.

B Test procedures shall include or reference the test configuration and test objectives.

C Test procedures shall also include provisions for assuring that suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed.

D Prerequisites shall include the following, as applicable: calibrated instruments, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.

E Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.

3.6 Test Results

3.6.1 Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure the test results have been satisfied, and who does not have direct responsibility for the work being performed.

3.6.2 The test status of an item shall be identified in accordance with Policy Q-14.1 - *Inspection, Test, and Operating Status*.

3.7 Test Documentation

3.7.1 Test records shall be established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements.

3.7.2 Test documentation shall identify the:

A Item or work product tested.
B Date of the test.
C Name of the tester and data recorders.
D Type of observation and method of testing.
E Identification of test criteria or reference documents used to determine acceptance.
F Results and acceptability of the test.
G Actions taken in connection with any nonconformances noted.
H Name of the person evaluating the test results.
I Identification of the measuring and test equipment used during the test, including the identification number and the calibration due date.

3.8 Qualification of Test Personnel

3.8.1 Personnel who perform testing shall be qualified in accordance with Policy Q-10.1 - *Inspection*, and/or Policy Q-02.2 - *Personnel Training and Qualification* as appropriate for the activity being performed.

3.8.2 Test engineers and other personnel who prepare and direct testing activities shall meet the qualification requirements in Policy Q-02.2 - *Personnel Training Qualification*.

4 Specific Requirements for DOE/RW-0333P QARD Requirements

4.1 Test planning shall include:

A Identification of the implementing documents to be developed to control and perform tests.
B Identification of item to be tested and the test requirements and acceptance limits, including required levels of precision and accuracy.
C Specification of characteristics to be tested, test methods to be employed, and instructions for performing the test.
D Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment and instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions, and provisions for data acquisition.
E Mandatory hold points.
F Methods to record data and results.
G Provisions for ensuring that prerequisites for the given test have been met.
H Selection and identification of measuring and test equipment based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

I Identification of the functional qualification level of personnel performing tests when required.

4.2 Test documentation will also include the identification of the measuring and test equipment used during the test including the identification number and most recent calibrated date.

5 Records

5.1 No additional record requirements are applicable to this policy**.**

6 Responsibilities

6.1 Organizations Performing Tests

Organizations performing tests are responsible for:

A Preparing test procedures, procedure change requests, or equivalent test planning documentation.

B Preparing data collection and/or data sheets (as required).

C Preparing test procedures and approving changes to test procedures.

D Obtaining appropriate reviews and approvals of test plans and procedures.

E Evaluating and accepting the test results/data that are generated by the test.

F Providing final disposition of test results/data.

G Initiating a nonconformance or deficiency report if acceptance test results do not meet specified acceptance criteria.

6.2 Engineering Manager

The Engineering Manager is responsible for providing and approving test requirements and acceptance criteria.

6.3 Organization or Personnel Performing Independent Verification

The verifying organization or personnel performing independent verification is responsible to see that test data and results are collected in accordance with test procedures and accurately recorded.

6.4 Quality Assurance Manager

The QA Manager is responsible for reviewing test control procedures and work control documents that specify use of test controls to ensure that quality assurance requirements of this policy have been appropriately incorporated.

Policy Q-12.1 Control of Measuring and Test Equipment

1 Purpose and Applicability

This policy identifies requirements and responsibilities for controlling measuring and test equipment (M&TE).

This policy applies to organizations that use or calibrate measuring and test equipment for determining acceptance of items and activities, process monitoring, data collection, or other activities affecting quality.

Calibration and control measures are not applicable for rulers, tape measures, levels, and other such coarse measurement devices that provide adequate accuracy as received from the manufacturer.

2 Implementation Strategy

Procedures describing the controls applicable to M&TE will be established and implemented for workers that use and calibrate M&TE. Equipment used for inspections and tests is to be calibrated and maintained. Traceability and accountability of this equipment is required.

M&TE procedures will define what equipment is considered M&TE. Calibration and traceability requirements for this equipment are also to be defined and based on its use. M&TE typically include instruments, tools, gauges, reference and transfer standards, and nondestructive examination equipment.

Calibration of M&TE is to be performed by trained individuals at specified intervals or just prior to and after use, as established by documented requirements. Calibration frequencies are to be based on required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting M&TE performance. M&TE will be labeled, tagged, or otherwise controlled to indicate calibration status. M&TE identification will provide traceability to calibration and test data.

Accuracy of M&TE calibration standards is to be established to ensure equipment being calibrated will be within required tolerances. Calibration standards will be traceable to national standards. If no national standards exist alternative standards will be identified.

M&TE found to be out-of-calibration or out-of-tolerance is to be tagged or segregated. Such M&TE will not be used until it has been either successfully re-calibrated or replaced. The M&TE control procedures will require formal documented review of the usage of such equipment dating back to its last known in-calibration date (reverse traceability). This review is to determine if such use resulted in the acceptability of items or processes being either invalid or indeterminate. The basis for acceptance of these nonconforming or indeterminate items and processes will be formally evaluated and documented.

During construction activities for the project, Construction maintains and controls M&TE used for testing, inspection, calibration of other instruments, process verification, or data collection for purposes of determining compliance with requirements. During commissioning activities the Operations Department will maintain and control M&TE used for testing, inspection, calibration of other instruments, process verification, or data collection for purposes of determining compliance with requirements. Each respective organizations will initiate records which will be maintained by Document Control to identify where the M&TE was used, identification of the measuring or test equipment calibrated, traceability to the calibration standard used for calibration, calibration data, identification of the individual performing the calibration. QA will perform independent assessments to verify implementation of the M&TE program.

M&TE will be controlled using approved procedures developed by Construction and Operations for their respective phase of project activities. The QA organization will review the procedures for the control of M&TE to ensure that the policy requirements are incorporated into the procedures.

3 Policy

3.1 General

3.1.1 M&TE requiring calibration shall include instruments or equipment used for testing, inspection, calibration of other instruments, process verification, or data collection for purposes of determining compliance with requirements.

3.1.2 Tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality shall be properly handled and stored, calibrated at specific intervals, adjusted, and maintained to required accuracy limits.

3.1.3 Selections of M&TE shall be controlled to ensure that such items are of a proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to requirements.

Note: Calibration implementing documents may be based on the requirements contained in the following calibration program standards and meet the requirements of this policy.

A ANSI/NCSL Z540-1-1994, American National Standard for Calibration-Calibration Laboratories and Measuring and Test Equipment-General Requirements.

B ANSI N323A-1997, American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.

3.2 Calibration

3.2.1 M&TE, including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, software changes, or prior to use, against reference calibration standards having traceability to nationally

recognized standards. If no nationally recognized standard or physical constants exist, the basis for calibration shall be documented.

3.2.2 For M&TE used in one-time-only applications, the calibration shall be done both before and after use.

3.2.3 Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated.

A If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements.

B The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.

3.2.4 The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.

3.2.5 A calibration or calibration check shall be performed when the accuracy of calibrated M&TE is suspect.

3.2.6 Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration.

3.2.7 Calibrated M&TE shall be uniquely identified to provide traceability to its calibration data.

3.2.8 Updates to software contained in M&TE that affect calibration requires re-calibration of the equipment prior to use.

3.3 Documenting the Use of Measuring and Test Equipment

3.3.1 The use of M&TE shall be documented. The documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.

3.4 Out-of-Calibration Measuring and Test Equipment

3.4.1 M&TE shall be considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist:

A The calibration due date or interval has passed without re-calibration.

B The device produces results known to be in error.

3.4.2 Out-of-calibration M&TE shall be controlled. The controls shall include the following requirements:

A Out-of-calibration M&TE shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated.

B When M&TE is found out of calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

1 The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

2 The evaluation shall be documented.

3.4.3 If any M&TE is consistently found out-of-calibration during the re-calibration process, it shall be repaired or replaced.

3.5 Lost Measuring and Test Equipment

3.5.1 When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

A The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

B The evaluation shall be documented.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements have been included in Section 3 – *Policy*.

5 Records

5.1 Records of M&TE calibration shall be maintained in accordance with Policy Q-17.1 – *Quality* Assur*ance Records*, and include the following information:

A Identification of the measuring or test equipment calibrated.

B Traceability to the calibration standard used for calibration.

C Calibration data.

D Identification of the individual performing the calibration.

E Identification of the date of calibration and the recalibration due date or interval.

F Results of the calibration and statement of acceptability.

G Reference to any actions taken in connection with out-of-calibration or nonconforming measuring and test equipment including evaluation results.

H Identification of the implementing document (including revision level) used in performing the calibration.

6 Responsibilities

6.1 All Personnel

All project organizations and suppliers using, calibrating, and maintaining M&TE, or procuring or requesting calibration services are responsible for implementing the requirements of this document as they apply to their functions.

6.2 Performing Organization Management (Operations/Construction)

Managers of affected organizations are responsible for implementation of adequate calibration programs and trained staff to meet the requirements of this policy.

6.3 Quality Assurance Manager

The QA Manager is responsible for reviewing M&TE calibration implementing documents.

Policy Q-12.2 Installed Process Instrumentation

1 Purpose and Applicability

This policy defines requirements and responsibilities for control of installed process instrumentation used to support project processes and facility operations.

This policy is applicable as appropriate to project organizations responsible for the calibration, control or use of installed process instrumentation for applicable processes or systems, including procurement of instrumentation including procurement of instrumentation or calibration services.

2 Implementation Strategy

Installed Process Instrumentation (IPI) is the installed equipment used for monitoring of, or collecting data from, plant processes and facility operations and is an integral part of the process system. Procedures describing controls applicable to IPI will be established and implemented. The IPI is to be calibrated and maintained by trained workers in accordance with these procedures. The Operations Manager will define what equipment is considered IPI, and the calibration requirements are to be specified and documented in implementing procedures. Each piece of IPI is to be uniquely identified with the identification either placed on or near the individual piece of instrumentation or affixed on the instrumentation with a tag. The identification will be used for traceability and accountability of the equipment.

Calibration of the IPI is to be performed by trained individuals at specified intervals, commensurate with the application of the equipment. The calibration frequencies and accuracy requirements will be based on the system monitoring requirements, stability characteristics, service conditions, and other factors determined by Engineering and Operations. The measuring and test equipment described in Policy Q-12.1 – *Control of Measuring and Test Equipment,* will be used to calibrate the IPI.

IPI determined to be out of tolerance is to be documented and reported to the responsible management. An evaluation is required to determine the effect on the validity of previous data collected by that IPI, and the impact on previously accepted data. Conclusions for these evaluations, which indicate conditions adverse to quality, are to be documented and resolved in accordance with Policy Q-16.1 - *Corrective Action.*

The Operations Manager is responsible for developing the IPI procedures. The Quality Assurance (QA) organization will review the procedures for the control of IPI to ensure policy requirements are incorporated into the procedures.

3 Policy

3.1 General

3.1.1 Installed process instrumentation shall be controlled, calibrated, and administered using written procedures or instructions as appropriate.

3.1.2 Installed process instrumentation, including instrumentation that contains software or programmable hardware, shall be calibrated prior to initial use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standard exist the basis for calibration shall be documented.

3.1.3 Installed process instrument shall be re-calibrated at a prescribed schedule commensurate with application functions or functional classification.

3.1.4 Installed process instrumentation used to take measurements or readings to satisfy regulatory requirements shall be calibrated prior to initial use and re-calibrated at a prescribed schedule.

3.1.5 Calibration uncertainties of specified measuring and test equipment (M&TE) used to calibrate or verify install process instrumentation calibrations shall be sufficiently small so that the accuracy of the measurement is not affected.

3.2 Identification and Control

3.2.1 Installed process instrumentation shall be uniquely identified. Where marking is not possible because of size, configuration, complexity, or location, the identification shall be affixed near the instrumentation to ensure that control is maintained.

3.2.2 Installed process, instrumentation shall be labeled, tagged, or otherwise suitably marked, or documented to indicate calibration due date or interval of calibration due date or interval of calibration.

3.3 Calibration

3.3.1 Calibration of installed process instrumentation shall be performed by qualified individuals in accordance with Policy Q-02.2 - *Personnel Indoctrination and Training*.

3.3.2 Written and approved procedures or instructions shall be used to calibrate or verify calibration.

3.3.3 Calibration results shall be documented with sufficient detail to show traceability to nationally recognized standards.

3.4 Calibration Frequency

3.4.1 The calibration frequency shall be established and approved by the appropriate organization for installed process instrumentation. The initial calibration frequency shall be based on:

A Manufacturer's recommendation.
B Service conditions/functional classification.
C Instrumentation type and stability.
D Degree of use, accuracy, and reliability.
E Historical data, if available, for similar process instrumentation.

3.4.2 The calibration frequency may be adjusted with approval from the appropriate organization based on a review of previous calibration results, inherent stability, purpose of use, and accuracy required.

3.4.3 One-time calibration frequency extensions up to 25% of the established frequency is allowed with documented prior approval from the appropriate organization and Quality Assurance when necessary to support facility testing.

3.5 Out-of-Calibration Installed Process Instrumentation

3.5.1 Installed process instrumentation shall be considered out-of-calibration and not used until calibrated if any of the following exist:

A The calibration due date or interval has passed without recalibration.
B The instrument produces results known to be in error.

3.5.2 Out-of-calibration installed process instrumentation shall be controlled to prevent inadvertent use until it is recalibrated.

3.5.3 When installed process instrumentation is found out-of-calibration during recalibration, the validity of results obtained using the instrumentation since its last calibration shall be evaluated and documented.

3.5.4 If any installed instrumentation is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced as appropriate.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD Requirements have been included in subsection 3 - *Policy*.

5 Records

5.1 Calibration records of installed process instrumentation shall include the following information as appropriate:

A Identification of the instrumentation.
B Traceability to the calibration standards.
C Calibration data.
D Identification of the individual performing the calibration.
E Identification of the calibration date or internal as appropriate.
F Results and acceptability of the calibration.
G Reference to any actions taken to address out-of-calibration instrumentation including evaluation results, as appropriate.
H Implementing documents used to perform the calibration.

6 Responsibilities

6.1 All Personnel

All project organizations and suppliers using, calibrating, and maintaining installed process instrumentation, or procuring or requesting calibration services are responsible for implementing the requirements of the policy as it applies to their functions.

6.2 Operations Manager

The Operations Manager is responsible for developing the implementing documents for this policy and providing adequate calibration program staff to meet the requirements of this policy.

6.3 Quality Assurance Manager

The QA Manager is responsible for reviewing implementing documents related to this policy.

Policy Q-13.1 Handling, Storage, and Shipping

1 Purpose and Applicability

This policy identifies requirements and responsibilities for handling, storing, cleaning, packaging, shipping, and preserving items to prevent damage or loss and minimize deterioration.

This policy applies to organizations that handle, store, clean, package, ship, and preserve items.

2 Implementation Strategy

Procedures and other work controlling documents specific to a task are to be established and implemented to control the handling, storing, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration (i.e., loss of specified function.) The controls established for storing and shipping are to be derived from national consensus standards, or technical documents if no standards exist.

Instructions for marking and labeling for packaging, shipment, handling, and storage of items are to be established as necessary to adequately identify, maintain, and preserve item integrity, including indication of the need for special environments or special controls. Procedures for offsite transportation will be established and implemented. The requirements for special protective measures are to be documented. Measures may include special containers, shock absorbers, accelerometers, inert gas atmospheres, and controls on temperature and moisture levels. Such measures are also to be specified and provided, when required, to maintain acceptable item quality during storage.

Work control documents (procedures and instructions) must describe, as appropriate, the processes for the identification of items with unique requirements and specify the necessary protective methods for sensitive or perishable items, such as special handling, shipping, and storage controls for precision instrumentation and limited shelf-life items, and for items requiring special protective environmental controls, such as temperature and humidity controls.

The requirements and responsibilities for identifying and controlling items are specified in Policy Q-8.1 - *Identification and Control of Items*.

Work control documents for handling, storing and shipping, shall be developed based on the requirements of this policy.

3 Policy

3.1 General

3.1.1 The handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings,

specifications, shipping instructions, or other pertinent documents or procedures specified for use in conducting the activity.

3.1.2 When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

3.2 Special Equipment, Tools, and Environment

3.2.1 When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

3.2.2 Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling.

3.2.3 Special handling tools and equipment shall be inspected and tested periodically or prior to use as necessary to ensure performance.

3.2.4 Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

3.2.5 Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained.

3.3 Marking and Labeling

3.3.1 Measures shall be established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item.

3.3.2 Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 - *Policy*.

5 Records

5.1 No additional records requirements are applicable to this policy.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager shall monitor quality assurance program implementation for handling, storage, and shipping activities within the company.

6.2 Organizations

Organizations that generate procedures for the handling, storage, and shipping of items shall comply with the requirements contained in this policy.

Organizations involved in handling, storage, and shipping activities shall comply with applicable handling, storage, and shipping procedures.

Policy Q-14.1 Inspection, Test and Operating Status

1 Purpose and Applicability

This policy identifies requirements and responsibilities associated with the use of status indicators to prevent inadvertent installation, use or operation of items.

This policy applies to organizations involved in controlling the inspection, test, and operating status of items during receipt inspection, construction, fabrication, operation, maintenance, and commissioning phases of facilities for which Bechtel National, Inc. (BNI) has responsibility.

2 Implementation Strategy

Managers of organizations that perform operating, support, or experimental functions are required to maintain physical status indicators and supporting documentation for those work processes that are under their control. Content, application, updating, or removal of physical status indicators will be controlled by procedure concurred with by the quality assurance (QA) organization and contain the requirements of this policy.

3 Policy

3.1 General

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed, and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.

3.2 Identification Methods

The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.

3.3 Identification of Status

3.3.1 Status shall be maintained through the use of legible and easily recognizable status indicators, such as physical location and tags, shop travelers, stamps, inspection or test records, or other suitable means.

3.3.2 Status indicators shall also provide for indicating the operating status of systems and components, such as by tagging valves and switches, to prevent inadvertent operation or changes in operating status.

3.4 Authority

The authority for application and removal of tags, markings, labels, and stamps shall be specified.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 – *Policy*.

5 Records

5.1 No additional records requirements are applicable to this policy.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for establishing and maintaining a system for identifying the quality status of items, which includes, but is not limited to, acceptance, rejection, hold for inspection, and conditional use.

6.2 Performing Managers

Affected Managers are responsible for establishing and maintaining a system to control equipment and system operational status and equipment lock-out and tag-out.

6.3 Organizations Performing Inspection, Test, or Operating Activities

Organizations that perform inspections, tests, or operating activities are responsible for complying with the status indicator requirements described in this document and procedures that implement these requirements.

Policy Q-15.1 Control of Nonconforming Items

1 Purpose and Applicability

This policy identifies requirements and responsibilities for controlling items that do not conform to specified requirements to prevent their inadvertent installation or use.

This policy applies to all Quality Level (QL) items, and items that are determined to be suspect/counterfeit items regardless of quality level.

The requirements identified in this policy are optional for the following items:

A Nonconforming items discovered while in an in-process status under work process control procedures that are re-worked within the scope of the work process control to meet existing design requirements.

2 Implementation Strategy

Management's role in achieving quality includes promoting, supporting, and encouraging effective problem identification and correction. The individual worker's role will be to meet the quality requirements and to recommend improvements in item quality. All personnel will be granted the freedom and authority to identify those items determined to be adverse to quality, and as appropriate, to stop work or request that work be stopped until effective corrective action is completed. The Quality Assurance (QA) Manager is responsible for developing the processes to detect and correct quality problems.

Project procedure(s) will require personnel to report identified nonconforming items. Identification methods include inspecting, testing, auditing, surveillances, and worker observation. Project procedure(s) will require nonconforming items to be reported and documented using the Nonconformance Report (NCR). NCRs will be reported to the organization responsible for dispositioning and the QA organization for tracking and trending in the project electronic database. The nonconforming items procedure will require that items not meeting established requirements be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction includes identifying the causes of problems and taking action to prevent recurrence. The extent of cause analysis for nonconforming items will be commensurate with the importance or significance of the problem.

Repetitive or significant problems with nonconforming items may require more extensive evaluation and analysis. When these conditions occur they are to be analyzed for root cause through the corrective action system (Policy 16.1 - *Corrective Action*) and documented. The corrective action system will require a root cause analysis, identification and implementation of steps necessary to prevent recurrence, and the reporting of results to senior project management. Implementation of the required corrective action is to be performed and documented by the responsible organization and verified by the QA organization. Nonconforming items that are subsequently re-worked, repaired, or replaced are to be inspected and/or tested to either the original requirements or to specified alternative requirements. Such inspections or tests are to be

conducted before the final acceptance of the item. Refer to Policy 11.1 - *Test Control* for the requirements for testing items.

Engineering is chartered with having an adequate technical understanding of the work, access to pertinent background information, and will be responsible for the analysis and disposition of nonconformances involving "Repair" or "Use-As-Is" dispositions.

QA activities associated with nonconforming items will include validation of the nonconformance, review of dispositions, verification of completion of disposition actions, and closure of the reporting document.

The nonconforming items procedure will be developed by the QA organization based on the following requirements of this policy.

3 Policy

3.1 General

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use of the item. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to relevant organizations.

3.2 Documentation and Evaluation

3.2.1 Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

3.2.2 Nonconforming items shall be evaluated, and recommended dispositions shall be proposed, evaluated, and approved.

3.2.3 The review shall include determining the need for corrective action according to the requirements of Policy Q-16.1 - *Corrective Action*.

3.2.4 Documentation of a nonconformance is required when a Quality Level (QL) item:

A Fails to meet required technical or quality requirements.

B Is of indeterminate quality.

C Is a suspect/counterfeit item.

D Has documentation deficiencies (i.e., missing, incomplete, illegible, or damaged documents, improper revisions; or documents having unauthorized changes) which render the quality of the item indeterminate and which cannot be corrected before further processing, delivery, installation, or use.

3.3 Notification

Organizations affected by the nonconformance shall be notified.

3.4 Personnel

Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information.

3.5 Responsibility and Authority

3.5.1 The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be defined.

3.5.2 Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.

3.5.3 Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

3.6 Identification

3.6.1 Nonconforming items shall be identified by marking, tagging, segregation, or other methods not detrimental to the item, the container, or the package containing the item. The identification shall be legible and easily recognizable.

3.6.2 If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, shall be identified.

3.7 Segregation

3.7.1 Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

3.7.2 When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of the nonconforming item.

3.8 Disposition

3.8.1 The disposition of use-as-is, reject, repair, or re-work for nonconforming items shall be identified and documented.

3.8.2 The technical justification for the acceptability of a nonconforming item that has been dispositioned repair or use-as-is shall be documented.

3.8.3 Items that do not meet original design requirements that are dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.

3.8.4 Required as-built records shall reflect the use-as-is or repair condition.

3.8.5 If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.

3.8.6 Any document or quality assurance record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation.

3.8.7 The disposition of an item to be re-worked, or repaired shall contain a requirement to re-examine (inspect, test), or nondestructively examine the item to verify acceptability.

3.8.8 The recommended disposition shall be evaluated and approved.

3.9 Re-examination

Repaired or re-worked items shall be reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

3.10 Quality Trending

Nonconformance documentation shall be at a minimum quarterly analyzed by the QA organization to identify quality trends in accordance with Policy Q-16.1 - *Corrective Action.*

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 – *Policy*.

5 Records

5.1 NCRs and associated documentation are considered quality records to be maintained in accordance with Policy Q-17.1 - *Quality Assurance Records*.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for establishing the procedure(s) for definition, implementation, and maintenance of the process for the control of nonconforming items. They or their designee are also responsible for:

A Reviewing and concurring with conditional use evaluations.

B Performing verification of implemented corrective actions.

C Ensuring that quality nonconformance control status tags are applied and removed as appropriate.

6.2 All Managers

Each manager is responsible and accountable for ensuring that:

A Ensuring procedures relating to the nonconforming item process are effectively implemented.

B Promoting an open environment and culture to support the identification and resolution of nonconforming items so that employees may report nonconformances without fear of reprisal.

C Ensuring that nonconforming items under their purview are identified, documented, and resolved in an effective and timely manner.

D Using designees to implement many of the activities to resolve nonconforming items and to ensure that adequate priority and resources are allocated for effective process implementation.

E Performing categorization and ensuring the completion of applicable reportability reviews and operability evaluations, as required, for nonconforming items.

F Ensuring nonconforming items are properly tagged or segregated to prevent inadvertent installation or use.

G Ensuring that nonconforming items that pose a threat to employee safety or health, or represents an imminent threat to the environment, the public or property are placed in a safe condition and that an evaluation is conducted to determine if stopping work is warranted.

6.3 All Personnel

All personnel are responsible for identifying and reporting items that could be categorized as nonconforming.

Policy Q-16.1 Corrective Action

1 Purpose and Applicability

This policy identifies requirements and responsibilities for ensuring that conditions adverse to quality are promptly identified, controlled, and corrected as soon as practical through the Corrective Action System.

This policy applies to all organizations responsible for achieving, maintaining, and verifying the quality of items, services, and activities of facilities, programs, and projects; and to those corresponding conditions that may be adverse to safety, health, operations, quality, security, and the environment.

This policy applies to conditions identified by external agencies and by employees in performance of their routine duties including internal independent audits, surveillances, and management assessments.

2 Implementation Strategy

One fundamental element of continuous improvement is the corrective action system. The objective of a corrective action system is to identify, control, document, evaluate, and trend conditions adverse to quality, and to develop and implement appropriate actions to correct the adverse condition. The corrective action system is a vital tool for implementing the continuous improvement element of the quality assurance program. Quality improvement is the essence of the feedback and improvement core function of Integrated Safety Management.

Project management will have the responsibility to achieve quality in the products produced and services provided. Management’s role includes promoting the corrective action system, and supporting and encouraging effective problem identification and correction. The individual worker's role will be to meet the quality requirements and to recommend improvements in service and process quality. All personnel have the authority and are encouraged to identify those services, and processes determined to be adverse to quality, and as appropriate, to stop work or request that work be stopped until effective corrective action is completed. The Quality Assurance (QA) Manager is responsible for developing the processes to detect and prevent quality problems.

Services and processes that do not meet established requirements are to be identified (through a variety of methods including assessments, audits, surveillances, and worker observations), documented, controlled, and corrected according to the importance of the problem and the work affected. Correction includes identifying the causes of problems and taking appropriate corrective action.

For conditions adverse to quality the condition will be documented, reported to responsible management, and corrected in an efficient and timely manner based on the nature and complexity of the problem. The condition adverse to quality will be tracked and trended by the QA organization using an electronic database.

Significant conditions adverse to quality (a subset of conditions adverse to quality) will be identified using a risk-based approach with criteria related to repetitive problems, statistically significant adverse trends, and impacts or consequences associated with personnel safety and health, the environment, and project milestones including cost and schedule. When these conditions occur they are to be analyzed for the root cause and identification of steps necessary to prevent recurrence. Significant conditions adverse to quality will be reported to senior project management. Determination of root cause will be based on guidance available in commercial industry standards. Commercial industry root cause methods include event and causal factor charting, barrier analysis, and the "Why" Stair Case, each is applied as appropriate to the nature and complexity of the significant condition adverse to quality. Implementation of the required corrective action(s) is to be performed and documented by the responsible organization and verified by the QA organization. Lessons learned from the corrective action process are shared with management to foster the prevention of recurrence.

Continuous improvement objectives are to be met by measuring and evaluating performance against key performance indicators/standards. Examples include repeat problems, timeliness of actions, trending in the number of deficiencies, and trends related to causes. Item characteristics, process implementation, and other quality-related information are to be reviewed as necessary, and the data analyzed to identify improvement opportunities and potential problem areas before they become significant. This data is to be used to identify trends that adversely impact quality and opportunities to improve items and processes. Data will be collected from a variety of sources such as management assessments, external audits, independent audits, surveillances, deficiency reports, and nonconformance reports. After data analysis, at a minimum, quarterly reports will be issued to senior management who has the responsibility to effect the changes they deem necessary.

The QA organization is responsible for developing the necessary project procedures that implement this policy based on the requirements of this policy.

3 Policy

3.1 General

3.1.1 Conditions adverse to quality are those conditions where a stated non-compliance with a QA requirement exists, or an implementing document requirement is not met. The general requirements for correcting conditions adverse to quality include:

A Classification of the condition as conditions adverse to quality or significant conditions adverse to quality.

B Conditions adverse to quality shall be identified promptly and corrected as soon as practical.

C In the case of significant conditions adverse to quality (a subset of conditions adverse to quality), the cause shall be determined and corrective action taken to preclude recurrence.

D The identification of, cause and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

E Follow-up action shall be taken to verify implementation of corrective action.

3.1.2 QA management shall retain the right to initiate a stop work order for significant conditions adverse to quality in any project activity.

3.2 Conditions Adverse to Quality

3.2.1 Responsible management shall perform investigative action to determine the extent of the adverse conditions and complete remedial action as soon as practical.

3.2.2 Conditions adverse to quality shall be documented and reported to appropriate levels of management responsible for the conditions and to the QA organization for tracking and trending.

3.3 Significant Conditions Adverse to Quality

3.3.1 Criteria for determining significant conditions adverse to quality shall be established and identified.

3.3.2 The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management responsible for the organization and to the QA organization for tracking.

3.3.3 Responsible management shall:

A Perform investigative action to determine the extent and impact of the conditions and document the results.

B Determine, document, and complete remedial action as soon as practical.

C Determine and document the root cause using formal root cause techniques defined in the root cause procedure.

D Identifying and implementing corrective actions that will preclude recurrence as soon as practical.

3.4 Follow-up and Closure Action

Completion of corrective actions shall be verified. Follow-up management assessments or independent audits should be scheduled (usually within three to six months) after verifying implementation of corrective actions to determine the effectiveness of the corrective actions.

3.5 Quality Trending

3.5.1 The QA organization shall establish criteria for determining adverse quality trends using appropriate statistical techniques and the guidance found in appropriate standards on trending and analysis.

3.5.2 Reports of nonconformance and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes.

3.5.3 Trend evaluation shall be performed at a minimum quarterly, and in a manner that provides for prompt identification of adverse quality trends.

3.5.4 Trend evaluations shall be distributed to the Project Manager and management of impacted organizations.

3.5.5 Identified adverse trends shall be reported to the management of the organization responsible for corrective action.

4 Specific Requirement for DOE/RW-0333P QARD Application

4.1 Conditions Adverse to Quality

The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied.

4.2 Significant Conditions Adverse to Quality

A Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine if a stop work order is warranted.

B QA management shall issue stop work orders to responsible management after a stop work condition has been identified.

C The QA organization shall concur with the proposed corrective action, including remedial action, the root cause, and actions taken to prevent recurrence, to ensure that QA program requirements are satisfied.

D QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.

4.3 Follow-Up

The QA organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.

5 Records

5.1 All records designated in implementing documents as quality assurance records. Shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for the following:

A Review and concurrence of procedures for reporting and controlling conditions adverse to quality in accordance with the requirements of this policy.

B Concurring with causal analysis and corrective action plans as required.

C Verifying implementation of corrective actions as required.

D Trending conditions adverse to quality.

E Evaluating conditions adverse to quality to determine reportability and Price-Andersen Amendment Act (PAAA) compliance.

6.2 Managers

Managers are responsible for ensuring that conditions adverse to quality are identified and controlled in accordance with approved procedures and for ensuring that an atmosphere is created in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels.

6.3 All Personnel

All personnel are responsible for identifying, documenting and reporting potential conditions adverse to quality.

Policy Q-16.2 Stop Work

1 Purpose and Applicability

This policy defines the requirements for stopping work and provides a mechanism for any employee to identify quality problems.

This policy applies to all personnel working at or for the project including subcontractors.

2 Implementation Strategy

An important attribute of integrated safety management is the ability of any project employee or subcontractor to stop work when such work presents an imminent danger to their safety or health, the environment, facilities or property. Project management is responsible for ensuring the safety of employees and subcontractors and for taking appropriate actions to correct the cause(s) for stopping work. Procedure(s) for implementing the stop work process will be developed by the quality assurance (QA) organization that contain the requirements of this policy.

3 Policy

3.1 General

3.1.1 The project empowers employees to stop work when a concern presents an imminent danger to employee safety and health, the environment, facilities, or property. Concerns will be transmitted to the Project Manager for action and disposition.

3.1.2 A stop work is initiated through the Project Manager for office work and the Construction or Operations Manager for site activities.

3.1.3 The following are typical situations in which work stoppage may be initiated.

A Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel.

B Continued work will require significant rework or repair to backfit corrective action.

C An organization, department, group, sections, or individual by a repetitive failure to comply with technical or administrative controls contributes to a condition that is a significant QA program deficiency.

D An uncontrolled chemical spill or radioactive release has occurred or is imminent.

3.1.4 Significant conditions adverse to quality shall be evaluated for a stop work condition by the management to determine if stopping work is warranted.

3.1.5 Management shall take appropriate action to lift and close (in part or total) the stop work based on the actions taken to address the significant condition adverse to quality.

3.1.6 QA management shall initiate a stop work order when conditions identified warrant a stoppage of work.

3.1.7 For stop work conditions initiated by QA management, only QA management shall take appropriate action to lift and close (in part or total) the stop work order based on the actions taken to address significant condition adverse to quality.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in Section 3 – *Policy.*

5 Records

5.1 No additional records requirements are applicable to this policy.

6 Responsibilities

6.1 Project Manager

The Project Manager is responsible for stopping applicable work activities when conditions warrant stoppage.

6.2 Performing Managers (Construction and Operations)

Affected managers are responsible for stopping applicable work activities when conditions warrant work stoppage.

6.3 Quality Assurance Manager

The QA Manager is responsible for issuing a work stoppage when conditions identified warrant the stoppage of work.

6.4 All Personnel

All employees have a responsibility to notify the supervisor when a concern presents an imminent danger to employee safety and health, the environment, facilities, or property and to stop the activity if warranted.

Policy Q-17.1 Quality Assurance Records

1 Purpose and Applicability

This policy identifies requirements and responsibilities for identifying, administrating, and temporarily storing documents and construction records designated as quality assurance (QA) records.

This policy applies to project personnel who prepare or process documents designated as QA records per Policy Q-06.1 – *Document Control.*

Note: The term "records' used throughout this section, is to be interpreted as *quality assurance* records.

2 Implementation Strategy

A document becomes a record when it is completed and validated. Records, sufficient to provide objective evidence of the quality of an item or activity, and if necessary, to support technical and regulatory decisions, will be identified and used for activities affecting completed work. Records are to be specified in documents affecting quality, and prepared, reviewed, approved, and maintained using a graded approach. Record maintenance will include provisions for record retention, protection, personnel access control, preservation, traceability, accountability, and retrievability. Quality-affecting implementing procedures are to identify which records must be maintained and controlled as a record. Records are to be stored as hard copy, microfilm, magnetic media, or on optical disks. Records requiring special processing and control, such as computer codes or information on high-density media or optical disks are to be controlled to ensure their validity and usability. Hardware and software needed to maintain and access these records will also require control to ensure their retrievability and readability.

Project document control facilities are to be used for records storage. The project may also use staging areas for records wherein records are indexed and prepared for transfer toproject document control . Staging areas are to be equipped with fire detection and suppression devices and include provisions for controlling access to the records. All of these areas will provide retention, protection, preservation, traceability, accountability, and retrievability of records.

The Business Services Manager is responsible for developing the procedures implementing the requirements of this policy that will be concurred with by the QA organization.

3 Policy

3.1 General

3.1.1 Records shall furnish documentary evidence that items or activities meet specified quality requirements.

3.1.2 Records shall be identified, generated, authenticated, maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented.

3.1.3 A project records system shall be maintained and enforced in accordance with written procedures, instructions, or other documentation.

3.1.4 Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

3.1.5 Records shall be distributed, handled, and controlled in accordance with written procedures.

3.2 Generation of Records

3.2.1 Records shall be legible and identifiable.

3.2.2 Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.

3.2.3 Individuals handling records shall protect them from damage or loss until the records are submitted to the records management system.

Note: Records may be originals or copies.

3.2.4 Implementing documents shall:

A Identify those documents that will become records.

B Identify the organization responsible for submitting the records to the records management system.

3.2.5 Individuals creating records shall ensure that the records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.

3.3 Authentication of Records

3.3.1 Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

3.3.2 If the nature of the record (such as magnetic or optical media) precludes stamping, initialing or signing, then other means of identifying the record as complete by authorized personnel are permitted.

3.4 Classification of Records

3.4.1 Records shall be classified as lifetime or nonpermanent.

3.4.2 Lifetime records are those that meet one or more of the following criteria:

A Those which would be of significant value in demonstrating capability for safe operation.

B Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.

C Those which would be of significant value in determining the cause of an accident or malfunction of an item.

D Those which would provide required baseline data for in-service inspections.

E Project personnel exposure records.

F Documents which are implementing documents as described in Policy Q-05.1 - *Instructions, Procedures and Drawings* shall be classified as nonpermanent records.

3.4.3 Documents that do not meet the requirements for lifetime records, but provide evidence that the QA program has been properly executed shall be classified as nonpermanent records.

Note: Nonpermanent records are those records required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

3.5 Receipt Control of Records

3.5.1 The organization responsible for the receipt of records shall designate a person or position responsible for receiving records.

3.5.2 The designee shall be responsible for organizing and implementing a system of receipt control of records for temporary storage including a method for verifying that the records are those designated.

3.5.3 Records shall be protected from damage, deterioration, or loss when received.

3.5.4 Legibility and completeness of records shall be verified.

3.5.5 As a minimum, a receipt control system shall include:

A A method for designating the required records.

B A method for identifying records received.

C Procedures for receipt and inspection of incoming records.

3.5.6 The receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

3.6 Storage of Records

3.6.1 Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

A Natural disasters such as winds, floods, or fires.

B Environmental conditions such as high and low temperatures and humidity.

C Infestation of insects, mold, or rodents.

3.6.2 The storage arrangement shall provide adequate protection of special processed records (e.g., radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored.

3.6.3 The storage area shall be protected from unauthorized entry, larceny, and vandalism.

3.6.4 Storage of records by the authenticating organization prior to transfer to a central file location shall minimize the risk of loss, damage, or destruction. As a minimum, records shall be stored and indexed for retrievability within a facility or container. The containers or facilities shall bear an Underwriter's Laboratories label (or equivalent) certifying 1-hour fire protection, or be certified by a person competent in the technical field of fire protection.

3.6.5 If a single facility, container, or combination is not capable of providing adequate protection, dual facilities, containers, or combination shall be provided for record storage at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

Note: Dual storage facilities are not required to meet the design and construction requirements specific for a long-term single storage facility.

3.6.6 Storage methods shall be developed to preclude deterioration of records. Approved filing methods shall require records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers appropriate for the record medium being stored.

3.6.7 Retrieval and Storage of Records

A The record management system shall provide for retrieval of records with planned retrieval times based on record type.

B Records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing document that provides:

1 A description of the storage facility.

2 A description of the filing system to be used.

3 A method for verifying that the records received are in agreement with the transmittal document.

4 A description of controls governing record access, retrieval, and removal.

5 A method for filing supplemental information.

6 A method for disposition of superseded records.

C Storage methods shall be developed to preclude deterioration of records in accordance with the following:

1 Approved filing methods shall require records to be firmly attached in binders or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the record medium being stored.

3.7 Retention and Disposition of Records

3.7.1 QA record retention periods shall be documented.

3.7.2 Records shall be maintained for their retention periods.

3.7.3 Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.

3.7.4 Nonpermanent records shall not be disposed of until the following conditions are met:

A Regulatory requirements are satisfied.

B Operational status permits.

C Purchaser's requirements are satisfied, or a minimum of three years whichever is longer.

3.8 Retrieval of Records

3.8.1 Records shall be retrievable.

3.8.2 Records shall be indexed to ensure retrievability. The indexing system shall include:

A Location of the records within the records management system.

B Identification of the item or related activity to which the records pertain.

C Classification of the record.

3.8.3 Records shall be submitted to storage after processing has been completed.

3.8.4 Access to storage facilities shall be controlled.

3.8.5 A list shall be maintained designating personnel who are permitted access to the records.

3.8.6 The record management system shall provide for retrieval of records with planned retrieval times based on record type.

3.9 Correcting Information in Records

3.9.1 Corrections to records including documents that will become records shall include the initials or signature of the person authorized to make the correction and the date the correction was made.

3.9.2 Corrections to records shall be approved by the originating organization.

3.9.3 If an organization that was originally responsible for approving a particular document is no longer responsible, the new responsible organization shall be identified.

3.9.4 When correction to a record is required, a single line shall be drawn through the information to be corrected. The individual revising the information shall initial and date the revision adjacent to the drawn line. Erasers or correction fluid or tapes shall not be used. Corrections, when required, shall be recorded adjacent to the information to be corrected or by recording the referenced location of the correction. Correction to authenticated records shall be resubmitted to the originating organization (or designee) for authentication. The implementing records procedures shall address the editorial correction of records.

3.9.5 Correction to an electronic record will be in accordance with established procedures.

3.10 Replacement of Records

3.10.1 Organizations originating records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged records.

3.10.2 Lost or damaged records shall be replaced or restored. When replacement or restoration cannot be achieved, the owning organization shall conduct and document an evaluation of the impact.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 Classification of Records

Documents that meet the following requirements shall be classified as lifetime records:

A Documents that provide evidence of the quality of items.

B Documents that provide evidence of the quality of activities related to items.

C Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

D Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form itself.

E Personnel training and qualification documents for individuals executing program requirements.

F Documents which are implementing documents as described in Policy Q-05.1 - *Instructions, Procedures and Drawings*.

5 Records

5.1 Records designated in implementing documents as quality assurance records shall be controlled in accordance with this policy.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for developing, maintaining, and interpreting the requirements of this policy.

6.2 Business Manager

The Business Manager is responsible for developing and maintaining a records management system and procedures that implement these requirements.

6.3 Personnel

All Personnel are responsible for carrying out requirements set forth in this policy, and for following the implementing procedures that define and control records. In addition, personnel handling records shall protect them from damage or loss until the records are submitted to the records management system.

Policy Q-18.1 Independent Assessment (Audit)

1 Purpose and Applicability

This policy identifies requirements and responsibilities for performing independent assessments (audits), both internal and external. Assessments are used to verify compliance with and to determine the effectiveness of the quality assurance (QA) program implementation and maintenance, and to identify continuous improvement opportunities.

The audited organization's management shall on a continuing basis, be apprised of the status, adequacy, and compliance aspects of the QA program. Appropriate management shall conduct and receive assessment reports.

This policy applies to those organizations involved in or subject to the performance of independent assessment audits.

2 Implementation Strategy

Independent audits/assessments are to be planned and conducted to measure item and service quality; to measure the adequacy of work performance; and to promote improvement. Independent audits are an important element of the feedback and improvement mechanism of the Integrated Safety Management System (ISMS). Audits will be conducted to evaluate the performance of work processes and to promote improvement with regard to requirements and management expectations. The focus of audits includes emphasis on results, technical adequacy, and the quality or work processes. Audits are to be performed by the trained and qualified personnel from the QA organization augmented as necessary by trained technical specialists as appropriate for the area being audited. These audits are separate from, and in addition to, surveillances identified in Policy Q-18.2 - *Quality Assurance Surveillance* and Management Assessments identified in Policy Q-18.3 - *Management Assessments*.

Documented independent audits are to be routinely planned, scheduled, and conducted to verify conformance of items, services, and processes to established requirements of the 18 plus policies of this manual and applicable project technical standards and other procedural or process requirements. The schedules, and the allocation of resources needed to meet these schedules, are to be based on the status, hazard, and complexity of the activity or process being assessed. Schedule flexibility will allow performance of additional audits in questionable areas. The audit process will include follow-up by project management to assure corrective action is implemented when deficiencies are identified.

Audit results are to be tracked and individuals in management responsible for their resolution clearly assigned. The need for follow-up review of areas found deficient during an audit will be determined by the QA Manager. Conditions adverse to quality identified during the audit process will be dispositioned by the responsible organization in accordance with either Policy Q-15.1 - *Control of Nonconforming Items*, or Policy Q-16.1 - *Corrective Action*, as appropriate.

Independent audit personnel will act in a management advisory capacity. Audits are to be performance-based with emphasis on results and with compliance viewed as the baseline.

Performance-based audits, focusing on items, services, and process improvement, will evaluate and report on the organization's achievement of quality and the effectiveness of the organization's management assessment programs. During the conduct of performance-based assessments, work will be monitored to identify problems, abnormal performance, and to promote improvement. Strengths and weaknesses (opportunities for improvement) affecting the quality of services and process should be identified so that meaningful action can be taken by responsible management to improve the process or service. Audit results are to be documented and provided to a level of management having the authority to implement necessary corrective actions and verify that identified problems have been satisfactorily resolved.

The qualification of independent audit personnel is specified in Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification.* The group performing independent audits will have sufficient authority and freedom from the line to carry out its responsibilities. Personnel performing independent audits will not have direct responsibilities in the area they are assessing. Participation by individuals (technical specialists) outside the project may be used to complement the independent assessment program.

Procedure(s) for conducting independent audits are to be developed by the QA organization utilizing the requirements of this policy.

3 Policy

3.1 Audits

3.1.1 Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program.

3.1.2 The lead auditor organizes and directs audits, reports audit findings, and evaluates corrective actions

3.2 Scheduling Internal Audits

3.2.1 Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with on-going work.

3.2.2 Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work.

3.2.3 Internal audits shall be scheduled to begin as early in the life of the work as practical, and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.

3.2.4 Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.

3.2.5 Internal audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.

3.2.6 An annual audit schedule will be developed, reviewed periodically, and revised as necessary to ensure that the QA program coverage is current.

3.3 Scheduling External Audits

3.3.1 The need for and frequency of external audits shall be determined after the supplier has been selected to perform work. The determination shall be based on the complexity and nature of the items or services being procured.

3.3.2 External audits shall not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, or adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery. The rationale for not performing audits for these items shall be documented.

3.3.3 The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs.

3.3.4 The audit schedule shall be developed annually and revised periodically to ensure that coverage is maintained current.

3.4 Audit Planning

3.4.1 The auditing organization shall develop and document an audit plan for each scheduled audit.

3.4.2 The audit plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, activities to be audited, organizations to be notified, applicable documents, schedule, and written implementing documents or checklists to be used.

3.4.3 Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

3.4.4 The scope of each audit shall be based on evaluation of implementing documents, activities, and items to be audited, the results of previous audits, and the impact of significant changes in personnel, organization, or the QA program.

3.5 Audit Team Independence

3.5.1 Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

3.5.2 Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

3.6 Selection of the Audit Team

3.6.1 An audit team shall be identified prior to the beginning of each audit, and shall not be selected by personnel having direct responsibility for the work to be audited, or include personnel responsible for the work being audited.

3.6.2 The audit team shall include representatives from the QA organization, and when appropriate, applicable technical organizations.

3.6.3 The audit team shall contain one or more auditors, one being designated the lead auditor who supervises the team, organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses.

3.6.4 Lead auditors and auditors shall be qualified in accordance with the requirements of Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

3.6.5 Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes.

3.6.6 Technical specialists, when used, shall be indoctrinated, trained and qualified in accordance with the requirements of Policy Q-02.2 - *Personnel Training and Qualification*, and Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

3.6.7 The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.

3.7 Performing Audits

3.7.1 The audit team leader shall ensure that the audit team is prepared before starting the audit.

3.7.2 Audits shall be performed in accordance with written procedures or checklists.

3.7.3 Elements selected for audit shall be evaluated against specified requirements.

3.7.4 Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.

3.7.5 Audit results shall be documented and reported to and reviewed by responsible managers.

3.7.6 Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

3.7.7 Identified conditions adverse to quality shall be documented and corrected in accordance with Policy Q-16.1 - *Corrective Action*.

3.7.8 Nonconforming items identified during an audit shall be controlled by the audited organization in accordance with Policy Q-15.1 - *Control of Nonconforming Items*.

3.8 Reporting

3.8.1 The lead auditor is responsible for preparing and signing the audit report and issuing the report to the audited organization and impacted organizations.

3.8.2 The audit report shall:

A Describe the audit scope.

B Identify auditors and persons contacted.

C Summarize audit results, documents reviewed, persons interviewed, (and the specific results of the reviews and interviews, that is, a summary of the checklist contents) issuing a statement on the effectiveness of the elements audited.

D Describe each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization in accordance with Policy 16.1 - *Corrective Action*.

3.9 Response

3.9.1 Management of the audited organization or activity shall investigate adverse audit findings, determine and schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of the actions taken or planned.

3.9.2 The adequacy of corrective actions for conditions adverse to quality shall be evaluated by the auditing organization in accordance with the requirements of Policy Q-16.1 - *Corrective Action*.

3.10 Follow-Up Action

Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished as scheduled in accordance with the requirements of Policy Q-16.1 - *Corrective Action*.

4 Specific Requirements for DOE/RW-0333P QARD Application

4.1 Internal audits of work to verify QA program compliance shall be performed annually or at least once during the life of the work, whichever is shorter.

4.2 External audits for compliance shall be performed triennially, as a minimum, with the initial audit to occur as early in the life of the activity as practical.

4.3 The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs.

4.4 Pre-award surveys, if applicable, may serve as the first triennial audit, provided**:**

A The supplier is implementing the same QA program for other contracts that is proposed for the purchasers contract,

B The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.

4.5 External audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.

4.6 Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits. The evaluation shall be documented and based on:

A Review of documentation furnished by the supplier (such as certificates of conformance, nonconformance notices, and corrective actions).

B Results of previous source verification audits, management assessments and receiving inspections, including audits from other sources.

C Operating experience of identical or similar work furnished by the same supplier.

D A review of procurement documents to determine what additional work the supplier has received since the initial contract.

5 Records

5.1 All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records.*

5.2 Audit records shall include audit plans, audit reports, written responses, and the record of completion of corrective action.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for:

A Conducting audits using personnel qualified/certified per Policy Q-02.3 - *Auditor/Lead Auditor Qualification and Certification*.

B Implementing an effective audit program.

C Developing and distributing audit schedules.

D Ensuring implementation of corrective actions are verified in a timely manner.

E Establishing and maintaining a site wide schedule for all required external supplier audits.

F Performing external supplier audits to evaluate supplier conformance with approved contractual requirements.

G Establishing and implementing a supplier qualification and/or requalification process.

H Ensuring that the auditors are independent of the work being audited.

6.2 Audited Organizations

Audited organizations are responsible for:

A Providing audit personnel with reasonable and timely access to the facilities, documents, and personnel needed for planning and performing audits.

B Providing responses to findings that describe the actions taken (or planned) in order to correct the problem and prevent recurrence.

C Providing for access by auditor(s)/lead auditor to appropriate levels of management to ensure resolution of audit findings.

D Implementing corrective actions within specified time frames identified in responses to findings.

E Demonstrating support for the audit process through management involvement in audits.

Policy Q-18.2 Quality Assurance Surveillance

1 Purpose and Applicability

This policy identifies requirements and responsibilities for performing quality assurance surveillances, both internal and external. Surveillances are used to evaluate the adequacy, effectiveness, and compliance to specified requirements, quality assurance (QA) program implementation and maintenance, and to identify continuous improvement opportunities.

This policy applies to those organizations involved in or subject to the performance of QA surveillances.

2 Implementation Strategy

Surveillance activities can be planned and/or conducted at any time on any activity to measure item and service quality; to measure the adequacy of work performance; and to promote improvement. Surveillances are an important element of the feedback and improvement function of the Integrated Safety Management System (ISMS). Surveillances are to be performed by the QA organization. Surveillance activities are separate from, and in addition to, the independent and management assessments. These documented surveillances are to be routinely conducted to verify conformance of items, services, and processes to established requirements. Flexibility in conducting surveillances will allow performance of additional surveillances in questionable areas. The surveillance process will include follow-up by project management to assure corrective action is implemented when deficiencies are identified in accordance with either Policy Q-15.1 - *Control of Nonconforming Items* or Policy Q-16.1 - *Corrective Action*, as appropriate.

Surveillance results are to be tracked and individuals in management responsible for their resolution clearly assigned. The need for follow-up review of areas found deficient during a surveillance will be determined by the QA organization. Conditions adverse to quality identified during the surveillance process will be dispositioned by the responsible organization in accordance with either Policy Q-15.1- *Control of Nonconforming Items* or Policy Q-16.1 - *Corrective Action*, as appropriate.

Opportunities for improvement can be identified by the surveillance process. Surveillance results are to be documented and provided to a level of management having the authority to implement necessary corrective actions and verify that identified problems have been satisfactorily resolved.

Procedure(s) for conducting surveillances are to be developed by the QA organization utilizing the requirements of this policy.

3 Policy

3.1 Surveillances

3.1.1 Surveillances shall be conducted to:

A Verify the quality of work in progress and compliance with applicable governing documents.

B Identify conditions adverse to quality.

C Ensure that prompt corrective action is taken by management responsible for performing the work.

D Verify the timely implementation, adequacy, and effectiveness of corrective action.

3.1.2 Surveillances shall be performed by personnel who are technically knowledgeable about, and not directly responsible for, the work under surveillance. Such personnel shall have sufficient authority and independence from the work activity to carry out their responsibilities.

3.1.3 Surveillances shall be documented in a report to appropriate management.

3.1.4 Surveillances shall be conducted to evaluate the quality of selected work subject to this policy.

4 Specific Requirements for DOE/RW-0333P QARD Applications

4.1 All applicable DOE/RW-0333P QARD requirements are included in subsection 3 - *Policy***.**

5 Records

5.1 All records designated in implementing documents, as QA records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

5.2 Surveillance records shall include assessment reports, written responses, and the record of completion of corrective action.

6 Responsibilities

6.1 Quality Assurance Manager

The QA Manager is responsible for:

A Planning, scheduling, and performing surveillances.

B Trending the results of surveillances.

C Assigning technically qualified personnel to perform surveillances.

D Providing the flexibility to conduct spontaneous, unscheduled surveillances to respond to immediate needs.

6.2 Organizations

Organizations are responsible for:

A Providing reasonable and timely access for surveillance personnel to review work activities and areas.

B Implementing corrective actions within the specified time.

C Providing responses to surveillance reports describing actions to be taken to correct discrepant conditions, which could not be corrected during the surveillance (on the spot), and the scheduled completion date for any corrective actions required.

Policy Q-18.3 Management Assessment

1 Purpose and Applicability

This policy identifies requirements and responsibilities for establishing and performing periodic management assessments of the adequacy of implementation of management process within their respective organizations.

This policy applies to all levels of project management and provides for their direct involvement in planning and conducting assessments to determine how well their organizations are performing in achieving strategic goals and performance objectives aligned with meeting customer requirements and expectations.

2 Implementation Strategy

Management Assessment implements, in part, the Integrated Safety Management System (ISMS) core function of feedback and improvement and demonstrates ISMS guiding principles of management responsibility, continuous improvement, and senior management involvement. Project management will use management assessment processes to evaluate the adequacy and effectiveness of its management control systems for improving processes and eliminating barriers to achieving project goals and objectives. Management participation in these assessment efforts is mandated by the Project Manager. While retaining overall responsibility for the assessment process, senior management requires managers at all levels to foster the continuous improvement process by assessing the performance of the activities assigned to their organization.

Such assessments are to be planned and performed as an on-going activity to verify conformance to applicable requirements and identify opportunities to improve performance and cost-effectiveness. Results and conclusions from these assessments will be documented and evaluated at the organizational level to assess the effectiveness of the entire integrated management system on achieving established goals and objectives, and fostering the continuous improvement process. Conditions adverse to quality identified in management assessments are to be promptly and effectively resolved as required by Policy Q-16.1 - *Corrective Action*. Provisions are to include tracking and follow-up on completed and planned corrective actions from the assessments.

Annually, project management with the support of the Quality Assurance (QA) organization will review and evaluate data from various internal and external sources, including their own personal knowledge, to identify problems that hinder the organization's ability to achieve its mission, performance objectives and encourage the continuous improvement process.

Management assessments will utilize an evaluation process to examine project performance, with particular emphasis on areas or activities that could have an adverse impact on worker and public safety or on the environment. The process should include activities for evaluating conditions as, for example, employee knowledge and morale, communications, material resources, and project documentation. Management from each organization will have the prime responsibility for planning and conducting such assessments. Significant issues and deficiencies as well as opportunities for improvement are to be identified and action plans developed and implemented.

Management assessments are part of the feedback and improvement function of the Project ISMS. Management assessments are implemented utilizing approved procedures based on the requirements of this policy.

3 Policy

3.1 Management Assessments

3.1.1 Management shall regularly assess the adequacy and effective implementation of their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

3.1.2 Procedures shall be in place and followed for the conduct of management assessments.

3.1.3 Management assessments are to be conducted at reasonable intervals not to exceed 12 months.

3.1.4 Management assessment shall:

A Be planned and documented and performed annually.

B Evaluate the following:

1 Adequacy of resources and personnel provided to achieve and assure quality.

2 Adequacy of procedure content and coverage.

3 Effectiveness of procedure implementation.

3.1.5 Management assessments shall be documented and results distributed to the appropriate management.

3.1.6 Conditions adverse to quality identified during the assessment process must be dispositioned in accordance with either Policy 15.1 - *Nonconforming Items* or Policy Q-16.1 - *Corrective Action* as appropriate.

3.2 Records

All records designated in implementing documents as quality assurance records shall be controlled in accordance with Policy Q-17.1 - *Quality Assurance Records*.

4 Responsibilities

4.1 Project Management

Project Management is responsible for:

A Implementing the management assessment program.

B Periodically reviewing and evaluating data from various internal and external sources (including their own personal knowledge) to identify problems that hinder the organization's ability to achieve its mission and performance objectives.

4.2 Managers

All levels of management are responsible for participating in management assessments.

Appendix A Quality Assurance Manual Acronyms

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASL	Approved Suppliers List
ASTM	American Society of Testing and Materials
CFR	Code of Federal Regulations
CI	counterfeit items
DOE	Department of Energy
DQO	data quality objective
EPA	Environmental Protection Agency
ES&H	Environmental, Safety, and Health
ET	electromagnetic testing
FSP	field sampling plan
GED	general equivalency diploma
IHLW	Immobilized High-Level Waste
ILAW	Immobilized Low-Activity Waste
IPI	Installed Process Instrumentation
ISI	in-service inspection
ISMS	Integrated Safety Management System
ISO	International Standards Organization
LT	leak testing
M&TE	measuring and test equipment
MT	magnetic particle testing
NCR	nonconformance report
NDE	nondestructive examination
OCRWM	Office of Civilian Radioactive Waste Management
ORR	Operational Readiness Reviews
PAAA	Price Anderson Amendment Act of 1988
PM	project manager
PSC	Project Safety Committee
PT	liquid penetrant testing

Appendix A Quality Assurance Manual Acronyms

QA	quality assurance
QAM	Quality Assurance Manual
QAP	quality assurance program
QAPjP	Quality Assurance Project Plans
QARD	Quality Assurance Requirement Document
RCRA	Resource Conservation and Recovery Act of 1988
RT	radiographic testing
RW	radioactive waste
S/CI	suspect/counterfeit item
SAP	sampling and analysis plan
SME	subject matter expert
SNT	Society for Nondestructive Testing
SOW	statement of work
SSC	systems, structures, components
STD	standard
UL	Underwriters Laboratory
UOR	Unusual Occurrence Report
UT	ultrasonic testing
VT	visual testing
WAC	Washington Administrative Code
WAP	waste analysis plan
WGI	Washington Group International
WTP	Waste Treatment and Immobilization Plant

Supplement I Control of the Electronic Management of Data

1 Purpose

This supplement applies to the processes and controls for the management of data that either exist or are used in an electronic format. This includes electronic formatted data used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling and analysis.

Development of software including database applications or software that performs functions of analysis or calculation shall be controlled in accordance with Policy Q-03.2 - *Software Quality*. The acquisition, development, and use of data are controlled by the requirements of Policy Q-03.1 - *Design Control.*

2 Applicability

This policy applies to organizations involved in the control of the electronic management for elements that affect the Immobilized High-Level Waste (IHLW) product quality, including but not limited to, waste form development, qualification, characterization, production process control, certification, and storage of the IHLW. All IHLW research and technology activities shall be conducted in accordance with the Quality Assurance (QA) Manual and this supplement.

3 Policy

3.1 Control of the Electronic Management of Data

Procedures will be established for process controls to ensure:

A Data are suitably protected from damage and destruction during their prescribed lifetime and are readily retrievable.

B A description is prepared of how data will be stored with respect to media, conditions, location, retention time, security, and access.

C Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).

D The completeness and accuracy of the data input and any subsequent changes to the data are maintained.

E The security and integrity of the data are maintained.

F Data transfers are error free, or within a defined permissible error rate, to ensure no information is lost in transfer and that the input is recoverable from the output. Examples of data transfer include copying raw data from a notebook to a computerized data form, copying from computer tape to disk, etc.

4 Records

4.1 Records requirements of this supplement are contained in Policy Q-03.1 – *Design Control*, Policy Q-03.2 – *Software Quality*, and Policy Q-17.1 – *Quality Assurance Records*.

5 Responsibilities

5.1 Engineering Manager

The Engineering Manager is responsible for incorporating the requirements of this supplement into applicable design control and software quality procedures.

5.2 Operations Manager

The Operations Manager is responsible for incorporating the requirements of this supplement into applicable research and technology procedures.

5.3 Quality Assurance Manager

The QA Manager is responsible for reviewing and concurring with the procedures developed for implementing the requirements of this supplement.

Supplement II Sample Control

1 Purpose

This supplement establishes requirements for the control of physical samples.

2 Applicability

This policy applies to organizations involved in sampling for elements that affect the Immobilized High-Level Waste (IHLW) product quality, including but not limited to, waste form development, qualification, characterization, production process control, and certification of the IHLW. All IHLW research and technology activities shall be conducted in accordance with the Quality Assurance (QA) Manual and this supplement.

3 Policy

3.1 General

A Samples shall be controlled and identified in a manner consistent with their intended use.

B These controls shall identify responsibilities including interfaces between organizations for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use.

C Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.

3.2 Traceability

A Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.

B Sample traceability shall ensure that the sample can be traced at all times from its collection through final use.

3.3 Identification

A Identification shall be maintained on the samples or in a manner which ensures that identification is established and maintained.

B Samples shall be identified from their initial collection through final use.

C Sample identification is documented and checked before released for use.

D Sample identification methods shall include use of physical markings.

E If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control).

F Physical markings, when used, shall:

1 Be applied using materials and methods that provide a clear and legible identification.

2 Not detrimentally affect the sample content or form.

3 Be transferred to each identified sample part when the sample is subdivided.

4 Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.

3.4 Conditional Requirements

The controls for samples shall address the following requirements, as applicable:

A If documents (such as the Site Characterization Plan, test plans, study plans, or job packages) contain specific identification or traceability requirements (such as identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented.

B If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life.

C If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

1 Maintenance or replacement of markings and identification tags damaged during handling or aging.

2 Protection of identification markings subject to excessive deterioration resulting from environmental exposure.

3 Updating related documentation.

3.5 Archiving Samples

Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified.

3.6 Handling, Storage, and Shipping

A Handling, storage, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents.

B If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used.

C Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples as necessary to adequately identify, maintain, and preserve the sample.

D Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

E If required for particular samples, special equipment (such as containers) and special protective environments (such as inert gas, and moisture and temperature limits) shall be specified and provided.

F Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.

1 Special handling tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained.

2 Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

3.7 Disposition of Nonconforming Samples

A Samples that do not meet requirements specified in work controlling documents (such as Job Packages, Travelers, or Work Requests) shall be documented, evaluated, identified, and segregated in accordance with Policy Q-15.1 - C*ontrol Of Nonconforming Items*.

B The disposition for nonconforming samples shall be identified and documented and shall be limited to “use-as-is”, “limited use”, or “discard”.

4 Records

4.1 Records of samples for IHLW product quality, including, but not limited to, waste form development, qualification, characterization, production process control, and certification of IHLW shall be maintained in accordance with this policy and Policy Q-17.1 – *Quality Assurance Records*.

5 Responsibilities

5.1 Operations Manager

The Operations Manager is responsible for developing the necessary procedure(s) that implement the requirements of this supplement.

5.2 Quality Assurance Manager

The QA Manager is responsible for reviewing and concurring with the procedures developed for implementing the requirements of this supplement.

Supplement III Scientific Investigation

1 Purpose

This policy establishes requirements for scientific investigations, including data identification, data reduction, and model development and use.

2 Applicability

This policy applies to organizations involved in scientific investigation for elements that affect the Immobilized High-Level Waste (IHLW) product quality, including but not limited to, waste form development, qualification, characterization, production process control, and certification of the IHLW. All IHLW research and technology activities shall be conducted in accordance with the Quality Assurance (QA) Manual and this supplement.

3 Policy

3.1 Planning Scientific Investigations

A Scientific investigations shall be planned in accordance with Policy Q-02.1 – subsection 1.4 – *Work Planning.*

B Planning shall be coordinated with organizations providing input to or using the results of the investigation.

C Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

3.2 Performing Scientific Investigations

A Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.

B Scientific notebooks shall contain the following:

1 Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics.

2 Identification of method(s) and computer programs to be used.

3 Identification of any samples or measuring and test equipment used.

4 Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries.

5 Description of changes made to methods used, as appropriate.

C Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to:

1 Retrace the investigations and confirm the results, or

2 Repeat the investigation and achieve comparable results, without recourse to the original investigator.

3.3 Data Identification

A Data shall be identified in a manner that facilitates traceability to associated documentation.

B Data shall be identified in a manner that facilitates traceability to its qualification status.

C Identification and traceability shall be maintained throughout the lifetime of the data.

3.4 Data Review, Adequacy, and Usage

A Data reduction shall be described to permit independent reproducibility by another qualified individual.

B Data that are directly relied upon to address safety and waste isolation issues shall be qualified from origin, accepted, or undergo a qualification process.

1 Data qualified from origin shall be reviewed by individuals other than those who acquired or developed the data in accordance with established review criteria to ensure technical correctness.

2 Accepted data need not undergo the qualification process. The rationale for considering data to be accepted shall be documented.

3 Unqualified data may be used in scientific investigation and design activities, provided traceability to its status as unqualified data is maintained. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with 3.4.C below at appropriate times during scientific investigation and design process and before

a) Office of Civilian Radioactive Waste Management (OCRWM) acceptance of DOE-owned high level waste;

b) Submittal of the license application;

c) Relying on the item for which the data were used as design input, to perform its function; or

d) Data are relied upon to resolve safety or waste isolation issues.

C Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified by one or a combination of the methods that follow:

1 Determination that the controls under which the data were generated are similar in scope, requirements, and implementation to the QA Manual.

2 Evaluation of corroborating data - Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.

3 Confirmatory testing.

4 Peer review in accordance with Policy Q-02.4 – *Special Reviews.*

5 Technical Assessment to independently evaluate data which includes one or a combination of the following:

a) Determination that the employed methodology is acceptable;

b) Determination that confidence in the data acquisition or developmental results is warranted; or

c) Confirmation that the data have been used in similar applications.

Methods 1, 2, and 3 above shall include a review to determine the technical correctness of the data in accordance with established review criteria. The qualification process shall be planned and documented. Documentation shall include the acceptance criteria used to determine if the data are qualified, and rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process.

3.5 Technical Report Review

Technical reports shall be reviewed in accordance with the requirements of Policy Q-05.1 – *Instructions, Procedures and Drawings.*

3.6 Model Development and Use

A Model development and approaches to validation shall be planned, controlled, and documented.

B Documentation shall be transparent and identify principal lines of investigation considered.

C Documentation shall be legible and in a form suitable for reproduction, filing, and retrieval.

D Documentation of models shall include:

1 Description of conceptual model(s).

2 Definition of the objective of the model.

3 Definition of inputs and their sources.

4 Results of literature searches or other applicable background data.

5 Identification and rationale for assumptions.

6 Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.

7 Identification of the originator, reviewer, and approver.

E Computer software used to develop or execute the model shall be qualified in accordance with the requirements of Policy Q-03.2 - *Software Quality.*

F The appropriate level of confidence for a model shall be determined by the intended use of the model and the importance of the model for assessing system performance.

G Model validation (i.e., development of confidence in a model) is a process to document the adequacy of the scientific basis for the model and to demonstrate the

model is appropriate and adequate for its intended use, and shall include one or more of the following activities:

1 Comparing analysis results against data acquired from laboratory, field experiments, natural analogue studies, or subsequent relevant observations.
2 Peer review or review by international collaborations.
3 Technical review through publications in the open literature.
4 Review of model calibration parameters for reasonableness and consistency in explanation of all relevant data.
5 Performance confirmation studies.
6 Comparison of analysis results with the results from alternative conceptual models.
7 Calibration and corroboration with experimental data sets.
8 For existing industry standard models and related software, use traditional validation approaches.

3.7 **Implementing Documen**ts

Implementing documents shall contain requirements for evaluating development and qualification results including final results within Waste Form Qualification Reports.

4 Records

4.1 Records requirements of this supplement are contained in Policy Q-03.1 – *Design Control,* Policy Q-03.2 – *Software Quality*, and Policy Q-17.1 – *Quality Assurance Records.*

5 Responsibilities

5.1 Engineering Manager

The Engineering Manager is responsible for incorporating the requirements of this supplement into applicable design control and software quality procedures.

5.2 Operations Manager

The Operations Manager is responsible for incorporating the requirements of this supplement into applicable research and technology procedures.

5.3 Quality Assurance Manager

The QA Manager is responsible for reviewing and concurring with the procedures developed for implementing the requirements of this supplement.

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Acronyms

AB	Authorization Basis
AIChE	American Institute of Chemical Engineers
AIHA	American Industrial Hygiene Association
ALARA	As Low As Reasonably Achievable
BNI	Bechtel National, Inc.
CAMS	Corrective Action Management System
CAR	Construction Authorization Request
CFR	Code of Federal Regulations
Ci	Curie
CM	Configuration management
CM Plan	RPP-WTP Configuration Management Plan
DAR	Deactivation Authorization Request
DBE	Design Basis Earthquake OR Design Basis Event
DC&C	Design, Construction, and Commissioning
DCD	Design Criteria Database
DOE	U.S. Department of Energy
DOELAP	DOE Laboratory Accreditation Program
DOE-RL	U.S. Department of Energy Richland Operations Office
DOH	Washington State Department of Health
DWPF	Defense Waste Processing Facility
EAL	Emergency Action Level
Ecology	Washington State Department of Ecology
ECP	Employee Concerns Program
EDSP	Engineering Design Safety Principle
EIS	Environmental Impact Statement
EMP	Emergency Management Program
EMS	Emergency Management System
EP	Emergency Plan
EPA	U.S. Environmental Protection Agency
EPIP	Emergency Plan Implementing Procedure
ER	Environmental Report
ERPG	Emergency Response Planning Guide
ERPP	Environmental Radiation Protection Program
ES&H	Environment, Safety, and Health
FHA	Fire Hazard Analysis
FR	Federal Register
FSAR	Final Safety Analysis Report
HAL	Highly Active Liquids
HAR	Hazard Analysis Report
HAZOP	Hazard and Operability (analysis)
HEPA	High-Efficiency Particulate Air (filter)
HLW	High-Level Waste
HRC	Hazards Research Corporation
Hwy	Highway
ICBO	International Conference of Building Officials
IPT	Integrated Product/Process Team

IRT	Independent Review Team
ISA	Integrated Safety Analysis
ISAR	Initial Safety Analysis Report
ISMP	Integrated Safety Management Plan
ISO	International Organization of Standards
ITS	Important to Safety
LAW	Low-Activity Waste
LWA	Limited Work Authorizations
MSDS	Material Safety Data Sheets
NAICS	North American Industry Classification System
NCRP	National Council on Radiation Protection and Measurements
NPH	Natural Phenomenon Hazard
NRC	U.S. Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OAR	Operating Authorization Request
OPM	Operational Preventive Measures
OSHA	Occupational Safety and Health Administration
PFD	Process Flow Diagram
PHA	Process Hazards Analysis
PHMC	Project Hanford Management Contractor
PSAR	Preliminary Safety Analysis Report
PSC	Project Safety Committee
PSM	Process Safety Management
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
QAPIP	Quality Assurance Program and Implementation Plan
QARD	Quality Assurance Requirements and Description
QL	Quality Level
RAMI	Reliability, Availability, Maintainability, and Inspectability
RCRA	*Resource Conservation and Recovery Act of 1976*
rem	Roentgen-Equivalent Man
RG	Regulatory Guide
RL	Department of Energy Richland Operations Office
RMP	Risk Management Plan
RPP	Radiation Protection Program
RPP-WTP	River Protection Project – Waste Treatment Plant
SAR	Safety Analysis Report
SDC	Safety Design Class
SDS	Safety Design Significant
SER	Safety Evaluation Report
SIXEP	Site Ion Exchange Effluent Plant
SNM	Special Nuclear Material
SPD	System Performance Demonstrations
SRD	Safety Requirements Document
SSC	Structures, Systems, and Components
STD	Standard (also Std)

TSR	Technical Safety Requirement
TEDE	Total Effective Dose Equivalent
TWRS	Tank Waste Remediation System
TWRS-P	Tank Waste Remediation System-Privatization
UBC	Uniform Building Code
USC	United States Code
USQ	Unreviewed Safety Question
VPP	Voluntary Protection Program
VSL	Vitreous State Laboratory
WAC	*Washington Administrative Code*
WISHA	Washington Industrial Safety and Health Administration

1.0 Project Safety Approach

The RPP-WTP Contractor's safety approach is implemented with the recognition that the defined work for processing and immobilizing Hanford tank waste involves inherent radiological and chemical hazards from which hazardous situations may arise. The RPP-WTP Contractor is committed to integrating the development of safety criteria and design requirements, the hazard analysis and accident analysis process, and the facility design to minimize the risk associated with these hazards and hazardous situations. The RPP-WTP Contractor accepts responsibility for the safety of the RPP-WTP and for adequate protection of the health and safety of the public, worker safety, environmental protection, and compliance with applicable laws and regulations.

This chapter of the Integrated Safety Management Plan (ISMP) provides an overview of the RPP-WTP design, construction, and commissioning (DC&C) Contractor (i.e., Bechtel National, Inc. [BNI]) safety approach developed for the River Protection Project – Waste Treatment Plant (RPP-WTP). The elements of this approach, through their evolutionary implementation in Part A of the project, form the bases for this ISMP. The ISMP is followed and will be further developed during Part B of the Project for detailed design, construction, operation, and deactivation of the facility.

The Project safety approach is summarized in Section 1.1, "Introduction". The components of the safety approach are described in greater detail in Section 1.2, "Summary". The elements of the safety approach are described in Section 1.3, "Description of the Integrated Safety Management Plan".

1.1 Introduction

The safety management practices outlined in the ISMP have been developed specifically for the Project. The development of these management practices was based on the experience of the Project team at other nuclear facilities in the areas of design, construction, and operation. These practices ensure implementation of the corporate policy that no activities are more important than the health and safety of its workers, contractors, the public, or protection of the environment.

The ISMP documents the process by which laws, regulations, and standards applicable to the nuclear, radiological, and process safety aspects of the Project are incorporated into programs for facility design, construction, operation, and deactivation to ensure adequate safety of workers and the public and protection of the environment. A further role of the ISMP is to demonstrate how practices are in line with the RPP-WTP Contractor policies to ensure that the safety culture achieved at other nuclear chemical facilities can be successfully sustained through the different phases of the RPP-WTP. At this stage in the project, the ISMP is biased towards the design and construction phase, during which most of the processes described are developed. However, the principles of the ISMP for later stages of the facility life through operation and deactivation and how the design and construction phase will be integrated into these later stages is discussed. The ISMP also describes how the safety management practices will be followed and further developed during Part B of the Project.

Table 1-1 BNFL Team Experience Related to the TWRS-P Project (this table has been deleted)

To accomplish its roles, the ISMP describes the following:

1) The facility defined work to process and immobilize Hanford Tank waste in a safe manner (ISMP Section 1.3.1, "Project Initiation")
2) The selection of a safe and proven technology (ISMP Section 3.7, "Proven Engineering Practices")
3) The development and use of the SRD (ISMP Section 1.3.3, "Safety Requirements Document")
    a) To establish the Safety Criteria by which the process hazard analysis (PHA) and accident analysis identify features required for worker and public safety
    b) To identify the design requirements that, when implemented, ensure that prevention and mitigation controls will perform their specified safety functions
4) The use of PHA to identify the full range of potential radiological and chemical hazards and hazardous situations (ISMP Section 1.3.4, "Process Hazards Analysis")
5) The accident analyses performed to identify engineered and administrative controls required for worker and public safety (ISMP Section 1.3.6, "Accident Analysis")
6) The iteration of the PHA, accident analyses, and design to ensure an adequate level of safety for the workers and the public (ISMP Sections 1.3.7, "Acceptable Level of Public Safety" and 1.3.8, "Acceptable Level of Worker Safety")
7) The development of the technical safety requirements, if required, that are based on:
    a) A process variable, design feature, or operating restriction that is an initial condition (i.e., the assumed facility state) for an accident analysis
    b) Structures, systems, and components that must function to maintain compliance with public and worker radiological and chemical exposure standards
8) The development of procedures and training to achieve and maintain the required administrative controls (ISMP Sections 1.3.12, "Training" and 1.3.13, "Procedures")
9) The development of an emergency preparedness program and implementing procedures (ISMP, Section 1.3.18, "Emergency Planning")
10) The assignment of design, construction, and operational roles and responsibilities and the use of assessments to ensure the necessary attributes of the ISMP are effectively accomplished (ISMP, Chapters 10.0, "Assessments", and 11.0, "Organizational Roles, Responsibilities, and Authorities")

Chapter 1.0 of the ISMP presents the BNI safety approach. Chapters 2.0 through 11.0 are formatted to correspond to the attributes included in RL/REG-97-07, *Guidance for the Review of TWRS Privatization Contractor Integrated Safety Management Plan Submittal Package* (DOE-RL 1997).

Throughout the ISMP, lists of items are numbered for the convenience of the reviewers in referring to individual items. The numbering is not an indication of the importance or sequence of the items.

Chapter 12.0, "Definitions", contains the definitions of some of the terms, phrases, or documents that are found throughout the ISMP. When used unmodified in the ISMP, "worker" refers to the facility and collocated worker, both individually and collectively.

Within this document, the *Safety Requirements Document* (SRD) (BNI 2001b and BNI 2001c), *Hazard Analysis Report* (HAR) (BNFL 1997b), *Quality Assurance Program* (QAP) (BNFL 1997a, BNFL 1998c), *Quality Assurance Manual* (QAM) (BNI 2001), and *Initial Safety Analysis Report* (ISAR) (BNI 2001d and 2001e), are cited using acronyms. Full reference information for these documents appears in Chapter 13.0, "References".

1.2 Summary

The Project safety approach is implemented with the recognition that the defined work of processing and immobilizing Hanford tank waste involves inherent radiological and chemical hazards from which hazardous situations may arise. The Project is integrating the development of Safety Criteria, design requirements, the hazard analysis and accident analysis processes, and the facility design to minimize the risk associated with these hazards and hazardous situations. The elements of this approach, through their evolutionary implementation in Part A of the Project, form the bases for this ISMP.

The safety approach for the Project is based on applying best industry practices and cost-effective processes that come from successful and safe operation in the commercial nuclear environment and the chemical process industry. The purpose of the safety approach is to achieve the following objectives.

1) Ensure an adequate level of safety at the facility for the workers and the public.
2) Comply with applicable laws and regulations.
3) Conform to top-level safety standards and principles stipulated by the U.S. Department of Energy (DOE-RL 1996b).

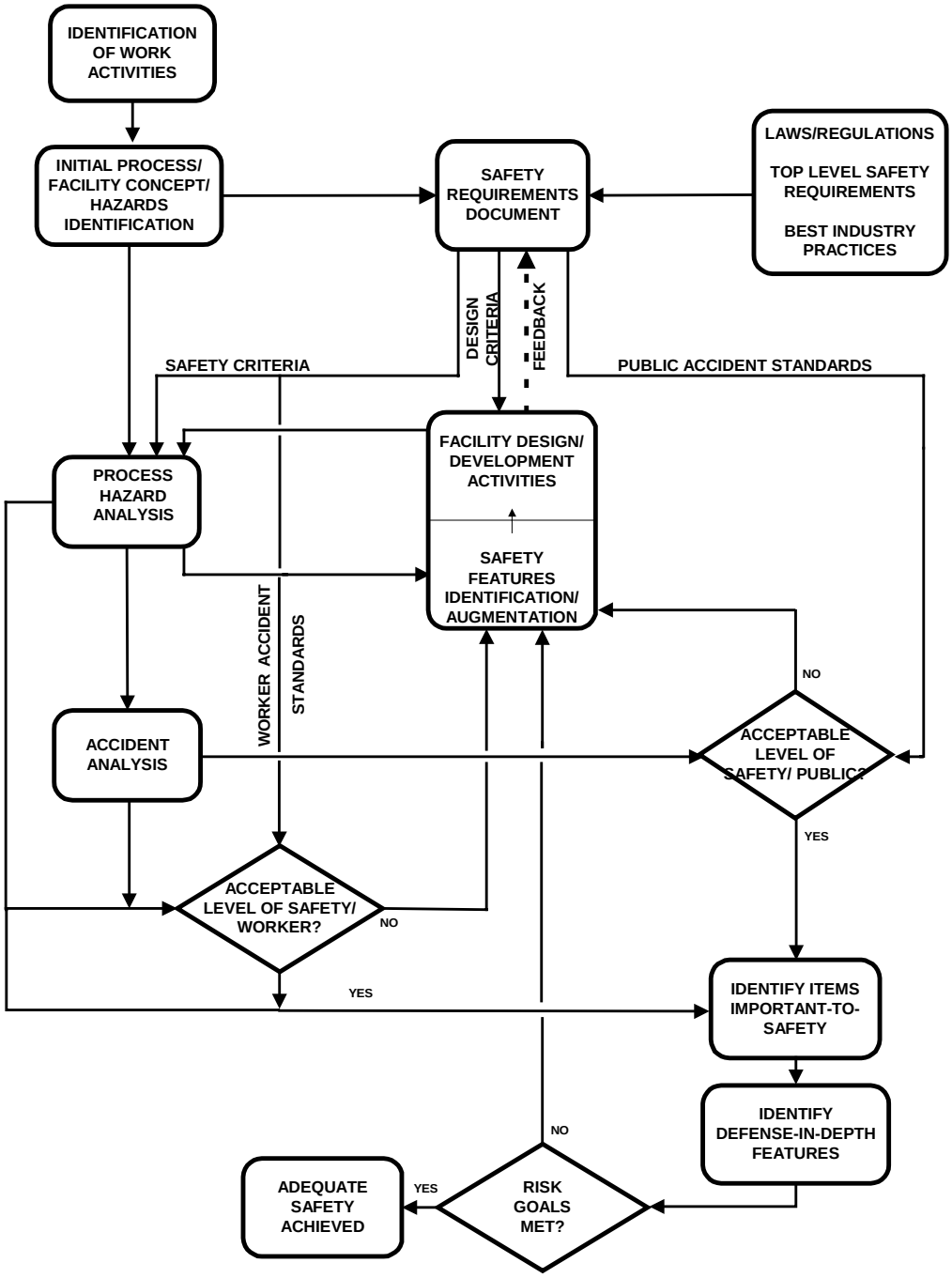
A diagram of the Project safety approach is presented in Figure 1-1. The safety approach begins with the definition of the work to be performed and continues with the development of the conceptual process flow diagrams (PFD) and other facility design information required to accomplish the defined work. The PFDs and design development give consideration to the types of work to be accomplished, the hazards identified for similar facilities, and the methods by which these hazards were previously eliminated or controlled for similar facilities. This conceptual information is used to identify appropriate hazards-based standards and initiate the development of the SRD.

The identification of hazards and hazardous situations helps to characterize the hazardous situations as those that may require prevention or mitigation. The identification and characterization of the hazards and hazardous situations establish a basis for describing approaches and measures to control the hazards. Safety Criteria are then developed that document the set of standards and requirements necessary to ensure implementation of the necessary hazard control strategies. These Safety Criteria are documented in the SRD and are based on applicable laws and regulations, the U.S. Department of Energy's (DOE) top-level safety requirements, and best industry practices. The SRD provides Safety Criteria to the PHA by which an initial assessment of the adequacy of the design is made.

As accident prevention and mitigation safety features are identified in the PHA, the resulting facility design impacts are fed back to the SRD process, as required, for further development of more detailed Safety Criteria and design requirements to ensure all safety features provide their specified safety functions.

As the PHA, PFDs, and facility design mature, accident analyses are performed to confirm judgements made during the PHA and to further characterize the accident scenarios to demonstrate compliance with radiological and chemical exposure standards for accidents. Additional protection for workers is identified by the PHA, the accident analyses, and the application, as appropriate, of Process Safety Management (PSM) required by 29 CFR 1910.110.

Figure 1-1 Project Safety Approach



Significant features of the Project safety approach are described as follows.

1) The approach continually integrates hazard identification, SRD development, design development, and accident analysis throughout the facility design, construction, operation, and deactivation phases.
2) The approach uses the best industry practices that include PHA, a rigorous design process based on a set of credible accidents and a defense-in-depth philosophy, and verification of the level of facility safety through accident analysis and validation of requirements implementation.
3) The PHA identifies and evaluates the significance of potentially hazardous situations. For each identified event, a defense-in-depth approach applies a level of protection in terms of engineered features and administrative controls that is commensurate with the severity of the unmitigated event. The hazards evaluation techniques satisfy the requirements of a hazards analysis process established by the American Institute of Chemical Engineers (AIChE 1992).
4) A conservative approach to accident consequence analysis is used in terms of input assumptions, boundary conditions, and modeling techniques. As the process and facility design mature, the modeling is refined to eliminate unnecessary conservatism. This strategy is consistent with risk-based approaches that allow the use of uncertainty analysis to better identify the impact of assumptions and state of knowledge on results from the safety analyses.
5) The safety approach documents how the identification of the engineered and administrative controls credited for public and worker safety and facility Safety Criteria is accomplished.

This approach to safety analysis is similar to that described in draft NUREG 1513, *Integrated Safety Analysis Guidance Document,* (NRC 1994) published by the U.S. Nuclear Regulatory Commission (NRC).

1.3 Description of the Integrated Safety Management Plan

Each of the elements of the safety approach are described in detail in the following sections.

1.3.1 Project Initiation

The Project safety approach began with a discussion to aid in understanding of the work to be accomplished and the development of the conceptual design of the processes and facility to accomplish this work. The development of the conceptual design considered the work to be performed, hazards and hazardous situations identified for similar facilities, and the methods to eliminate or control these hazards and hazardous situations. Early in the development of the conceptual design, hazards identification and evaluation techniques appropriate for the preliminary nature of the process and facility design were selected and applied.

1.3.2 Laws/Regulations/Top-Level Safety Requirements/Best Industry Practices

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006 (DOE-RL 1996b) provides a set of top-level radiological, nuclear, and process safety standards and principles prescribed by DOE for accomplishing the required level of safety for the RPP-WTP. This document is used as one resource for the development of the SRD. Included in DOE/RL-96-0006 are radiological exposure and risk standards for evaluation of normal and offnormal events. Additional resources for the identification of standards were derived from the U.S. and United Kingdom (UK) commercial nuclear and chemical industries. The identification of the remaining requirements is described in the following section.

1.3.3 Safety Requirements

The SRD defines the Safety Criteria and the design requirements (implementing codes and standards) necessary to protect the public and workers from radiological, nuclear, and process hazards and hazardous situations. The Safety Criteria and codes and standards of the SRD are applied to the RPP-WTP. The SRD, as well as the ISMP, applies to Project contractors. By application of the SRD and ISMP to all Project activities, a consistent project-wide approach is applied to Environmental, Safety, and Health (ES&H) matters. The hazards and hazardous situations at the facility will change significantly throughout the construction, operation, and deactivation phases of the Project. The SRD was developed by an iterative process that will continue as the design matures through the construction, commissioning, operation, and deactivation of the facility. The development involved identifying the work to be performed, identifying hazards and hazardous situations of the facility operation by the PHA and accident analyses, reviewing of pertinent regulations and industry practices, and identifying engineered and administrative controls.

Once the work activity was identified for the Project and the hazards associated with this work determined, the Safety Criteria were defined by the requirements necessary to ensure protection of the public and workers from radiological, nuclear, and process hazards. The Safety Criteria are based on the following:

1) Mandated regulatory requirements (statutory and contractual; including those identified as top-level safety requirements [standards and principles]) and equivalent requirements
2) Requirements and guidance documents deemed relevant to waste management facilities such as this Project
3) Best industry practices from the government, commercial nuclear, and chemical industries

The engineered and administrative controls necessary to eliminate and control hazards and hazardous situations are established via the PHA, the accident analysis, and the necessary level of protection required to satisfy the SRD Safety Criteria. Once the controls are selected, the SRD identifies the implementing codes and standards necessary to ensure that engineered and administrative controls are properly designed, implemented, and maintained. The requirements, guidance documents, and practices are incorporated into the SRD, tailored toward applicability to RPP-WTP operations, the control of hazards, and the adequacy to protect public and worker health and safety. These codes and standards are used by the appropriate organizations to ensure that the design, construction, testing, and maintenance of Important-to-Safety SSCs are such that they can perform their specified public and worker safety functions when required. Additional detail on the SRD and definition of Important-to-Safety is provided in ISMP Section 4.1, "Safety Management Processes" and Section 1.3.10, "Classification of Structures, Systems, and Components".

1.3.4 Process Hazards Analysis

The PHA process is a systematic team-based approach used to identify and analyze the significance of potentially hazardous situations associated with the operation and maintenance of the RPP-WTP. Other hazardous situations unique to the deactivation phase will be identified near the end of waste processing operations. The PHA process includes preliminary hazard analysis and Hazard and Operability (HAZOP) Analysis. The process is enhanced by the experience gained by the Project team from similar analyses performed at similar facilities. The PHA is performed to ensure the facility is designed to provide accident prevention and mitigation controls as required to meet safety criteria established for the protection of the public and workers. The PHA team includes members experienced in the engineering design and operation of the chemical process being evaluated and at least one member knowledgeable in the specific PHA methodology being used. The results of the PHA are also strengthened by the use of the operational and maintenance experience of the team members to compliment the design process. Specifically, the goals of PHA are to

1) Identify hazards and potential hazardous situations associated with a process or activity
2) Identify features in the design or operation of the facility that could lead to accidents
3) Assist designers in identifying the need for design features to eliminate or control hazards and hazardous situations
4) Identify principal operability concerns to assist designers in eliminating or minimizing the associated risk

The focus of the analysis is on process safety issues, such as the acute effects of unplanned radiological and chemical releases on the public or workers. The PHA supplements the more traditional industrial health and safety activities that consider, for example, protection against slips or falls, use of personal protective equipment, and monitoring for employee exposures. Additional detail on the PHA is provided in ISMP Section 5.5, "Process Hazards Analysis".

1.3.5 Facility Design/Development Activities and Safety Features Identification

The PHA and the accident analyses identify the need for accident prevention and mitigation controls to satisfy the SRD Safety Criteria. There will be differences between the prevention and mitigation techniques needed during facility operation and those needed during the deactivation process. Both sets of needs are communicated to the design groups for the selection of the most effective and efficient means of achieving the required controls. In the selection of required controls, preference is given to accident prevention over mitigation and engineered features over administrative controls. Preference is also given to passive engineered features over active engineered features (ISMP Section 3.7, "Proven Engineering Practices"). Reliance on human intervention would be used only when reliance on other means of eliminating or mitigating the hazardous situation cannot be used. The features identified are maintained or changed, as needed, as the facility moves from operation to deactivation. Control of the features is discussed in more detail in ISMP Section 3.5, "Quality Assurance Program (QAP)", Section 1.3.16, "Configuration Management", and Section 5.3, "Configuration Management".

1.3.6 Accident Analysis

During the design phase, the set of potential accidents identified by the PHA is carried forward to the accident analysis to identify the need for prevention and mitigation controls required during operation or for deactivation to satisfy the SRD Safety Criteria. The Project team experience with accident analyses for similar facilities is particularly valuable in developing the models for the accident scenarios to be analyzed. Well-established methods that include factors such as the material at risk and the rate and duration of the release of hazardous material are used in the determinations of the source terms (NRC 1988; DOE 1994).

Evaluating potential accidents involves the following tasks:

1) Separating the lower-risk accidents adequately addressed by the PHA from the higher-risk accidents that warrant quantitative analysis to confirm risk acceptance guidelines are satisfied
2) Grouping the accidents based on considerations such as the location of the accident, the phenomena involved, the accident type, and the nature of the hazardous material at risk
3) Calculating the radionuclide or chemical release from the facility and the impact of the release on the facility operators whose actions are credited to maintain the public and workers radiological and chemical exposures within defined standards

1.3.7 Acceptable Level of Public Safety

During the facility design evolution, a consequence analysis is performed for each accident involving a radionuclide or chemical release. For those accidents that involve a radionuclide release, the calculated exposures are compared to the radiological exposure standards of Table 1-2 to determine the need for accident prevention or mitigation features credited for public safety. For chemical release, the projected exposure is compared to the standards of SRD Safety Criterion 2.0-2. If the radiological or chemical release standards are not satisfied, the need for engineered or administrative controls to prevent or limit the release is addressed. These features are designed and maintained to the highest applicable standards to ensure their functional performance in the prevention or mitigation of accidents. Features credited for satisfying the public radiological exposure standards of Table 1-2 and chemical release exposure standards of SRD Safety Criterion 2.0-2 are classified as Safety Design Class (which is a subset of Important-to-Safety as discussed in Section 1.3.10, "Classification of Structures, Systems, and Components). The location of the public (i.e., offsite receptor) for the purpose of establishing compliance with Table 1-2 and the chemical release standard, is established at the most limiting exposure location along the near exposure bank of the Columbia River, Highway 240, and a southern boundary as shown in Figure 1-2. If credit is taken for operator action to satisfy the public radiological exposure standards of Table 1-2, adequate radiation protection is provided to permit access and occupancy of the control room or other control locations under accident conditions without personnel receiving radiation doses in excess of 5 rem TEDE whole body gamma and 30 rem beta skin for the duration of the accident. If credit is taken for operator action to satisfy public chemical exposure to the standards specified in SRD Safety Criterion 2.0-2, provisions are made so that the operator exposure does not exceed the standard specified in SRD Safety Criterion 4.3-7.

Table 1-2 Radiological Exposure Standards Above Normal Background (Sheet 1)

Description	Estimated Frequency of Occurrence f (yr^{-1})	General Guidelines	Worker	Collocated Worker	Public
Normal Events: Events that occur regularly in the course of facility operation (e.g., normal facility operations); including routine and preventative maintenance activities.	>0.1	Normal modes of operating facility systems should provide adequate protection of health and safety.	5 rem/yr 50 rem/yr any organ, skin, or extremity 15 rem/yr lens of eye 1.0 rem/yr ALARA design objective per 10 CFR 835.1002(b) (1)	5 rem/yr 1.0 rem/yr ALARA design objective per 10 CFR 835.1002(b) (1)	10 mrem/yr (airborne pathway) 100 mrem/yr (all sources) 100 mrem/yr (public in the controlled area) 25 mrem/yr (radioactive waste)
Anticipated Events: Events of moderate frequency that may occur once or more during the life of a facility (e.g., minor incidents and upsets).	10^{-2}<f10^{-1}	The facility should be capable of returning to operation without extensive corrective action or repair.	5 rem/event (2, 3) 1.0 rem/event design action threshold (4)	5 rem/event (2, 3) 1.0 rem/event design action threshold (4)	100 mrem/event (3)

Table 1-2 Radiological Exposure Standards Above Normal Background (Sheet 2)

Description	Estimated Frequency of Occurrence f (yr^{-1})	General Guidelines	Worker	Collocated Worker	Public
Unlikely Events: Events that are not expected, but may occur during the lifetime of a facility (e.g., more severe incidents).	10^{-4}<f10^{-2}	The facility should be capable of re-turning to operation following poten-tially extensive corrective action or repair, as necessary.	25 rem/event (2, 3)	25 rem/event (2, 3)	5 rem/event (3)
Extremely Unlikely Events: Events that are not expected to occur during the life of the facility but are postulated because their consequences would include the potential for the release of significant amounts of radioactive material.	10^{-6}<f10^{-4}	Facility damage may preclude returning to operation.	25 rem/event (2, 3)	25 rem/event (2, 3)	25 rem/event 5 rem/event target (3) 300 rem/event to thyroid
Location of Receptor			Within the Controlled Area Boundary	The most limiting location at or beyond the Controlled Area Boundary	The most limiting location along the near river bank/Hwy 240/ southern boundary

(1) In addition to meeting the listed design objective of 10 CFR 835.1002(b), the inhalation of radioactive material by workers and collocated workers under normal conditions is kept ALARA through the control of airborne radioactivity as described in 10 CFR 835.1002(c).

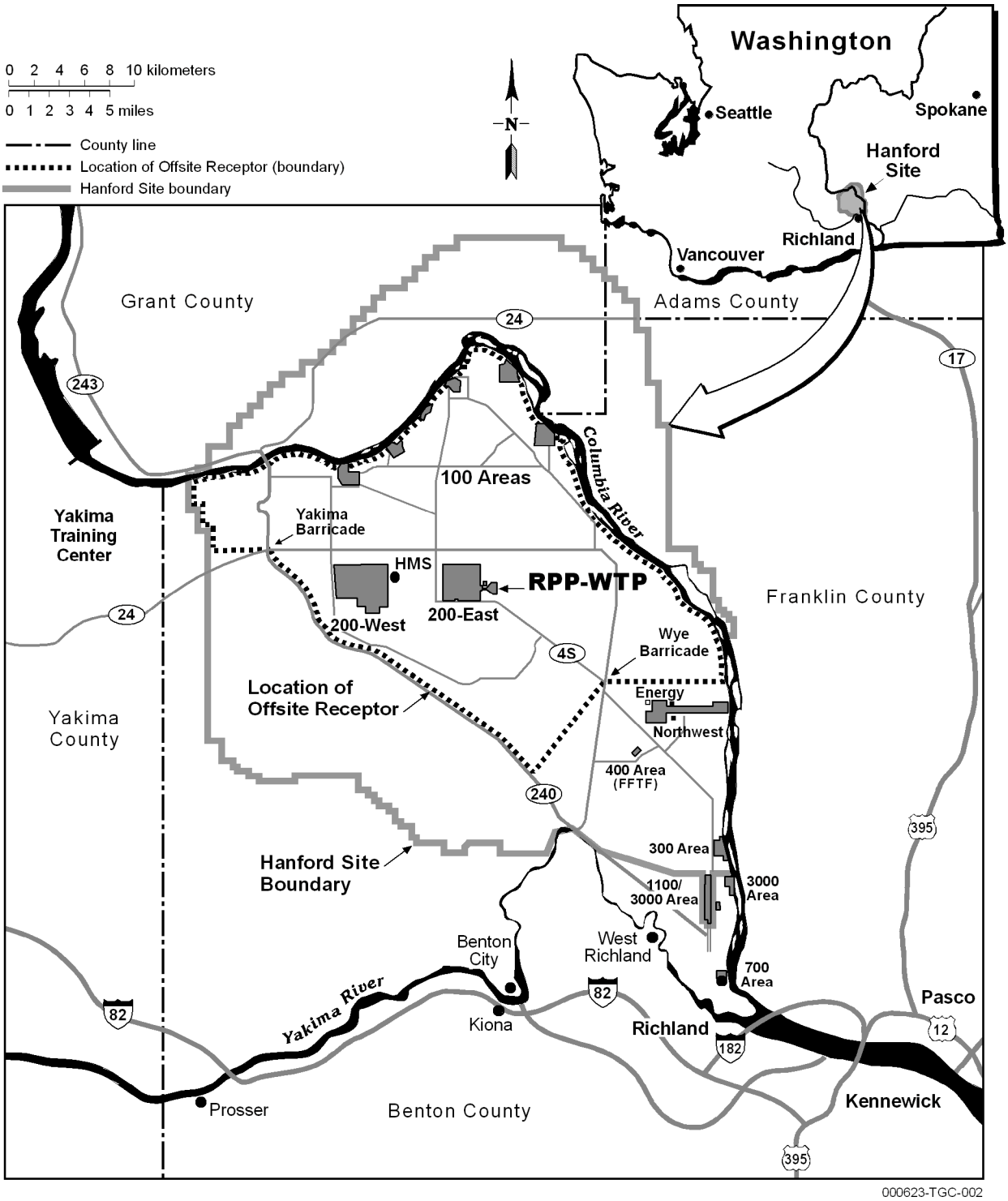
(2) In addition to meeting the listed worker and collocated worker exposure standards for accidents, the Worker Accident Risk Goal is satisfied through the calculation of the risk from accidents with accident prevention and mitigation features added as necessary to meet the goal.

(3) In addition to meeting the listed exposure standards for accidents, the Project approach to accident mitigation is to evaluate accident consequences to ensure that the calculated exposures are far enough below standards to account for uncertainties in the analysis and to provide for sufficient design margin and operational flexibility.

(4) When a calculated accident exposure exceeds this threshold, appropriate actions are taken. These include carrying out a less bounding (i.e., more realistic) evaluation to show that the accident consequences will be below the threshold or evaluating additional safeguards for cost effectiveness and/or feasibility. This threshold is not a limit; it does not require the implementation of additional preventative or mitigative features if they are not both cost effective and feasible.

A conservative approach is applied to accident consequence analysis in terms of input assumptions, boundary conditions, modeling techniques, and compliance with public radiological and chemical release standards. As the process and facility design mature, the analysis is refined to eliminate unnecessary conservatism that may have been applied solely to cover uncertainties in design. This strategy is consistent with a risk-based approach that allows the use of uncertainty analysis to better identify the impact of the assumptions and state of knowledge on results from the safety analysis.

Figure 1-2 Location of Public Receptor



1.3.8 Acceptable Level of Worker Safety

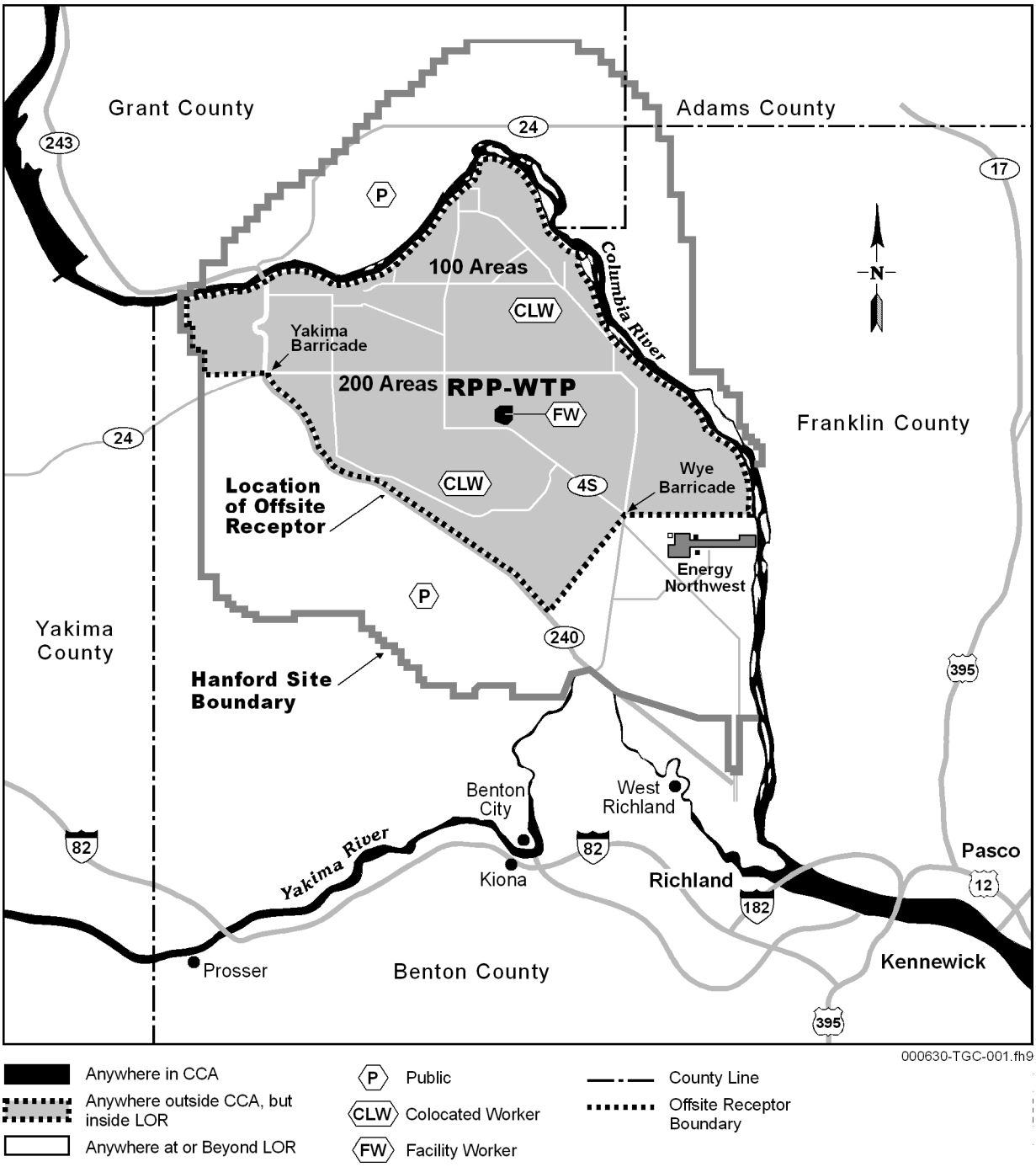
Radiological exposure standards applied to the facility worker and collocated worker are provided in Table 1-2. The location of the workers is shown in Figure 1-3. A 5 rem/event standard is applied to the workers for anticipated events, and a 25 rem/event exposure standard is applied to workers for unlikely and extremely unlikely events. The 25 rem/event standard corresponds to the once-in-a-lifetime accident or emergency exposure for radiation workers which, by recommendation of the National Committee on Radiation Protection (NCRP 1963), may be disregarded in the determination of their radiation exposure status. In addition, an exposure of 25 rem/event corresponds to a conditional probability of fatality of about 2×10^{-2}. For unlikely events (defined in Table 1-2 as having a maximum occurrence frequency of 10^{-2}/yr), this equates to a maximum increase in worker lifetime risk of premature death of about 2×10^{-4}/yr, which is less than the average of the accidental death risk for workers in some of the safest industries, such as retail and wholesale trade, manufacturing, and service (EPA 1991).

Compliance with the 25 rem/event worker standard is established using qualitative methods of the PHA supported, where necessary, by numerical analyses that may include the development of event trees and fault trees or the performance of consequence analyses. From this process, preventative and mitigative engineered and administrative controls to be added to the design are identified. The PHA identifies hazards and operability problems based on the design detail available and experience with similar facilities. Further hazard evaluation takes place in parallel with design development to ensure that safety is built into the design process. Having generated the list of hazards, this list is subject to a further systematic team-based review where a binning process takes place. The binning process is essentially the risk-based categorization of hazards and hazardous situations according to a frequency/consequence matrix.

The 25 rem/event worker standard for unlikely or extremely unlikely events applies to events with frequencies less than 10^{-2}/yr. For those frequencies, the PHA assigns serious and major hazardous situations as either undesirable, acceptable with controls, or acceptable. For a hazardous situation to be acceptable, the situation must have consequences less than 25 rem. Where there is uncertainty concerning the appropriate hazard category to be assigned, the hazard is binned to the higher category to ensure that the accident analysis remains conservative.

For those accidents that involve a radionuclide release, the calculated exposures are compared to the radiological exposure standards of Table 1-2 to determine the need for accident prevention or mitigation features credited for worker safety. For chemical release, the projected exposure is compared to the standards in ERPG-2. If the analysis of radiological or chemical exposures do not confirm the adequacy safety, the need for engineered or administrative controls to prevent or limit the release is addressed. These features are designed and maintained to the highest applicable standards to ensure their functional performance in the prevention or mitigation of accidents. Features credited for satisfying the radiological exposure standards of Table 1-2 and chemical release exposure standards of ERPG-2 (AIHA 1988) are classified as Safety Design Class.

Figure 1-3 Location of Facility and Collocated Workers



The worker accident risk goal is stated in DOE/RL-96-0006 as, "The risk, to workers in the vicinity of the Contractor's facility, of fatality from radiological exposure that might result from an accident should not be a significant contribution to the overall occupation risk of fatality to workers" (DOE-RL 1996b, Section 3.1.3). This goal is satisfied by calculating the risk of facility operation to the workers at the RPP-WTP. This is a best-estimate analysis based on realistic input and modeling assumptions. In performing this analysis, all SSCs capable of preventing or mitigating the event are considered. The evaluation of the availability and reliability of the SSCs include factors such as failures to start and failures to operate, as well as unavailability resulting from maintenance activities. Accident prevention and mitigation controls are added to the design as necessary to satisfy the worker accident risk goal.

If credit is taken for operator action to satisfy the worker radiological exposure standards of Table 1-2, adequate radiation protection is provided to permit access and occupancy of the control room or other control locations under accident conditions without personnel receiving radiation exposures in excess of 5 rem whole body gamma and 30 rem beta skin for the duration of the accident. If credit is taken for operator action to satisfy worker chemical exposure to the standard specified in SRD Safety Criterion 2.0-2, provisions are made so that the operator exposure does not exceed the standard specified in SRD Safety Criterion 4.3-7.

Additional details on the radiological exposure standards applied to the public and workers are provided in Appendix D of 24590-WTP-SRD-ESH-01-001-02, *Safety Requirements Document Volume II*, which also provides information on the basis for the assumed location of the receptors.

1.3.9 Quality Assurance Program

The quality assurance program (QAP) is an important tool in achieving the goal of the safe operation of the RPP-WTP. The QAP defines the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work to be performed. The Project developed its quality assurance program (QAP) in compliance with the requirements of 10 CFR 830.120, "Quality Assurance Requirements", so the integration of the QAP for the TWRS-P Project began during the initial phases of the project. The QAP document for Part A has been submitted to and approved by the U.S. Department of Energy (DOE) (Sheridan 1997). The QAP document for Part B activities has been submitted to DOE; this version (BNFL 1998c) has been approved by the DOE Regulatory Unit (Gibbs 2000). BNI revised the BNFL/CHG QAP document into a Quality Assurance Manual (QAM). This QAM (BNI 2001) superceded the CHG QAP document (i.e., BNFL-5193-ISP-01, Revision 8) in its entirety.

As a result of early development of the QAP, the PHA, SRD, and HAR were developed in accordance with the requirements in the QAP. The application of the requirements of the QAP continues during design, procurement, construction, commissioning, inspections, operations, maintenance, modifications, and deactivation of the facility. Administrative processes such as training, procedure development, and configuration management are subject to the requirements of the QAP. The QAP is used by the Project team to ensure that all aspects of the integrated safety approach have been implemented for the Project.

The RPP-WTP Project QAP document (i.e., BNFL-5193-QAP-01, Revision 8) was restructured to reflect BNI QA program policy, as well as use of NQA-1-1989 (ASME 1989), QARD (DOE 2000), and DOE O 414.1A (DOE 1999), as issued in a *Quality Assurance Manual* (BNI 2001). This QAM serves as the Authorization Basis document for implementation of the Project QA program. The QAP requires periodic assessments of activities, both by management and by knowledgeable, independent personnel, as described in QAM section 18. The conduct of audits to objectively evaluate the effectiveness and proper implementation of the QAM for activities affecting quality of SSCs and surveillances of specific project activities (e.g., process controls, preparation of safety documentation, configuration and document control, and records management) to supplement the compliance audit program are also described in the QAM. The QAM also describes the process of qualifying personnel who perform assessments, audits, and surveillances, as well as documentation of results and review by management.

Performance monitoring is used to verify that the necessary programs, plans, and procedures are functioning to ensure that activities are maintained in compliance with the applicable requirements. The findings of performance monitoring are used to determine if changes are needed to ensure that the high standards of performance expected are achieved.

The QAP ensures that identified corrective actions are implemented and any follow-up actions, such as the performance of a re-audit of a deficient condition, are conducted.

Different aspects of the implementation of the QAP are discussed in the following parts of the ISMP:

1) Chapter 2.0 “Compliance with Laws and Regulations”
2) Section 3.5 “Quality Assurance Program”
3) Section 5.4 “Compliance Audits”
4) Chapter 10.0 “Assessments”

1.3.10 Classification of Structures, Systems, and Components

The design classification process used on the Project provides a consistent, project-wide approach for the classification of the RPP-WTP SSCs based on their importance to controlling normal releases and accident prevention and mitigation. This approach ensures that SSCs are designed, constructed, fabricated, installed, tested, operated, and maintained to quality standards commensurate with the importance of the functions that need to be performed. As the facility moves to deactivation, and the safety functions change, the classification of SSCs will be revised as necessary.

The design classification system provides assurance to DOE that the defined safety functions of SSCs will perform as intended.

In this system, SSCs are designated as Important-to-Safety in accordance with the definition of this term as provided in *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors* (DOE-RL 1996b).

SSCs defined as Important-to-Safety for the RPP-WTP include the following.

1) SSCs needed to prevent or mitigate accidents that could exceed public or worker radiological and chemical exposure standards of Table 1-2 and SSCs needed to prevent criticality. This set of SSCs includes both the front line and support systems needed to meet these exposure standards or to prevent criticality. This set of Important-to-Safety SSCs are designated as Safety Design Class.
2) SSCs needed to achieve compliance with the radiological or chemical exposure standards for the public and workers during normal operation; and SSCs that place frequent demands on, or adversely affect the function of, Safety Design Class SSCs if they fail or malfunction. This set of Important-to-Safety SSCs are designated as Safety Design Significant.

The processes for identifying the SSCs for each of the two groups of SSCs Important-to-Safety and the requirements assigned to each of the two groups are discussed below.

Safety Design Class SSCs typically are identified by the results of accident analyses that show the potential for exposure standards to be exceeded. However, additional items also are designated Safety Design Class independent of a specific accident analysis. These are items that protect the facility worker from potentially serious events. Typically, these events are deemed to present a challenge to the facility worker severe enough that mitigation is prudent, without the need to perform a specific consequence analysis. These latter items are identified by the results of the HAR.

Safety Design Significant SSCs are identified in several ways including: (1) SSCs identified as significant contributors to safety by the risk analyses that confirm the facility accident risk goals are met (this is one way to identify SSCs that place frequent demands on, or adversely affect the function of, Safety Design Class SSCs if they fail or malfunction), (2) SSCs that are needed to ensure that standards for normal operation are not exceeded (e.g., bulk shield walls or radiation monitors), (3) SSCs selected based on the dictates of nuclear and chemical facility experience and prudent engineering practices, and (4) SSCs whose failure could prevent Safety Design Class SSCs from performing their safety function (e.g., Seismic II/I items).

SSCs identified in ISAR Section 4.8, “Controls for Prevention and Mitigation of Accidents” as Design Class I and II are Safety Design Class SSCs. SSCs provided to protect the health and safety of the public and collocated workers usually are considered to also provide adequate protection of the environment. As stated in ISAR Section 4.8, “The selection of engineered and administrative controls is based on the conceptual design of the facility. Additional or different features may be identified during Part B”. The more complete group of Important-to-Safety SSCs will be identified in Part B and provided in the Preliminary Safety Analysis Report (PSAR) as part of the Construction Authorization Request. The PSAR and the Final Safety Analysis Report also will describe SSCs that are not designated as Important-to-Safety. The descriptions of these SSCs will note that they are not classified as Important-to-Safety.

When a SSC is designated as Safety Design Class it has the following attributes:

1) Quality Level 1 (QL-1) is applied to the SSC. The QAP describes the requirements associated with QL-1.

2) For an active system or component, the safety function is preserved by application of defense-in-depth such that failure of the system or component will not result in exceeding a public or worker accident exposure standard. For a mitigating feature, this means that, given that the accident has occurred, the consequence of the accident will not result in exceeding a public or worker exposure standard. For a preventative feature, this means that the failure of the system or component will not allow the accident to occur and progress such that a public or worker accident exposure standard is exceeded. This requirement may be achieved by designing the Safety Design Class system or component to withstand a single active failure or by designating two separate and independent systems or components as Safety Design Class.

3) The SSC is designed to withstand the effects of natural phenomena such that it can perform any safety functions required as a result of a natural phenomena event. For example, if an earthquake can produce exposures to the public or workers in excess of standards, the Safety Design Class SSC that prevents or mitigates the exposures would be designed to be DBE-resistant and designated as Seismic Category I for radiological hazards (or Seismic Category III for chemical hazards). However, DBE-resistance is not applied automatically to Safety Design Class SSCs. It is applied only when the earthquake is the initiating event, or when the earthquake could cause the initiating event. A Safety Design Class SSC that does not have a DBE mitigating function is designated as Seismic Category III.

   This natural phenomenon hazard (NPH) design philosophy is used for all severe natural phenomena events (i.e., earthquake, flood, high wind). Therefore, if a Safety Design Class SSC is needed for meeting public or worker exposure standards for a given NPH event, the NPH loads associated with that event are taken from SRD Volume II, Table 4-1, “Natural Phenomena Design Loads for Important-to-Safety SSCs with NPH Safety Functions”. All other NPH loads for the Safety Design Class SSC may be taken from SRD Volume II, Table 4-2, “Natural Phenomena Design Loads for SSCs without NPH Safety Functions” in lieu of SRD Table 4-1.

4) General design requirements are applied as identified in Section 4.0 of the SRD for Safety Design Class SSCs. See SRD Safety Criterion 4.1-5 as an example.

5) Specific design requirements based on the type of component are applied as invoked in SRD Chapter 4.0. For example, SRD Safety Criterion 4.4-5 provides requirements associated with Safety Design Class air treatment systems.

6) Other design requirements may be applied based on the specific safety function to be performed by the Safety Design Class SSC. This specific safety function is determined from the accident analysis that identified the need for prevention or mitigation by Safety Design Class SSCs.

7) Operational requirements (e.g., periodic testing and preventative maintenance) are applied to Safety Design Class SSCs through the application of Technical Safety Requirements (discussed in ISMP Section 4.2.3.4 “Technical Safety Requirements”).

When a SSC is classified as Safety Design Significant it is has the following attributes.

1) Quality Level 2 (QL-2) is applied to the SSC. The QAP describes the requirements associated with QL-2.
2) The SSC is designed to withstand the effects of natural phenomena such that it can perform its safety functions required as a result of a natural phenomena event. If an earthquake can produce exposures to the public or workers in excess of standards, the Safety Design Class SSC that prevents or mitigates the exposures would be designed DBE-resistant as discussed above. The same NPH loads also are applied to a Safety Design Significant SSC if failure of the item could prevent the Safety Design Class SSC from performing its safety function required as a result of the DBE. Such an SSC is designated Seismic Category II. It should be noted, however, that DBE resistance is not automatically applied to Safety Design Significant SSCs. It is applied only when the earthquake is the initiating event, or when the earthquake could cause the initiating event. A Safety Design Significant SSC that does not have a DBE mitigating function is designated Seismic Category III.

   This NPH design philosophy is used for all severe natural phenomena events (i.e., earthquake, flood, high wind). Therefore, if a Safety Design Significant SSC is needed to meet public or worker exposure standards for a given NPH event, the NPH loads associated with that event are taken from SRD Volume II, Table 4-1, “Natural Phenomena Design Loads for Important-to-Safety SSCs with NPH Safety Functions”. All other NPH loads for the Safety Design Significant SSC may be taken from SRD Volume II, Table 4-2, “Natural Phenomena Design Loads for SSCs without NPH Safety Functions” in lieu of SRD Table 4-1.
3) General and specific design requirements are applied as identified in Section 4.0 of the SRD for Safety Design Significant SSCs.
4) Other design requirements again may be applied based on the specific safety function to be performed by the Safety Design Significant SSC.

1.3.11 Quality Levels

The assignment of Quality Levels (QL) is the method by which the implementation of the graded quality approach discussed in 10 CFR 830.120, “Quality Assurance Requirements” is ensured. Designation of correct quality levels helps to ensure that the appropriate quality assurance requirements are applied to specific RPP-WTP SSCs. The quality levels of the Project quality assurance approach and their applications are described in the QAP.

1.3.12 Training

Training serves an important role in the Project by ensuring that the personnel involved with the project have sufficient knowledge to safely fulfill the roles and responsibilities of their assigned tasks. Training has a direct impact on safety during design, construction, operation, and deactivation of the project by:

1) Improving technical ability
2) Enhancing personal skills
3) Increasing awareness of signs of potential hazardous situations in the workplace

4) Increasing personal awareness of the potential impact of actions taken with regard to the safety of the individual, others, and the facility
5) Establishing a safety culture that clearly assigns the responsibility for safety to the individual

During the design and construction phases of the project, the training focus is on the requirements such as design evolution, compliance with regulations and commitments, construction activities, and quality assurance.

Operator training and qualification is of specific importance in the training program. The operator training program is enhanced by the experience of the Project team at other similar facilities and by the information made available during the design phase and the commissioning program. In addition, operation of the demonstration plants provides invaluable training opportunities for the facility operators.

In recognition that different training is required for different assignments, the training plan addresses the assessment of training requirements and responsibilities and the evolution of the training plan required as the project matures. Additional information on training is provided in ISMP Section 3.15 “Training and Qualification” and Section 4.2.2, “Training and Procedures”. The training plan is described in ISAR Section 3.4, “Training and Qualification”.

1.3.13 Procedures

Procedures are one tool by which compliance with requirements is ensured during the design, construction, operation, and deactivation of the project. All activities that may affect safety of the public and workers are performed in accordance with step-by-step instruction provided in procedures. The range of activities covered in procedures includes, but is not limited to:

1) Design control
2) Procurement activities
3) Monitoring contractors
4) Identification and resolution of nonconforming conditions
5) Operations and maintenance
6) Emergency plan implementing procedures

There is a defined hierarchy of procedures commensurate with the philosophy used to developed the tailored levels of design classification and quality levels. For example, procedures supporting the implementation of Technical Safety Requirements that are credited for accident prevention or mitigation will have a greater safety significance than procedures supporting maintenance activities on other SSCs. Those procedures, at the highest level, are subject to increased rigor with respect to their development, review, implementation, and change. Increased rigor includes requirements for independent review and approval by qualified and experienced personnel or safety committees. Training emphasizes the importance of the hierarchy as well as the content of the procedures and the requirement to follow procedures to ensure safe and efficient activities.

One category of procedures is the operating procedures. These procedures are developed during the design and construction phase, when more detailed design information is available. The design information, test data, and design requirements are incorporated into the operating procedures. The operating procedures address normal and off-normal facility conditions, process startup and shutdown, and emergency events. The development and control of the operating procedures are summarized in ISMP Section 5.6.1, "Procedure Development", and is addressed in ISAR Section 3.9, "Procedures".

1.3.14 Commissioning

Another integral portion of the safety approach is the commitment to a thorough startup testing program. The program validates that the design, construction, hardware, programs, and personnel are ready to support the safe operation of the facility. The tests performed ensure that the equipment and facility are properly built and will operate as designed prior to transition to the operational phase. In addition, the startup testing program documents the as-built configuration and the initial operating parameters of the facility. The program serves as an opportunity to perform a final system analysis and to detect significant faults prior to facility operation. The startup testing program is also used to confirm the adequacy of training and procedures to be used for facility operation.

The method of testing used in the startup testing program can require analysis, demonstration, examination, inspection, or functional test. The selection of the appropriate test method and scope of the tests are determined using a systematic analysis and are described in ISAR Chapter 3.0, "Conduct of Operations". In general, the startup testing program is a phased program, with successful individual component testing leading to system functional and interface testing, followed by the integrated system testing. A final phase of the program, testing with design waste feed materials, must be successful completed before the facility transitions to an operational phase. Additional information is provided in ISMP Section 3.14, "Startup Testing and Operation" and Section 5.6.4, "Startup Review".

1.3.15 Operations

The Project safety approach, which began with the design phase and is followed through the construction and testing phases, is also emphasized in the operational phase by establishing a set of principles for achieving excellence in operation of the RPP-WTP. This set of principles is implemented as a Conduct of Operations program (see ISAR Section 3.11, "Operational Practices") that controls and conducts the operations of the facility. Attributes of the program include the following.

1) Operation of the facility in accordance with the Technical Safety Requirements
2) The establishment of high standards
3) The communication of those standards to the workforce
4) Provisions for the sufficient number of qualified personnel required to perform the activities necessary to meet the standards
5) Implementation of a philosophy to hold workers and managers accountable for their performance

The conduct of operations program practices are major contributors to the safety of the public and workers. The practices are summarized in the ISAR Chapter 3.0, "Conduct of Operations", and detailed guidance on the practices will be incorporated in the RPP-WTP procedures. The conduct of operations program includes shift routines and operational practices (e.g., operator inspection tours, log keeping, response to indications, and resetting protective devices), control area activities (e.g., communications and on-shift training), control of equipment status, lockouts and tagouts, independent verification, operations turnover, required reading, operations procedures, operator aid postings, equipment and piping labels, and incident investigation and reporting.

Another key element in the safety approach is the involvement of operations personnel throughout the design process and the involvement of the design personnel through turnover of the facility to the operations staff (see ISAR Section 3.10.1, "Testing Program Description"). This involvement allows operations personnel not only to provide input to the design process to develop a safe and operable facility, but also to become knowledgeable in the features and limitations of systems and components of the facility. Additionally, the development of facility control system simulators in advance of facility testing strengthens the ability and confidence in the performance of the systems and the operational interfaces. The simulators provide an important integration of the design and operating personnel during the testing in further support of a smooth transition to the operational phase of the project. This interface between the designers, the operators, and the simulators ensures the ability of the Project team to demonstrate operational readiness in advance of final testing activities of the facility.

1.3.16 Configuration Management

Configuration management is one of the fundamental principles to achieve safety. Throughout the life cycle of the RPP-WTP, configuration management is applied to all activities to ensure that programmatic objectives related to radiological, nuclear, and process safety are achieved. Work is performed and controlled to pre-approved plans and procedures that delineate responsibilities. Records that define the requirements, design, verification, and acceptance of the RPP-WTP are retained to provide an accurate record of the design including approved changes to the design. Operating organizations define operational requirements and participate in design review, procedure preparation, training, and planning activities to become familiar with the features and limitations of components included in the design of the facility. Organizations that manage or interface with subcontractors or suppliers of items, activities, or services involving configured items flow down applicable requirements to ensure that the configuration management process as defined in the *RPP-WTP Configuration Management Plan* (CM Plan) (BNI 2001f) are properly implemented.

The WTP Configuration Management Program provides direction to identify and document the physical and functional characteristics of facility structure, systems, components, and computer software applications. Its application to design, construction, and commissioning activities ensures proposed changes to these characteristics are properly developed, approved, implemented, verified, and incorporated into facility design documentation. The CM Plan is based upon ISO 10007:1995(E), *Quality Management - Guidelines for Configuration Management*.

The project formally identifies and establishes configuration baselines, systematically evaluates and dispositions changes, and records the implementation of approved changes. The Configuration Management Program establishes the policies, guidelines, and responsibilities serving to ensure that:

- The engineered configuration of the project is controlled to ensure it meets design, performance, and acceptance requirements.
- Approved configuration changes are assessed for their impact on performance and safety.
- The configuration status of the technical baseline is maintained.

Configuration management is implemented through project plans and procedures that incorporate requirements from the CM Plan and other top-level requirements documents. Records including Authorization Basis documents; engineering and other source requirements documents; design documents; identification of structures, systems, and components; and links between the design documents and the requirements documents are maintained in an electronic data management system managed by Project Document Control.

Effective implementation of configuration management and supporting processes is assessed through management self-assessments in accordance with approved project procedures. Additionally, formal audits performed by Quality Assurance to their normal auditing practices verify compliance with approved project procedures.

1.3.16.1 Configuration Management Approach

The RPP-WTP configuration management program implements a process consisting of four basic steps, as follows:

1) **Identification and documentation.** The activities comprising selection of configured items, documenting their physical and functional characteristics, and allocating unique identification characters and numbers to the configured items and their configuration documents.
2) **Change control.** The activities comprising the control of changes to a configured item after formal issue of its configuration documents.
3) **Status tracking and reporting.** Formal recording and reporting of configuration documents, and the approved changes to those documents.
4) **Configuration audit.** Examination of review, inspection, and test records to determine that a configured item conforms to its configuration documents.

Project plans and procedures fully implement the configuration management process by delineating responsibilities for organizations that manage activities and provide services related to configuration management. Implementing procedures are cited in the CM Plan (BNI 2001f).

1.3.16.2 Configured Item Identification and Documentation

Configured items are selected and documented taking into consideration at what level functional and physical characteristics can be best managed to achieve the overall WTP Project performance objectives related to radiological, nuclear, and process safety. Items identified for configuration management include structures, systems, and components; plant installed software; project interfaces; and Authorization Basis documents.

1.3.16.3 Change Control

Design configuration is controlled in accordance with approved project procedures to maintain an accurate record of the design. Changes are documented to describe the change, the reason for the change, and to identify the configured item and related documents to be changed.

Change control is a formal process comprised of change documentation, evaluation, approval, and implementation.

1.3.16.3.1 Documentation

Changes must be documented except for insignificant changes, i.e., those with no affect on safety, environmental protection, the Authorization Basis, scope, schedule, or cost. When the change control process uses separate change documents, the change documents shall have unique identification numbers for status tracking and convenient to establish links to affected or related documents in the electronic data management system.

1.3.16.3.2 Evaluation

Engineering evaluates proposed changes to identify interface or discipline subject matter impacts and to establish that a proposed change should be implemented. Factors to be considered in the evaluation include compliance of the change with regulations, the Authorization Basis, applicable codes and standards, and safety and environmental significance. Environmental, Safety, and Health monitors the impact evaluation process.

1.3.16.3.3 Approval

The approval process for changes is commensurate, in detail and approval authorities, with the approval process for the original configuration. This may include obtaining authorization from the PSC, customer, or regulators prior to implementing the change.

1.3.16.3.4 Implementation

Approved changes are implemented in accordance with WTP Project procedures identified in the CM Plan specific to the various configured item types encountered in design, procurement, construction, and commissioning activities.

1.3.16.4 Status Tracking and Reporting

Status tracking and reporting consists of recording and reporting information required to manage and administer the configuration management process and related activities. Information is recorded, links to related documents entered, and sorted for reporting in the electronic data management system managed by Project Document Control.

1.3.16.5 Configuration Audits

Configuration audit is the examination of items and documents to determine whether a configured items conforms to its configuration documents. Configuration audit typically consists of functional and physical confirmation.

Functional confirmation is accomplished by identifying the individual functional and performance requirements of a configured item and confirming through review, inspection, and test records that the requirements are achieved.

Physical confirmation is accomplished by examining the physical or as-built and tested configured item for compliance to its configuration documents. Together, the functional confirmation and the physical confirmation demonstrate that the configured item, as defined by its configuration documents, conforms to the physical and functional requirements.

1.3.16.6 Functions and Requirements Management

The Contract, *Basis of Design*, *Functional Specification*, *Operational Requirements Document*, and Authorization Basis design requirements are compiled in an Access © database, designated the Design Criteria Database (DCD). The database has full text and keyword search capabilities. This database is used by design and safety personnel to identify applicable safety functions and requirements for use in the WTP design. The database is updated by procedure each time a source document is revised.

The configuration management organization maintains the *Basis of Design* and DCD to integrate design requirements, safety standards, and operational requirements.

1.3.16.7 Training

The configuration management organization develops, maintains, and provides training on the configuration management program for the project. This training includes a description of the program, reasons why the program is used, the elements of configuration management, and how the program is implemented on the project. This training is provided to employees as part of the Safety and Quality Design Required Training.

1.3.17 Incident Investigations

The importance of the identification and correction of nonconforming conditions as part of a safety approach for the Project is recognized. To ensure that significant incidents that could adversely affect the quality, security, environment, operations, or health and safety of public and workers are brought to the attention of management, the project regulator, and the DOE Occurrence Reporting and Processing System, the ISMP requires incident investigation and reporting. The incident investigations for the Project are expanded in scope to include accidental radionuclide releases and the construction and startup testing phases of the project. Also, reporting of events of less severity than those required of process safety management are included in the program. Incidents to be reported to the regulator include, for example, events or conditions at the facility that resulted in degradation of the principal safety barriers or in a condition beyond the design basis or emergency procedures. The incident investigation process requires that serious events or conditions are addressed and resolved and that the findings of the investigation are resolved.

The investigations are conducted in accordance with the Safety Criteria in SRD Volume II, Section 7.7, “Reporting and Incident Investigation”. Additional detail on the implementing procedures are contained in ISAR Section 3.7, “Incident Investigations”.

1.3.18 Emergency Planning

An important aspect of the safety approach is to ensure the health and safety of the public and the workers during emergency situations at the RPP-WTP. This is accomplished through the development of an emergency management plan for the prompt, efficient, and effective response to emergencies in accordance with the applicable local, state, and federal regulations. The development and the implementation of the emergency management plan are enhanced by the involvement of BNI with the existing Hanford emergency management community. The emergency management plan is fully implemented before radioactive wastes or hazardous chemicals are introduced into the facility. The construction manager implements state and federal emergency preparedness requirements for hazardous situations that may arise during construction.

The scope of the emergency management plan will be determined following the final assessment of the hazards and hazardous situations to be completed during Part B. The implementing procedures will ensure compliance with the applicable requirements that are identified during the development of the emergency management plan. Additional information is included in ISMP Section 3.10, “Emergency Preparedness” and is presented in ISAR Chapter 9.0, “Emergency Management.

1.3.19 Deactivation

All of the previously discussed elements of the RPP-WTP safety approach are applied to the deactivation phase of the project.

In addition, the RPP-WTP incorporates design provisions to facilitate deactivation and final decommissioning. These provisions reduce radiation exposure to Hanford Site personnel and the public during and following deactivation and decommissioning activities and minimize the quantity of radioactive waste generated during deactivation.

A deactivation plan is prepared prior to construction of the RPP-WTP. The deactivation plan provides details on how the following activities will be accomplished to achieve a deactivated status for the facility.

1) Verification of the completion of the facility deactivation end point. (The term facility deactivation end point refers to the set of conditions that comprise the completion of facility deactivation [i.e., radiological, structural, equipment, and documentation])
2) Documentation of the regulatory status, conditions, and inventories of remaining radioactive and hazardous materials and health and safety requirements
3) Modification of the facilities, structures, support systems, and surveillance systems to provide for confinement and monitoring of the remaining contamination, radiation, and other potential hazards
4) Posting and securing of the facility
5) Removal of packaged special nuclear materials and other packaged radiological and chemical materials
6) Confirmation that security systems and procedures are adequate and in place to prevent unauthorized entry

2.0 Compliance with Laws and Regulations

General compliance with statutes that relate to radiological, nuclear, and process safety is described in this chapter. Compliance with 10 CFR 830.120 and 10 CFR 835 is discussed respectively in Section 2.2, "Compliance with 10 CFR 830.120, 'Quality Assurance Requirements' " and Section 2.3, "Compliance with 10 CFR 835, 'Occupational Radiation Protection'".

2.1 Statutory Compliance

New laws, regulations, and guidance documents are identified and reviewed for applicability to the design, construction, operation, and deactivation of the River Protection Project – Waste Treatment Plant (RPP-WTP). This review is coordinated by the Environmental, Safety, and Health (ES&H) Department and performed by the professional staffs of the ES&H, Quality Assurance (QA), Engineering, and Operations organizations (see Chapter 11). Changes to laws, regulations, and guidance documents are identified by review or survey of a number of sources, such as the following:

1) *Code of Federal Regulations*
2) *Federal Register*
3) *State of Washington Administrative Code*
4) *The Bureau of National Affairs Inc. Environmental Reporter*
5) Working contacts with the U.S. Environmental Protection Agency (EPA), the State of Washington, and other regulatory agencies
6) Trade journals
7) Corporate memberships on regulatory committees
8) Web sites of various agencies (e.g., US DOE, EPA, NRC, OSHA, and DOH) and organizations

For regulations that require the submittal of an implementation plan, the plan is submitted to the regulatory authority for acceptance on the schedule defined in the regulation. Exemption requests may be considered for specific elements of a regulation. However, until the granting of such a request, all elements of the regulation are considered applicable. Exemption requests are considered for the following reasons.

1) The requirement conflicts with the requirements of other regulations.
2) Meeting the requirement is not necessary to achieve its purpose.
3) A special situation exists that is not encountered by most other projects for which the regulation applies.
4) There is a net benefit to health and safety by not following the requirement.
5) There is other public interest in the granting of an exemption.
6) Temporary relief is appropriate while a program to meet requirements is being implemented. (This item would not be considered prior to operation of the RPP-WTP.)

Actions necessary to achieve compliance with laws and regulations are included in the configuration management program, which includes the identification of the need to document changes to the authorization basis. Changes to the authorization basis are managed in accordance with ISMP Section 3.3.3, which describes the process for evaluating changes to the facility design and administrative controls for potential impact on the authorization basis (AB), including performance of safety evaluations to determine whether prior DOE approval is required (for changes other than those to the approved QAP and RPP) and requests to amend the AB, if DOE approval is required. After issuance of the Production Operations Authorization, potential unreviewed safety questions (USQs) will be evaluated in accordance with the USQ process described in ISMP Section 3.16.4. The Preliminary Safety Analysis Report (PSAR) will provide a draft USQ plan.

A change being made to the RPP-WTP technical baseline configuration relating to areas of the site; structures, systems and components (SSCs); staffing; procedures; training; and computer software are performed, reviewed, and documented in accordance with procedures to ensure that a high level of protection is maintained for the public, workers, and environment. Additional information on the Project configuration management program is provided in Integrated Safety Management Plan (ISMP) Section 1.3.16, “Configuration Management”, and Section 5.3, “Configuration Management”. Details on the Project configuration management program are provided in ISAR Section 3.1, “Configuration Management”.

2.2 Compliance with 10 CFR 830.120, “Quality Assurance Requirements”

The Project quality assurance program (QAP) is implemented to ensure that the design, procurement, construction, testing, inspection, operation, maintenance, and deactivation activities conform to regulatory and contractual requirements. The QAP for Part A was submitted to and approved by the U.S. Department of Energy (DOE) (BNFL 1997a, Sheridan 1997). The QAP for Part B activities has been submitted to DOE (BNFL 1998c) and was revised several times. This version (BNFL 1998c) was approved by the DOE Regulatory Unit (Gibbs 2000) in January 2000. The RPP-WTP Project QAP document was restructured to reflect BNI QA program policy, as well as use of NQA-1-1989 (ASME 1989), QARD (DOE 2000), and DOE Order 414.1A (DOE 1999). The restructured QA document was issued as the RPP-WTP Project *Quality Assurance Manual* (QAM) (BNI 2001). This QAM serves as the Authorization Basis document for implementation of the Project QA program.

The QAP for the Project meets the requirements of 10 CFR 830.120, “Quality Assurance Requirements”, as presented in 24590-WTP-QAM-QA-01-001, *Quality Assurance Manual* (BNI 2001). The implementation plan required by the 10 CFR 830.120 rule detailing implementation of the QA program as well as reflecting use of NQA-1-1989 (ASME 1989), QARD (DOE 2000), and DOE Order 414.1A (DOE 1999) is provided as a stand-alone Quality Assurance Provisions Document (BNI 2001a). This document is not considered part of the RPP-WTP Authorization Basis, but is a supporting document.

Adherence to the Project QAP ensures the following:

1) Missions and objectives are effectively accomplished.
2) Products and services provide their required safety functions and meet or exceed the requirements and expectations of the Project regulator. Products and services that do not meet requirements are identified, controlled, and corrected (including identification of the cause and corrective action).
3) Hazards to workers, the public, and the environment are minimized.
4) Prospective suppliers are evaluated and selected on the basis of specified criteria.

The process by which the QAP is integrated into Project activities is discussed in ISMP Section 1.3.9, "Quality Assurance Program", and Section 3.5, "Quality Assurance Program". Updating the QAP is addressed in ISMP Section 3.3.3, "Changes to the Authorization Basis". Safety Requirements Document (SRD) Volume II, Section 7.3, "Quality Assurance Program (QAP)", provides criteria for the QAP.

2.3 Compliance with 10 CFR 835, "Occupational Radiation Protection"

Implementation of 10 CFR 835 and the radiation protection program is described in this section.

2.3.1 Implementation of 10 CFR 835

BNI will be in full compliance with the applicable sections of 10 CFR 835 as discussed in the RPP. A radiological controls program that implements the requirements of 10 CFR 835 and additional requirements specified in SRD Volume II Chapter 5.0 "Radiation Protection" is established. The program includes the following components:

1) Implementation of the as low as reasonably achievable (ALARA) design goal
2) Development of the Radiation Protection Program (RPP) and implementing procedures
3) Training of personnel to the RPP and procedures
4) Selection of qualified personnel to ensure safe work performance in radiological environments
5) Maintenance of records
6) Performance of reviews and audits
7) Implementation of a lessons-learned program
8) Respiratory protection
9) Sealed sources
10) Solid radioactive waste storage, packaging, and handling

Updating of the RPP is addressed in ISMP Section 3.3.3, "Changes to the Authorization Basis".

2.3.2 Potential Exemption Request (this section has been deleted)

2.3.3 Radiation Protection Program

Title 10 CFR 835.101, "Radiation Protection Programs", requires submittal of an RPP that includes the following components:

1) Content that is commensurate with the nature of the activities performed and that includes formal plans and measures for applying the ALARA process to occupational radiation exposure
2) Specification of existing or anticipated operational tasks intended to be within the scope of the RPP
3) A program that addresses, but is not necessarily limited to, each requirement of 10 CFR 835
4) A program that includes plans, schedules, and other measures for achieving compliance with the requirements of 10 CFR 835

The RPP is managed and controlled through the establishment of procedures developed according to the requirements of the QAP.

The sequence of activities for submittal of the RPP is provided in ISMP Chapter 9.0, "Scheduling of Safety-Related Activities". Part 835 does not provide a specific schedule for submittal of the RPP for a new facility. However, Section 835.101(j) implies that DOE must be given at least 180 days for review and approval of the RPP. The sequence of activities included in ISMP Chapter 9.0 allows for a DOE review of 180 days. DOE approval of the RPP specific to Part B design activities will be requested before these activities are initiated.

The formalization and implementation of the design-related components of the ALARA program are critical to all stages of design per 10 CFR 835.1002, "Facility Design and Modifications".

2.4 Environmental Radiation Protection Program

The Environmental Radiation Protection Program (ERPP) documents the program standards, requirements, administrative controls, responsibilities, and authorities for protecting the public health and safety and environment from radiological hazards associated with the RPP-WTP during normal operations. The ERPP addresses the following elements and additional requirements of SRD Volume II, Section 5.3, "Environmental Radiation Protection", and Section 5.3.1, "Environmental Radiological Monitoring", as appropriate:

1) Activities and areas of the site subject to the ERPP
2) Measures to be used to implement the ERPP
3) Methods to be used to monitor, report, and record compliance with the ERPP
4) Models and methods used for dose assessment including bioaccumulation and dose-conversion factors
5) As Low As Reasonably Achievable (ALARA) Program
6) Effluent and environmental monitoring
7) Groundwater protection
8) Radiological protection in the management of radioactive waste

9) Controls on the release of materials

10) Property containing residual radioactive materials

The outline for the ERPP is included in the ISAR as Appendix 5B "Environmental Radiation Protection Program Outline".

2.5 Compliance with 10 CFR 820, 'Procedural Rules for DOE Nuclear Facilities'

The Price-Anderson Amendments Act (PAAA) provides indemnification to DOE contractors, subcontractors, and suppliers who manage or conduct nuclear activities in the DOE complex. DOE issued 10 CFR 820, "Procedural Rules for DOE Activities", to implement the PAAA and an enforcement policy (Appendix A to Part 820) that sets forth the DOE strategy for ensuring contractor compliance. These documents subject DOE contractors, subcontractors, and suppliers to potential civil and criminal penalties for violations of DOE rules, regulations, and compliance orders that contain nuclear safety requirements. Proactive compliance by the contractor with the enforcement policy could result in the reduction, or possible elimination of, civil penalties for a noncompliance with a nuclear safety requirement. Rules that have been issued by DOE to implement the provisions of 10 CFR 820 include 10 CFR 830.120, "Quality Assurance Requirements", and 10 CFR 835, "Occupation Radiation Protection". A number of rules have been drafted but are not yet issued for implementation. Following issuance of a specific rule under 10 CFR 820, BNI will develop implementation plans as required by that rule. BNI will comply with the requirements of 10 CFR 820. To facilitate compliance to 10 CFR 820, including nuclear safety requirements contained within the regulation, training and procedures will be developed in Part B for the following activities:

1) Identifying, reporting, correcting, and tracking non-compliances

2) Preparation, review, and approval of implementation plans for nuclear safety requirements

3) Requesting and receiving exemptions to nuclear safety rules

4) Roles and responsibilities of the BNI and DOE staff implementing 10 CFR 820

5) Procedural rules for nuclear activities

Several ancillary procedures and systems also will be developed to implement 10 CFR 820, such as a procedure for performing audits and assessments, a procedure for performing root cause analysis, a system for trending non-compliances, and a commitment database for tracking corrective actions for identified deficiencies.

3.0 Conformance to Top-Level Safety Standards and Principles

This chapter discusses the methods used to conform to top-level safety standards and principles. The top-level standards and principles include any of the safety standards or principles established in DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors* (DOE-RL 1996b). Among the many topics covered in the following sections are defense-in-depth, quality assurance, safety culture, training and qualification of personnel, emergency preparedness and internal safety oversight. Integrated Safety Management Plan (ISMP) Section 4.1.1, "Development of the Safety Requirements Document", provides additional information on how the top-level safety standards have been addressed for the Project.

3.1 Defense-In-Depth

3.1.1 Approach to Defense-in-Depth

The BNI approach to the control of hazardous situations is by prevention and mitigation. Prevention of hazardous situations takes place either by removing the hazard or hazardous situation by design (for example, by substituting a non-hazardous chemical for a hazardous chemical) or by providing administrative and engineered controls such that the frequency of the hazardous situation is acceptably low. Mitigation of hazardous situations is accomplished by providing reliable and robust protection such that, if the hazardous situation were to occur, its consequences would be acceptably low. This reliability and robustness is achieved, in part, by the preference for passive engineered features with their inherent safety. Administrative controls for accident prevention include training and procedures related to normal operation and facility maintenance and the commitment to a strong safety culture (Section 3.4 "Safety/Quality Culture"). Engineered features that enhance accident prevention and mitigation include application of proven engineering practices (Section 3.7, "Proven Engineering Practices").

BNI uses a deterministic approach to control hazardous situations. This is accomplished in tandem with the evolving design. Early recognition of hazardous situations when the design is most flexible allows maximum use of this approach. Where hazardous situations cannot be removed by design, protection is identified to prevent or mitigate the hazardous situation. The degree of protection applied is commensurate with the consequence and frequency of the hazardous situation. Defense-in-depth means that multiple layers of protection are applied against the hazardous situation such that no one layer of protection is completely relied on to ensure safe operation of the facility. The number of layers of protection, or barriers, is dependent upon the severity (i.e., consequence) of the hazardous situation to be prevented or mitigated. The analysis to show compliance to the accident risk goals (SRD Safety Criteria 1.0-3 and 1.0-5) may identify the need not only for additional barriers to satisfy the accident risk goals, but also to achieve additional defense-in-depth. One aspect of defense in depth is that no single failure of protection will allow a hazardous situation to occur. Protection is either passive or active; passive protection features are inherent features of the design that provides protection without the need for any action (e.g., shielding).

An element of the line of defense against the occurrence of hazardous situations is training and procedures that serve to reduce the probability of operator error and facilitate prompt and proper operator response to offnormal conditions. This prompt and reliable operator response serves to reduce the challenges to preventative and mitigative engineered safety features.

While operator response is an element of defense-in-depth in achieving effective mitigation of accident conditions, in the evaluation of the consequence of accidents to the chemical and radiological exposure standards, credit is normally taken only for engineered features.

When offnormal situations occur, the protection against release of radiological and chemical materials is ensured through multiple confinement barriers. Primary confinement is the process vessels, piping, and the dedicated process vessel ventilation system (with filtration). Secondary confinement is the cell or glovebox and its ventilation system. Tertiary confinement is provided by the operating corridor outside the cell together with another dedicated ventilation system. Design features that reduce exposure are conservatively assessed to ensure adequate protection against hazardous situations.

Design features that offer defense against the potential for exposure include shielded maintenance areas (bulges), ventilation systems providing filtered release, and area radiation and airborne monitoring systems that warn personnel of changing or unsafe conditions.

The application of the requirements of the quality assurance program during design, procurement, construction, commissioning, inspections, operations, maintenance, and modifications provides assurance that the engineered and administrative controls perform as required. Surveillances of specific project activities are conducted to determine compliance of in-process activities to quality assurance program requirements. Performance monitoring is used to verify that the necessary programs, plans, and procedures are established and implemented to ensure that activities are maintained in compliance with the applicable requirements.

Emergency preparedness is the final element of the Project approach to defense-in-depth. Emergency preparedness provides assurance that, should a significant radiological and chemical release occur, prompt action can be achieved to limit the exposure to the public and workers. Emergency preparedness includes emergency plan implementing procedures as administrative controls and instrumentation to detect and monitor the progression of accidents as engineered features.

Defense-in-depth is applied by specifying that protection against a hazardous situation is always a combination of engineered features and administrative controls providing prevention and mitigation. This means that excessive reliance is not placed on any one system to provide the majority of protection. Each protection system (i.e., mitigative or preventative, engineered, and administrative) provides the required degree of protection on its own. The design process bins hazardous situations according to their assessed consequences and frequency, which results in obtaining a hierarchy of hazardous situations according to their severity. The more severe the hazardous situation, the greater the level of protection specified. For hazardous situations identified as having the potential to exceed the public or worker exposure standards, certain engineered features are designated as Safety Design Class (see ISMP Section 1.3.10, “Classification of Structures, Systems, and Components”). These engineered features are subject to additional design, quality assurance, operational, and maintenance requirements adding confidence in their ability to perform their specified safety function.

An example of the application of defense-in-depth is the protection provided against entry into a melter maintenance room when the melter cell shield door is open. The first line of defense against such entry is training and procedures. The training informs personnel of the high radiation field present when the melter cell shield door is open and the procedures to be followed for entry into the melter maintenance room. Procedures are used to control entry into a melter maintenance room including the use of a personnel access door key lock. Engineered features that protect against inappropriate entry include a door interlock that inhibits entry when a high radiation field exists in the maintenance room.

Facility design germane to defense-in-depth typically includes SSCs that function as the following:

1) Barriers to contain uncontrolled hazardous material or energy release
2) Preventative systems to prevent hazardous situations and to protect barriers
3) Systems to mitigate uncontrolled hazardous material or energy release given barrier failure
4) Interlocks and controls to prevent hazardous situations
5) Indication and alarms that warn of the occurrence of hazardous situations
6) Interlocks and controls to prevent access to high radiation sources

Administrative controls are linked to the overall safety management programs that directly control operation. Administrative features include the following aspect of operator interfaces:

1) Procedural restriction or limits imposed
2) Manual monitoring or critical parameters
3) Equipment support functions

In addition, risk analyses are performed to confirm that facility accident risk goals of *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006 (DOE-RL 1996b) are met. These risk analyses may show that certain events are significant contributors to the overall accident risk. Additional defense-in-depth items will be specified to reduce that risk. Conversely, if the risk assessment identifies areas of excessive conservation, unnecessary controls may be removed.

In summary, defense-in-depth is applied in the following manner:

1) Conservative identification of the hazardous situation
2) Conservatism is applied in assessing design features for normal operations such that they also provide protection against hazardous situations
3) If the hazardous situation cannot be eliminated from the design the potential consequence of the hazardous situation is conservatively assessed. This can be qualitative assessment (use of a binning matrix and judgement) or a quantitative frequency and consequence calculations if deemed appropriate

4) Use of operator training and procedures as an element of defense-in-depth (i.e., the operator responds appropriately to the development of a hazardous situation to return the facility to normal operation or to place the facility in a safe state)
5) The combination of engineered features and administrative controls provided depend on the overall severity class of the hazardous situation
6) If the potential for exceeding the public or worker radiological or chemical exposures standards exists, Safety Design Class engineered features are specified
7) Application of the quality assurance program to design, procurement, construction, and operation to provide additional assurance that administrative and engineered controls are effective
8) Emergency preparedness to provide assurance that, should a significant radiological and chemical release occur, prompt action can be achieved to limit the exposure to the public and workers

Implementation of defense-in-depth for the Project is accomplished by the *Implementing Standard for Defense In Depth*.

3.2 Safety Responsibilities

BNI recognizes its corporate responsibility for safety during the design, construction, and commissioning (DC&C) phase of the project. Safety responsibilities are assigned to and by the Project Manager. The DC&C responsibilities are assigned to functional areas as shown in ISMP Tables 9-1 through 9-3. The roles assigned to organizations are provided in ISMP Chapter 11.0, “Organization Roles, Responsibilities, and Authorities”. By these assignments, facility safety becomes a facility-wide responsibility with safety responsibilities identified for each functional area.

In addition, by these assignments, assurance is provided that the roles identified in the Safety Analysis Reports are carried out.

The Facility design is based on the design and operational experience gained at other nuclear and chemical facilities. As such, the potential hazards are well understood and lessons learned from earlier facilities are applied.

Part of the preparatory work for hazard identification studies is to review safety and incident reports from similar operating facilities to ensure that credible events are considered at an early stage in the design. For the RPP-WTP, the operating histories of Sellafield’s Vitrification Plants, Site Ion Exchange Plant, the Enhanced Actinide Removal Plant, the Savannah River Project, and the Hanford Site plants are reviewed to take account of their operating experience. In this way, lessons learned are incorporated into the RPP-WTP design and plans for operation. One such example is ion exchange resin stability. An explosion occurred at the Hanford Z-Plant because of contact between an organic ion exchange resin and strong nitric acid (HRC 1976). Because the RPP-WTP uses both organic ion exchange resins and strong nitric acid within its processes, careful consideration is being given to design of ion exchange resin handling and storage for the RPP-WTP. Section 4.4.1, “Comparison to the Hazards Analysis Results of Other Facilities”, of the Hazard Analysis Report (HAR) provides a discussion of the application of lessons learned at other facilities to the Facility process hazards analysis (PHA) and design.

3.3 Authorization Basis

In this section, the content, control, and update of the authorization basis are discussed. The authorization basis is the composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the DOE grants permission to perform regulated activities.

3.3.1 Content of the Authorization Basis

The authorization basis for RPP-WTP includes the documentation discussed in the following sections. This documentation includes that information submitted in connection with a request for Standards Approval, a request for Construction Authorization, or a request for Operations Authorization as described in DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, and any other information submitted by BNI in connection with these requests (DOE-RL 1996a). Amendments to this information may be in the form of revisions to the previously submitted documents, or new information that supplements previously submitted information. The authorization basis begins at the Standards Approval regulatory action and continues throughout the design, constructions, operation, and deactivation of the RPP-WTP. The following Sections 3.3.1.1 through 3.3.1.8 delineate the elements of the authorization basis.

3.3.1.1 Integrated Safety Management Plan

The ISMP defines the process by which applicable laws, regulations, and standards are incorporated into design, procedures, and training to ensure adequate safety of the public, workers, and the environment. Further detail is provided in ISMP Section 1.1, “Introduction”.

3.3.1.2 Safety Requirements Document

The Safety Requirements Documents (SRD) defines the radiological, nuclear, and process safety objectives and standards ensuring the RPP-WTP is designed, constructed, operated, and deactivated in a manner that protects the health and safety of the public and workers and protection of the environment. These safety objectives and standards (SRD Safety Criteria), are included as a part of the RPP-WTP authorization basis to establish a formal agreement with the regulator on the necessary facility design features and management processes and the expectations on the features and processes required to safely achieve the defined work of processing Hanford tank waste. The “Radiological Exposure Standards for the Project” is included in the SRD.

Additional information on the SRD is provided in ISMP Section 4.1, “Safety Management Processes”.

3.3.1.3 Safety Analysis Reports

The Safety Analysis Reports (SAR) document the safety analysis for the facility to demonstrate that it can be safely operated, maintained, and shut down. The Initial Safety Analysis Report (ISAR) was developed during Part A based upon a conceptual design of the facility. Those portions of the ISAR that relate to the fundamental aspects of design are considered to be part of the authorization basis. The Preliminary Safety Analysis Report (PSAR) is based on the facility design and plans for construction and demonstrates adequate planning for the operational phase. The Final Safety Analysis Report (FSAR) documents the completed design and construction and provides details on the plans for operation. The FSAR includes facility and process drawings and fabrication and construction specifications important to the safety analysis of the facility. Specifications and drawings not submitted to the regulator are not part of the authorization basis. The FSAR identifies significant changes made in the facility design and plans for operation from what was presented in the PSAR. Near the end of waste processing activities, FSAR Chapter 11.0, "Deactivation and Decommissioning", is expanded as necessary to discuss the RPP-WTP operating history as it affects deactivation, the hazards associated with deactivation, and the condition of the facility when it is turned over to DOE for decontamination and decommissioning.

3.3.1.4 Technical Safety Requirements (TSR)

The TSRs are based on the accident analyses included in the FSAR as related to protection of the public and workers from chemical and radiological exposures. The TSRs are maintained current so that they reflect the RPP-WTP as it is analyzed in the FSAR. It includes items in the following categories:

1) Safety limits
2) Limiting conditions for operation
3) Surveillance requirements

The limiting conditions for operation are based on the following:

1) Process variables, design features, and operating restrictions that are the initial conditions for accident analysis
2) SSCs that must function to prevent or mitigate accidents to achieve compliance to public and worker radiological and chemical exposure

The detailed content of the TSRs is prepared in accordance with Safety Criterion 9.2-3 of SRD Volume II.

The TSR Bases is a supporting document that describes the basis for the individual technical requirement (excluding administrative controls) but is not a part of the TSR.

3.3.1.5 Quality Assurance Program (QAP)

The QA Program is organized to meet the requirements of 10 CFR 830.120, principles stipulated in *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006 (DOE-RL 1996b), and the specific contract requirements for QA. The RPP-WTP Project QAP document (i.e., BNFL-5193-QAP-01, Revision 8) was restructured to reflect BNI QA program policy, as well as use of NQA-1-1989 (ASME 1989), QARD (DOE 2000), and DOE Order 414.1A (DOE 1999). The restructured QAP document was issued as the RPP-WTP Project *Quality Assurance Manual* (QAM) (BNI 2001). This QAM serves as the Authorization Basis document for implementation of the Project QA program. The QAP, as described in the QAM, provides assurance that the design, procurement, construction, testing, inspection, operation, deactivation, waste form qualification, modification, and maintenance activities conducted at the facility conform to regulatory and contractual requirements and reflect best industry practices. To support meeting project radiological, nuclear, and process safety requirements, the QAP complies with elements of NQA-1 (ASME 1989), as defined in the QAM.

The provisions of the Quality Assurance Requirements and Description document DOE/RW/0333P will be applied to QL-1 and QL-2 items and activities associated with HLW services from design through production and acceptance.

The objectives of the Project QAP are to:

a) establish the project organizational structure, management controls, functional responsibilities, levels of authority, and interfaces for managing, performing, and assessing the work; and
b) ensure confidence in the safe completion of project work in full compliance with radiological, nuclear, and process safety requirements, waste product acceptance quality requirements, and mission objectives.

Adherence to the DOE-approved QAP also ensures the following.

1) DOE mission and objectives related to Project are effectively accomplished.
2) Products and services are safe, reliable, and meet or exceed the requirements and expectations of the user.
3) Hazards to the public and workers are minimized.

The extent to which quality requirements are applied to the Project is based on a graded approach, reflecting the safety implications of the activity. Quality-related activities performed by organizations providing equipment, services, or support to the Project are conducted in accordance with the requirements documented in the approved QAP.

Additional information on the QAP is provided in ISMP Section 3.5, “Quality Assurance Program (QAP)”. Additional information on the audit and management assessment aspect of the QAP is provided in ISMP Section 5.4, “Compliance Audits”, and Chapter 10.0, “Assessments”.

3.3.1.6 Radiation Protection Program (RPP)

The occupational RPP documents the program standards, requirements, administrative controls, responsibilities, and authorities associated with the scope of RPP-WTP radiological activities. The RPP is the program required by 10 CFR 835, "Occupational Radiation Protection". The RPP provides the regulatory technical basis that ensures the radiological safety of facility workers, collocated workers, facility visitors, and the onsite members of the public. Additional information on the RPP is provided in ISMP Section 2.3, "Compliance with 10 CFR 835, Occupational Radiation Protection".

3.3.1.7 Emergency Plan

The Emergency Plan, describing the provisions for responses to operational emergencies, documents the Emergency Management Program. All aspects of the Project Emergency Management Program (EMP) as required by DOE and applicable federal, state, and local requirements are addressed. The EMP, an element of an integrated and comprehensive DOE Emergency Management System (EMS) (DOE 1995a), is designed to address emergency planning, preparedness, response, recovery, and readiness assurance activities. The DOE system considers emergency conditions that might place individuals at risk; which goes beyond radiological hazards. In addition, the relationships of the EMP to existing DOE Headquarters, DOE Richland Operations Office, and Hanford Site Contractors' programs, are documented in the Project Emergency Plan. A discussion of critical interfaces and the division of responsibility among these different agencies is included in the Emergency Plan. The elements of the Emergency Plan are designed to ensure that the Project, as part of the overall DOE EMS, is prepared to respond promptly, efficiently, and effectively to any emergency to protect the public and workers.

The Emergency Plan ensures that emergency response requirements are considered throughout the planning and design process. Emergency drills and exercises are performed to evaluate the emergency plans and RPP-WTP staff response to offnormal conditions. The exercise program includes coordination with Hanford Site, state, and local emergency response organizations. The Project will participate in Hanford Site exercises and drills for other facilities as invited.

The Emergency Plan is submitted to support the request for an operating authorization. Chapter 9.0, "Emergency Management", of the PSAR will address emergency preparedness as required to support the construction authorization request. Procedures developed by the RPP-WTP construction manager implement state and federal emergency preparedness requirements for hazardous situations that may arise during construction.

Additional information on the Emergency Plan is provided in ISMP Section 3.10, "Emergency Preparedness".

3.3.1.8 Other Information

Other documents generated by the regulator or BNI may become part of the authorization basis for the Project. This includes correspondence concerning the safety aspects of the facility design, construction, operation, and plans for deactivation. Those portions specified in Appendix E of the Part A Hazard Analysis Report (HAR) that constitute bounding or significant hazards or hazardous situations are considered to be part of the authorization basis.

3.3.2 Control of the Authorization Basis

The authorization basis for RPP-WTP is considered as an element of the technical baseline for the facility. Changes to the technical baseline are managed by a configuration management program. For further information concerning configuration management see ISMP Sections 1.3.16 and 5.3, "Configuration Management".

3.3.3 Changes to the Authorization Basis

Changes to the authorization basis include changes to the facility design and administrative controls (e.g., procedures, programs, plans, or management processes) that are described in the authorization basis or are relied on to ensure conformance to the authorization basis. Changes to the authorization basis are managed by a configuration management program discussed in ISMP Sections 1.3.16 and 5.3, "Configuration Management". As described in these sections, the change management program includes the use of qualified personnel, procedures developed and approved under the Project procedure process, and implementation under the approved QAP.

By 10 CFR 830.120(b)(3), a contractor may, at any time, make changes to the approved QAP so long as the QAP, as changed, will continue to satisfy the requirements of 10 CFR 830.120. For the Project the commitment has been made that changes that reduce commitments to a previously approved QAP, as described in the QAM, will be submitted to the DOE for review and approval per the QAM requirements for its change. Annual submittal of the QAM to DOE must also identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of 10 CFR 830.120.

As allowed by 10 CFR 835.101(I) BNI may make changes to the approved RPP so long as the change does not decrease the effectiveness of the RPP and the RPP, as changed, continues to meet the requirements of 10 CFR 835. Proposed changes that decrease the effectiveness of the RPP are not implemented without submittal to and approval by DOE. Updates to the RPP are required if a change or addition is made to the RPP. Updates of the RPP are considered approved 180 days after submittal unless rejected by the regulator.

In accordance with *DOE Position on Contractor Initiated Changes to the Authorization Basis*, RL/REG-97-13 (DOE-RL 2000), BNI may make changes to the facility or administrative controls if a review of the Authorization Basis is performed and either:

a) The review demonstrates that a proposed change is consistent with the existing Authorization Basis, or

b) The Authorization Basis is revised prior to the implementation of the proposed change.

3.3.3.1 Authorization Basis Revisions

BNI may make revisions to the authorization basis, other than to the QAP and RPP as discussed above, without prior approval of the DOE provided that the following safety evaluation and documentation requirements are met:

a. An evaluation is performed that demonstrates that the revision:

   1) Does not involve deletion or modification of a standard previously identified or established in the approved SRD.

   2) Does not involve a modification of an approved Technical Safety Requirement.

   3) Does not result in a reduction of a commitment described in the Authorization Basis.

   4) Does not result in a reduction in the effectiveness of any program, procedure, or plan described in the Authorization Basis.

   5) Does not result in an Unreviewed Safety Question (USQ), if a Production Operations Authorization has been issued.

b. A written evaluation is performed that demonstrates that the revisions to the authorization basis:

   1) Will continue to comply with all applicable laws and regulations, conform to top-level safety standards, and provide adequate safety.

   2) Will continue to conform to the original submittal requirements associated with the authorization basis document(s) affected by the revision.

   3) Will not result in inconsistencies with other commitments and descriptions contained in the authorization basis or an authorization agreement.

   The format, content, and level of detail associated with an acceptable "safety evaluation" is highly dependent on the nature of the proposed revision to the authorization basis. Rather than establishing comprehensive guidance on appropriate evaluation format, content, and level of detail, the position identifies the most fundamental basis that can applied to evaluating proposed revisions. There is a wide range of acceptable safety evaluation approaches. Also, the appropriate degree of rigor and documentation associated with the safety evaluation should be tailored to the specific authorization basis revision. The position does not indicate that an explicit and detailed case be made and documented showing that the fundamental criteria have been satisfied for all revisions to the authorization basis.

c. The following documentation requirements are met:

   1) All changes, authorization basis revisions, and associated evaluations performed in accordance with paragraphs a and b above will be documented.

   2) Documentation will be retained and readily available for DOE review.

   3) Evaluations should be documented in sufficient detail such that a knowledgeable individual reviewing the evaluation can identify the technical issues considered during the evaluation and the basis for the determinations.

   4) The DOE will be notified of revisions to the authorization basis within 30 days of completing such revision.

3.3.3.2 Authorization Basis Amendments

An authorization basis revision that does not meet the conditions of subsection 3.3.3.1 paragraph a but meets the conditions of subsection 3.3.3.1 paragraph b may be implemented following approval by the DOE of a request to amend the authorization basis. A request to amend the authorization basis includes:

1) A description of the proposed revision
2) The reason for the proposed revision
3) A descriptions of the proposed implementation schedule for the revision and associated change(s)
4) A copy of the authorization basis document or appropriate excerpt showing the proposed revision(s)
5) The safety evaluation for the proposed revision, as described in subsection 3.3.3.1 paragraphs a and b
6) If the revision involves the deletion or modification of a standard previously identified in the approved SRD, certification that the revised SRD will continue to identify a set of standards that will provide adequate safety, comply with all applicable laws and regulations, and conform to the top-level safety standards.

3.3.3.3 Decisions to Deviate from the Authorization Basis

During the design and construction phase prior to the Start of Cold-Testing, BNI may implement design changes that deviate from the Authorization Basis, provided that the provisions of paragraphs 1, 2, and 3 below are met.

1. Evaluation

   Prior to implementing a change that deviates from the Authorization Basis, BNI will perform an evaluation that determines that:

   a. The change complies with applicable laws and regulations, conforms with top-level safety standards, and satisfies the SRD Safety Criteria.

   b. The specific changes will not cause or threaten imminent danger to the workers, the public, or the environment from radiological, nuclear, or chemical hazards.

2. Documentation of Decision to Deviate from the Authorization Basis

   Documentation of BNI's decision to deviate from the Authorization Basis will be completed prior to implementing the change and will include the following:

   a. Identification of the specific changes to be implemented.

   b. Identification of the specific deviation(s) from the Authorization Basis.

   c. The evaluation described in paragraph 1.

   d. The signature of the manager(s) having the authority to approve changes that deviate from the Authorization Basis and the date such changes were approved.

   Such documentation will be readily retrievable and made available to the DOE upon request.

3. Time Limits and Notification

   a. During the construction phase, if prior approval by the DOE is required, BNI will notify the DOE (or his/her designee):

      1) either verbally or in writing within 24 hours of the decision to deviate from the Authorization Basis (as recorded in 2.d above), and

      2) in writing within 72 hours of the decision to deviate from the Authorization Basis (as recorded in paragraph 2.d above). This notification will include a copy of the documentation of the decision to deviate from the Authorization Basis described in paragraph 2 above.

   b. If prior approval by the DOE is not required, BNI will revise the Authorization Basis within 30 days following the decision to deviate from the Authorization Basis (as recorded in 2.d above) and notify the DOE within 30 days of completing such revision.

   c. If prior approval by the DOE is required, BNI will submit a request to amend the Authorization Basis to the DOE within 30 days following the decision to deviate from the Authorization Basis (as recorded in 2.d above).

   d. If provisions 3.b or 3.c are not met, or if approval of the amendment request is not obtained within 90 days of the decision to deviate from the Authorization Basis (as recorded in paragraph 2.d above):

      1) All physical work associated with implementing the change that deviates from the Authorization Basis will stop, and

      2) Corrective action will be initiated immediately, in accordance with paragraph 4 below.

4. Tracking and Resolution of Deviations from the Authorization Basis

   Changes that deviate from the Authorization Basis will be entered into the project's Corrective Action Management System (CAMS) as a condition adverse to quality, as described in the QAP. If the provisions of paragraph 3.d are invoked, the change will be recorded as a significant condition adverse to quality, and corrective action will be tracked to completion. CAMS records related to deviations from the AB will be uniquely identified to facilitate retrieval and generation of reports of the current status of such deviations upon request by the DOE.

   All revisions to the Authorization Basis associated with approved Authorization Basis deviations will be completed and all deficiencies documented under paragraph 2 will be resolved prior to Start of Cold-Testing.

3.4 Safety/Quality Culture

The BNI team understands the importance of a strong safety and quality culture in achieving excellence. To achieve a culture in which individuals involved in safety-related activities accept responsibility for the safety and quality through all phases of the Project, BNI establishes the following policy:

1) Outlining expectations and performance standards
2) Communicating those expectations
3) Implementing procedures that facilitate achieving expectations
4) Performing assessments to measure the compliance with and the appropriateness of BNI safety goals.

To achieve safety and quality throughout design, construction, and operation of the facility, BNI establishes measurable goals in the areas of industrial health and safety of workers, radiological and chemical exposure limits for the public and workers, and environmental release limits. The team then establishes policies that require the communication of the goals to employees and contractors. Communication techniques include posters, meetings, newsletters, recognition of outstanding performance, and incorporation of the goals into performance plans for groups and individuals. Another important aspect of communication is training. Employees are provided information regarding the inherent hazards of the work and tools effective in controlling the hazards or responding to hazardous situations encountered during the work processes. Managers and supervisors are expected to be familiar with the work processes and to understand the potential hazards and hazardous situations.

Other policies that establish standards of conduct and job site work rules are communicated to employees. The policies empower RPP-WTP employees to stop the activity in which they are involved if the work procedure or process is not clear or the activity appears unsafe. The policies also direct that performance reviews emphasize the requirements for safety and quality.

The safe completion of a quality job requires planning that takes into consideration aspects such as adequate work packages, appropriate level of instructions, evaluation of the impact of the task on other SSCs or processes, and an evaluation of the completed activity. Procedures governing these activities specify that trained and qualified personnel are required to participate in planning process. This includes craft and operations personnel supporting technical and administrative workers.

To ensure that safety and quality procedures are being followed and that the implemented procedures are adequate to facilitate achieving the expectations, assessments of work activities performed and the results of compliance with goals are conducted. Where practices are identified that improve safety and quality, those practices are incorporated into operations. Any required corrective actions identified are tracked to completion. Results of these assessments are provided to managers and workers.

As the project moves through design and operations to deactivation, the BNI team revises the goals and procedures to reflect the activities required for each phase.

3.5 Quality Assurance Program (QAP)

The Project QAP for all activities meets the criteria of 10 CFR 830.120, "Quality Assurance Requirements". Implementation of 10 CFR 830.120 is addressed in ISMP Section 2.2, "Compliance with 10 CFR 830.120, "Quality Assurance Requirements".

Integration of the QAP into the Project safety approach began with the PHA, SRD, and HAR developed by specific procedures in accordance with the requirements of the QAP. This included the establishment of personnel training and qualification requirements, confirmation that personnel met the training and qualification requirements, application of technical review, and documentation of results. The performance of the accident analysis and the comparison of the results of the analysis to the radiological and chemical exposure standards is also performed in accordance with the requirements of the QAP. This includes training and qualification requirements; computer code verification; independent review of input assumptions, analytical methods, and calculations; maintenance of a calculation log; and documentation of the results.

The application of the QAP to design, procurement, construction, testing, inspection, modification, and maintenance of SSCs credited with public and worker safety is discussed in the QAP. The manner in which requirements of the QAP are imposed on subcontractors is discussed in ISMP Section 5.2, "Control of Subcontractors".

Personnel training and qualification and procedure development credited for public and worker safety during facility operation are developed in accordance with the requirements of the QAP. The QAP is applied to the Emergency Management Program in the areas of training and qualification of emergency response team members, assessment of the program effectiveness, and records documentation. Additional details on these aspects of the emergency response program are provided in ISAR Chapter 9.0, "Emergency Management".

Project compliance with DOE/RW-0333P, *Quality Assurance Requirements and Descriptions for the Civilian Radioactive Waste Management Program (QARD)* (DOE 1995b) is addressed in ISMP Section 3.3.1.5 "Quality Assurance Program (QAP)". The provisions of the Quality Assurance Requirements and Description document DOE/RW/0333P will be applied as described in the QAP.

ISMP Section 5.3, "Configuration Management", Section 5.4, "Compliance Audits", and Section 8.0, "Document Control and Maintenance" provide additional information on the application of the QAP to the Project safety approach.

3.6 Facility Design for Postulated Events

This section describes the facility design for normal operation, anticipated operational occurrences, and accident conditions.

3.6.1 Normal Operations

The facility design provides for control of radiological exposure to the public and worker such that the exposures are within the standards provided in Table 1-2 for normal events. In addition, the design satisfies the Operations Risk Goal of *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006 (DOE-RL 1996b) and of SRD Volume II, Safety Criterion 1.0-4. Those SSCs required for achieving compliance with the public and worker exposure standards for normal operation are designated as Important-to-Safety Safety Design Significant as discussed in ISMP Section 1.3.10, "Classification of Structures, Systems, and Components".

The process follows a logical approach, beginning with defining the basis of design and developing the overall process flowsheet. System-specific flow diagrams, such as ventilation flow diagrams, are also developed if required. The next stage is the production of operation and maintenance philosophy documents for each area of the facility, tied together by an overall control philosophy document. These documents define the design principles for each area and allow specific equipment selection or design to commence. These principles are based on existing successful operation of structures, systems, and components. However, where a new process or system that has the potential to provide a cost-effective and safe alternative is identified, a research and development program is initiated to support the design process.

Flow diagrams and documents are subject to review during their development, addressing different aspects of the design. The Technical Organization ensures a consistent design approach is taken across the project and that all of the project requirements are being addressed. The PHA team, which includes representatives from operations, reliability, and relevant technical disciplines, addresses each component of the design from a safety and operability aspect.

This process is used at the RPP-WTP to ensure that safe, efficient operation is built in at the design stage. Application of this process is demonstrated in various philosophy documents and plant layouts that describe features to be used in the RPP-WTP. The following is a list of these features:

1) Fluidic devices (pumps and valves) that contain no moving parts are used to transport and divert highly radioactive liquids. These items require no maintenance
2) Fully welded pipework systems minimize the risk of leakage
3) Automated sampling and transport systems allow efficient process operations while minimizing radiation exposure to workers
4) Canister HEPA (high efficiency particulate air) filters ease handling and installation operations.

The type of control identified through the design process for the RPP-WTP also leads to the reduction of the risk to public and workers while allowing efficient process operation. The distributed control system allows the facility to be operated under normal conditions from a central control room, thus reducing radiological exposure to personnel. Hardwired backup systems are used for some safety systems that are totally independent from the operational control system.

The close relationship between Hanford tank farms operations and the RPP-WTP may require additional administrative controls and documentation in support of AP-106 operations (e.g., master pump shutdown). Such concerns are addressed and resolved at a site-wide level through interface control meetings.

3.6.2 Anticipated Operational Occurrences

The RPP-WTP will have anticipated operational occurrences that are not considered part of the normal process operation. Certain features are built into the design to minimize the risk to personnel, the impact to the process operation, and to enable equipment to be maintained in a safe manner during normal operation and anticipated operational occurrence. Examples of these features include the following:

1) Flasking systems that allow maintainable plant items to be removed from the cell environment and taken to specifically designed maintenance areas
2) Cell bulge systems that enable equipment to be safely maintained without needing to enter the high radiation level cell confinement
3) Standby filtration systems that allows filters to be changed offline
4) Distributed control system that contains a dedicated mode that is interlocked to prevent the maintenance of an item until it is fully isolated.

3.6.3 Accidents

During postulated accidents, the RPP-WTP is designed to maintain confinement of radioactive materials, thus preventing a significant release from the facility.

During facility design evolution, hazardous situations identified by the PHA and the accident consequence analysis are compared to the radiological and chemical exposure standards provided in SRD Safety Criteria 2.0-1 and 2.0-2. Hazardous situations considered include both internal and external events. If the radiological or chemical exposure standards are not satisfied, the need for engineered or administrative controls to prevent or limit the release is addressed. Preference is given to engineered features over administrative controls.

Hazardous situations considered include both internal and external events. The HAR Section 5.0, “Hazard Evaluation by Process Step”, discusses the internal events and HAR Section 2.1, “Site Description”, discusses external events. The ISAR Chapter 4.0, “Integrated Safety Analysis”, presents additional consideration given to internal and external events.

The engineered features are designed and maintained to the highest applicable standards to ensure their functional performance in the prevention and mitigation of accidents. Recognized and accepted consensus codes and standards are used. Features credited for satisfying the public and worker radiological and chemical exposure standards of SRD Safety Criteria 2.0-1 and 2.0-2 are classified as Safety Design Class. Details on the classification process and the quality assurance provisions provided for each classification are provided in ISMP Section 1.3.10, “Classification of Structures, Systems, and Components”, and Section 1.3.11, “Quality Levels”. Additional information on the design of SSCs credited for worker and public protection is provided in ISMP Sections 3.1, “Defense-in-Depth”, 3.7, “Proven Engineering Practices”, and 3.11, “Safety Systems Design”.

A specific list of SSCs credited for worker and public protection is provided in ISAR Section 4.8, "Controls for the Prevention and Mitigation of Accidents". These SSCs are identified in the master equipment list, which is maintained by the Configuration Management Program as discussed in ISMP Section 5.3, "Configuration Management".

3.7 Proven Engineering Practices

The RPP-WTP design incorporates the use of proven technologies so that lessons learned from the use of the technology is incorporated into the operation of the facility. For the novel uses of existing technologies (such as the use of specific ion exchange resins), the PHA ensures that the safety aspects are examined in a structured research and development program to be assured that hazard potentials are reduced as far as practicable or that protection put in place is commensurate with the assessed magnitude of the hazard.

Facility processes are based on selected technologies that minimize the risk of radiological and chemical exposure. For example, sampling and maintenance activities do not require breach of confinement; hands-on maintainable items within active areas are accessible via shielded access areas that have decontamination facilities installed; and samples with high activity levels are dispensed and transported remotely.

New and novel uses of existing technologies and processes are employed to enhance the process while maintaining safe operation. These uses (e.g., selection of ion exchange resins and the melter feed processes) are examined through a program of research and development. Such development work includes operating a pilot (cold operation) melter and associated feed and mechanical handling systems. This prototype is used to examine and prove novel processes, test the design and maintainability of components, and provide operator training in operational and maintenance activities. To support the use of new and novel uses of existing technologies and processes and new equipment, it may be necessary to develop ad hoc standards. The use of ad hoc standards is discussed in SRD Volume I, Section 3.4.2, "Identification of Consensus Codes and Standards".

The RPP-WTP design incorporates passive and active engineered features that prevent and mitigate the potential for radiological and chemical exposures to the public, worker, and the environment. In the selection of required controls, preference is given to accident prevention over mitigation and engineered features over administrative controls. Preference is also given to passive engineered features over active engineered features. The designation of safety features is made during the hazard evaluation and accident analysis processes.

Examples of passive and active features are described in the following sections.

3.7.1 Passive Features

Facility processes are confined by at least two barriers. Facility and process equipment provides the first barrier and a cell or similar enclosure provides the second. This secondary confinement barrier has appropriate levels of shielding to ensure that radiological exposure does not exceed standards. Confinement and shielding design are established, as are the codes and standards that are used. Aspects of confinement design ensure that failure of one barrier does not lead to failure of the other (i.e., confinement is diverse). For example, should a process vessel or pipework leak (loss of primary confinement), the liquor drains to the cell sump where it can be recovered. The cell is lined to prevent liquor leakage. The potential for failure of a process vessel or piping is reduced by the selection materials resistant to erosion and corrosion and the use of direct inspection or erosion/corrosion coupons as discussed in Section 3.13, "Reliability, Availability, Maintainability, and Inspectability (RAMI)".

3.7.2 Active Features

The facility ventilation systems are designed to minimize the potential for radiological and chemical release into or out of the facility. The air flow into the facility is drawn through areas designated as having low or no potential for radiological or chemical release, through areas of successively higher potential. Except for the facility ventilation systems serving areas evaluated as having marginal potential for radiological contamination, this air is then filtered before release. Ventilation systems are exhausted to the atmosphere via monitored stacks. The principles behind the design and the systems employed are tried and tested components. Additionally, important to safety ventilation systems contain redundant equipment (fans, filters, electrical supply) to protect against single active failures.

The selection of facility equipment required to perform a safety function is based on proven design. The safety performance function requires that suitable testing and maintenance regimes are in place to ensure reliability. For example, where programmable logic controllers are used, specific attention is given to their unique requirements relative to software verification and protection against electromagnetic interference (See SRD Safety Criterion 4.3-1).

Protection systems are an integral part of defense-in-depth as described in ISMP Section 3.1, "Defense-in-Depth".

Preference is given in the facility design to components failing in their safe position on loss of motive power. During the design process, the failure modes of safety features are determined and specified. Simple and proven items of equipment (e.g., valves and pumps) are used, the (required) failure modes of which are well understood and categorized.

3.8 Criticality Safety

A criticality event within a nuclear chemical facility can have severe consequences; therefore, the preferred approach is to preclude the possibility of the hazard by the use of design features. Where this cannot be achieved (because of the presence of a large mass of fissile material within the process) or is impracticable, stringent criticality controls are required. Handling large amounts of fissile material (as in plutonium finishing), criticality control is achieved through a combination of geometry, inventory control, concentration (for solutions), moderation, and suitable instrumentation backed up by administrative controls. The need for these controls is established during the design phase by considering worst-case scenarios and applying conservative assumptions. Worst-case scenarios are modeled using validated computer codes to determine system reactivities and the degree of criticality control required.

The modeling and worst-case scenarios include considerations for uncertainties in the data and calculation methods, uncertainties in the immediate environment under accident conditions, and the presence of water moderation and reflections unless the presence of water is shown to not be credible. The analysis will show that the multiplication factor, k_{eff}, will not exceed 0.95 at a 95% confidence level for credible normal, off-normal, and accident conditions. Exceeding a multiplication factor of 0.95 is prevented by either the control of two independent process parameters, or a system of multiple controls on a single process parameter. This is application of the double contingency principle.

This methodology has also been applied to the RPP-WTP process. The amount of fissile material present in the contract feed has been conservatively estimated, then modeled under process conditions using conservative assumptions. The application of this methodology indicates there is insufficient concentration of fissile material to give rise to a significant potential for criticality within the RPP-WTP. The results of this preliminary analysis are provided in ISAR Chapter 6.0, “Nuclear Criticality Safety”. If any significant potential for criticality becomes apparent, appropriate controls will be implemented commensurate with the assessed potential. Additional detail regarding criticality prevention are provided in ISAR Chapter 6.0, “Nuclear Criticality Safety”.

The RPP-WTP criticality program includes the following:

1) Establishment and maintenance of controls needed to ensure that material specification for proposed feed to the facility are fully compatible with the process and are within the fissile material content bounds of the criticality assessments
2) Performance of nuclear criticality safety assessments when and where appropriate to ensure that changes do not occur that impact assumptions made in criticality evaluations
3) Maintaining appropriate access to trained nuclear criticality experts.

The need for criticality alarms is determined by evaluation to the requirements of Safety Criterion 3.3-6 of SRD Volume II. Alarms, if required by this criterion, are installed in accordance with Safety Criteria 3.3-7 and 3.3-8.

3.9 Radiation Protection Practices

The radiation protection design practice for normal operations at the Project consist of two main elements, radiation protection design and as low as is reasonably achievable (ALARA) design. These design practices ensure that the RPP-WTP can be operated in a manner that maintains normal occupational exposures and emissions of radioactive effluents within limits and ALARA. The radiation design process also considers features to facilitate deactivation and decommissioning of the facility and will be applied to the deactivation planning near the end of waste processing operations.

3.9.1 Radiation Protection Design

Radiation protection design addresses material confinement, shielding and access control features, and monitoring. Each of these is addressed in the following sections.

3.9.1.1 Radioactive Material Confinement

Confinement systems present barriers to the uncontrolled release of radioactive material and against the spread of contamination through the RPP-WTP. For the facility, the process vessels and piping and the process vessel ventilation system provide the primary confinement barrier. The process cell structures and associated ventilation system provide the secondary confinement barrier. The operating area structures and associated ventilation systems provide a tertiary confinement barrier. Ventilation flow is from areas of lower potential contamination to areas of higher potential contamination. The effluents are treated as necessary to control exposures to collocated workers and members of the public during normal operations and under accident conditions.

Throughout the RPP-WTP confinement barrier, boundaries are identified and design criteria established for these boundaries and for the associated ventilation systems. Design documents covering the confinement systems are reviewed to ensure the design criteria are adequately implemented.

The confinement systems under normal operations are assessed based on upper-bound conditions identified in the PHA. The projected annual radiological exposure from normal operations is compared against the criteria provided in SRD Volume II, Chapter 2.0, “Radiological and Process Standards”, and facility features are modified and added to the facility as necessary to meet the criteria (BNFL 1997d).

3.9.1.2 Radiation Shielding and Access Control Features

The RPP-WTP is divided into radiation zones. The zoning reflects the intensity of the radiation sources in the area, if any, and the anticipated personnel access requirements. Maximum allowable exposure rates in accessible areas are defined to ensure that personnel exposure standards are not exceeded. Shielding requirements are then established as necessary to ensure that the exposure rates in the radiation zones are maintained under all anticipated operating conditions and that commitments to ALARA are satisfied. Shielding and access control features are provided in accordance with 10 CFR 835 and additional criteria provided in SRD Volume II, Chapter 2.0, “Radiological and Process Standards”, and Chapter 5.0 “Radiation Protection” (BNFL 1997d).

Radiation protection features such as facility zoning, minimum shielding requirements, and access control features will be documented on applicable facility layout drawings and other design documents. These documents are reviewed to ensure that the requirements are met. Details, such as penetrations are analyzed to ensure that potential streaming paths are identified and properly shielded.

3.9.1.3 Radiation Monitoring

Fixed area radiation monitoring is provided in areas where the area exposure rates may change suddenly. These sudden changes may be a result of process operation or maintenance activities. Continuous air monitors are provided in accessible locations where concentrations of airborne radionuclides may vary. Air sampling capability is also provided. Effluent sampling is provided as necessary to demonstrate compliance with regulations. The radiation monitoring locations will be shown on drawings developed during detailed design.

3.9.2 ALARA Design

Project procedures are established to implement an ALARA program. These procedures include guidance on ALARA design considerations appropriate to the facility and delineate the ALARA design responsibilities of individuals on the project. The ALARA guidance is derived from federal and commercial nuclear operating experience as well as from industry standards such as NRC Regulatory Guide 8.8, *Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations will be As Low as is Reasonably Achievable* (NRC 1978) and DOE G 441.1-2, *Occupational ALARA Program Guide*. The ALARA guidance addresses considerations for reducing exposures within the RPP-WTP from operations and from final decommissioning activities. It also addresses considerations for reducing effluents from the RPP-WTP.

ALARA design criteria and ALARA design considerations are provided to project staff in controlled documents. These criteria and considerations are arranged by topic area (for example, General Criteria, Dose Criteria, Environmental Criteria, Facility Arrangement Considerations, Shielding Considerations, System Design Considerations, etc.). Design engineers are responsible for implementing and documenting ALARA design criteria and ALARA design considerations in their work. Supervisors are responsible for ensuring that individuals in the group are trained in ALARA criteria and considerations, and for reviewing designs against those criteria and consideration. The WTP ALARA program also requires an ALARA review of proposed changes to the facility.

Periodic interdisciplinary project ALARA reviews are conducted to ensure that ALARA concepts are being integrated into the design and to discuss implementation of the ALARA design goal and the rationale for exceptions from specific ALARA design considerations.

In addition, collective exposure estimates assess projected exposures to provide insight into the sources of exposure and indicate areas that may require additional attention. The estimates are compared to those from similar operating facilities.

Radioactive systems at the RPP-WTP are designed to minimize the potential for leaks of radioactive material. Radioactive leaks are collected and segregated from non-radioactive waste streams. To the extent possible, radioactive leaks are returned to the process stream.

Melter offgas streams are treated to scrub out radioactive particulates before passing through filter media. The scrub streams are returned to the process stream.

The interfaces between non-radioactive service systems (e.g., cooling water) and radioactive systems are designed so that any leakage is from the clean side to the radioactive side of the interface.

The confinement system design and access control features described above serve to minimize the spread of radioactive contamination in the RPP-WTP. During operation, movement of clean materials into potentially contaminated areas is minimized to aid in contamination control, minimize replacement and survey costs, and minimize radioactive waste volumes and costs. Tools in contaminated areas are controlled and reused to the extent possible.

3.10 Emergency Preparedness

The Project implements and maintains an emergency management program to respond promptly, efficiently, and effectively to emergencies involving RPP-WTP, activities, or operations. The applicable requirements of federal, state, and local agencies are integrated into a single comprehensive program. The magnitude and scope of the emergency management program are determined by the final assessment of the hazards and hazardous situations to be completed in Part B.

The Project emergency management program is being designed to function within the existing Hanford emergency management community. Community planning partners are the DOE; DOE contractors; the Energy Northwest; U.S. Ecology; the State of Washington; and Benton, Franklin, and Grant Counties. The Project emergency management program is being developed and will be implemented to be consistent with the *Hanford Emergency Response Plan* (DOE-RL 1994), to ensure a timely and integrated response and to eliminate duplication of effort within the planning community. Agreements will be established to enable the Project to use existing Hanford response capabilities (e.g., fire, medical, hazardous materials spill response, consequence assessment, law enforcement, and communications). The facility design facilitates access and intervention by the Hanford Site fire department (e.g., the ability to connect to the interior standpipe system). The RPP-WTP Emergency Management Administrator participates in and supports Hanford Site and local area emergency planning organizations, including the Hanford Emergency Planning Council and the local Emergency Planning Committee.

The Project emergency management program is being developed for compliance with the requirements of 40 CFR 355, “Emergency Planning and Notification”, 29 CFR 1910.38, “Employee Emergency Plans and Fire Prevention Plans”, and WAC 173-303-350, “Contingency plan and emergency procedures”.

The Emergency Response Plan incorporates into one document an overview of the emergency management program for the Project. The plan provides a description of how the Project implements the provisions of all applicable requirements. RPP-WTP specific emergency implementing procedures are developed to implement the requirements of the plan.

Table 3-1 lists the information to be included in each section of the Emergency Response Plan. Additional information on the Project Emergency Management Plan is presented in ISAR Chapter 9.0, “Emergency Management”.

3.11 Safety Systems Design

For facilities designed and built by the RPP-WTP contractor, a proven method for identifying the requirements of operational and engineered protective measures is undertaken, the results of which are applied during the entire project design phase. The RPP-WTP contractor approach to facility design applies a suite of company targets to facilitate compliance with RPP-WTP contractor standards and compliance with applicable radiological exposure standards. Where practical, passive features are used rather than active features. Potential faults are minimized by a design that moves the facility towards a safe state in response to failures, or by incorporating permanently available, passive features that render the facility safe following a failure. In some cases, however, it may be necessary to incorporate active engineered features into the design of a facility that act in response to the fault to render the facility safe.

The following hierarchy of safety measures is incorporated into the RPP-WTP design.

1) Operational Preventive Measure (OPM) is a corrective action taken by an operator to terminate the development of a fault sequence. Examples include operator responses to system parameters, sampling and chemical analyses, control system indications or alarms, and procedural instructions. An OPM is considered the first line of protection against a hazard under normal facility operating conditions. Should the OPMs fail, protective systems and devices are designed to automatically operate.
2) Engineered Protection Systems operate automatically to prevent a hazard from occurring, and generally use hardwired trips, mechanical devices, or programmable electronic systems (such as programmable logic controllers) commensurate with the potential risk of the hazardous situation. If protective measures fail, a hazardous situation may occur, the consequences of which can be reduced by the action of mitigating systems.
3) Mitigating Systems attenuate the consequence of a hazardous situation once it has occurred. They include ventilation systems, radiological alarm systems, and evacuation systems.

Table 3-1 Outline And Content of Emergency Response Plan (Sheet 1)

Section Title	Content
Introduction	The purpose and scope of the plan is presented and all requirements applicable to the Project emergency response program are identified. A description of the operational use of the Emergency Plan and Emergency Plan Implementing Procedures is provided. The types of emergencies to which the Emergency Plan applies and does not apply are identified. A description of the boundaries, facilities, and site for which the Emergency Plan applies is provided. The concept on which emergency planning is based is discussed and the documents, reports, surveys, and assessments used to develop the Emergency Plan are referenced. A summary of the results of the RPP-WTP safety analysis is given.
Emergency Response Organization	The overall organizational structure of the Project, and the emergency response organization, including its relationship to the overall structure, is described. The functions, authority, and responsibility of all internal organizational elements with emergency responsibilities are delineated. The chain of command in the event of an emergency is identified. The organizational structure, authorities and responsibilities, and roles played by each position are defined and the succession of authority for each position is identified.
Offsite Response Interfaces	An overview of the relationships with offsite organizations is provided. A description of the agreements with state, federal, and other agencies, specifying the role of the agency, potential response, regulatory control, and notification chain required is provided. Also, a list of all memoranda of agreement and memoranda of understanding with offsite organizations is included.
Emergency Categorization and Classifications	The definitions of operational emergencies, emergency classes, and the criteria used to define an emergency are stated. A brief description of the methodology used to develop criteria is given and specific technical supporting documents are identified. The Emergency Action Levels (EAL) used to define an emergency are discussed. The methodology used to develop EALs is described and reference technical supporting documents are identified. The criteria for each emergency classification are stated. Personnel (positions) responsible for declaring an emergency and their required qualifications and training are identified.
Notifications and Communications	The required and proceduralized notification process for onsite and offsite notifications for all operational emergencies is discussed. Personnel (positions) responsible for both initiating and receiving notifications are identified and the methods used to perform notification are identified. The notification procedure for termination of an incident is described. Personnel (positions) required to be notified for any emergency are identified. The circumstances under which the DOE and Hanford Site contractors are notified of an emergency are discussed and descriptions of the communications interfaces with offsite organizations are provided. Equipment, back up equipment, readiness assurance, and testing procedures are identified.
Consequence Assessment	The procedure(s) used to determine the potential consequences based on the results of hazard assessments and input from other pertinent areas are described. The methodologies used for consequence assessment and referenced technical supporting documentation are identified. The procedure for coordination with federal, state, and local organizations to obtain the information necessary to make accurate and timely consequence determinations is discussed.
Protective Actions and Recovery	The purpose and intended use of protective actions are discussed. The protective actions used at the facility and under what circumstances they are implemented, modified, or terminated, and how this information is communicated, both onsite and offsite are described. A description of the provisions for implementing protective actions at the facility and for recommending protective actions to offsite agencies is included. Conditions, procedures, and authorities for the protection of local populations are identified and the size of the plume emergency planning zone is provided. Discussion of the criteria for reentering areas under emergency conditions or reentering areas that have been access-restricted during the emergency is included. Provisions to place and maintain the facility in a safe state following an accident are discussed. Personnel (and their relationship to the emergency organization) who can develop, approve and, implement reentry are identified. A description of the system to ensure safe shutdown of operations following the declaration of an emergency is given.

Table 3-1 Outline And Content of Emergency Response Plan (Sheet 2)

Section Title	Content
Emergency Medical Support	The medical capabilities available onsite and offsite (e.g., local communities) to respond to an emergency are described. The transportation and evacuation capabilities, equipment, and the process for moving contaminated and non-contaminated casualties are described. The personnel (and their positions) with the responsibility and authority to evacuate injured or ill staff are identified.
Emergency Termination and Recovery	The plan and criteria for declaring an emergency condition terminated and for transitioning to recovery activities is described. Termination authority and responsibility, recovery criteria for protection of workers and the general public from hazardous exposure, exposure guides for recovery personnel, facility accessibility (including recognition of uninhabitable areas), security considerations, access to protective clothing and equipment, availability of medical assistance, and requirements for establishing the recovery organization are identified.
Public Information	The program to provide information and answer questions concerning the emergency to workers, media, and the general public, including information release approval, is described. The facilities and communications equipment used to disseminate information to the public are identified. The education program to inform workers and the public of the dangers present, and provide information that can be used for emergency actions, including recommended evacuation routes and sheltering is discussed.
Emergency Facilities and Equipment	All primary and back up facilities to be used for emergency response and the equipment capability and limitations, quantity of equipment, locations (both fixed and portable equipment), consumables, maintenance requirements, certification requirements, expiration dates, and computer/communications compatibilities are listed and described.
Training and Drills	The goals and objectives of the training and drills program; courses given to emergency management personnel; and identification of training requirements for key emergency management positions and response teams are provided. The periodicity of courses and employee requirement for training and retraining or refresher training are identified. Also described are the system of training available to, and required for visitors, vendors, and subcontractors; the training available to offsite organizations, and supporting organizations in order to support their abilities to participate in site emergency response actions; and the system of recordkeeping to verify training requirements are met. The drill program, including the goals, frequency, complexity, and integration of lessons learned into emergency planning is described.
Exercises	The intended purpose of the exercise program is discussed. How exercises are controlled and evaluated, and how lessons learned from exercises, improvements, and/or corrective actions, are incorporated into emergency planning is described. The varying degree to which outside agencies will participate in exercises is also discussed.
Program Administration	The Project Emergency Management Program Administrator is identified. The procedure used to control the Emergency Plan and to ensure periodic review and update; and the site internal assessment program are described. The provisions for document control and records management are provided.

Application of the design standards results in a facility in which systems operate safely, with operators monitoring the systems so that actions can be taken to terminate the development of a fault sequence. However, no credit is taken for that operator response, so the facility is designed with engineered features that will function automatically to prevent the development of hazardous situations. If system operations, operator actions, and engineered features fail to preclude the event, mitigating systems are designed to attenuate the consequences of the event.

Another important aspect in safety system design is the evaluation of the conditions in which the systems are expected to operate. The design will incorporate the expected environmental conditions into the specifications for the SSCs that must function to prevent hazardous situations or mitigate the consequences of accidents. Requirements regarding the environmental qualification of Safety Design Class systems and components, including considerations for aging, are provided in SRD Volume II as Safety Criterion 4.4-2. While suppliers of Safety Design Significant systems and components are not specifically required to provide test results relative to aging, the procurement specifications for these systems and components will specify the environmental conditions (e.g., temperature, humidity, and radiation field) to be expected during normal operation and the accident duration for which the system component must function. Specifying Safety Design Significant systems and components in this manner provides reasonable assurance to DOE that they will perform their safety function when required.

The safety system design process for the RPP-WTP uses a project-wide approach for the classification of the SSCs based on their importance to accident prevention and mitigation. This approach ensures that specifications for SSCs are commensurate with the importance of the functions that need to be performed.

Safety Design Class SSCs are those necessary to ensure that the radiation and chemical exposure standards for members of the public or workers are not exceeded as a result of accidents. The Safety Design Class designation is also applied to those SSCs necessary to prevent criticality events. The highest levels of design, quality assurance, and operational requirements (e.g., periodic testing and preventative maintenance) are applied to Safety Design Class SSCs.

Safety Design Significant SSCs are those needed to achieve compliance with the radiological or chemical exposure standards for the public and workers during normal operation. SSCs are also designated as Safety Design Significant if they place frequent demands on, or adversely affect the function of, Safety Design Class SSCs if they fail or malfunction. High levels of design, quality assurance, and operational requirements are applied to Safety Design Significant SSCs.

Additional information on the SSC classification process is provided in ISMP Section 1.3.10, “Classification of Structures, Systems, and Components”.

3.12 Human Factors

In the design of the Project, careful attention is paid at every interface between the operating personnel and the facility to ensure that good human factors and ergonomics practices are followed. This ensures the facility is user-friendly to minimize errors of omission and commission and to ensure the operator is in the best possible position to respond to those situations in which human response is beneficial or required. Attention is given to the placement of instruments and controls in the control room to ensure that clear and unambiguous indications of facility status to the operators. The acceptability of instruments placement is confirmed by constructing a physical or computer mockup of the panels prior to fabrication of the panels. This mockup ensures that compatibility with human psychology and physical characteristics is achieved and enables the required human tasks to be performed reliably and efficiently.

Human factors specialists conduct human factors reviews of training, operator capabilities, work spaces, and the design of the Safety Design Class and Safety Design Significant SSCs and functions that are judged to be critical to facility performance and that have a high potential for human error. These specialists will have many years of experience on a wide variety of nuclear or chemical facilities, including facilities similar to the RPP-WTP. During the early design phase, the specialists identify opportunities for design improvement and provide recommendations to address human factors principles and processes. The specialists conduct interviews with operations personnel from similar facilities to identify lessons-learned relative to human-machine interfaces. In addition, information from incident databases is used to identify where human-machine interfaces are contributing factors in recorded incidents. Human factors specialists are involved in the specification and use of mockups and models of instrument panels and controls rooms. These specialists are also involved in the performance of task analysis that evaluates the functions to be performed by operating and maintenance personnel against the facility design, procedures, and training.

Task analyses are carried out on operations that involve personnel and required to maintain the safety functions of the facility. This includes analyzing the demands on the operating personnel in terms of perception, decision making, and action. The analyses provide an assessment of the feasibility of the proposed tasks and an input to the design of interfaces in accordance with human capabilities. The results of such task analyses also provide the basis for the development of the design, the operating procedures, and personnel training.

Personnel with safety responsibilities are provided with expectations for their safety functions. These expectations include the responsibilities of the operations personnel who monitor and control facility response to faults as well as the responsibilities of those personnel who perform tests, maintenance, or other activities.

The design effort commences with the general layout of the facility and continues through the detailed design stages for each aspect of human involvement during the life of the facility. Adequate instrumentation in the control room and at local control stations is particularly important to allow operators to detect and correct abnormal conditions. Display systems, panel layouts, and workspace access are also important to ensure that routine and special maintenance can be completed safely.

These considerations support the formation of the basis for interactions with other aspects of human factors design, which include training, the preparation of operating instructions, the proposed staffing levels, and the implications for safety management. In this respect, training of operations personnel and other staff is influenced to ensure compatibility with the proposed facility operating regime, and the operating procedures are developed to ensure full compatibility with the design of the tasks and the design of the equipment. Operating instructions are validated for reliable interpretation and implementation by the user. The validation includes the interactions with initiating, sustaining, and terminating cues. The staffing levels are proposed based on the results of the human factors studies to ensure that adequate levels are achieved at all times.

3.13 Reliability, Availability, Maintainability, and Inspectability (RAMI)

To ensure that the facility meets operational requirements, it is necessary to address issues associated with reliability, availability, maintainability, and inspectability.

Reliability is used as a measure of the ability of an item or system to complete a task, and it is normally expressed as a probability of failure. Reliability is designed in through the use of appropriate design techniques and control of the mode of operation and the environment. Design techniques to be used vary because they are dependent on the specific item or system and the task to be performed. Their purpose is to optimize reliability by the following:

1) Use of proven materials and components
2) Design simplicity
3) Testability
4) Control of manufacturing standards
5) Control of operational mode (e.g., prevention of misuse and overloads)
6) Control of environment (e.g., protection against corrosion and vibration).

Consistent with the process for tailoring hazard controls using the potential radiological and chemical consequences of individual events, reliability is assigned to SSCs based upon the importance of the SSC to the prevention or mitigation of accidents. The significance of accident prevention and mitigation is determined by the severity of the accident to workers or the public. To implement this tailoring in a clear, consistent, and defensible manner, an Implementing Standard for Safety Standards and Requirements Identification was developed. This Implementing Standard includes a Severity Level ranking system which provides the hazard assessment and control teams with a defined way to categorize the potential severity of those events that can result in radiological or hazardous exposure to the workers or the public. The Implementing Standard provides the means by which the hazard assessment and control teams establish target reliabilities for SSCs.

Availability is a measure of the degree to which an item or system is in an operable condition. It is expressed quantitatively as the ratio of the mean time between failures to the sum of the mean time between failures and the mean time to repair. System availability is calculated to determine the potential for downtime. In this way, systems are identified that contribute to decreased availability. Required availability is achieved by specifying additional systems or increasing reliability of existing systems.

Maintainability is a measure of the ability to restore a failed item or system to an operable condition in a specified time. Maintainability is designed into the facility and processes through use of appropriate design techniques, (e.g., the use of specially designed, remotely removable, and replaceable pumps and valves in process systems, and the placement of active pumps or valves within shielded accessible areas equipped with appropriate decontamination facilities that allow hands-on maintenance activities) and logistic support (e.g., scheduling and procedures). Benefits of these design techniques are that they simplify maintenance operations in high radiation areas and remove high maintenance equipment from high radiation areas.

Testability of Safety Design Class systems and components is facilitated by such features as redundancy that allow for a system or component to be removed from service for maintenance or testing without loss of safety protection.

Inspectability is the measure of the ease with which items or systems can be inspected for preventative maintenance or assessment of condition. Inspectability is used to monitor facility items in order to maintain their reliability. Inspectability of facility items can be designed in by the use of shielded access areas (as above, to reduce radiation exposure) for active equipment or the provision of monitoring equipment (e.g., material coupons for determining vessel corrosion rates, and in-cell cameras).

During the design phase, the RPP-WTP and processes are evaluated for reliability, availability, maintainability, and inspectability. BNI uses a number of validated modeling techniques (computer codes, mathematical modeling, failure modes, and effects analysis) for determining reliability and availability of the facility and processes. These are used to identify those facility and process areas that are sensitive with respect to influencing overall facility and process performance. Optimum reliability is established by the use of appropriate standards and quality control. The determination of maintenance and inspection needs is based on facility and process reliability requirements. It is a mixture of process optimization, provision of appropriate design features to aid preventative and scheduled maintenance and inspection, and the development of maintenance and inspection programs (administrative and procedural controls) whose objectives among other things, are to facilitate these activities. Reliability targets are assigned to SSCs only when a quantitative value has been credited for the reliability of an SSC in safety analysis.

A hypothetical example of the application of RAMI to the RPP-WTP is the cooling water supply system to the technetium/cesium product storage tank. Cooling water is supplied to the this vessel to keep the contents from boiling thereby preventing the release of radionuclides and steam to the ventilation system. Failure of the cooling water system supply could lead to a hazardous situation or, at the least, operability concerns. The system comprises a closed-cycle primary system supplying chilled water to cooling coils within the vessel. Chilled water is supplied via a secondary chilled water circuit and heat exchanger. It should be noted that physical considerations indicate that the tank contents may reach their boiling temperature, but the predicted time required is on the order of several days. A conservative estimate of the minimum time to boiling assumes there is no heat transfer from the tank (ISAR Section 4.7.2.4, “Technetium/Cesium Product Storage Tank”).

This supply system is analyzed using a commercially available computer program. The system is first broken down into major components (e.g., pumps and valves); for each component reliability data are obtained and an acceptable repair time specified. The computer model calculates total availability of the system throughout the “operating life” of many years. The overall reliability of the system is then determined by application of fault tree analysis. Failure rates for postulated faults are determined and sensitive items of the system with respect to failures are identified.

No maintainability of the in-cell components (primary circuit) is required, as the design takes this into account (e.g., all welded pipework and enhanced testing). Inspection of the primary circuit takes place either indirectly through the use of coupons within the circuit to assess corrosion rates of the pipework and cooling coils or directly through visual (closed circuit television) means.

3.14 Commissioning and Operation

A structured test program ensures that SSCs function correctly against their specific performance requirements, including safety functions. The test program depends on the facility design being systemized, which allows each individual system to be fully tested in isolation before being integrated with the others leading towards full facility operation. Design documentation, such as process and system descriptions, are used as a resource to develop the startup testing program. Full facility operation is dependent on the successful demonstration of the process performed by the facility. Facility operation is not initiated until the systems testing adequately demonstrates their performance objectives in support of the process. Fault detection sooner rather than later is the philosophy to ensure cost-effective design, manufacture, and fabrication, leading to a structured design and testing methodology with the emphasis on systems analysis early in the design process. The RPP-WTP is systemized for design and procurement, allowing the BNI design and testing philosophy to be applied consistently with the Tank Farm facility.

The RPP-WTP includes chemical process and mechanical handling operations, performed by a number of mechanical, electrical, instrument, and control systems contained within a suitable civil structure. Each system is tested to demonstrate performance, as scheduled by a test plan, and is only integrated with other systems when test acceptance criteria have been met.

During testing, diagnostic data are collected, and the initial operating parameters recorded. Operating points are adjusted to conform to the design basis of the system or component. Deficiencies detected in testing are tracked to ensure their resolution.

The method of testing is predetermined to be either analysis, demonstration, or examination, depending on the function performed and the type of SSC. Testing begins at the component level. Only components that have met qualification requirements are integrated into their respective system. Each system is tested, as appropriate, with particular attention given to the system interface(s) with its associated system(s). These interfaces are simulated for the purposes of testing.

Manufactured systems and components are typically tested at their point of fabrication, and held there until proven acceptable for delivery to the construction site. All installed systems are subject to installation and startup tests, to ensure that they perform as they did at their point of manufacture, and that they have not been damaged during transit. These tests include energizing equipment and checking mechanical operation, instrument calibration, electrical cable continuity, and pipe and structural integrity.

A phased testing program is implemented for the RPP-WTP, with the testing schedule established by the availability of systems and their dependence on associated systems. Specific tests are implemented for each system including testing of the supporting or supported systems. Interface testing is of prime importance to the success of testing in this phased manner because the consequences of failure affects the overall schedule. System integration only occurs when each end of an interface has been adequately tested to give confidence that integration will succeed.

When systems have sufficiently demonstrated their ability to function, process operation may begin. A series of system performance demonstrations (SPD) are typically performed to commission new facilities, and the number of SPDs depends on the function of the facility and the materials handled. For the RPP-WTP, the following four levels of SPD are demonstrated:

1) Process systems using water (cold test)
2) Mechanical handling systems (cold test)
3) Facility operation using simulants (cold test)
4) Facility operation using active materials (hot test).

All SPD levels are not applied for all systems and components. For example, the first level would not be applied to the melters or vent systems.

Because the fourth-level SPD is the first time that the facility becomes radioactive, faults identified during previous testing can be corrected without any decontamination costs or radiological hazards. On successful completion of the fourth-level SPD, the facility is ready for normal operations.

The involvement of operations personnel throughout the design process and the involvement of design engineering personnel through the beginning of operations when the facility is turned over to operations are key elements in the design and testing philosophy. The development of facility control system simulators in advance of facility testing also strengthens the ability and confidence in the performance of the facility control systems and operator interfaces.

Such simulators have several purposes: they allow testing of the control systems software offline, without risk to personnel or the facility; they permit proving of the testing, commissioning, and operational procedures and documentation; and they facilitate training of operational and maintenance personnel so they may support testing. Integration of design and operating personnel during testing is important to the successful turnover of the facility for operations because it ensures a relatively smooth transition. These activities ensure that the facility is able to demonstrate operational readiness independently of the testing schedule and in advance of hot testing activities.

3.15 Training and Qualification

Training plays an important role in the safe operation of the RPP-WTP by ensuring that personnel have sufficient knowledge to safely fulfill the roles and responsibilities of their assigned jobs. Operator training for normal operation takes benefit of facility design information, results from the startup test program, operation of similar facilities, and operation of Project demonstration facilities. Training for accident conditions is based, in part, on the safety analyses performed for the RPP-WTP including the hazard analysis and accident consequence analyses.

The training objectives include the following:

1) Improving technical ability (understanding of processes)
2) Enhancing of personal skills (communication, worker-management)
3) Increasing awareness of the workplace and signs of potential hazardous situations

4) Educating personnel in the importance of acting with regard to their own safety and the safety of others
5) Establishing a safety culture that assigns safety responsibility to the individual.

A training plan, described in ISAR Section 3.4, "Training and Qualification", incorporates the above objectives. The plan notes the following requirements that constitute a thorough approach to personnel training and qualification for the RPP-WTP.

1) Recognition of the different types of training that is required. For example achievement of a necessary level of job competence, knowledge of the requirements of applicable laws and regulations pertaining to the handling of radioactive and chemical materials, specialist training for maintenance activities, and detailed knowledge of process operations.
2) Assessment of training needs. Training is most effective when matched to the needs of the individual. This can happen with two-way communication between the training section and the individual. Each person is assessed on training needs, in conjunction with their line management and training personnel. These needs vary from individual to individual and are dependent on job type.
3) Clear definition of responsibility for training. The plan outlines which functional office within the Project is responsible for training and how this responsibility for training was assigned. Personnel are encouraged to take an active interest in their own training and development and are able to discuss with their line management how their needs can best be met.
4) The establishment of learning objectives. These objectives are derived from analyses that describe the desired performance after training.
5) Training requirements evolve as the facility and its safety program evolves. As the facility and process develop from design to testing and operations, and lessons learned from other facilities become available, training information and requirements change. For example, facility operators may need training in a new type of process developed as a result of a facility modification during operations. The training program is flexible to reflect changing requirements. However, training is continuous to reflect these changing requirements and to ensure that job proficiency is maintained; it is not driven solely by changes to administrative or engineered controls.
6) Training evaluation. A feedback process is established to ensure current training needs are being met by assessing the following:
   a) The training being given is appropriate for the task and effective (i.e., individuals learn from the training)
   b) Personnel performance in the job setting
   c) Requirements for new or updated training are being met.
7) Auditability. The training program and individual development are visible. The maintenance of training log books and regular appraisal of an individuals training needs are important in demonstrating that the RPP-WTP personnel are always correctly trained in the current procedures. The training program is evaluated by oral testing, written exams, or assessment of the work product.

Training and qualification credited for public and worker safety are in accordance with the requirements of the QAM. The program for establishing the qualification requirements for RPP-WTP personnel is summarized in ISMP Section 6.1.3, "Personnel Qualification and Resources". Details on the training and qualification programs are described in ISAR Section 3.4, "Training and Qualification".

3.16 Internal Safety Oversight

Internal safety oversight for the Project involves several oversight functions to ensure safety of the public and workers and to preclude environmental degradation. These internal safety oversight functions include corporate safety assessments, management assessments, independent assessments and audits, safety committees, incident investigations, maintenance of the authorization basis, and the USQ process. In ISMP Section 5.4, "Compliance Audits", and Chapter 10.0, "Assessments", other facets of internal safety oversight are covered. Several administrative functions provide information on the adequacy of the oversight functions and also provide information used to define the scope of future internal safety oversight functions. This information includes: performance monitoring; performance indicators; lessons learned and industry experience; and feedback and trending.

The staff possess the unique skills to perform internal safety oversight. Some of the skills applied are as follows:

1) Conducting performance-based assessments that emphasize work activity in progress
2) Reporting deficient conditions to line management
3) Following up on corrective actions to prevent a recurrence of the deficiency
4) Applying performance trending to determine existence of programmatic issues and plan for future oversight areas
5) Understanding the requirements of the Price Anderson Amendments Act and 10 CFR 820, "Procedural Rules for DOE Nuclear Activities"
6) Assisting line management to establish a positive safety culture
7) Incorporating applicable lessons learned from previous RPP-WTP incidents and industry experience at other DOE sites and the commercial power industry to the project oversight program
8) Maintaining a continuing interaction with the RPP-WTP regulator on the status and direction of project oversight activities.

Internal oversight may include participation of staff external to BNI. The external members are selected based on their experience and qualifications to provide different perspectives or expertise in specific functional areas.

3.16.1 Safety Committees

The Project Safety Committee (PSC) structure provides the overview, review, and approval functions for nuclear, radiological, and process safety, occupational safety, and environmental protection matters. The RPP-WTP contractor Executive Committee addresses corporate safety policies and matters as they relate to the Project. The RPP-WTP PSC addresses RPP-WTP-specific safety policies and regulatory requirements. This two-tier structure affords open communications and sharing of relevant information between the corporate staff and the Project.

During the design and construction phase, the Executive Committee and the RPP-WTP PSC focus on nuclear, radiological, and process safety (as related to the development of the facility design and operations) and on worker safety (as related to construction activities). As the construction phase nears completion, the safety committees' focus shifts to commissioning activities and preparations by the various Project organizations to ensure the effectiveness of their nuclear and worker safety programs during operation. During operation, the committees focus on operations, management, performance of personnel, equipment, and systems, and incidence reporting. Near the end of waste processing operations, radiological control and worker safety during deactivation also are addressed.

As part of safety communication throughout the Project, workers will be invited to participate in the safety committee meetings (e.g., during regular updates on worker safety performance, review of proposed corrective actions for incidents involving worker activities). Facility operators also serve as active members on other RPP-WTP safety committees.

3.16.1.1 RPP-WTP Contractor Executive Committee

The RPP-WTP Contractor Executive Committee provides independent oversight and review of Project matters that affect nuclear, radiological, and process safety; occupational safety; and environmental protection. The membership comprises the RPP-WTP Project Manager and senior level management of the RPP-WTP Contractor corporate organization. To accomplish its objective, the Executive Committee periodically reviews areas such as:

1) Safety programs that implement RPP-WTP policy and regulatory requirements applicable to the Project
2) Recommendation of the approval to proceed with hot operations
3) The significance of new regulations applied to Project programs, procedures, and policies
4) Unusual and off-normal incident reports
5) Reports and meeting minutes issued by the PSC
6) The effectiveness of Project safety programs and associated management controls.

The Executive Committee also initiates special independent assessments or audits, as necessary, to obtain additional information concerning the effectiveness of programs or management controls at the Project.

3.16.1.2 Project Safety Committee

The PSC provides advice to the Project Manager on matters related to safety. PSC members are specified from facility management and staff. Specialists in specific fields and external subject matter experts may also be specified, as required. The members are specified from several different organizations and backgrounds to ensure that advice on safety matters is representative of an integrated evaluation of the matters under consideration.

The PSC Chairperson coordinates and facilitates the committee decision making process to achieve consensus on decisions and recommends approval by the Project Manager or designee.

The PSC reviews the management and the performance of the RPP-WTP nuclear, radiological, process, and occupational safety and environmental protection activities, including the following:

1) Results from the Safety Improvement Program
2) Identification, resolution, and implementation of recommendations and corrective actions resulting from nonconforming items or activities, incident investigations, audits and assessments, inspections and reviews, or emergency exercises
3) Unusual and off-normal incident reports, including TSR violations
4) Reports covering such topics as proposed RPP-WTP modifications, emergency exercises, and the implementation of findings from management assessments
5) Performance indicators and trends of the RPP-WTP for worker, public, and environmental safety activities
6) Results of training programs for safety-related activities
7) Operating problems
8) Effectiveness of the safety/engineering interface with respect to the incorporation of safety and environmental requirement in the design.

The PSC is also responsible for reviewing and recommending approval to the Project Manager or his designee, for safety-related documents, such as the following:

1) Proposed changes to the authorization basis
2) Positive USQ determinations prior to submittal to the regulator
3) Procedure development processes and selected facility procedures
4) Proposed Important-to-Safety design changes
5) Responses to Notices of Violations from the regulator
6) Authorization requests and other regulatory submittals
7) State of Washington permits and license applications
8) RPP-WTP pre-operational testing programs including summaries of test procedures and test results

The PSC reviews audit and assessment reports and recommends actions.

The PSC may make use of subcommittees, as appropriate, to provide oversight to specific functional areas or complete specific tasks or evaluations.

3.16.2 Safety Improvement Program

A safety improvement program is developed and implemented by the PSC. The key theme in the safety improvement program is that it is owned by all RPP-WTP personnel with the demonstrable commitment and leadership of senior RPP-WTP management.

The safety improvement program is coordinated, monitored, and implemented by the following:

1) The establishment of the PSC to oversee safety performance
2) The establishment of safety improvement groups to identify and implement improvement initiatives within their work area
3) The senior management support and demonstrated commitment to the PSC by attendance at committee meetings
4) The reviews of safety performance and implementation of safety improvement action plans about four times per year via an appropriately constituted review group established by the PSC. Representatives are selected based on the scope of the review, personnel expertise required for the review, and personnel qualifications.

3.16.3 Incident Investigations

Incident investigations involve the identification, categorization, notification, reporting, and processing of information related to incidents, emergency events, and accidents associated with the RPP-WTP. Incident reports are sent to the DOE Occurrence Reporting and Processing System. Although the incident reporting process is usually initiated with operation of a nuclear facility, the process is developed and implemented for the RPP-WTP construction and testing activities in preparation for operation.

The incident investigation and reporting procedures, and the training to these procedures, ensure that the RPP-WTP regulator, the DOE Program Office, and RPP-WTP management are kept informed on a timely basis, of events and conditions during construction, testing, and operational activities that could adversely affect quality assurance, security, environment, operations, or the health and safety of the public and workers. Incident reports are evaluated for a potential noncompliance to a nuclear safety requirement reportable by the requirements of 10 CFR 820 “Procedural Rules for DOE Nuclear Activities”.

For an incident that indicates a potential inadequacy of previous safety analyses as defined in an approved safety analysis report or that indicates a possible reduction in safety margins as defined in the TSRs, actions are taken to place or maintain the facility in a safe state and a safety evaluation is performed. The completed safety evaluation is submitted to the regulator before removing any operational restrictions initiated in response to the incident.

Additional detail on incident investigations is included in ISMP Section 5.6.7, “Investigation of Incidents” and ISAR Section 3.7, “Incident Investigations”.

3.16.4 Unreviewed Safety Questions

1) The probability of occurrence or the radiological or chemical consequences of an accident or malfunction of equipment important to safety, previously evaluated in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis, may be increased
2) A possibility for an accident or equipment malfunction of a different type than any evaluated previously in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis, may be created
3) Any margin of safety is reduced.

Proposed temporary or permanent changes to administrative and engineered controls are reviewed by qualified USQ evaluators to determine if they would involve a USQ. An activity will not be undertaken without DOE review and approval if the initiation of the activity would itself involve an unreviewed safety question. If the proposed change does involve a USQ, one of the following three options are pursued.

1) The proposed activity is abandoned.
2) The proposed activity is modified to remove the USQ.
3) The proposed activity is submitted to the regulator for review and approval prior to completion of the activity.

The following organizations have key roles in the RPP-WTP USQ process.

1) The ES&H Organization is responsible for the developing the USQ procedure, developing the training and qualification requirements for USQ evaluators, and maintaining the list of qualified evaluators.
2) The Facility Manager approves the USQ procedure and the training and qualification requirements for USQ evaluators.
3) The Configuration Management Organization is responsible for establishing and implementing the process by which proposed changes, tests, and experiments are reviewed by the USQ process.
4) The PSC approves USQ determinations prior to their submittal to the regulator.

3.16.5 Performance Monitoring

Performance monitoring is used at the RPP-WTP to verify that ES&H and other RPP-WTP programs, plans, and procedures exist; are in place; are adequate; are functioning as designed; and are in compliance with applicable regulatory or permit requirements. Performance monitoring is conducted by a RPP-WTP multidisciplinary team consisting of quality assurance, environmental protection, industrial safety, process safety, health physics, nuclear safety, and regulatory staff. Performance monitoring includes, but is not limited to, reviewing records, plans, and procedures; visually observing operations/activities; and interviewing key personnel. Findings are provided in written reports with recommendations for improvements as applicable. During design and construction, the findings are provided to the Project Manager and during pre-operational testing, operation, and deactivation, the findings are provided to the Facility Manager.

Performance monitoring is conducted to ensure high standards of performance in the following areas:

1) RPP-WTP site monitoring program
2) Health and safety program
3) Personnel training program
4) Employee concerns program
5) Hazardous material inventory and waste tracking systems
6) Facility safety requirements
7) Conduct of operations and maintenance
8) Environmental program
9) Housekeeping
10) Employee compliance to established safety and quality criteria (See ISMP Section 3.4, “Safety/Quality Culture”)
11) Quality Assurance Program.

3.16.6 Performance Indicators

Performance indicators for safety and environmental protection objectives are established for the Project. Performance is monitored on a periodic basis to determine progress of the Project in achieving these indicators. Examples of performance indicators are as follows:

1) A change in the number of lost-time accidents and recordable injuries
2) Radiological exposures of facility personnel
3) Radiation workers exceeding a specified annual exposure level
4) Operation outside the established limits for discharge and disposal of waste
5) Entry into TSR actions statements for reasons other than TSR-required surveillance

6) Violations of TSRs
7) Findings of audits and assessments
8) Unusual incidents
9) Maintenance backlog
10) Effectiveness of the maintenance program (e.g., time to repair, control room annunciators, and equipment out of service)
11) Fire impairments.

3.16.7 Lessons Learned

The lessons-learned program, established and maintained by the ES&H Organization, includes the identification, documentation, validation, and dissemination of lessons-learned information from the Project. An industry experience program that draws on lessons learned, events, deficiencies, and other similar information from other operating sites for the purpose of enhancing the safety of the facility will be established early in Part B.

This information is used in the revision of applicable procedures, development of training curricula, and in the modification of training materials. Personnel potentially affected by lessons-learned material can participate in this training process by providing feedback on information distributed and identifying information for potential inclusion in the process.

3.16.8 Feedback and Trending

As described above, incidents occurring in the RPP-WTP are used as lessons learned to feed relevant information back to appropriate RPP-WTP staff members and the training programs to assist in precluding recurrence. The lessons learned are applied in a broad manner within the RPP-WTP, rather than focused only on the specific administrative or engineered control involved in the incident. Significant lessons learned are provided to the Project Manager during design and construction and to the Facility Manager during operation and deactivation.

Trending within various performance areas, such as operations, training, and maintenance, is used to verify that continuous improvement is being achieved in the Project. In the event that repeat events, findings, or other deficiencies are indicated, follow-up actions are initiated to identify additional corrective actions needed to preclude further recurrence. These additional corrective actions are tracked to completion and their adequacy to correct adverse trends is verified. Adverse trends are also evaluated to determine the existence of a programmatic failure of nuclear safety requirements subject to reporting in accordance with 10 CFR 820, “Procedural Rules for DOE Nuclear Activities”.

4.0 Standards-Based Management

This chapter summarizes the development of the safety management processes and describes how activities and documentation are tailored to the identified hazards and hazardous situations.

4.1 Safety Management Processes

The Project safety management processes are developed through the safety approach as described in Integrated Safety Management Plan (ISMP) Chapter 1.0, "Project Safety Approach", and shown in Figure 1-1.

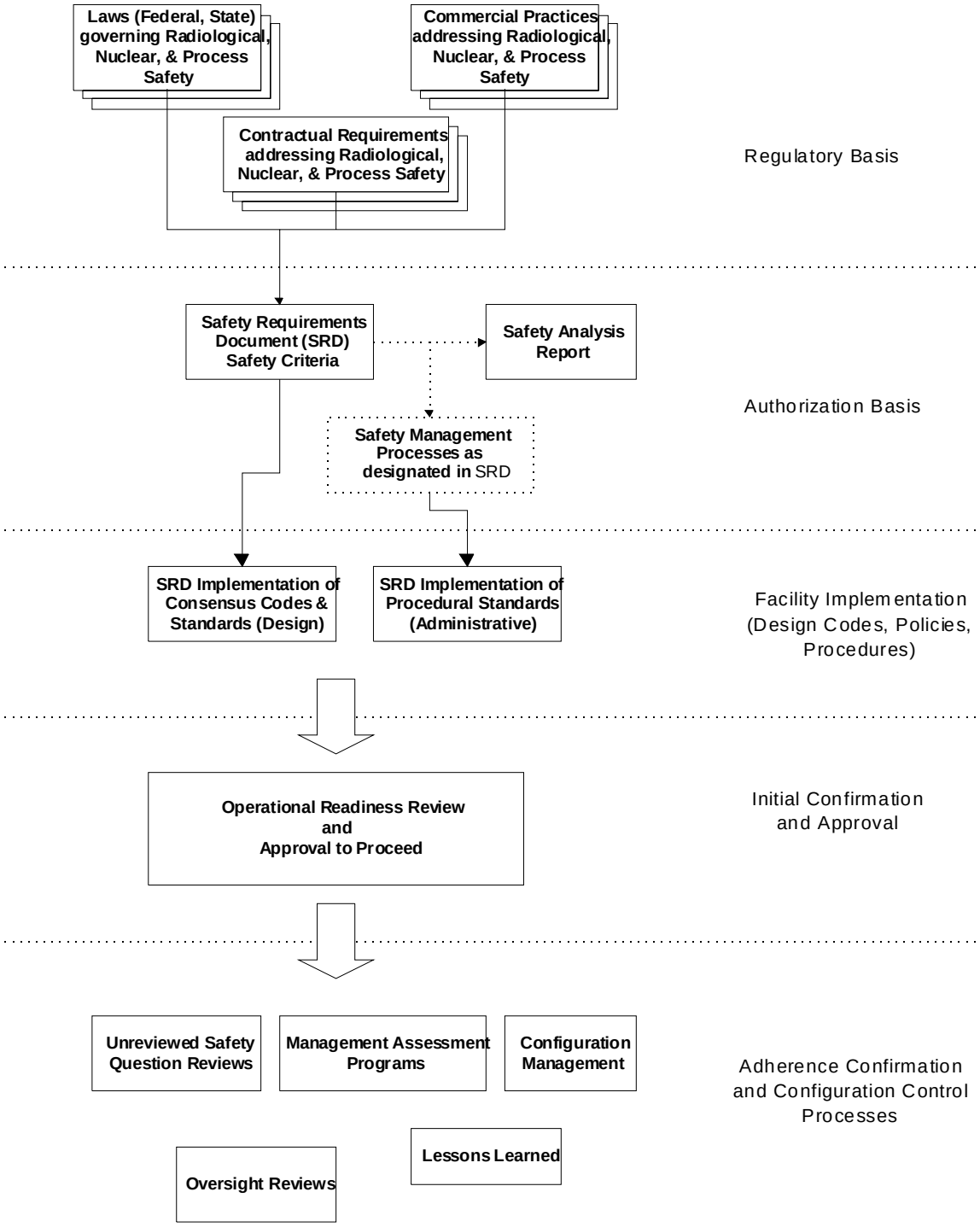
4.1.1 Development of Safety Management Processes

The safety management processes governing radiological, nuclear, and process safety are identified and developed as a part of the Safety Requirements Document (SRD) as shown in Figure 4-1. The SRD development process is discussed in the *Safety Requirements Document* (BNI 2001b).

Development of the Standards-Based Safety Management Programs through the safety approach as part of the SRD development has the following benefits:

1) Continually integrates hazards identification, SRD development, design development, and accident analysis during all phases of the facility life cycle through deactivation
2) Documents the safety management process drivers within the SRD. It also ensures the processes are established in accordance with the applicable regulatory, commercial, and U.S. Department of Energy (DOE) standards and the DOE Top-Level Safety Principles as appropriate to control hazards and hazardous situations associated with the RPP-WTP.
3) Adopts the use of "best industry practices" that include process safety management, a rigorous design process based on a set of credible accidents and a defense-in-depth philosophy, and verification of the level of facility safety through safety analysis and validation of requirements implementation
4) Documents that the facility design meets the required Safety Criteria and documents how and why the engineered and administrative controls credited for public and worker safety were identified. In Part B, when policies and procedures are written to implement the administrative controls, these policies and procedures will be identified in the SRD.

Figure 4-1 Safety Management Processes



4.1.2 Identification of Safety Management Program Drivers

Through the SRD development process, the following safety management programs are identified that:

1) Directly implement regulatory requirements for programs that provide protection of the public and workers from radiological, nuclear, and process hazards (e.g., Risk Management Plan, Radiation Protection Program)
2) Are credited for providing adequate protection to the worker or public (e.g., Emergency Preparedness Program)
3) Place controls on the design, operations, or maintenance of structures, systems, and components (SSC) that are credited for providing adequate protection to the worker or public (e.g., Configuration Management, Conduct of Operations, Quality Assurance, Maintenance).

The following sections outline the programs and identify the SRD sections governing the development of the safety management programs for the RPP-WTP.

4.1.2.1 Nuclear and Process Safety Program

The Nuclear and Process Safety Program addresses the Project integrated approach to nuclear and process safety. It identifies the methodology and Safety Criteria for assessing that the risks posed by the operation of the RPP-WTP are within the overall safety objectives and commitments. The Nuclear and Process Safety Program addresses the following attributes: prevention of accidents, accident and operations risk goals, defense-in-depth, hazards analysis; accident analysis; and criticality. These programs are defined in the SRD Volume II, Chapters 1.0 “Radiological, Nuclear, and Process Safety Objectives”, and 3.0 “Nuclear and Process Safety”.

4.1.2.2 Engineering and Design Programs

The Engineering and Design Program provides the principles governing the design of and identifying design expectations for those SSCs credited for protection of the public and workers. The engineering and design programs include topics such as the configuration management of facility and system design, design practices and procedures for SSCs credited for protection of public and workers, and the facility’s fire protection program. These programs are defined in the SRD Volume II, Chapter 4.0, “Engineering and Design”.

4.1.2.3 Radiation Protection Program

The Radiation Protection Program addresses the protection of the public and workers (when accessing controlled areas) in accordance with 10 CFR 835, *Occupational Radiation Protection*. The Environmental Radiation Protection Program addresses the protection of the public and the environment from normal activities that may release radiological effluents. These programs are defined in the SRD Volume II, Chapter 5.0, “Radiation Protection”.

4.1.2.4 Commissioning Program

The Commissioning Program addresses those requirements applicable to startup of the RPP-WTP and to other operational processes. Commissioning program topics include equipment and system acceptance, pre-operational testing, and validation of operational procedures. This program is defined in the SRD Volume II, Chapter 6.0, "Startup".

4.1.2.5 Management and Operations Program

The safety management programs covered under the umbrella of Management and Operations Programs address programs that establish principles governing the conduct of day-to-day operations which are important in maintaining a safe facility. Included in these programs are the following topics:

1) Management and organization
2) Training, qualification, and procedures
3) Commitment tracking
4) Quality assurance
5) Management assessments
6) Lessons learned
7) Unreviewed safety questions
8) Conduct of operations
9) Conduct of maintenance
10) Employee feedback
11) Incident investigation and reporting
12) Emergency preparedness.

These programs are defined in the SRD Volume II, Chapter 7.0, "Management and Operations".

4.1.2.6 Deactivation and Decommissioning Program

The Deactivation and Decommissioning Program addresses the commitment for deactivation and the design and operational considerations for decommissioning. As the facility approaches deactivation, requirements that provide adequate safety for the activities and inherent hazards of the deactivation process are added to the SRD. This program is defined in the SRD Volume II, Chapter 8.0, "Deactivation and Decommissioning".

4.1.3 Development of Safety Management Programs

The majority of policies, procedures, and instructions fully defining the safety management programs will be developed prior to commissioning of the RPP-WTP. Procedural development will be based on accepted industry practices for ensuring safety through adequate training, conduct of operations, and engineering and design programs. Procedures will be developed internally by the responsible Project organizations.

When developed, these policies, procedures, and instructions (administrative standards) are linked to the driver requirements (Safety Criteria) contained in the SRD. This linking of implementing standards to Safety Criteria ensures that the safety management programs, as defined in the SRD, are fully implemented.

In addition, the consensus codes and standards used in the design of SSCs are linked to SRD Safety Criteria. This link is implemented through Project documents like the Design Input Memorandum. Design guides provide additional detailed project-specific guidance and specifications for topical areas (e.g., radiation protection, human factors, natural phenomena design) and individual systems and areas of the facility (e.g., process ventilation system, melter cell walls, process offgas). All of these links are controlled to ensure that configuration management of the linkage to the SRD is maintained at all times.

Figure 4-2 shows the implementation of the SRD through the design process using these guidance documents.

A key feature of the SRD process is the ability to effect changes to the SRD (when such a change is appropriate). As shown in Figure 4-3, these SRD changes may arise as a result of design evolution or may be identified through the hazard evaluation process. Changes of the first type occur when a proposed design position offers benefits (cost, safety, reliability) but is not fully in compliance with the SRD as written. Changes of the second type may result from newly identified accidents or off normal conditions (indicated by dashed boxes). In either case, all activities are documented, and no change to the SRD is initiated without a formal review for compliance with the standards and requirements on which the SRD is based.

4.1.4 Compliance to and Maintenance of Safety Management Programs

The SRD applies to BNI project contractors.

Compliance to a standard which is included in Volume II of the SRD means that all mandatory statements (shall/will/must) applicable to nuclear, radiological, or process safety are implemented or deviations justified and approved by the DOE. Compliance with non-mandatory statements (should/may) are not required; but are reviewed and considered for each standard on an individual basis. This review is documented. Compliance to statements not applicable to nuclear, radiological, or process safety may in many cases be required to ensure compliance to regulations outside the scope of the DOE review (e.g., environmental protection); however, if no other regulatory entity requires compliance via the standard, compliance is not required to be reviewed on an individual basis.

Safety Management Programs will be scrutinized and revised, as appropriate, as a part of the biannual SRD revision process. This revision process incorporates updated hazards and design information as well as potential new regulatory requirements. This biannual review will ensure that the safety management programs are appropriately tailored to the hazards posed by the facility and comply with laws, regulations, and contractual commitments.

In addition, linking the implementing procedures to the SRD Safety Criteria provide a means of ensuring that revisions to these procedures are reviewed to confirm the safety management programs remain implemented.

Figure 4-2 SRD Link to Design

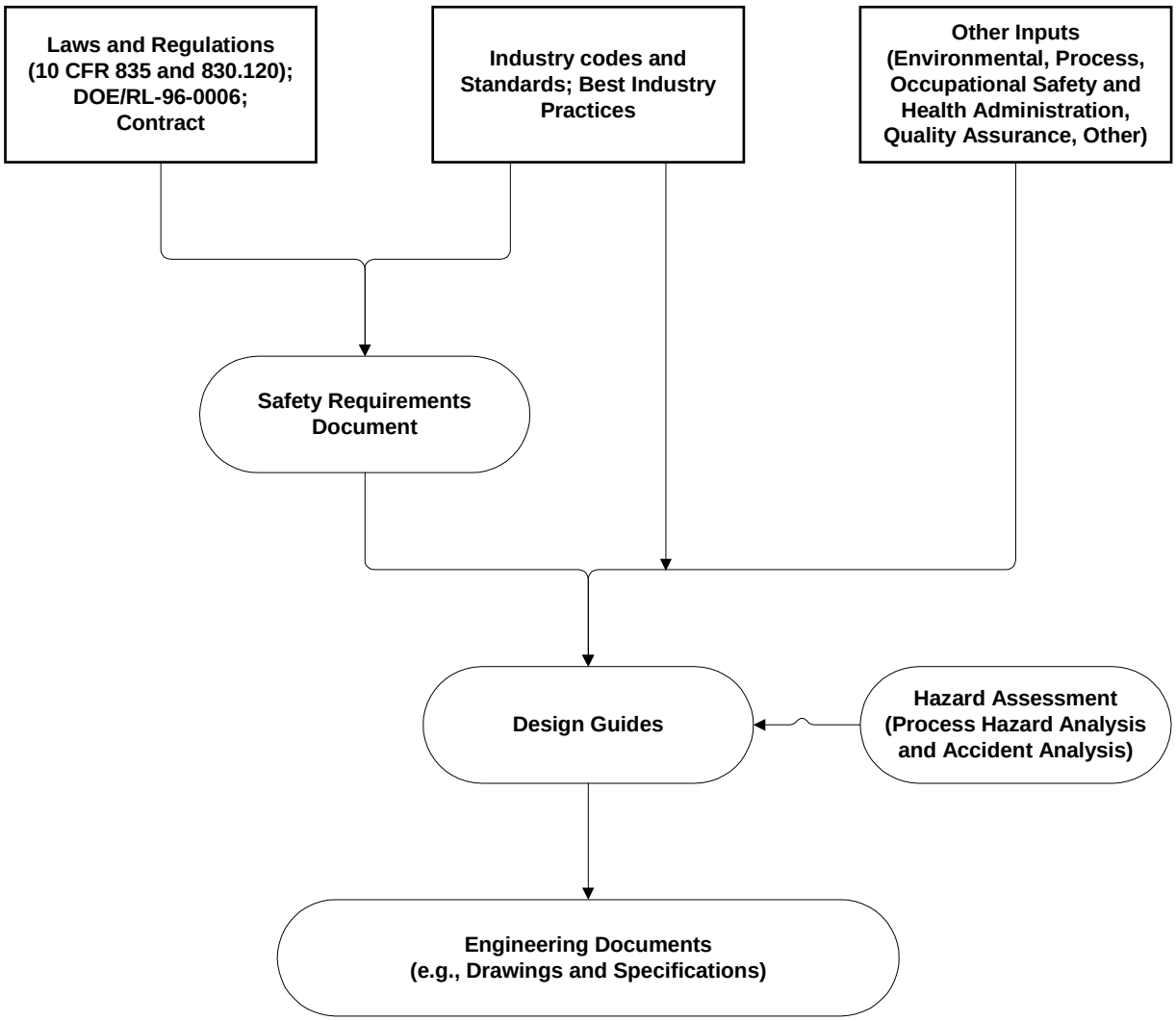
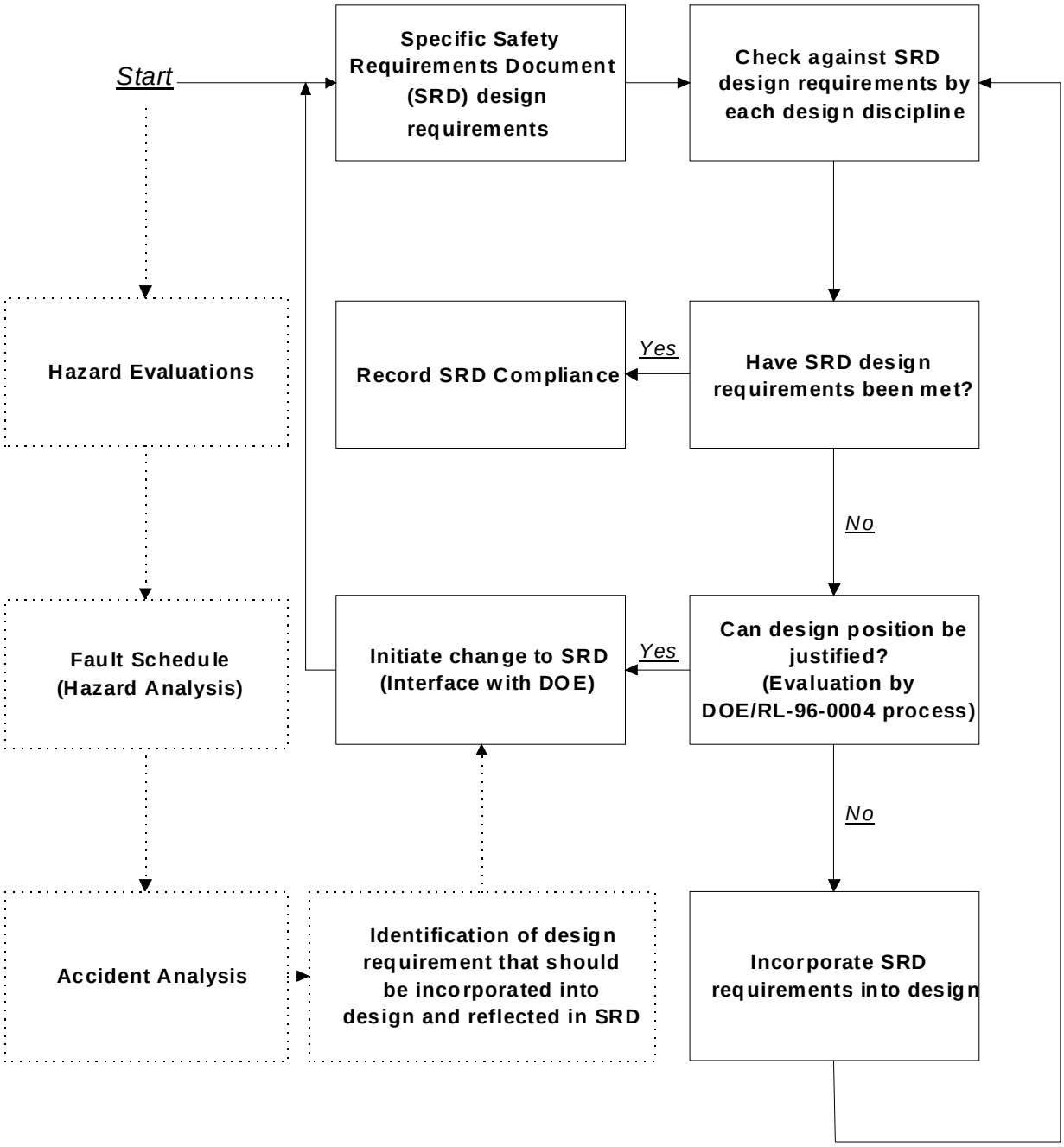


Figure 4-3 SRD Change Process



Proposed changes to the SRD are evaluated for impact on safety compliance with regulations and the authorization basis (including hazard and accident analysis) and then are reviewed and approved commensurate with the process applied to the original configuration, including regulatory approval before implementing changes that could be considered as decreasing the prescribed level of safety. The essential elements of DOE/RL-96-0004 *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, as addressed in the original development of the SRD, are maintained, including the use of subject matter experts and the use of an equivalent level or review and approval of the proposed change. Changes are made by an established configuration management process.

4.2 Tailoring Safety Management Processes

The aspects of the RPP-WTP design that are critical to safety are identified through Process Hazard Analysis (PHA). This process is a systematic team-based review of the facility and process designs that identifies hazards and hazardous situations to a level of detail commensurate with the available design detail. Major hazards and hazardous situations are identified as the level of design detail increases and additional PHAs are performed in Part B. Having generated the list of hazards and hazardous situations, this list is subject to a further systematic team-based review where a binning process takes place.

Hazardous situations are assessed and binned according to a qualitative, and experience, and team-based judgement of frequency and consequence (severity). This binning process receives benefit from the BNI team's experience with safety analysis and operation. Frequency bands are defined and labeled as normal, anticipated, unlikely, and extremely unlikely. Consequences range from negligible through minor to serious and major. The binning process is essentially risk based with categories of hazard defined according to a frequency/consequence matrix. This approach is consistent with the American Institute of Chemical Engineers (AIChE) guidelines on hazard evaluation (AIChE 1992). The binning process assigns hazards as acceptable, acceptable with controls, undesirable, or unacceptable.

In this way, a hierarchy of hazards and hazardous situations is identified. This hierarchy is reviewed and, where possible, the design is modified to eliminate hazards. Where this cannot be done, protection systems are identified that would prevent, protect against, or mitigate the hazardous situation. Protection systems would be a combination of engineered features (e.g., alarms, trips, and interlocks) and administrative controls (i.e., operator actions).

The application of protection systems is tailored to the hazard severity. For example, high-frequency hazards with severe consequences have protection systems involving diverse engineered features and training and procedures requirements as discussed in Section 4.2.2, "Training and Procedures". Less significant hazards would require fewer protection systems that may lean heavily on administrative procedures, the importance of which will have been stressed through adequate worker training. This ensures the appropriate level of safety is provided.

4.2.1 Engineered Features

Engineered features include SSCs that provide for public and worker safety. The design, fabrication, construction, installation, testing, operation, maintenance, and quality assurance requirements for engineered features are tailored by the classification process discussed in ISMP Section 1.3.10, "Classification of Structures, Systems, and Components".

4.2.2 Training and Procedures

Operator training and procedures ensure that the facility is operated safely. The development of the training and procedures during facility design and commissioning takes account of the differing safety requirements. Procedures support the safe operation of the facility in varying ways. A hierarchy of procedures is developed that reflects the level of safety importance. Factors that determine the level of safety importance for training and procedures include support they provide for maintaining compliance to the Technical Safety Requirements (TSR) and maintenance of Safety Design Class and Safety Design Significant SSCs. Those at the highest level are subject to increased rigor with respect to their development and implementation. Increased rigor means independent review and endorsement by suitably qualified and experienced personnel or safety committees. All procedures that have an impact on the safe operation of the facility are developed and implemented with a suitable degree of rigor commensurate with their safety importance.

Operator training and qualification requirements are tailored to operator requirements. Facility area operators are trained and qualified in their specific areas of operation, radiological and chemical hazards, and necessary emergency requirements (facility recovery and facility and site evacuation). Facility supervisors and operators with increased responsibility receive additional training (e.g., in specific operations, resetting of facility items required for safety, and emergency response). Training ensures that operators receive the necessary knowledge and experience to conduct operations with due regard for safety. Training of maintenance and technical personnel is tailored to the involvement of these personnel in the establishment and maintenance of administrative and engineered controls. More in-depth and frequent training is provided for those individuals involved with Safety Design Class and Safety Design Significant engineered features.

4.2.3 Tailoring of Safety-Related Documentation

The following sections describe how the safety analysis reports (SAR), Integrated Safety Management Plan (ISMP), Safety Requirements Document (SRD), TSRs, and emergency plan are tailored to the phases, hazards and hazardous situations of the RPP-WTP.

4.2.3.1 Safety Analysis Reports. The format and content of the Preliminary Safety Analysis Report (PSAR) and Final Safety Analysis Report (FSAR) are in accordance with the guidance provided in U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 3.52, *Standard Format and Content for the Health and Safety Sections of License Applications for Fuel Cycle Facilities*, draft (NRC 1995a). To facilitate the review of the SARs by the regulator, the SAR content also gives consideration to the review guidance provided in *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*, NUREG-1520, draft (NRC 1995b).

The format and content of the SARs are tailored to the nature of the RPP-WTP relative to the hazards and hazardous situations identified by the PHA. Table 4-1 lists the planned deviations from the format and content guidance of Regulatory Guide 3.52 in this regard. These deviations include both format changes in terms of added SAR sections and content changes for several of the SAR sections.

Table 4-1 Deviations from the Safety Analysis Report Content Guidance of Regulatory Guide 3.52 [1] (Sheet 1)

Chapters	Addition or Subtraction	Basis
1.3 Site Description	Regulatory Guide (RG 3.52) suggests that Section 1.3 summarize information used in preparing the Environmental Report. Specific information is referenced, but not duplicated in the safety analysis report (SAR).	The Environmental Report provides this information.
1.3.2 Demography and Land Use	The population distribution as a function of distance and direction is not to be provided. The distances to nearby population centers are provided.	There are no residences on the Hanford Site and the nearby population is low.
3.3 Quality Assurance	Section 3.3.4, "Quality Program Description", addresses the 10 criteria of 10 CFR 830.120, "Quality Assurance Requirements" in lieu of the 18 criteria listed in RG 3.52.	By contract compliance to the 10 CFR 800 series of nuclear safety requirements is required. This includes compliance to 10 CFR 830.120, "Quality Assurance Requirements". The differences in the criteria to be addressed are not significant because the quality assurance programs are based on consensus standards.
3.5 Human Factors	RG 3.52 states that a formal human factors program is not required if the facility has no requirement for safety-class actions. Human factors are considered in the Preliminary Safety Analysis Report (PSAR) independent of whether or not human actions are required for protection of the public or workers.	The requirements of DOE/RL-96-0006 (DOE-RL 1996a), Section 4.2.6, "Human Factors", extend beyond consideration of human factors as related to actions taken to protect the public. Final Safety Analysis Report (FSAR) Section 3.5 documents how compliance to contract Section 4.2.6 is achieved.
3.10 Testing Program and Preoperational Safety Review	This section is added to address the initial and commissioning testing programs.	Addition of this section facilitates documentation of compliance to DOE/RL-96-0006 (DOE-RL 1996b), Section 4.2.8, "Pre-Operational Testing", and Section 5.2.6, "Pre-Startup Safety Review", and DOE/RL-96-0003 (DOE-RL 1996a), Section 4.3.2, "Contractor Input", item 13.
3.11 Operational Practices	This section is to added to address such conduct of operations considerations as shift routine and turnover, control area activities, communications, control of on-shift training, control of equipment and system status, lockout and tagout, independent verification of equipment status, logkeeping, and operational aids postings.	These items are discussed to address what is normally considered conduct of operations.

Table 4-1 Deviations from the Safety Analysis Report Content Guidance of Regulatory Guide 3.52 [1] (Sheet 2)

Chapters	Addition or Subtraction	Basis
4.7 Results of the Integrated Safety Assessment	The results for unmitigated accidents are compared to the radiological standards discussed in Integrated Safety Management Plan (ISMP) Section 1.2, "Detailed Description of the Safety Approach" rather than to 10 CFR 20, "Standards for Protection Against Radiation". A full assessment of the hazardous situations that might present themselves during facility operation is provided. This includes estimates of radiological and chemical releases for this range of events. Additional details are provided on the methodology used for consequence analysis, bounding conditions, input assumptions, and accident sequences.	The standards provided in RG 3.52 were derived from 10 CFR 20, "Standards for Protection Against Radiation", which is applicable to normal operation. The nature of the accidents for the RPP-WTP requires more discussion of consequence analysis than that required of fuel fabrication facilities.
4.8 Controls for Prevention and Mitigation of Accidents	This section identifies the specific safeguards selected for protection of the facility workers, as well as safeguards selected for protection of the public and collocated workers.	The nature of the accidents for the RPP-WTP requires more discussion of consequence analysis than that required for fuel fabrication facilities.
5.0 Radiation Safety	Chapter 5.0 provides the upper-level statutory standards and program policies that ensure the radiological safety of employees, visitors, and onsite members of the public. Deviations from RG 3.52 are as follows: 1) As an U.S. Nuclear Regulatory Commission (NRC) document, RG 3.52 references and specifies applicable portions of 10 CFR 20. Because 10 CFR 835 is the radiation safety regulation for the RPP-WTP, the focus of this section is on 10 CFR 835. 2) The implementation-level standards and guidance documents referenced in RG 3.52 is being incorporated into the Radiation Protection Plan (RPP).	Compliance with 10 CFR 835 is a requirement of the contract. The RPP required by 10 CFR 835 is required to include some of the information required of RG 3.52. There is no need to present this information in two documents.
5.1 As Low As Reasonably Achievable (ALARA) Policy and Program	RG 3.52 states that Regulatory Guide 8.10, Revision 1R (*Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable)* should be used in the development of the ALARA program. DOE guidance such as DOE G 441.1-2, *Occupational ALARA Program Guide* will also be used to develop the RPP-WTP ALARA program for normal operation.	DOE practices have proven to be successful for facilities similar to the RPP-WTP.
5.3 Radiological Safety Standards	Section 5.3 is added to provide the radiation standards by which the program operates. The standards specifically identify regulatory exposure standards, administrative exposure control levels, and other key standards of the radiation protection program.	The contract requires compliance to the 10 CFR 800 series of nuclear safety requirements. This includes compliance to 10 CFR 835, "Occupational Radiation Protection". Section 5.3 documents the compliance to the exposure standards of those regulations that have been promulgated.

Table 4-1 Deviations from the Safety Analysis Report Content Guidance of Regulatory Guide 3.52 [1] (Sheet 3)

Chapters	Addition or Subtraction	Basis
5.8 External Exposure (renumbered 5.9 from RG 3.52)	By RG 3.52, the applicant is expected to participated in the National Voluntary Laboratory Accreditation Program (NVLAP) external dosimetry. Section 5.8 allows for participation in either the NVLAP or U.S. Department of Energy (DOE) Laboratory Accreditation Program (DOELAP) accreditation programs.	The option of participating in either the NVLAP or the DOELAP provides maximum flexibility and equivalent dosimetry program quality
5.14 Radioactive Waste Management	RG 3.52 does not require a discussion of waste management systems.	Section 5.14 is added to the SARs as the Process Hazards Analysis (PHA) completed for the RPP-WTP have identified hazards and hazardous situations with the waste management features of the facility. It is a requirement of DOE/RL-96-0003 (DOE-RL 1996a), Section 4.1.2, "Contractor Input", that deliverables be tailored to the nature and level of hazards associated with its waste processing activities.
Appendix 5A Radiation Protection Program Outline	This appendix is added to address compliance to 10 CFR 835.	The contract requires compliance to the 10 CFR 800 series of nuclear safety requirements. This includes compliance to 10 CFR 835, "Occupational Radiation Protection".
Appendix 5B Environmental Radiation Protection Program Outline	This appendix is added to address compliance to the requirements of the Environmental Protection Agency (EPA) and Washington State laws and regulations.	The contract requires submittal of an outline for the environmental radiological protection plan.
Chapter 6.0 Nuclear Criticality Safety	The methodology for criticality analyses is provided in the SARs to the extent the need to perform criticality calculation is found to be appropriate. The RPP-WTP SARs provide fewer details and commitments compared to fuel fabrication facilities relative to: 1) Nuclear criticality safety organization (Section 6.2.1) 2) Criticality training (Section 6.2.5) 3) Specific maintenance and quality assurance provisions for criticality prevention (Sections 6.2.3 and 6.2.4) 4) Audits and inspection (Section 6.2.6)	RG 3.52 focuses heavily on accidental criticality which is a more significant concern for fuel fabrication facilities which have a much higher inventory and concentrations of fissile material than the RPP-WTP. See ISMP Section 3.8, "Criticality Safety", for additional information.

Table 4-1 Deviations from the Safety Analysis Report Content Guidance of Regulatory Guide 3.52 [1] (Sheet 4)

Chapters	Addition or Subtraction	Basis
7.4 "Hazardous Waste Management"	Section 7.4 of the RPP-WTP SARs address all chemical inventories that are identified by the PHA as representing a significant hazard.	By Section 4.2.2, "Contractor Input", of DOE/RL-96-0003 (DOE-RL 1996a), the Initial Safety Analysis Report (ISAR) is to address process safety as well as radiological and nuclear safety. The need to address all aspects of chemical safety is also an NRC requirement of RG 3.52, Section 7.4, and NUREG-1513, "Integrated Safety Analysis Guidance Document", (draft) (NRC 1994). The NUREG-1513 definition of "integrated" provided in Section 2.1, "Definition", makes reference to chemical safety. Specific guidance for chemical safety is provided in Section 2.6.2, "Process Safety Information", of the NUREG-1513.
10.0 Environmental Protection	This chapter references the Environmental Report	Protection of the environment is addressed in a separate document.
11.0 Deactivation and Decommissioning	This chapter addresses design and operational provisions considered to facilitate deactivation and decommissioning. It does not address the financial considerations for decommissioning.	The scope of the contract (DOE-ORP 2000) of Part B is limited to design support for deactivation.

1. Standard Format and Content for the Health and Safety Sections of License Applications for Fuel Cycle Facilities, Regulatory Guide 3.52, Revision 2, draft, U.S. Nuclear Regulatory Commission, Washington D.C. (NRC 1995a).

For example, the results of criticality calculations summarized in the ISMP Section 3.8, "Criticality Safety", indicated that criticality is not a significant hazard for the RPP-WTP. Therefore, the content of SAR Chapter 6.0, "Nuclear Criticality Safety", is reduced. However, because accident consequence analyses are important to the Project safety approach, the content of Initial Safety Analysis Report (ISAR) Section 4.7, "Results of the Integrated Safety Assessment", will be strengthened, in the PSAR, in terms of the discussion of the methodologies used, boundary conditions, input assumptions, and the descriptions of the accident sequences.

The content of the PSAR and FSAR is tailored to the purpose of these two documents. The PSAR supports the request for the construction authorization by documenting the safety criteria, the principal design and construction requirements, and the initial safety analysis. The FSAR documents application of these criteria to the completed RPP-WTP, documents the final safety analysis, and establishes the facility can be operated safely. The PSAR places greater emphasis on design criteria and construction practices than conduct of operations. The FSAR places emphasis on conduct of operations. Table 4-2 lists the planned differences between the content of the PSAR and FSAR to achieve this focus.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 1)

Title	PSAR	FSAR
1.0 General Information		
1.1.1 Facility Description	A description of the facility design is provided in sufficient detail to demonstrate the facility design and construction requirements of the Safety Requirements Document (SRD). The details are also sufficient to support an understanding of the safety analysis provided in Section 4.2, "Facility Description".	This section updates the general description of the facility design.
1.1.2 Process Description	This section describes the process design in sufficient detail to demonstrate the system and component design and fabrication requirements of the SRD are satisfied. Details on the process design sufficient to support an understanding of the safety analysis are provided in Section 4.3, "Process Description".	This section updates the general description of the process design.
1.2 Institutional Information	This section provides the information required by RG 3.52, draft (NRC 1995a).	This section updates any changes in the institutional information provided in the Preliminary Safety Analysis Report (PSAR).
1.3 Site Description	A description of the site land use, meteorology, hydrology, geology, and seismology is provided.	This section addresses any existing or planned changes in land use from that provided in the PSAR. The Final Safety Analysis Report (FSAR) provides any new meteorology, hydrology, geology, and seismology data made available. However, the level of detail provided for these subject areas is not significantly different between the two SARs. The FSAR summarizes data obtained during the Facility excavation that confirms the adequacy of design. This includes the results of field and laboratory investigation of soil properties.
2.1 Organization and Administration	The Project organizational charts with a focus on the design and construction management organizations are provided. An organization chart for the operational phase is also presented. More definitive information on the roles, responsibilities, and interfaces for project management, engineering, construction management, inspections, procurement, quality assurance, records management, and nuclear safety functions is included. Section 2.1 also provides the criteria to determine minimum staffing requirements. A summary of procedures to be developed to implement the regulatory requirements addressed in this section is presented.	The section contains an update to the organizational structure of Project with a focus on operational and operational support organizations. This section also includes: 1) Title of each position that is important to public and worker safety and reporting relationship 2) Description defining qualifications, responsibilities and authorities for each position related to safety 3) Organizational charts of the line organization and safety organization 4) Title of the individual delegated overall responsibility for the safety programs who has the authority to shut down operations if they appear to be unsafe, including independence of this authority from operational constraints 5) Lines of responsibility and authority for safety 6) Lines of communication and interfaces between organizations inside the facility 7) Availability of personnel within the safety organization to carry out the assigned function. Specific information on procedure development and minimum staffing requirements is provided.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 2)

Title	PSAR	FSAR
2.2 Safety Committees	Information on responsibilities, authorities, and proposed charters of safety committees, and oversight groups is provided.	This section updates information on safety committees, and oversight groups that are established following issuance of the PSAR and addresses any new safety committees that have been established.
3.1 Configuration Management	This section contains specific information on 1) Content and reference to procedures used to maintain effective configuration management of the RPP-WTP 2) Scope of identified systems, structures, and components (SSCs) and their relationship to the contents of Chapter 4.0, "Integrated Safety Analysis" 3) Description of the design information package contents to be provided to the safety analysts 4) Change control system specifics, including identification, technical and management reviews, documentation, and implementation 5) Specific physical configuration assessment, and periodic equipment performance monitoring 6) Design, installation, and testing of facility modifications 7) Revision of operating, test, calibration, surveillance, and maintenance procedures and drawings 8) Selection and control of replacement parts 9) Description of how the RPP-WTP design requirements and design basis were established and documented. A summary of procedures developed to implement the regulatory requirements addressed in this Section 3.1 is presented. This section also includes a draft of the unreviewed safety question process.	Specific information on the content of procedures and training developed is provided. The final unreviewed safety question process is provided.
3.2 Maintenance	A list of Safety Design Class and Safety Design Significant SSCs is provided. The maintenance implementation plan is described to such a level that maintenance philosophy and approach are evident.	The FSAR may modify the list of SSCs actions to be addressed based on safety analysis of the final design. Specific information on procedures and training developed to implement the requirements of Section 3.2 is provided. In addition, the elements of the finalized maintenance implementation plan is described. Also discussed is the application of information obtained from demonstration testing and commissioning programs to the maintenance program (the latter by FSAR amendment after initial submittal.)

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 3)

Title	PSAR	FSAR
3.3 Quality Assurance	Information related to the roles, responsibilities, and interfaces for project management, engineering, construction management, inspections, procurement, quality assurance, records management, and nuclear and process safety functions is provided. Included is the organizational structures of the quality assurance organization. The PSAR describes the quality assurance requirements of SSCs. Requirements for procedures to implement the regulatory requirements is presented.	For the FSAR, this section focus on the quality assurance program for the operating RPP-WTP. Specific information on procedures and training developed to implement the requirements of Section 3.3 is provided.
3.4 Training and Qualification	A description of the performance-based training program for operational and support personnel, including a detailed description of the training development process, is provided. The administrative process, to be applied to training activities is described to a level such that the elements of the program and management's commitment to training is evident.	Details on the training and qualification program are provided. Also discussed is the application of information obtained from demonstration testing and commissioning programs (the latter by FSAR amendment after initial submittal.)
3.5 Human Factors	This section documents the criteria by which human factors are considered in the facility design and operation.	This section states how human error in facility operations was taken into account in the design by facilitating correct decisions by operators and inhibiting wrong decisions. Consideration given in the design to detecting and correcting or compensating for errors is discussed.
3.6 Audits and Assessments	Information on the performance of audits and assessments is incorporated into this section.	This section is focused on audits and assessments performed during RPP-WTP operation. Specific information on procedures and training developed to implement the requirements of this section is provided.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 4)

Title	PSAR	FSAR
3.7 Incident Investigation	This section includes the following: 1) Provisions for establishing investigating teams 2) Functions, responsibilities, and scope of authority of investigating teams 3) Qualifications of internal and/or external investigators on investigating teams 4) A description of the procedures to ensure prompt investigation of an incident 5) Policy directives that the investigative process and the investigating team be independent of line management and that participants be assured of no retribution from participating in investigations 6) The approach proposed to determine the root cause(s) of incidents to ensure that the process is reasonable, systematic, and structured 7) Methods to ensure that corrective actions to resolve findings from incident investigations are tracked to completion 8) Identification and application of lessons learned 9) Specific reporting criteria for incident reporting during the construction phase. A summary of procedures developed to implement the regulatory requirements addressed in Section 3.7 is presented.	Specific information on procedures and training developed to implement the requirements is provided. Included are specific reporting criteria for incident reporting during the operations phase.
3.8 Records Management	This section contains the organization structure and a description of the records management system, including authorities, responsibilities, and qualifications of personnel managing Environmental Safety and Health (ES&H) records. A summary of procedures developed to implement the regulatory requirements contained in Section 3.8 is presented.	Specific information on procedures and training developed to implement the requirements is provided.
3.9 Procedures	A description of the administrative controls to ensure that work is performed in accordance with established technical standards and using approved instructions and procedures is provided.	This section describes the detailed processes of selecting activities requiring operating, emergency, and support procedures; preparing procedures; verifying and validating procedures; and reviewing and approving procedures. In addition, the program to administratively control procedures and their use is described in detail.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 5)

Title	PSAR	FSAR
3.10 Testing Program and Preoperational Safety Review	This section describes the analysis used to identify and define pre-operational and commissioning tests and describes tests required to ensure compliance to safety specifications. The testing program and controls are described to a level such that the testing philosophy and approach are evident. The prestart safety review approach is described to a level such that the areas to be evaluated and the evaluation approach are evident.	This section may modify the list of required safety improvement program and commissioning tests based on safety analysis of the final design. In addition, the administrative and program controls applicable to the test program are described in full.
3.11 Operational Practices	A description is provided of operational practices influenced by design details, (i.e., communications systems, operational hazards associated with systems and hardware, and control area arrangements).	A description is provided of the operational practices influenced by the final design. In addition, final descriptions are provided on controls and administration of operational practices.
4.0 Integrated Safety Analysis	The methodology for hazards identification and accident analyses is described. The accident consequence analyses include margins in assumptions, boundary conditions, modeling and comparisons to acceptance criteria, as appropriate, to account for uncertainties in the design and plans for operation. Section 4.7 addresses the relationship of these uncertainties to the need to provide sufficient information in the construction authorization package to allow for issuance of the construction authorization.	Assumptions used in the PSAR to account for uncertainties in the design and plans for operations are removed from the FSAR analysis to the extent that these uncertainties have been resolved.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 6)

Title	PSAR	FSAR
4.2 Facility Description	In addition to providing a general description of the facility, this section discusses the basic civil/structural criteria to be applied to the design. For those structures classified as Safety Design Class, this includes the following: 1) Design codes, standards, and specifications 2) Loading criteria and load combinations 3) Design and analysis methodology 4) Structural acceptance criteria 5) Criteria for identifying testing and in service inspection requirements 6) Material specifications 7) Special construction features. This section also discusses 1) Assumed soil properties 2) Excavation, backfill, and recompaction criteria 3) Assumed bearing capacity of the soil and the safety factor applied to this capacity 4) Expected static and dynamic building total and differential settlements. Less detail is provided for Safety Design Significant structures. Section 4.2 gives specific attention to those structures classified in Section 4.8 as Safety Design Class. Structures located away from the buildings containing significant hazards and that have no relationship to nuclear or process safety are briefly described (e.g., structural design, and the contents and functions of the building) and identified on a plot plan.	The FSAR updates the facility description and basic civil/structural criteria provided in the PSAR. It follows with discussions of the results of the application of these criteria to specific features of the facility. Examples are as follows: 1) The confirmation of soil properties obtained during excavation 2) A table providing the building total and differential settlement data obtained 3) Derived soil damping values 4) The results of the soil/structure analysis 5) Developed floor response spectra and time histories 6) A list of moderate and high energy systems 7) A list of specific missile and jet impingement sources, targets, and barriers provided. Also provided are updated plan and section drawings for structures classified as Important-to-Safety. These drawings show the basic floor arrangements, location of major systems and equipment, and basic building dimensions. For those structures classified as Safety Design Class, the drawings also show key structural elements, such as panel and floor reinforcements, cell liners, leak chases, major equipment anchors, and the use of masonry walls.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 7)

Title	PSAR	FSAR
4.3 Process Description	The description of process systems includes process flow diagrams for the major systems with instrumentation, sample points, and control features noted to the extent they have been developed. Heat loads are provided for heat transfer systems important to the safety analysis. Design features and parameters important to Section 4.7, "Results of the Integrated Safety Assessment", are provided. This section contains the following additional detail for each system classified as Safety Design Class: 1) The specified safety function(s) with reference to PSAR Section 4.7 for the basis 2) The design basis to be applied in the development of the system design 3) Design margins to be applied 4) The criteria to be used for the development of material specifications 5) Criteria to be used to determine design limits (such as pressure and temperature) 6) Criteria to be used to identify the need for instrumentation to monitor process conditions and the design criteria for such instrumentation (e.g., application of the single-failure criterion, and testability). For many cases, the design criteria provided are those included in the Safety Requirements Document (SRD).	This section updates the PSAR description of process systems. Process and instrumentation diagrams are provided for major systems. In addition, for those systems classified as Safety Design Class, the FSAR describes how the design requirements provided in the PSAR are reflected in the final design. For each system classified as Safety Design Class, the following are provided: 1) The specified safety function(s) with reference to Section 4.7 for the basis 2) The design basis 3) The design safety margins provided by the final design 4) Important quantitative design parameters met by the system design with their basis (e.g., heating, ventilation, and air-conditioning flow, and what established the minimum and maximum flow limits) 5) Material specifications 6) Established design limits and their basis (e.g., maximum pressure and temperature limits and what established these limits) 7) Instrumentation provided with attributes, including redundancy, diversity, in situ testability, environmental qualification, failure mode on loss of power, and the surveillance requirements as defined in Section 4.8, "Controls for Prevention and Mitigation of Accidents". The means by which the monitoring requirements established in Section 4.8 are also to be discussed in the FSAR. Potential adverse system interactions between systems of various design classification are addressed.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 8)

Title	PSAR	FSAR
4.7 Results of the Integrated Safety Analysis (ISA)	In addition to providing the results of the Process Hazards Analysis (PHA) and accident analysis, this section discusses the uncertainties of the PHA and accident analysis and relates these uncertainties to the required content of the construction authorization package. Section 4.7 provides the basis for the conclusion that resolution of the uncertainties will not have a significant impact on the construction authorization request. This discussion includes the following: 1) Characterization of the specific technical information that must be obtained to demonstrate acceptable resolution of the uncertainties 2) An outline and schedule of the program to resolve uncertainties 3) A discussion of the design and/or operational alternatives to resolve the uncertainties. Section 4.7 of the PSAR also describes the preliminary Fire Hazard Analysis (FHA) and the consequence of each design-basis fire scenario, including the consequences in the area of origin and adjacent areas.	This section documents the resolution of any uncertainties identified in the PSAR. The FSAR describes the final FHA and all resolved uncertainties previously included in the PSAR and additional fire protection measures and equipment design.
4.8 Controls for Prevention and Mitigation of Accidents	Draft Technical Safety Requirements are included.	Final Technical Safety Requirements are included.
5.0 Radiation Safety	This chapter identifies the radiological exposure standards by which the radiation safety program is developed and the facility is operated to ensure the radiological safety of the public and workers. This chapter identifies the radiation protection criteria to be implemented in the facility design.	This chapter reflects the final facility design developed to the radiation protection criteria. It also describes the facility organization and plans for the conduct of operations. This chapter includes detail on facility operation within the radiological protection program exposure standards and other radiological protection requirements.
6.0 Criticality	The methodology for criticality analyses is provided to the extent the need to perform criticality calculation is found to be appropriate. The analyses may include margins in assumptions, bounding conditions, modeling and comparisons to the acceptance criterion, as appropriate, to account for uncertainties in the design and plans for operation.	Assumptions used in the PSAR to account for uncertainties in the design and plans for operations are removed from the FSAR criticality analysis to the extent that these uncertainties have been resolved. The FSAR describes the remaining criticality controls appropriate for the RPP-WTP.
7.0 Chemical Safety	The chapter identifies the program standards by which the chemical safety program is developed and operated to protect the public and workers against chemical hazards and hazardous situations. This chapter identifies criteria to be used for the development of chemical safety controls.	The chapter reflects the final facility design and facility organization and the developed plans for conduct of operations as related to chemical safety. This section also identifies the specific chemical safety controls to be implemented for protection of the public and workers.

Table 4-2 Planned Differences Between PSAR and FSAR Content (Sheet 9)

Title	PSAR	FSAR
8.0 Fire Safety	This chapter describes automatic and manual fire protection features and administrative controls of the fire safety program. Also described are features of the ventilation system, building layout, and emergency egress routes important to fire safety.	Administrative controls to be implemented for the fire safety program are described, including final responsibilities of response forces, and the pre-fire plan used by firefighting personnel to suppress fires safely and effectively.
9.0 Emergency Management	This chapter identifies the applicable requirements and criteria to which the RPP-WTP Emergency Management Program are developed. A general outline of the program is presented and the relationship to the Hanford Site and local emergency management programs is discussed. Information is presented to demonstrate that the RPP-WTP staff will be able to attain an acceptable state of emergency preparedness by the time the facility becomes operational.	The FSAR discusses and references the specific emergency plan and implementing documentation prepared for the RPP-WTP. Specific aspects of all elements of the emergency preparedness program are discussed. Information is presented demonstrating the developed emergency preparedness program is compliant with applicable requirements, regulations, criteria and guidance, and capable of responding to any operational emergency at the facility.
10.0 Environmental Protection	This chapter references the RPP-WTP Environmental Report submitted in Part A.	This chapter references the RPP-WTP Environmental Report as a new or revised Environmental Report and is not required to support the operating authorization request.
11.0 Deactivation and Decommissioning	This chapter identifies design considerations given to facilitate deactivation and decommissioning. It also discusses in general terms, the planning, safety analysis, and regulatory considerations to be given to deactivation.	The chapter describes the specific design features included to facilitate deactivation and decommissioning. The level of detail for planning, safety analysis, and regulatory considerations to be given to deactivation is about the same as that provided in the PSAR. The FSAR is amended near the end of waste processing operation to provide more specific information regarding deactivation. (See Integrated Safety Management Plan [ISMP] Table 9-5).

4.2.3.2 Integrated Safety Management Plan

The ISMP is tailored to the various phases of the Project. It is currently focused on design and construction. However, ISMP Sections 1.3.14, “Commissioning” through 1.3.19, “Deactivation” address integrated safety management for the Project throughout the life cycle of the project (i.e., from commissioning through deactivation). In addition, the administrative controls developed for design and construction (such as training and procedures, configuration management, incident investigation, and quality assurance), are applicable to the operations and deactivation phases. As the project nears operation, the ISMP is revised to give greater attention to the conduct of operations, operational assessments, incident reporting, and maintaining the authorization basis for the facility. Near the end of waste-processing operations, the ISMP is revised again to address the hazards associated with deactivation. This ISMP revision also discusses the integration between the various deactivation activities, such as preparation of the deactivation management plan; development of the deactivation baseline, end point criteria, and surveillance and maintenance requirements; updating of the PHA; and proposed revisions to TSRs.

4.2.3.3 Safety Requirements Document

The SRD is tailored to reflect adequate control of hazards and hazardous situations associated with RPP-WTP operation. This tailoring activity includes identifying only those Safety Criteria that are required to accomplish Project activities safely, and then applying the implementing codes and standards to these criteria based on the risks posed by the hazardous situations being controlled. Features controlling hazardous situations with the potential for greater impacts (such as an offsite release affecting the public) have more rigor applied to them than those features controlling hazardous situations with lower impacts.

4.2.3.4 Technical Safety Requirements

The TSRs are based on the FSAR and any facility-specific commitments made. They are tailored to focus on the protection of public and worker health and safety. The TSRs are further tailored based on the following needs:

1) Control process variables, design features, and operating restrictions that are initial conditions (i.e., the assumed facility state) for accident analysis credited for meeting the public and worker radiological or chemical exposure standards
2) Assure that SSCs credited for achieving compliance to public and worker radiological and chemical exposure standards will function when required.

The TSRs are kept current so that they reflect the facility as it exists and as it is analyzed in the FSAR. The RPP-WTP is operated to the approved TSRs.

As the RPP-WTP operation nears the end of waste-processing operations, changes are initiated to the TSRs to control the hazards and hazardous situations associated with deactivation.

4.2.3.5 Emergency Plan

The RPP-WTP emergency management plan documents the provisions for response to operating emergencies. The emergency plan establishes effective and efficient emergency management operations that provide acceptable levels of protection for RPP-WTP workers, Hanford Site employees, and the public. The scope of the RPP-WTP emergency management program, from which the emergency plan is derived, is determined by performing a Hazards Survey and Assessment for the facility.

The Hazards Survey briefly describes the potential impacts of emergency events or conditions and summarizes applicable federal, state, and local planning and preparedness requirements. The Hazards Survey identifies the required scope of the RPP-WTP emergency management program.

If the Hazards Survey identifies hazardous materials at the facility in excess of predetermined thresholds, a facility-specific Hazards Assessment is performed. A Hazards Assessment includes the identification and characterization of hazardous materials specific to the facility, analyses of potential accidents or events, and evaluation of potential consequences. The Hazards Assessment provides the technical basis for the RPP-WTP emergency management program and includes information sufficient to determine the scope and extent of the specific elements that make up the emergency management program. These program elements, along with their bases, are documented in the emergency plan. The extent of planning and preparedness directly corresponds to the type and scope of hazards present and the potential consequences of accidents and events.

5.0 Process Safety Management

The Facility may contain highly hazardous chemicals in amounts that exceed the thresholds listed by the Occupational Safety and Health Administration (OSHA) in 29 CFR 1910.119, "Process Safety Management of Highly Hazardous Chemicals" (the Process Safety Management [PSM] Standard). Among these chemicals are, for example, anhydrous ammonia and nitric acid. If threshold quantities of hazardous chemicals were exceeded, it would be necessary to develop a PSM program that complies with OSHA requirements and with similar requirements of the prevention program in the U.S. Environmental Protection Agency (EPA) Risk Management Program, 40 CFR 68, "Chemical Accident Prevention Provisions".

Even though compliance with 29 CFR 1910.119 and 40 CFR 68 does not apply to the RPP-WTP, the Project must comply with the top-level process safety management principles in Section 5.0 of DOE/RL-96-0006, *Top Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors* (DOE-RL 1996b). Because the top-level principles mirror most of the elements of the PSM standard (with the exception of employee involvement and trade secrets), a program that satisfies the OSHA PSM standard also satisfies the top-level principles.

This chapter focuses on the management systems that ensure the RPP-WTP operates safely, from the perspective of applying commercial industry practices and approaches that are compliant with PSM.

5.1 Process Safety Information

A compilation of written process safety information is maintained to enable the RPP-WTP employees involved in operating processes to identify and understand the hazards posed by those processes involving hazardous chemicals. The following information is retained:

1) Toxicity information
2) Permissible exposure standards
3) Physical data
4) Reactivity data
5) Corrosivity data
6) Thermal and chemical stability data
7) An assessment of the effects of inadvertently mixing different materials

Most of this information is available in Material Safety Data Sheets, which are made accessible to all employees. Information on interactions is prepared in the form of an interaction matrix developed for the Process Hazard Analysis (PHA). The interaction matrix for the RPP-WTP is provided in Section 4.2, "Chemical Interactions", of the Hazard Analysis Report (HAR). A list of the process chemicals used in the RPP-WTP and their hazardous characteristics is also provided in the HAR Section 4.1.2, "Process Chemicals".

Information pertaining to the technology of the process is also required. This information includes the following:

1) Block flow diagrams and simplified process flow diagrams
2) The process chemistry
3) The maximum intended inventory
4) Safe upper and lower limits for such variables as temperatures, pressures, flows, and compositions
5) An evaluation of the consequences of deviations, including effects on the health and safety of employees.

Process technology information is developed as the design evolves. Confirmation that the process safety equipment is appropriate for the process operation is established from engineering review of the completed design and the updated hazard and accident analysis. Changes in the technology are reviewed by PHAs and controlled by the configuration management process.

Another group of information is required that pertains to equipment in the process. This information includes the following:

1) Materials of construction
2) Process and instrumentation diagrams
3) Electrical classification
4) Relief system and design basis
5) Ventilation system design
6) The design codes and standards employed
7) Material and energy balances
8) Safety systems (e.g., interlocks and detection or suppression systems).

This information is assembled as the design evolves.

The RPP-WTP configuration management system ensures that Process Safety Information is maintained and kept up to date. Section 1.3.16, "Configuration Management", of the Integrated Safety Management Plan (ISMP) provides a summary of the Facility configuration management program. Additional details on this program are provided in Initial Safety Analysis Report (ISAR) Section 3.1, "Configuration Management".

5.2 Control of Subcontractors

BNI is responsible for ensuring that all subcontractors work as safely as the BNI employees. BNI's responsibilities include the following:

1) Informing the subcontractors of known fire, explosion, or toxic hazards relating to the subcontractor's work and the process
2) Explaining to the subcontractor the applicable provisions of the emergency plan
3) Developing and implementing safe work practices to control the entrance, presence, and exit of subcontractor employees, including their presence in areas of the process covered by the PSM standard
4) Periodically evaluating the performance of subcontractors in fulfilling their obligations as stated
5) Maintaining an illness and injury log relating to the subcontractor work in the process areas

Each subcontractor's responsibilities include the following:

1) Ensuring that subcontractor employees are trained in the work practices necessary to safely perform their assignments
2) Ensuring that subcontractor employees are instructed in the known hazards of the process as related to their job assignments, and in the relevant provisions of the emergency management plan
3) Documenting that each subcontractor employee has received and understood the training required to work safely at the RPP-WTP
4) Ensuring that each subcontractor employee follow the safety rules of the RPP-WTP and the site safe work practices, and advise the contractor of any unique hazards presented or found during the course of the subcontractor's work

Project environment, safety, and health (ES&H) requirements are imposed on subcontractors in contracting documents. This includes commitments included in the SRD and ISMP. Subcontractors are required to appoint an ES&H representative who is the interface with the Project team on all ES&H matters.

Before starting any work, ES&H personnel meet with the subcontractor's workers to apprise them of the job-specific ES&H requirements. In addition, oversight is provided of all subcontractor safety and compliance activities.

The system employed on the Project to track subcontractor work includes procedures with detailed checklists and specific record keeping and reporting requirements. The key elements of this system are subcontractor pre-qualification, worker job-specific training, day-to-day monitoring, and regular reporting to the contractor. These elements are described in the paragraphs that follow.

The QAP requires that subcontractors and suppliers providing services and items Important-to-Safety submit their quality plans to Project QA for review and approval.

The QAM describes how the procurement of items and services is controlled to ensure conformance with specified requirements. Audits of suppliers and subcontractors are described in the QAM.

Controls are established by the Project to ensure that purchased items and services conform to the procurement documents. These controls include provisions for source evaluation and selection, objective evidence of inspection at the subcontractor's source, examination of items or services upon delivery, and assessments. Verifications of subcontractors' and suppliers' activities during fabrication, inspection, testing, and shipment of materials, equipment, and components are planned and performed with the Quality Assurance organization participation to ensure conformance with the purchase order requirements.

Subcontractors and suppliers develop procedures for the disposition of items, materials, and services that do not meet procurement requirements to ensure that incorrect or defective items, materials, and services are not used in the RPP-WTP and that reporting requirements are satisfied. BNI validates that approved suppliers can continue to provide acceptable items and services based on a documented evaluation of their past performance.

Pre-qualification. Subcontracting procedures contain subcontract language to ensure that BNI subcontractors understand their obligation to comply with the Project ES&H programs and procedures and all applicable federal, state, and local requirements. Subcontractors are also required to submit an extensive ES&H history form documenting their capability of meeting these obligations. Subcontractors are also required to submit their safety and health program for Project review. Before work is carried out, subcontractors are required to validate that their workers have current training for the work activities they are to perform. This training must be documented as quality assurance records.

Day-to-day monitoring. The subcontractor's ES&H performance is measured against their contractual obligations and ES&H performance. This oversight is the responsibility of the project team, which includes ES&H professionals familiar with the subcontractor scope and the specific ES&H project requirements. Instructions for compliance oversight are specified in the BNI subcontracting procedures and policies. These procedures also contain guidance to initiate contract termination if a subcontractor is found to be in default of these contract obligations, including failure to respond to ES&H infractions.

Regular reporting. Subcontractors maintain their own records of accidents and illnesses and are responsible for notifying BNI immediately of any lost work day injuries/illnesses, occupational fatalities, OSHA-recordable injuries, hazardous material or radiation exposure, or property damage in excess of $500 occurring in areas under BNI control. Subcontractors are also responsible for environmental compliance as defined by applicable procedures, regulations, and laws. These submittals are reviewed by ES&H professionals to give BNI an early warning of performance degradation and to allow BNI to take effective, preventative action when necessary.

The above approaches are formalized in Project policies, procedures, and instructions. Appropriate training is also provided at all levels including employees, supervisors, and management.

To ensure that BNI subcontractors are performing their work safely, both formal and informal safety reviews and audits are performed. Results of these evaluations are transmitted to both Project management and to the affected subcontractors.

5.3 Configuration Management

The configuration management program ensures that the RPP-WTP establishes and maintains consistency among design requirements, physical configuration, administrative controls, and facility documentation to the technical baseline throughout the operating and deactivation phases. Procedures are developed to manage changes to process chemicals, technology, equipment, and procedures, together with changes to facilities that affect a covered process. The procedures ensure that, prior to a given change, the following considerations are addressed:

1) The need to perform an unreviewed safety question (USQ) evaluation
2) The impact of the proposed change on the authorization basis (i.e., RL/REG-97-13)
3) The technical basis for the proposed change
4) The impact of the change on safety and health
5) Modifications to operating procedures
6) Schedule consideration for completion of the activity
7) The authorization requirements for the proposed change
8) The training of employees who are affected by the change prior to commissioning of the process or the affected part of the process
9) Necessary changes in the process safety information and the authorization basis
10) The potential need for changes to the Technical Safety Requirements
11) Necessary changes to the master equipment list.

In the chemical process industries, the above requirements are addressed by a Management of Change procedure. The Management of Change procedure is considered the central element of PSM and its primary purpose is to ensure that change is managed safely. For the Project, the Management of Change procedure is part of the configuration management system that goes beyond the requirements of 29 CFR 1910.

The ISMP Section 1.3.16, “Configuration Management”, provides a summary of the Facility configuration management program. Additional detail on this program is provided in ISAR Section 3.1, “Configuration Management”.

The configuration management program database includes Safety Design Class and Safety Design Significant SSCs. The database relates design information and requirements to the applicable SSCs and associated documentation. The inter-relational nature is such that proposed or identified changes to any part of the controlled design, configuration, or documentation identifies other affected design, configuration, or documentation entities for which consideration of acceptability of the change must be addressed. Within the database are the performance specifications for Safety Design Class and Safety Design Significant electrical and mechanical equipment. These specifications include the conditions under which the equipment must function during the accident condition (e.g., load, pressure, voltage, temperature, radiation field, and humidity).

A proposed change would be disapproved if:

1) The change was found to compromise safety
2) The change would result in non-compliance with a regulation or law
3) The change would result in non-compliance with the contract.

5.4 Compliance Audits

Compliance audits for the PSM program are conducted by BNI at least once every three years to verify that the procedures, practices, and maintenance activities developed to ensure nuclear and process safety are adequate and being followed. These compliance audits are performed by individuals knowledgeable of the process. The audits are often performed with the aid of a checklist. A report of the audit findings is developed in which corrective actions and their schedule for completion are provided. Additional detail on this program is provided in ISAR Section 3.6, “Audits and Assessments”.

5.5 Process Hazards Analysis

The PHA is a key element in achieving and maintaining safety throughout the life of the RPP-WTP. The PHA technique evolves as the design matures. The appropriate technique is chosen by using the methodology recommended by the American Institute of Chemical Engineers (AIChE) in its *Guidelines for Hazards Evaluation Procedures* (AIChE 1992). At the conceptual design stage, a preliminary hazard analysis is used. As the design matures, the chosen technique is the Hazard and Operability (HAZOP) Analysis.

Thus, the PHA technique is tailored to the information available and to the complexity of the RPP-WTP processes. In addition, the chosen techniques are among those in the list of acceptable techniques promulgated by OSHA in 29 CFR 1910.119 (e) (2). A discussion of the hazards analysis techniques selected for the Facility is discussed in HAR Section 3.2, “Selection of a Hazard Evaluation Methodology”. Application of the selected techniques is discussed in HAR Section 3.3, “Hazard Evaluation Methodology”.

The chosen PHA techniques address the hazards of the process by systematically evaluating potential deviations from design intent caused by the failure of engineered or administrative controls, including appropriate detection methodologies that provide early warning of release. Human factors are addressed by identifying those causes of deviations from design intent that are caused by human error. Further detail on human factors is given in ISMP Section 3.12, “Human Factors”.

OSHA also requires that the PHA consider how accidents in the process can affect other areas, such as the control room, office buildings, or other nearby structures and processes. Also, the PHA team considers how external events might affect the process. This is accomplished by considering these siting issues in the context of the causes and consequences of the deviations from design basis. The discussion of causes and consequences includes a review of previous incidents at the site and at similar facilities. For the Facility, considerations for siting are addressed in HAR Section 2.1, “Site Description”, and the comparison the results of the PHA to those of other facilities is provided in HAR Section 4.4, “Comparison to Similar Facilities”. The consideration of consequences also includes a qualitative evaluation of the possible effects on the health and safety of facility workers.

A written plan will be developed in Part B for participation of employees and their representatives in the conduct of the PHA and other elements of the Project PSM program.

The documentation of the PHA is consistent with the examples of documentation given in the AIChE's *Guidelines for Hazards Evaluation Procedures* (AIChE 1992). The results of the PHA for the Facility are included in HAR Section 6.0, "Hazards Analysis Results Summary".

The results of the PHA are submitted to the regulator for review to support the construction authorization package, operating authorization package, and deactivation request as discussed in ISMP Section 9.2, "Scheduling of Events for Regulatory Submittals". The schedule for these submittals of the PHA is shown in ISMP Figure 9-1. The PHA, including revisions, is maintained by the document control process discussed in Chapter 8.0, "Document Control and Maintenance". Access to the PHA and other PSM information is made available to employees.

The PHA is performed in accordance with the requirements of the Project QAP. This includes establishment of personnel training and qualification requirements, confirming that personnel meet these requirements, application of management reviews, and documentation of results.

5.6 Conformance to Other Top-Level Safety Standards and Principles

This section addresses the attributes of a PSM program dealing with procedures and training, maintenance of the HAR, hot work operations, mechanical integrity, commissioning review, incident investigations, and emergency actions.

5.6.1 Procedure Development

Operating procedures provide clear instructions for safely operating the RPP-WTP during commissioning, normal operations, temporary operations, emergency shutdown, emergency operations, normal shutdown, and process startup following a turnaround or emergency shutdown. The procedures cover conditions under which emergency shutdown is required and assignment of shutdown responsibility to qualified operators, thus ensuring that emergency shutdown is executed in a safe and timely manner.

The procedures consider the consequences of deviations from outside normal operating limits and the steps required to correct those deviations. They contain safety and health considerations, such as the properties of, and hazards presented by, the chemicals used in the process. The procedures also contain the precautions necessary to prevent exposure, including engineered features, administrative controls and personal protective equipment, and control measures to be taken if physical contact or airborne exposure occurs. The procedures also address safety systems and their operation, and control of hazardous chemical inventory levels.

The operating procedures are periodically reviewed for human factors considerations and to ensure that they reflect current operating practice. The operating procedures are readily accessible to employees who work in or maintain a process. Safety Criteria 7.2-6, 7.2-7, and 7.2-8 of Volume II of the Safety Requirements Document (SRD) provide criteria for procedures required to implement PSM.

All operations that may affect safety are carried out in accordance with approved procedures that clearly delineate responsibility. Procedures provide step-by-step instructions on how to operate the facility or equipment routinely and safely. Some procedures are developed prior to the commissioning phase and serve to discipline the testing design intent to confirm facility operation to the design. During this phase, procedures are tested to demonstrate that they provide adequate direction for safe performance of facility operations.

There is a defined hierarchy of operating procedures, the position within which depends the safety significance of the operation to which the procedure refers. For example, procedures supporting the implementation of Technical Safety Requirements (TSR) or credited as defense-in-depth features for accident prevention and mitigation have a greater safety significance than those supporting operations with a lower impact on safety. Operator training emphasizes the importance of this hierarchy as well as the need to follow all procedures to carry out facility operations safely and efficiently.

The term “operating procedures” covers the entire range of procedures important for safe and efficient facility operations, in addition to those that detail routine facility operations. Procedures are provided for maintenance and emergency situations as well as day-to-day operations.

5.6.2 Updating of the Hazard Analysis Report

At least annually after the receipt of hazardous material at the RPP-WTP, the PHA and HAR are updated by a qualified team. This is to assure that the process hazard analysis is consistent with the current process. The PHA and HAR are also updated as required by the configuration management program.

Additional control of the HAR is provided by SRD Safety Criterion 3.1-7 which requires that changes in the processes or assumptions be accurately reflected in the hazards analysis. Changes to process or assumptions occurring between periodic updates of the hazards analysis are governed by the USQ process (described in ISMP Section 3.16.4, “Unreviewed Safety Questions”, and described in ISAR Section 3.1, “Configuration Management”) and by control of the authorization basis as described in ISMP Section 3.3.2, “Control of the Authorization Basis”. The periodic reviews and updates of the hazards analysis are performed in accordance with the Safety Criteria of SRD Volume II, Section 3.1, “Hazards Analysis”, governing the conduct of the hazards analyses, as implemented and described in ISAR Section 4.9, “Administrative Control of the Integrated Safety Assessment”.

5.6.3 Development of the Operator Training Program

The operator training program is developed and implemented in accordance with SRD Volume II, Section 7.2, “Training and Procedures”. Details on the Project training and qualification programs are provided in ISMP Section 3.4, “Safety/Quality Culture”, and Section 3.15, “Training and Qualification”. ISAR Section 3.4, “Training and Qualification”, further addresses the training policy and describes the level of training required to receive to efficiently and safely perform their intended duties.

The BNI program implements the above-referenced SRD criteria which contain a requirement to develop an operator training program that includes an overview of the facility processes and operating procedures, the specific safety and health hazards, operating limits, emergency operations, safe work practices, and refresher training.

Each employee involved in operating a process is trained in an overview of the process and in the operating procedures and instructions. The training includes emphasis on the specific safety and health hazards, operating limits, emergency operations including shutdown, and safe work practices applicable to the employee's job tasks.

Refresher training is provided at least every 3 years for PSM activities, and more often if necessary, to each employee involved in operating a process to ensure that the employee understands and adheres to the current operating procedures and instructions of the process and is proficient in the procedures to follow if conditions exceed the design basis of the facility.

5.6.4 Commissioning Review

Prior to operation of the RPP-WTP with radioactive materials and chemicals considered to pose a hazard, commissioning tests of the facility systems and personnel are performed in accordance with the Safety Criteria of SRD Volume II, Section 6.0, "Commissioning". This testing confirms that Safety Design Class and Safety Design Significant structures, systems, and components (SSC) are capable of performing their specified safety functions and personnel are knowledgeable and proficient in the performance of procedures. A review is also performed to ensure that the necessary safety, operating, maintenance, and emergency preparedness procedures are in place and adequate prior to operation of the facility. The content of the commissioning plan is provided in ISAR Section 3.10, "Testing Program and Preoperational Safety Review".

5.6.5 Mechanical Integrity

Procedures are established to maintain the integrity of process equipment, including pressure vessels and storage tanks, piping systems and pipe-mounted components, relief and vent systems and devices, emergency shutdown systems, controls (including monitoring devices and sensors, alarms and interlocks), and pumps. Inspections and tests that follow generally accepted good engineering practices are performed on process equipment. The frequency of inspections and tests is determined by manufacturer's recommendations, good engineering practices, and the vulnerability of components to the effects of aging, modified as necessary by operating experience. Inspection and test results are documented. Equipment deficiencies identified by the inspections or tests are corrected in a safe and timely manner.

The Project training program includes the training of each employee involved in maintaining the integrity of process equipment.

The Project QAP includes requirements for procedures to ensure that equipment, as fabricated, is suitable for the process application for which it will be used. Checks and inspections are performed to ensure that equipment is installed properly, and is consistent with design specifications and the manufacturer's instructions. A spare parts management system ensures that maintenance materials, spare parts, and equipment are suitable for the process application for which they are used.

Central to maintaining chemical and radiological exposures at a minimum is the requirement to maintain the mechanical integrity of SSCs. Maintenance activities related to this requirement are categorized as follows:

1) Routine
2) Planned replacement
3) Preventative
4) On demand (i.e., in response to failures).

The requirement for mechanical integrity is dependent on the duty of the equipment and its accessibility for routine inspection and maintenance. Therefore, in-cell equipment (which resides in a high radiation area) requires a higher level of reliable mechanical integrity than readily accessible out-cell equipment. The other important factor that influences the required degree of integrity is the role of the SSC in accident prevention or mitigation. Appropriate mechanical integrity of facility equipment is ensured using the following methods:

1) Early identification of safety significance and maintenance requirements (e.g., degree of accessibility and reliability)
2) Application of the appropriate manufacturing standards and quality assurance
3) Facility (equipment) acceptance testing
4) Inspection and monitoring requirements (preventative maintenance)
5) Training and maintenance instruction requirements.

5.6.6 Hot Work Operations

Hot work operations are reviewed and conducted in accordance with SRD Safety Criterion 4.5-19 which governs administrative controls to minimize fire hazards. These controls include those governing the use of ignition sources, reviewing proposed work activities for fire protection impacts, and the establishment of compensatory controls for activities that may impair fire prevention or mitigation features. The fire protection program is described in detail in ISAR Section 8.0, “Fire Safety”.

Implementation of other safety work practices, such as system and equipment tagout, use of scaffolding, and confined space entry, are also developed. They are addressed in detail in ISAR Section 3.11, “Operational Practices”.

5.6.7 Investigations of Incidents

For incidents that have the potential to result in a major accident or a release of hazardous or radioactive material from the controlled area of the RPP-WTP, an investigation is conducted in accordance with the Safety Criteria of SRD Volume II, Section 7.7, "Reporting and Incident Investigation". Incidents are categorized as soon as possible and, in all cases, within 2 hours as Emergency, Unusual, and Off-Normal occurrences. When the categorization is not clear, the occurrence is conservatively categorized at the higher level. Investigation of the incident is initiated as promptly as possible, but not later than 48 hours following the incident. The focus of the RPP-WTP incident investigation program is the identification of the events and near misses, determination of root causes, identification of corrective actions, dissemination of information to the lessons learned program, reporting of incidents, and the monitoring of the effectiveness of corrective actions. Additional information on incident investigation is provided in ISMP Section 3.16.3, "Incident Investigations". The incident reporting procedure and additional detail on the incident investigation program is contained in ISAR Section 3.7, "Incident Investigations".

An incident investigation team is established for incidents that have the potential to result in a major accident or a release of hazardous or radioactive material from the controlled area. The team consist of at least one person knowledgeable in the process involved, including a subcontract employee if the incident involved work of the subcontractor, and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident. A report is prepared at the conclusion of the investigation. The report is reviewed with all affected personnel whose job tasks are relevant to the incident findings. The incident report includes as a minimum:

1) Date of incident
2) Date investigation began
3) A description of the incident
4) Results of the root cause analysis
5) The factors that contributed to the incident
6) Any recommendations resulting from the investigation.

A system is established to promptly address, resolve, and document the incident report findings and recommendations.

The incident categorization is one factor used in determine the extent of the incident investigation in terms of the size of the investigation team, its independence, and the depth of the root cause analysis. By this process, the extent of the incident investigation is tailored to the consequences of the event or the potential consequences of a "near miss". For example, by tying the incident investigation to the event categorization, an increasing level of investigation is applied to the following events: 1) a hazardous substance release that exceeds 50% of a CERCLA reportable quantity; 2) a chemical release that violates environmental requirements in state or federal permits; and 3) a chemical release that had reported effects on collocated workers.

The categorization process is not the only factor that determines the extent of the incident investigation. For example, incidents that are repeat occurrences will receive more in-depth investigation, in part, to determine the reason for ineffectiveness of the corrective actions. Where repeat incidents or recurring causes are indicated, prompt follow-up action is initiated to identify additional corrective actions needed to preclude recurrence. These additional corrective actions are tracked to completion and their adequacy verified to ensure correction of the problem. An evaluation also is conducted for repeat occurrences to determine if the trend represents a programmatic failure reportable under 10 CFR 820.

The investigative process is used to gain an understanding of the incident, its causes, and corrective actions necessary to prevent recurrence. The process is summarized below.

1) The scope and depth of analysis of a particular incident is tailored to the significance of the incident. The tailoring of the analysis (i.e., incident investigation) is in part dependent on the categorization of the incident, if the incident is a repeat occurrence, and if the incident is considered a significant condition adverse to quality.
2) If the investigative process warrants a team investigation as determined from the evaluation above, at least one member of the investigative team is assigned from the organization most closely involved with the activities that were ongoing at the time of the event or incident. This member provides detailed first-hand knowledge of the performance of the activities. Other members are independent, and all members are knowledgeable of facility design and operations or are experts in safety (industrial or process).
3) At least one member is formally trained in at least one of the various industry-accepted methods of incident investigation and cause determination.
4) The team investigates the event, identifies underlying causes, formulates corrective action recommendations, and documents the results of the investigation.
5) The incident investigation process, its implementation, and its effectiveness are reviewed periodically by the Project Safety Committee or by audits or assessments.

5.6.8 Emergency Action Plan

For accidents that result in the need to take additional actions to protect the public and workers, and the environment from accidental releases of hazardous or radiological material, an emergency response program is provided in accordance with the Safety Criteria of SRD Volume II, Section 7.8, “Emergency Preparedness”. Emergency preparedness is addressed in ISMP Section 3.10, “Emergency Preparedness”. The Emergency Response Plan is outlined in ISAR Section 9.0, “Emergency Management”. This ISAR section describes how the plan complies with the requirements of 29 CFR 1910.38, “Employee Emergency Plans and Fire Protection”, 40 CFR 355, “Emergency Planning and Notification”, DOE/RL-94-02, *Hanford Emergency Response Plan*, (DOE-RL 1994) and DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors* (DOE-RL 1996b).

6.0 Integrated Safety Management

This chapter describes how safety management is integrated into work planning and performance. Lines of responsibility and authority for environment, safety, and health (ES&H) issues are described. Personnel qualification, resource allocation, and hazard assessments, controls, and operating conditions are discussed.

6.1 Integration Into Work Planning and Performance

The Project safety management process protects the public, workers, and the environment through implementing work practices that never compromise safety for the sake of production or expediency. This is achieved by BNI by way of the following:

1) Conduct activities in an atmosphere of trust and confidence based on open, honest, and responsible communication
2) Encourage employee feedback
3) Use proven and effective approaches to risk identification and control
4) Conduct business with integrity and mutual respect for employees and interfacing organizations
5) Apply a systematic approach to all activities that affect ES&H
6) Establish clear ownership and accountability
7) Define and reach agreement with the employees on the work to be accomplished by the facility operation and the expectation to accomplish the work in a safe manner
8) Promote teamwork through involvement of knowledgeable parties
9) Empower employees to effectively protect themselves, the public, and the environment
10) Allocate appropriate resources to support ES&H activities
11) Support continuous improvement of ES&H performance
12) Manage and conduct a consistent and project-wide integrated approach to ES&H for all activities
13) Encourage and promote sharing ES&H information and resources
14) Assignment of a qualified person for overall responsibility for the development, implementation, and integration of the safety management process.

Application of the above work practices allows the BNI team to effectively implement BNI guiding principles for integrating safety management into work planning and performance efforts. These guiding principles include establishing line management responsibility for ES&H, establishing and making clear lines of authority, ensuring that personnel have the necessary qualifications to perform the work, providing effective allocation of resources, performing pre-work hazard assessments, establishing appropriate controls for hazards and hazardous situations, and establishing operational requirements.

These work practices and principles are an integral part of the BNI team safety culture. They are formalized in Project policies, procedures, and instructions and are incorporated into all activities described in the following sections. The flowdown of these work practices and principles to subcontractors is discussed in Section 5.2, "Control of Subcontractors".

6.1.1 Line Management Responsibility for ES&H

Line management responsibility and accountability for ES&H is one of the key principles of the BNI approach to ES&H integration. To ensure maximum effectiveness in ES&H performance, employees are informed of their responsibility and accountability for creating and maintaining a safe and healthy workplace and protecting the environment.

In addition, ES&H individuals do not assume roles that reside with the line organization. This creates an environment where accountability is clearly focused and ES&H priorities are never sacrificed to another line mission or objective.

6.1.2 Lines of Authority and Responsibility

Clear and unambiguous lines of authority and responsibility are established throughout the Project through its design, construction, operation, and deactivation phases. The flowdown of ES&H responsibility and accountability starts with the Project Manager during construction and the Facility Manager during operation (which includes deactivation) and extends through the management and supervisory chain to each worker, irrespective of the type of work being performed. This flowdown is captured in policies and procedures, communicated to the workforce through orientation and training, reinforced by group and individual performance evaluations, and monitored and assessed by independent oversight provided by ES&H professionals.

Stop-work authority also flows down from senior management to individual workers who are explicitly empowered to halt any activity in which they are engaged that is unsafe or potentially harmful to the environment.

6.1.3 Personnel Qualification and Resources

The Project training provides personnel with the knowledge, skills, and direction necessary to perform their duties in a safe and environmentally sound manner. Training is performed using a tailored approach, commensurate with the level of risk and individual responsibility.

The Project training addresses relevant ES&H requirements and is provided at all levels of the organization as follows.

1) Employees are trained to ensure they recognize, understand, and anticipate the hazards and the environmental requirements associated with performing their work.
2) Supervisors are trained to ensure they understand their responsibilities for assisting employees in analyzing the work for safety hazards and environmental compliance requirements; to assist employees in maintaining physical protection at work sites; and to enforce (and reinforce) performance standards, protective measures, and environmental practices.

3) Managers are trained to understand their responsibilities for providing necessary ES&H support and direction to supervisors, employees, and subcontractors and for demonstrating ES&H leadership through their actions and communications.

Resources are assigned to ensure that protection is provided for the public, workers, and the environment. The risk assessment process, discussed in Section 6.1.4, "Hazard Assessments, Controls, and Operating Conditions", provides the key input to the resource allocation process by identifying the significant risks associated with RPP-WTP work activities.

6.1.4 Hazard Assessments, Controls, and Operating Conditions

The performance of hazard assessments, the specification of appropriate controls, and the establishment of safe operating conditions are all achieved through the use of a risk assessment system that ensures that all significant risks are identified. The RPP-WTP risk assessment system evaluates tasks and the work environment to anticipate, recognize, evaluate, and control situations, conflicts, and stressful situations, and other conditions that may significantly affect the health, safety, or efficiency of the Project employees. Each of the following basic components of the systems is performed with a degree of rigor based on the scope of the work effort and commensurate with the potential hazardous situation it presents as follows.

1) Pre-job planning encompasses the task description, expected hazards and hazardous situations, protection methods, anticipated exposure levels, waste generation, and emergency response.
2) Baseline evaluations determine the status of a facility area or system.
3) Integrated hazard analyses detail the evaluations of the potential hazards and the controls needed to protect the public, personnel, and the environment.
4) Radiological work planning outlines routine and special radiological controls, precautions, surveillances, and instructions to personnel, as well as prerequisite conditions (e.g., tagouts and system isolations).
5) Assessments and surveillances including formal and informal appraisals, monitoring, and oversight activities to verify that specific elements of the policies, programs, plans, and procedures are being effectively implemented; that work is being performed safely; and appropriate compliance and commitment tasks are being performed.
6) Investigations of work-related injuries or illnesses, near misses, motor vehicle accidents, property damage, environmental spills and releases, fires, and explosions through accident and incident response to identify the root cause and contributing causes of the event and the corrective actions necessary to prevent recurrence.

The above safety management processes provide a coherent, integrated, and formalized methodology to ensure that the risks associated with potential health, safety, and environmental hazards and hazardous situations are identified and properly addressed, and that the RPP-WTP can be operated safely and in compliance with environmental regulations.

7.0 Regulatory Interfaces

This chapter describes the BNI interface with regulatory agencies regarding environmental protection, occupational health and safety, and safeguards and security. Section 7.4 "Resolution of Conflicting Requirements and Standards" covers the resolution process when standards and requirements conflict.

7.1 Environmental Protection Interface

The U.S. Department of Energy (DOE) and the State of Washington have analyzed the environmental impacts from treatment of tank waste by vitrification in the Tank Waste Remediation System (TWRS) Environmental Impact Statement (EIS). This EIS satisfied both the requirements of the *National Environmental Policy Act* and the *State Environmental Policy Act*. In addition, the Record of Decision (62 FR 8693) for the TWRS-EIS selected the phased implementation option that called for the deployment of two Phase I facilities to treat the tank waste.

To support the Record of Decision resulting from the TWRS-EIS, the BNFL team prepared an environmental report (ER) in accordance with the requirements of 10 CFR 1021.216, "Procurement, Financial Assistance, and Joint Ventures". The environmental report updates the information provided by the DOE and the Washington State Department of Ecology (Ecology) in the EIS.

The Environmental Protection Agency (EPA) has provided Ecology and the Washington Department of Health (DOH) the authority to permit air emissions including those from the Facility. Ecology is responsible for regulating criteria pollutants and toxic air pollutants (WAC 173-460 and 173-400). The DOH regulates radioactive emissions.

Ecology regulates the RPP-WTP with respect to the *Resource Conservation and Recovery Act of 1976* (RCRA). The regulations for the management of dangerous waste are found in WAC 173-303. A contract Part A deliverable is a Draft Dangerous Waste Permit Application for review by the DOE. Many meetings with Ecology to date have focused on the Draft Dangerous Waste Permit Application to obtain early benefit of input from Ecology.

The WTP project team identified all of its environmental permits and monitoring in an Environmental Plan. In addition to the air permits and the Dangerous Waste Permit Application, the plan identified activities to be performed by the team during Part B to protect the environment.

To support early development of the Environmental Plan, the BNFL team prepared a Permitting Plan in conjunction with the DOE, Ecology, and the DOH. This plan provided the tentative dates for major permitting activities for the RPP-WTP. In addition, the Permitting Plan documented all of the permitting interfaces with other DOE waste treatment, storage, and disposal facilities, and provides public involvement opportunities. The Permitting Plan was approved and signed by representation of DOE, Ecology, DOH, and the WTP contractor.

BNI participates in information exchanges with the environmental agencies through routine Permitting Task meetings and workshops. Ecology and the DOH are regular participants in these meetings along with DOE. BNI maintains communication with the regulatory agencies through these meetings, occasional technical meetings on specific topics, and by numerous discussions either in person or by telephone to exchange additional information.

7.2 Occupational Health and Safety Interface

BNI complies with all applicable federal, state, and local safety and health regulations to ensure occupational health and safety for RPP-WTP workers. The project occupational safety and health program is regulated by the US Department of Energy (DOE).

The DOE has drafted a memorandum of understanding with the OSHA for the DOE to provide onsite observation of OSHA compliance similar to that conducted by the U.S. Nuclear Regulatory Commission (NRC) at nuclear reactors. BNI responds to observations provided by the DOE to both the OSHA and the DOE. In addition, any responses to OSHA inquires are sent to both entities.

BNI ensures non-radiological safety and health (i.e., occupational health and safety) compliance with applicable regulations by the design, testing, and maintenance of structures, systems, and components and through administrative controls to address health and safety hazards. The identification and mitigation of occupational health and safety hazards occurs through application of the RPP-WTP Project non-radiological worker health and safety program and, for hazardous materials above threshold quantities, compliance with the Process Safety Management (PSM) regulation found in 29 CFR 1910.119, as discussed in ISMP Section 5.1, “Process Safety Information”. Identification of hazards includes the use of Material Safety Data Sheets and other methods as specified in 29 CFR 1910.1200, “Hazard communication”. The Project maintains records of compliance activities as part of the protocols found in ISMP Chapter 8.0, “Document Control and Maintenance”, to support non-radiological safety and health inspections.

7.3 Safeguards and Security Interface

The preliminary assessment of the composition of candidate radioactive waste feeds indicated the quantities and types of special nuclear materials (SNM) to be handled at the RPP-WTP should be classified as Attractiveness Level E and Nuclear Material Safeguards Category IV. These are the lowest classification levels. Safeguards and security requirements for SNM appropriate for the RPP-WTP will be developed with DOE. These considerations will be consistent with the economic and strategic value of the materials present at the facility. Any conflicts that arise between considerations for safeguards and security and radiological, nuclear, and process safety will be resolved by discussions among BNI and the DOE.

7.4 Resolution of Conflicting Requirements and Standards

Conflicting standards and requirements can arise internal to the radiological, nuclear, and process safety regime and external to this regime. The Project safety management process addresses both types of conflicts as described below.

Internal Conflicts

Internal conflicts are identified as a direct consequence of the Project approach to design. The ISMP Section 4.1.3, "Development of Safety Management Programs", describes how the Safety Requirements Document (SRD) is linked to the design process to ensure that standards are properly implemented. Because all standards and requirements information flows down into lower level design guides (see Figure 4-2), internal conflicts are recognized. At this point, the process established to maintain the SRD is used to resolve the conflict. The process for maintaining the SRD is described in SRD Volume I, Section 3.6, "Maintenance of the SRD".

External Conflicts

To ensure that current regulatory requirements and regulatory changes are promptly and accurately identified, BNI team members maintain access to multiple regulatory resources, as discussed in Section 2.1.

When the potential applicability of an existing, new, or revised regulatory requirement is identified, any conflicts are resolved. The impact on project cost and schedule, along with the feasibility of implementing the requirement, are included in the evaluation.

Routine meetings with the regulator offer a forum for identification and discussion of external conflict issues. Letters between the regulating agencies and the BNI team provide formal documentation of issue resolutions.

In the cases where safety and environmental regulations conflict, absent the granting of an exemption from the regulation, the more stringent regulation is followed.

The nature of taking responsibility for operation of the double-shell tank AP-106 requires the resolution of a number of interface concerns. From an early stage, interface meetings were held among the WTP Project contractor, the DOE, and the Project Hanford Management Contractor (PHMC) to identify and resolve these concerns. Interface responsibilities are agreed on and recorded in interface control documentation. Adding concerns to this documentation and accepting their resolution requires approval of all parties involved with the interface issue.

8.0 Document Control and Maintenance

The Quality Assurance Manual (QAM) requirements for the Project records management system is provided in Section 5, “Instructions, Procedures, and Drawings”, Section 6, “Document Control”, and Section 17, “QA Records” of the QAM (BNI 2001).

Documents are prepared, reviewed, approved, issued, and revised to prescribe processes, specify requirements, and establish design. Safety documents developed as a part of the safety management process controlled by the QAP include but are not limited to those identified in Table 8-1. The column “Records” lists the documents that address the items in the “Subject” column.

Table 8-1 Safety Management Records (Sheet 1)

Subject	Records
Authorization basis	• Integrated Safety Management Plan • Safety Requirements Document • Radiation Exposure Standard for Workers Under Accident Conditions • Preliminary Safety Analysis Report • Final Safety Analysis Report • Technical Safety Requirements • Quality Assurance Plan and Implementation Plan • Radiation Protection Program • Emergency Plan • Safety Evaluation Reports • Written communication with the regulator • Safety analyses
Design	• Master equipment list • Software verification and validation • Equipment and system testing requirements • Equipment qualification requirements • Facility and equipment description and drawings • Design control procedures • Design Criteria and bases for Safety Design Class and Safety Design Significant structures, systems, and components (SSC) • Records of facility changes (configuration management) and associated integrated safety analyses • Specifications for Safety Design Class and Safety Design Significant SSCs • ALARA documents
Construction	• Records of site characterization measurements and data • Construction procedures • Inspection and test records • Construction material certifications • Calibration and test records • Nonconforming condition reports and closure records • Procurement specifications • Craft qualification records

Table 8-1 Safety Management Records (Sheet 2)

Subject	Records
Management Organization and Administration	• Administrative procedures with safety implications • Performance Plans • Employee concerns program, discipline, and employee action records (for protected activities) • Evidence of deliberate misconduct • Organization charts, position statements, training, and qualification records • Safety and health compliance records, medical records, and personnel exposure records. • Safety statistics and trends • Incident reports • Technical and experience qualifications (design, construction, and operation)
Operations	• Commissioning test results • Operating logs • Maintenance records • Calibration and testing data • Material balance, inventory, transfer, and disposal records • Material storage records • Facility operating procedures • Change control records for Safety Design Class and Safety Design Significant procedures • Operator aids (e.g., charts and drawings used to assist operator in performing job) • Training records • Special test records • Corrective action determination and close-out reports • Unreviewed safety question screening and evaluation reports • Records pertaining to disposal of radioactive and mixed wastes
Integrated Safety Analysis	• Integrated Safety Analyses and supporting data, analyses, calculations, and documents • Change control records for Safety Design Class and Safety Design Significant changes to facility • List of Safety Design Class and Safety Design Significant SSCs • Methods for setting acceptable safety limits and controls (including nuclear criticality safety) • Fire hazard analysis • Initial Safety Analysis Report • Hazard Analysis Report
Radiological Safety	• Radiation protection (and contamination control) records • Radiation Work Permits • Radiation protection training records • Records pertaining to radiological process incidents, unusual incidents, and accidents • Individual monitoring (10 CFR 835.702) • Monitoring and workplace (10 CFR 835.703) • Administrative (10 CFR 835.704) • ALARA records • Dosimetry records • Release of property and equipment • Exposures exceeding applicable limits • Records pertaining to sealed sources, accountability, and control • Receipt and transportation or radioactive materials

Table 8-1 Safety Management Records (Sheet 3)

Subject	Records
Nuclear Criticality Safety	• Nuclear criticality control procedures and statistics* • Records pertaining to nuclear criticality incidents, unusual incidents, and accidents* • Records pertaining to nuclear safety analyses (* criticality analysis may show these records to be unnecessary)
Chemical Safety	• Chemical process safety procedures • Records pertaining to chemical process inspections, audits, investigations, and assessments • Chemical process safety reports and analyses • Chemical process safety training
Fire Safety	• Hot-work permits and fire-watch records • Records pertaining to inspection, maintenance, and testing of fire protection equipment • Records pertaining to fire protection training • Pre-fire emergency plans
Emergency Management	• Review of emergency plan from outside emergency response organizations and supporting entities • Memoranda of understanding with outside emergency response organizations • Records pertaining to the training of personnel involved in emergency preparedness functions • Emergency drill and exercise records • Records pertaining to inspection and maintenance of emergency response equipment and supplies
Environmental Protection	• Environmental release and monitoring records • Environmental Report • Environmental Permits (e.g., air, water, and waste)
Occupational Safety and Health	• Material Safety Data Sheets • Training records of staff and contract employees • Inspection and testing reports • Equipment deficiency reports and resolution
Deactivation and Decommissioning	• Deactivation records • Incident reports to support decommissioning (e.g., radiological and chemical spills)
Quality Assurance	• Training and qualification/certification records • Audit and assessment procedures and reports • Surveillance reports • Nondestructive testing procedures, calibration data, and test results • Calibration results • Nonconforming condition reports and closure documentation • Defective and counterfeit items • Procurement documentation • Supplier assessments and vendor inspections • Project review of vendor drawings • Certified vendor information

9.0 Scheduling of Safety-Related Activities

This chapter provides the sequence of events for safety-related activities and deliverables for the design, fabrication and construction, commissioning, operation, and deactivation phases of the Project. The safety-related activities to be conducted during these phases are also presented.

9.1 Scheduling Safety-Related Activities

Figure 9-1 shows the sequence of events and interdependencies between the safety-related Part B activities. A schedule addressing Figures 2, 5, 6, and 7 of DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, (DOE-RL 1996a) was provided in BNFL Inc. letter of November 4, 1998 (reference 000500).

Tables 9-1 through 9-5 describe key safety-related activities and show the assignment of these activities to functional areas.

9.2 Scheduling of Events for Regulatory Submittals

This section addresses the scheduling of regulatory submittals required by DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors* (DOE-RL 1996a) and the Safety Requirements Document (BNFL 1997d). Figure 9-1 provides the sequence of events for the following deliverables to DOE.

1) The construction authorization package, which will include the Preliminary Safety Analysis Report (PSAR). The PSAR will address Items 1-5, 7-15, 18, and 20 of DOE/RL-96-0003, Section 4.3.2, “Contractor Input”, (DOE-RL 1996a). The remaining items will be provided separately from the PSAR.
2) The operating authorization package, which will include the Final Safety Analysis Report (FSAR). The FSAR will address Items 1-5, 7-9, 12, 15, 17, 18, 20, 21, and 23 of DOE/RL-96-0003, Section 4.4.2, “Contractor Input”, (DOE-RL 1996a). The remaining items will be provided separately from the FSAR.
3) The submittal of the deactivation authorization request. This will include revision to the Integrated Safety Management Plan (ISMP) to provide additional detail on deactivation activities.

The self-assessment documents identified in Item 4 of DOE/RL-96-0003, Section 4.5.2, “Contractor Input” are provided to the DOE within 90 days of the completion of the assessment.

Revisions to the Quality Assurance Program will be submitted to the DOE with the standards approval package for construction, operation, and deactivation which is submitted fourteen weeks prior to the scheduled authorization request submittal.

Figure 9-1 Sequence of Safety Related Activities (Sheet 1 of 3)

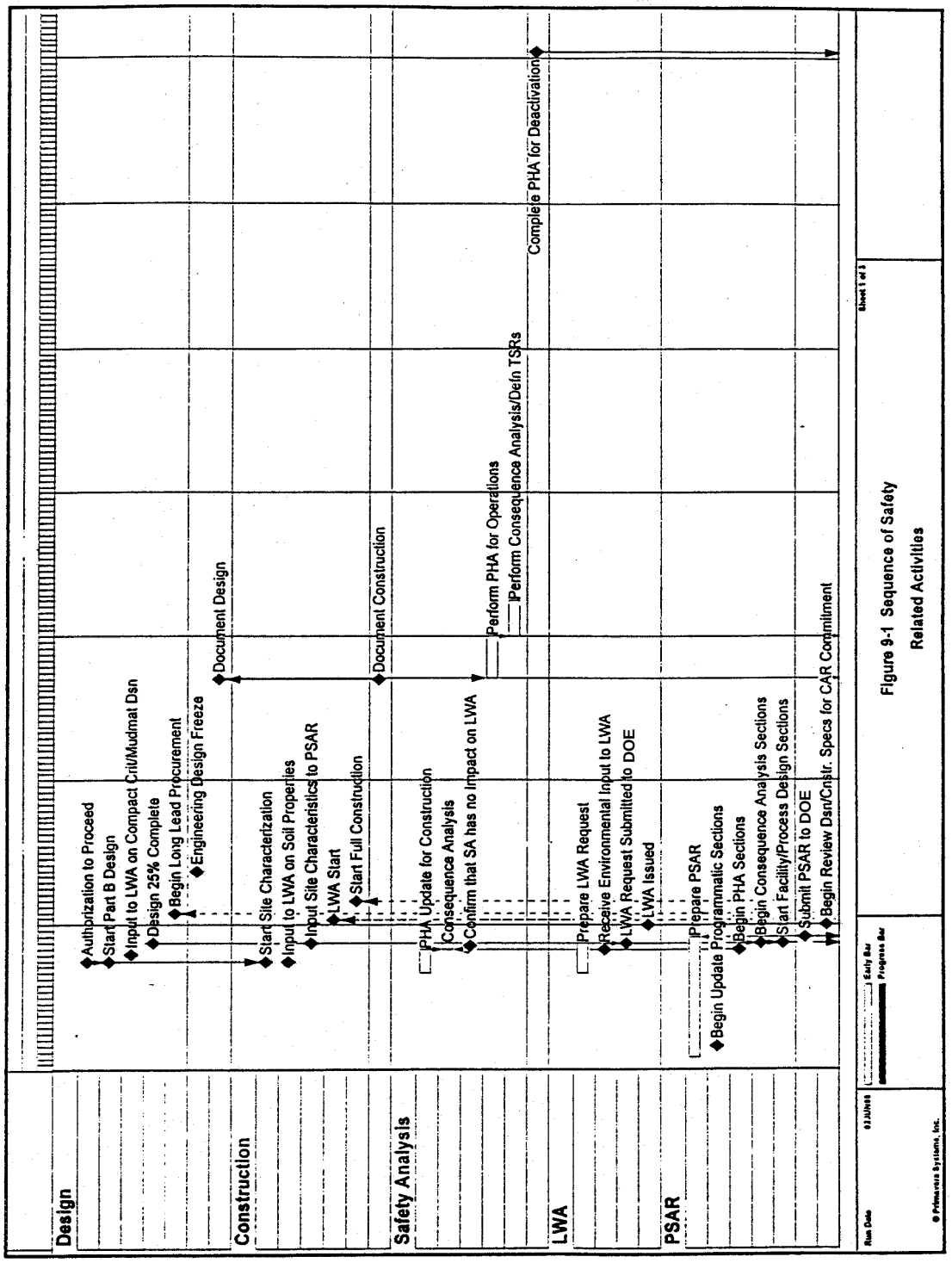


Figure 9-1 Sequence of Safety Related Activities (Sheet 2 of 3)

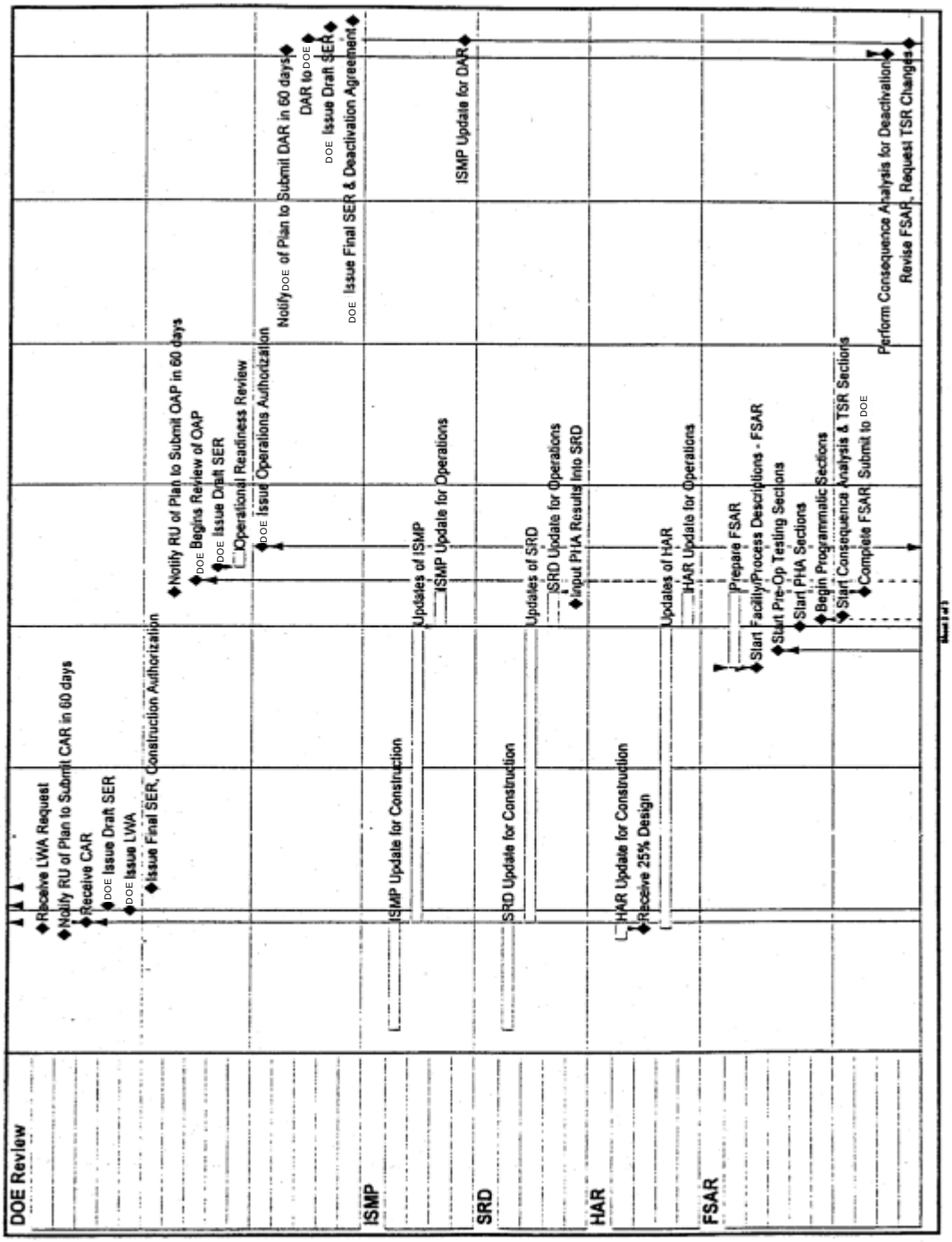


Figure 9-1 Sequence of Safety Related Activities (Sheet 3 of 3)

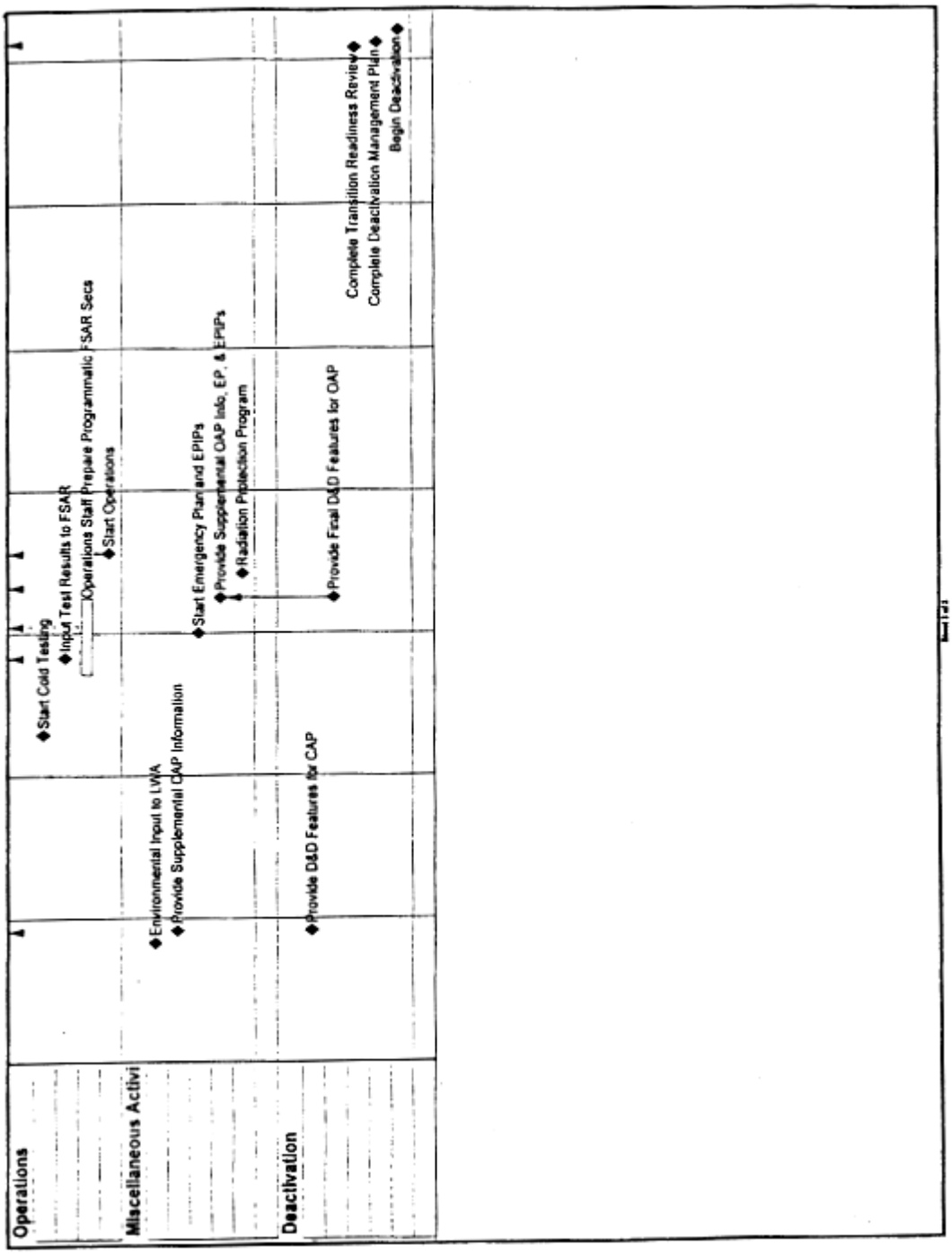


Table 9-1 Key Safety-Related Activities – Design Phase (Sheet 1)

Safety-Related Activities	Functional Area
Planning:	
• Define safety policy and objectives	• Project Management
• Define critical safety interfaces for the various phases of the project	• Project Management
• Implement safety policy and objectives	• Line Managers, all functional areas
• Assign roles for safety-related activities	• Project Management
• Develop procedures to implement safety objectives and organizational plans	• Environment, Safety, and Health
• Develop plans and procedures to address internal safety and oversight functions	• Environment, Safety, and Health
• Develop plans and procedures to address quality assurance and quality control functions	• Quality Assurance
• Develop plans and procedures for identification and resolution of employee concerns	• Human Resources
• Develop performance measures	• Project Management
• Develop employee feedback program	• Project Management
• Develop configuration management program	• Configuration Management
• Develop and implement a regulatory commitment tracking system	• Environment, Safety, and Health
Analysis / Regulatory:	
• Update Process Hazards Analysis (PHA)	• Environment, Safety, and Health
• Update Hazard Analysis Report	• Environment, Safety, and Health
• Identify requirements of the facility design for environmental regulatory compliance	• Environmental Protection
• Identify requirements of the facility design for Occupational, Safety, and Health (OSHA) Administration compliance	• Environment, Safety, and Health
• Prepare applications for state and federal environmental permits	• Environmental Protection
• Update Standards Requirements Document	• Environment, Safety, and Health
• Update Integrated Safety Management Plan	• Environment, Safety, and Health
• Prepare limited work authorization request	• Environment, Safety, and Health
• Prepare Preliminary Safety Analysis Report	• Environment, Safety, and Health

Table 9-1 Key Safety-Related Activities – Design Phase (Sheet 2)

Safety-Related Activities	Functional Area
Design Functions:	
• Develop the quality assurance program plan for the design phase	• Quality Assurance
• Develop facility design that will achieve the defined work activity and satisfy commitments of the construction authorization package	• Engineering
• Incorporate into the design measures that minimize the hazards associated with processing and storing radioactive liquid and solid waste, and fissionable materials	• Engineering
• Incorporate into the design measures to facilitate performance of Technical Safety Requirement surveillances	• Engineering
• Incorporate design features to ensure personnel exposure is as low as reasonably achievable	• Engineering
• Identify design requirements for security	• Environment, Safety, and Health
• Incorporate design requirements for security	• Engineering
• Implement consideration for deactivation and decommissioning into the facility design	• Engineering
• Verify and validate design products against safety requirements	• Engineering
• Implement configuration management control program	• Configuration Management
• Define acceptance criteria for the construction testing program	• Engineering
• Perform systematic design reviews to determine readiness to authorize construction of Safety Design Class and Safety Design Significant systems, structures, and components	• Engineering

Table 9-2 Key Safety-Related Activities – Fabrication and Construction Phase

Safety-Related Activities	Functional Area
Construction:	
• Implement quality assurance program plan for the construction phase	• Quality Assurance
• Incorporate regulatory and quality commitments into procurement, fabrication, inspection, and testing	• Engineering
• Incorporate regulatory requirements and quality commitments into facility construction, procurement, fabrication, inspection, and testing specification, training, and procedures	• Engineering and Construction Management
• Implement procedures and training to enhance construction safety	• Engineering
• Develop a program to ensure that the designer's configuration management program is implemented and that as-built information critical to safety is supplied to the facility operator	• Configuration Management
• Develop procedures for hazardous material handling, packaging, labeling, and shipping practices	• Construction Management
Inspection and Testing:	
• Conduct audits and inspections that verify compliance to requirements by the construction contractor, subcontractors, and Safety Design Class and Safety Design Significant suppliers of systems, structures, and components	• Quality Assurance
• Implement construction testing program to verify that SSCs meet acceptance testing requirements	• Construction Management
• Perform a systematic review(s) to determine readiness to authorize facility turnover in preparation for commissioning testing	• Environment, Safety, and Health

Table 9-3 Key Safety-Related Activities – Commissioning Phase

Safety-Related Activities	Functional Area
Planning:	
• Develop objective and scope for startup testing (scope to include initial and boundary conditions and simulated single failures, as appropriate)	• Technical Support
• Identify the role of design and accident analyses organizations in the identification of the tests to be performed and acceptance of the test results	• Technical Support
• Develop testing program that emphasizes testing with non-radioactive streams	• Operations
• Identify tests to be performed and their acceptance criteria	• Technical Support
• Develop the quality assurance program plan for an operating facility	• Quality Assurance
• Develop operating staff training program	• Operations
• Conduct staff training	• Operations
• Develop program for procedure preparation, review, validation, approval, change, deviation, and internal control	• Operations
• Define the maintenance program that includes preventive, predictive, and corrective maintenance practices and incorporates vendor-recommended maintenance activities	• Technical Support
• Develop operating procedures	• Operations
• Develop administrative procedures	• Operations
• Develop maintenance procedures	• Maintenance
• Develop procedures for hazardous material handling, packaging, labeling, and shipping practices	• Technical Support
• Prepare Final Safety Analysis Report	• Environment, Safety, and Health
• Implement a process safety management program	• Environment, Safety, and Health
Startup Testing:	
• Write test procedures	• Technical Support
• Develop processes for evaluating and resolving unreviewed safety questions and for requesting discretionary enforcement relief from Technical Safety Requirements	• Environment, Safety, and Health
• Perform testing and document results to acceptance criteria	• Operations
• Collect safety component and process baseline data for future performance monitoring and maintenance planning	• Configuration Management

Table 9-4 Key Safety-Related Activities – Operations Phase

Safety-Related Activities	Functional Area
Planning Prior to Facility Operations:	
• Develop Technical Safety Requirement (TSR) surveillance testing and evaluation program	• Environment, Safety, and Health
• Provide independent internal oversight review to ensure facility operation within the authorization basis	• Environment, Safety, and Health
• Develop the radiation protection program	• Radiation Protection
• Develop emergency response procedures	• Operations
Facility Operation:	
• Implement the operational phase quality assurance program	• Quality Assurance
• Implement the emergency preparedness plan including conduct of emergency exercises	• Operations
• Implement the radiological protection program	• Radiation Protection
• Implement a monitoring, evaluation, and reporting program in compliance with the operating authorization	• Environment, Safety, and Health
• Implement the operational phase program for internal safety and oversight functions	• Environment, Safety, and Health
• Implement performance measures and feedback systems	• Facility Management
• Implement a management assessment function	• Facility Management
• Implement a maintenance program	• Maintenance
• Perform testing and monitoring required by the TSRs	• Maintenance
• Operate facility to achieve defined work activity and within the operating authorization and authorization basis	• Facility Manager
• Perform incident investigations including reporting, root cause analyses, identification of corrective actions, and tracking of effectiveness of corrective actions and apply lessons learned from relevant facilities	• Environment, Safety, and Health
• Maintain an operating history to facilitate deactivation of the facility	• Configuration Management

Table 9-5 Key Safety-Related Activities – Deactivation Phase

Safety-Related Activities	Functional Area
Planning:	
• Define deactivation interfaces for surveillance, maintenance, and deactivation	• Technical Support
• Develop the surveillance and maintenance criteria and end point criteria	• Technical Support
• Assign roles and responsibilities for safety-related activities for deactivation	• Facility Manager
• Identify deactivation measures that minimize hazards associated with treating and storing radioactive, liquid, and solid waste, and fissionable materials	• Technical Support
• Prepare deactivation management plan	• Technical Support
• Modify plans and procedures addressing internal safety and oversight functions for deactivation phase	• Environment, Safety, and Health
• Modify plans and procedures addressing quality assurance and quality control functions for the deactivation process	• Quality Assurance
• Develop deactivation performance measures	• Facility Manager/Technical Support
• Develop/modify operating and maintenance instructions for post-deactivation operational equipment	• Maintenance
• Develop design modifications to facilitate deactivation	• Technical Support
Analysis / Regulatory:	
• Perform a job hazard analysis and update the Hazard Analysis Report	• Environment, Safety, and Health
• Identify critical aspects of facility deactivation that would effect environmental regulatory compliance	• Environmental Protection
• Prepare applications for changes to state and federal environmental permits	• Environmental Protection
• Prepare a deactivation Safety Analysis Report and modify facility authorization basis	• Environment, Safety, and Health
Deactivation:	
• Initiate the quality assurance program plan for the deactivation phase of the facility	• Quality Assurance
• Implement facility modifications to facilitate performance of Technical Safety Requirement surveillances	• Technical Support
• Initiate deactivation	• Operations
• Monitor deactivation activities to ensure personnel exposure meets as low as reasonably achievable objectives	• Radiation Protection
• Verify and validate the deactivation process against safety requirements	• Environment, Safety, and Health
• Confirm the facility has achieved a passive state that meets the end point criteria	• Environment, Safety, and Health

During operation of the RPP-WTP, reports will be submitted to DOE that report the following:

1) The quantity of each principal radionuclide in excess of background released to the unrestricted area in liquid and gaseous effluents
2) The calculated annual dose to the maximally exposed members of the public
3) The calculated collective dose to members of the public.

In addition, the PHA and HAR are reevaluated and updated annually.

Figure 9-1 does not provide a schedule for the initial safety assessment as the figure addresses only Part B activities. The initial safety assessment package was delivered to the Regulatory Unit in December 1997 as part of the Part A activities (BNFL 1997c).

9.3 Flow of Safety-Related Work and Deliverables

Figure 9-1 shows the interdependencies between the deliverables.

The scope of the proposed Limited Work Authorization (LWA) included in Figure 9-1 provides for early initiation of construction activities. The LWA allows for excavation, backfill, recompaction, and installation of the mud mat and ground grid. The LWA request would include information on site suitability (addressing hazards from natural phenomena and nearby facilities as they would impact the requested construction activity); excavation, backfill, and recompaction criteria; stability of surface soils; design requirements and Quality Assurance Program to be applied to the requested LWA activities; current SRD standards and ISMP program applicable to LWA activities; description of planned safety-related testing to be performed during LWA activities; references to the procedures to be employed for the requested work; and the environmental impacts of implementing the requested work activity.

10.0 Assessments

Assessments of the Project verify that public and worker safety considerations are reflected in the design, procurement, construction, commissioning, operation, and deactivation of the facility. The role of safety committees in achieving these objectives is discussed in Integrated Safety Management Plan (ISMP) Section 3.16.1, "Safety Committees".

Assessments in compliance with 10 CFR 830.120(c)(3)(i) and (c)(3)(ii) involve the following:

1) Management assessments. Managers assess their management processes so that problems that hinder the organization from achieving its objectives are identified and corrected. These assessments are discussed in Section 10.1, "Management Assessments".
2) Independent assessments. Independent assessments are performed to measure item and service quality, measure the adequacy of work performance, and promote improvement. These assessments are discussed in Section 10.2, "Independent Assessments".

During the design and construction phase, assessments are directed at such activities as:

1) The development of regulatory documents
2) Performance of safety analysis
3) Qualification of personnel, training, and procedures as related to design and construction
4) Design control
5) Construction work packages
6) Worker safety
7) Fire protection
8) Equipment procurement.

Assessments during operation and deactivation provide oversight of these same areas and extend to the following areas:

1) Radiation control
2) Unreviewed safety questions evaluations
3) Compliance with the authorization basis
4) Maintenance training and work performance
5) Hazardous waste management
6) Emergency exercises
7) Compliance to deactivation end point criteria
8) Fire protection.

The following sections provide a summary of the more significant aspects of the assessment processes.

10.1 Management Assessments

Management assessments are conducted annually by the line manager of each RPP-WTP organization to measure the effectiveness of their activities in achieving public and worker safety. The assessments focus on the various functional programs for which managers have safety responsibility.

The assessments cover, but are not limited to the following:

1) Interfaces among groups with safety roles
2) Use of safety performance indicators
3) Adequacy of resources
4) Staff training and qualification
5) Supervisory oversight and support.

Management assessments involve the following:

1) Evaluating the implementation of applicable portions of the quality assurance program
2) Identifying barriers hindering the accomplishment of safety objectives, documenting response actions, and implementing corrective actions
3) Developing a plan for each management assessment that includes the schedule, scope, level of effort, and team qualifications
4) Issuing a final report with identification of problems and corrective actions
5) Evaluating the effectiveness of the corrective actions in preventing recurrences.

Section 18 of the QAM addresses the purpose and conduct of management assessments and specific managers' responsibilities in the assessment process.

10.2 Independent Assessments

Independent assessments measure the effectiveness of activities in achieving public and worker safety. The staff performing independent assessments have sufficient authority and freedom outside the line organization to carry out their responsibilities. Individuals performing independent assessments are technically qualified and knowledgeable in the areas being assessed. Independent assessments are performed to identify the following:

1) Work performance and process effectiveness
2) Abnormal performance and potential problems
3) Improvement opportunities
4) Effectiveness of root cause identification and corrective actions in preventing recurrence of previous problems
5) Lessons learned from other organizations with similar activities or concerns.

The frequency of the assessments for various functional areas is based on the following:

1) Status, complexity, and importance of the activity or process being assessed
2) Past performance of the activity or process being assessed
3) Performance indicator results and trending to ensure activities are achieving adequate public and worker safety.

Section 8 of the QAM addresses the purpose and conduct of independent assessments, independence and qualifications of assessment personnel, documentation of results, management responses and actions, and specific managers' responsibilities in the assessment process.

10.3 Corrective Action Implementation and Tracking

An administrative system is established for tracking corrective action items. Problems are evaluated and trended to determine if any should be reported in an incident report or reported under 10 CFR 820, "Procedure Rules for DOE Nuclear Facilities" as a significant noncompliance with a nuclear safety requirement. Effectiveness of the corrective actions in preventing recurrence of previous problems is evaluated in a subsequent management assessment.

10.4 Support of DOE Inspection and Corrective Action/Enforcement Action Programs

This section addresses the DOE inspection and corrective active/enforcement action programs including the Project's responsibilities relative to these programs.

10.4.1 DOE Inspection Program

The DOE inspection program is described in *Inspection Program Description for the Regulatory Oversight of TWRS Privatization Contractors*, (DOE-RL 1998b). The purposes of this inspection program are described as:

1) Confirming Contractor performance to the authorization basis and Contract in the areas of radiological, nuclear, and process safety
2) Ensuring timely identification and implementation of corrective actions such that regulatory conditions detrimental to safety and the interests of fixed-price contracting are avoided
3) Developing independent inputs for subsequent regulatory authorization or actions thereby fostering regulatory efficiency.

The DOE inspection program is executed in a planned, disciplined, and predicable manner. This is accomplished through appropriate planning, preparation, and performance of inspections and through the use of established protocols (DOE-RL 1998b).

The Project supports the DOE inspection program by:

1) Making available for DOE review, documentation such as program plans, manuals, procedures, instructions, technical reports, self-assessment reports, meeting minutes, records, data reports and event reports
2) Providing briefings and discussions and support interviews on selected subjects as requested by the DOE and prearranged with BNI.
3) Supporting on-location DOE observations of Project operations and activities as requested by the DOE and prearranged with BNI.
4) Supporting unannounced on-location DOE observation of Project construction, operation, and deactivation activities
5) Attending and supporting pre-inspection and inspection entrance and exit meetings
6) Responding to findings of DOE inspection activities.

The above-mentioned RPP-WTP operations and activities to be observed include, but are not limited to, 1) monitoring of equipment performance during operation, inspection, or testing, 2) witnessing of tests, and 3) the performance of independent analyses.

10.4.2 DOE Corrective Action/Enforcement Action Program

The DOE corrective action/enforcement actions program is described in *Corrective Action/Enforcement Action Program Descriptions* (DOE-RL 1998a). The Project supports the DOE corrective action and enforcement actions program by:

1) Self-identification of non-compliant conditions and the prompt reporting of such conditions to DOE
2) Responding to corrective action notices issued by DOE
3) Prompt implementation of a safety-rework, suspend operation, stop work, and Compliance Orders issued by the DOE.

11.0 Organization Roles, Responsibilities, and Authorities

The responsibility for the design, construction, commissioning, operation, and deactivation of the River Protection Project-Waste Treatment Plant lies with the designated RPP-WTP contractors throughout these various life-cycle phases of the Facility. These contractors to the Department of Energy, Office of River Protection will include the Design, Construction, and Commissioning (DC&C) contractor, the Operations contractor, and the Deactivation contractor.

As addressed in this ISMP, these contractor's roles, responsibilities, and authorities include defining and implementing nuclear, radiological, and process safety standards and the related safety bases for protection of the RPP-WTP occupational workers and the public. These RPP-WTP contractors have the sole responsibility for defining and implementing DOE-approved safety standards and communicating those safety standards as requirements to all RPP-WTP Project team members and subcontractors who conduct work on the Project.

While the Project team members manage subcontractors, the RPP-WTP contractors retain responsibility for oversight of team members and subcontractors performance and for overall project safety. The commitment inherent in this structure is that line management retains the responsibility for development and implementation of the safety basis. Although some specific roles may be reassigned within the organization, line management's responsibility for safety is invariant.

The RPP-WTP contractors assign safety roles to functional areas as indicated in Tables 9-1 through 9-5. Table 9-1 assigns roles for key elements of the design phase functional groups. The organization chart for the DC&C contractor organization is provided in Figure 11-1. The Operations and Deactivation contractors organization charts will be defined as the Project nears these phases of the Project. Project roles, responsibilities, and authorities for the DC&C contractor are presented in Section 11.1. Envisioned roles, responsibilities, and authorities for the Operations contractor are presented in Section 11.2.

11.1 Design, Construction, and Commissioning Contractor Organization Roles, Responsibilities, and Authorities

Safety-related roles, responsibilities, and authorities for the DC&C phase of the operation, as assigned to individuals and organizations within BNI (the DC&C Contractor), are discussed below.

Project Manager

The Project Manager safety-related roles, responsibilities, and authorities include:

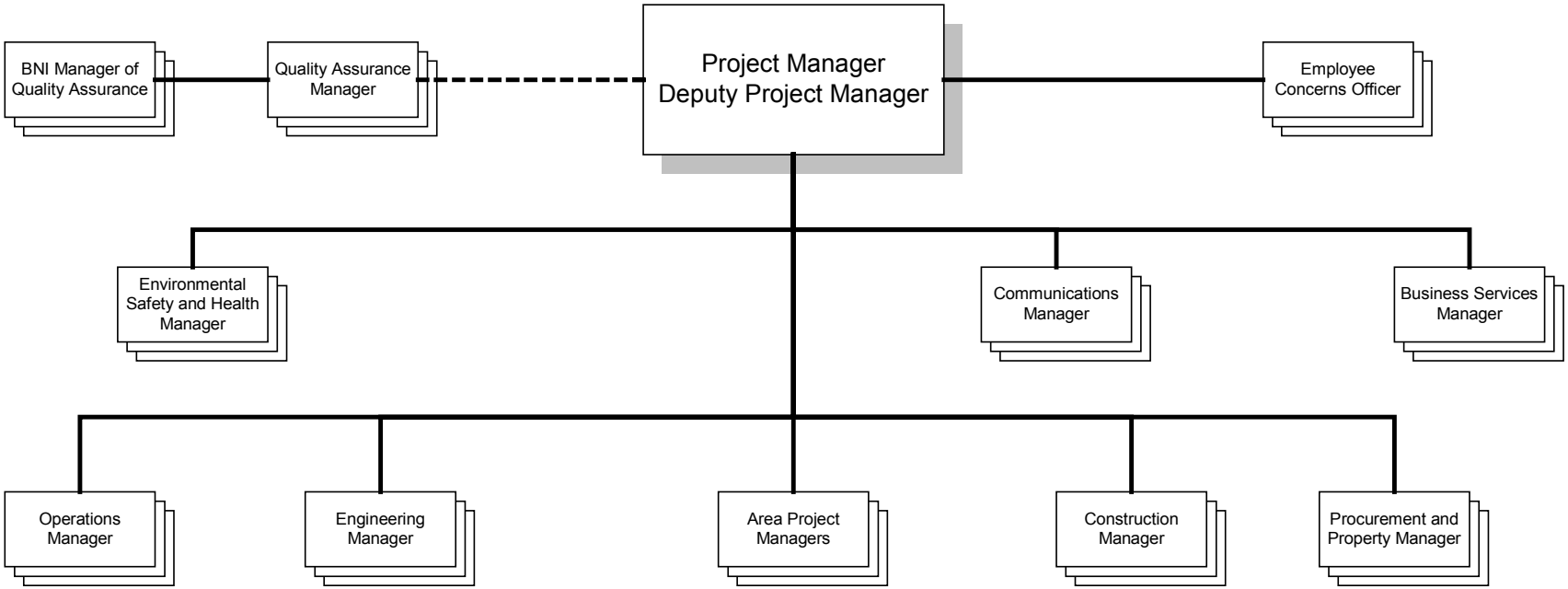
1) Responsibility for RPP-WTP safety
2) Defining safety policy, objectives, and interfaces
3) Assigning roles and responsibilities for safety-related activities
4) Setting performance expectations
5) Developing management assessment policies
6) Signatory on permit applications for construction of the Facility
7) Serving as a member of the Executive Committee
8) Ensuring implementation of the Quality Assurance Program (QAP)

Deputy Project Manager

The Deputy Project Manager safety-related roles, responsibilities, and authorities include:

1) Ensuring that the RPP-WTP is designed, constructed, tested, commissioned, operated, and maintained in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements
2) Integrating nuclear and industrial safety, quality, and environmental protection into all work
3) Managing the design transition, facility and process design, construction, acceptance testing, commissioning, procurement, and operations
4) Integrating the Area Project Managers and functional managers
5) Creating an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels
6) Stopping activities within his area of responsibility, which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements

Figure 11-1 Management Structure and Organization for the BNI Design, Construction, and Commissioning Contract



Area Project Managers

The safety-related roles, responsibilities, and authorities of the Area Project Managers, in their respective areas of responsibility, include:

1) Managing design and construction effort, in their respective area of responsibility.
2) Implementing management assessment policies, in their respective area of responsibility.
3) Implementing the contractor requirements of 10 CFR 820, "Procedural Rules for DOE Nuclear Activities", in their respective area of responsibility.
4) Ensuring the development and implementation of the incident reporting program, in their respective area of responsibility.
5) Ensuring approval by the Engineering Manager of final designs of Safety Design Class and Safety Design Significant features, in their respective area of responsibility.
6) Serving as principal interface with DOE on technical issues, in their respective area of responsibility.
7) Developing and managing the readiness review program to support commissioning, in their respective area of responsibility.

Engineering Manager

The Engineer Manager oversees the engineering design activities that are assigned to the DC&C contractor. The safety-related roles, responsibilities, and authorities of the Engineering Manager include:

1) Approving final designs of Safety Design Class and Safety Design Significant features
2) Updating the treatment process, civil, architectural, structural, electrical, and mechanical design criteria
3) Completing the civil, structural, support system, and facility designs including the incorporation of regulatory and quality commitments
4) Preparing specifications for procurement of pre-purchased equipment
5) Incorporating regulatory and quality commitments into the design, procurement, fabrication, inspection, and testing of systems and components
6) Designing measures to facilitate performance of Technical Safety Requirement (TSR) surveillances
7) Designing features to implement the design requirements of 10 CFR 835 Occupational Radiation Protection including features for ensuring personnel exposure during operation is as low as reasonably achievable (ALARA)
8) Selecting materials for fabrication and construction; defining methods for corrosion control; and specifying welding procedures, requirements for nondestructive examination, and codes and standards
9) Designing fire prevention, detection, and suppression features in compliance with state and federal requirements
10) Incorporating deactivation and decommissioning features into the facility design
11) Evaluating proposed changes to civil, structural, support system, and facility designs
12) Updating the process design specifications, process descriptions, basis of design documents
13) Completing the process design including the incorporation of regulatory and quality commitments

14) Developing and implementing the configuration management (CM) program to control the safety and design bases
15) Obtaining documentation defining the physical configuration of the facility and forwarding this documentation to the Project Administration and Controls Organization
16) Developing and implementing of CM program database

Construction Manager

The safety-related roles, responsibilities, and authorities of the Construction Manager include:

1) Implementing procedures and training to enhance construction safety
2) Providing input to the configuration management program including as-built information
3) Supporting the incident reporting system for construction-related incidents
4) Developing procedures for the handling of hazardous material during construction, including packaging, labeling, storage, and shipping practices
5) The packaging and manifesting of dangerous waste arising from construction activities
6) Interfacing with subcontractors on process safety management and ES&H matters
7) Incorporating regulatory and quality commitments of SSCs into the construction
8) Implementing the construction testing program to verify that SSCs meet acceptance testing requirements

Environment, Safety & Health (ES&H) Manager

The safety-related roles, responsibilities, and authorities of the ES&H Manager include:

1) Implementing internal safety and oversight functions
2) Developing safety basis and safety-related performance measures
3) Implementing the process safety management program
4) Developing and implementing the regulatory commitment tracking system, and the incident reporting program
5) Interfacing with regulators, stakeholders, and Hanford Site contractors on ES&H matters
6) Evaluating proposed changes that involve implementation of nuclear, radiological, and process safety and environmental matters
7) Implementing the fire protection program
8) Coordinating cooperative agreements with outside agencies such as fire, police, ambulance, and medical services
9) Developing and managing the ES&H portions of the readiness review program to support commissioning
10) Serving as a member of the Project Safety Committee, supporting independent safety review in the ES&H area of responsibility and serving as the PSC alternate chairperson.
11) Updating the process hazards analysis

The ES&H Manager also oversees activities related to radiological, nuclear, and process safety and environment protection. These activities include the following:

1) Identifying and evaluating new laws and regulations that may affect the Project safety programs
2) Preparing the Limited Construction Authorization (LCA) request
3) Interfacing with the regulators during onsite inspections
4) Updating the Hazard Analysis Report (HAR), Safety Requirements Document (SRD), and Integrated Safety Management Plan (ISMP)
5) Preparing the Preliminary Safety Analysis Report (PSAR) and Final Safety Analysis Report (FSAR)
6) Environmental reporting
7) Identifying requirements for worker and public safety, security, and environmental regulatory compliance
8) Preparing the environmental characterization and monitoring plans
9) Preparing permit applications and plans as required for state and federal environmental regulations
10) Monitoring environmental compliance during construction
11) Developing and implementing the Environmental Radiation Protection Program

Quality Assurance Manager

The safety-related roles, responsibilities, and authorities of the QA Manager the following:

1) Developing the Quality Assurance Program (QAP)
2) Assessing and auditing project activities to verify compliance with the QAP and other requirements and to determine the effectiveness of the QAP
3) Providing support for the development of qualification and training programs to ensure that required capabilities are achieved and maintained by project personnel
4) Reviewing project documents (e.g., design documents, nuclear and process safety deliverables, work plans, and source evaluation plans) to verify inclusion of appropriate QAP requirements
5) Recommending and exercising work stoppage or controls over further processing in response to quality concerns
6) Assessing and auditing vendor and subcontractor activities to verify compliance with the QAP and other requirements and to determine the effectiveness of the QAP
7) Serving as a member of the Project Safety Committee, supporting independent safety review in the QA area of responsibility

The QA Manager has the authority and responsibility to stop project work when the work, if allowed to continue, would result in activities or documents being in noncompliance with stated QAP requirements. The QA Manager is responsible for determining when appropriate corrective or preventative actions have been taken and for lifting the stop work order to allow work to proceed.

Operations Manager

The safety-related roles, responsibilities, and authorities of the Operations Manager include:

1) Developing a program for operations procedure preparation, review, verification, validation, approval, change, deviation, and internal control
2) Writing and maintaining operating procedures including post-deactivation activities
3) Performing administrative responsibilities including maintaining a qualified staff and ensuring effective employee performance
4) Performing radioactive commissioning testing to demonstrate compliance with the acceptance criteria and documenting the results to acceptance criteria.
5) Serving as the chairperson for the Project Safety Committee
6) Developing and managing the readiness review program to support commissioning

Research and Technology Manager

The safety-related roles, responsibilities, and authorities of the Research and Technology (R&T) Manager include:

1) Serving as a member of the Project Safety Committee, supporting independent safety review in the R&T area of responsibility.

Process Technology Manager

The safety-related roles, responsibilities, and authorities of the Process Technology Manager include:

1) Ensuring that technologies are developed and demonstrated
2) Evaluating the completed process design and proposed changes to the design
3) Identifying commissioning tests to be performed and their acceptance criteria
4) Incorporating regulatory and quality commitments into procurement, fabrication, inspection, and testing of process components
5) Performing systematic design reviews to determine readiness to authorize fabrication and construction of structures, systems, and components (SSC)
6) Implementing design considerations for deactivation and decommissioning

Commissioning Manager

The commissioning organization manages the commissioning program. The safety-related roles, responsibilities, and authorities of the Commissioning Manager include:

1) Developing the objectives and scope for the startup program
2) Developing and evaluating proposed changes to the commissioning program
3) Verifying and validating operation and maintenance procedures during performance of testing

4) Providing information from the startup program to the operations, training, and procedures groups, and maintenance for verification and validation of operating administrative controls

Procurement and Property Manager

The Procurement and Property Manager safety-related roles, responsibilities, and authorities include:

1) Providing the processes and procedures for procuring items and services important to safety.
2) Providing full support to the Quality Assurance Program described in the *Quality Assurance Manual* (QAM), thereby assuring that all work performed under his cognizance will conform to and support the requirements of the QAM.

Business Services Manager

The safety-related roles, responsibilities, and authorities of the Business Services Manager include:

1) Implementing an employee feedback program
2) Controlling the facility policy manual (containing the Project Manager safety policy) and all procedures
3) Developing and maintaining the records management program (See Table 8-1)

11.2 Operations Contractor Organization Roles, Responsibilities, and Authorities

The envisioned safety-related roles, responsibilities, and authorities for the Operations phase of the operation, as assigned to individuals and organizations within the Operations Contract, are discussed below.

Facility Manager

Responsibilities and roles of the Facility Manager include the following:

1) Ensuring the development and implementation of facility controls to protect the health and safety of the public, and workers and to protect the environment from hazardous situations associated with the chemical and radiological hazards of the facility
2) Ensuring that operational activities are properly staffed and controlled
3) Managing operation of the facility to obtain the defined work activity while maintaining the authorization basis for the facility
4) Approving Facility activities, including modifications to Safety Design Class and Safety Design Significant SSCs
5) Ensuring that work is performed in conformance with procedures, policies, and safety requirements

6) Implementing the contractor requirements of 10 CFR 820, "Procedural Rules for DOE Nuclear Activities"
7) Serving as the Emergency Director during events categorized as emergencies
8) Assigning roles and responsibilities for activities related to safety including operations, performance improvements, safety improvements, and deactivation of the facility

Operations Manager

Roles of the Operations Manager include the following:

1) Developing a program for procedure preparation, review, verification, validation, approval, change, deviation, and internal control
2) Writing and maintaining operating procedures including post-deactivation activities
3) Performing administrative responsibilities including maintaining a qualified staff and ensuring effective employee performance
4) Performing radioactive startup testing to demonstrate compliance with the acceptance criteria and documenting the results to acceptance criteria
5) Managing daily facility operation to obtain the define work activity while maintaining compliance to the TSRs
6) Performing TSR surveillances assigned to operations and supporting those TSR surveillances assigned to the Maintenance Organization
7) Scheduling and managing process system outage activities
8) Initiating and managing deactivation
9) Obtaining an understanding of the features and limitations of the facility SSCs to facilitate radioactive startup testing, facility operation, and the development of procedures and training
10) Developing and implementing the operating staff training program
11) Writing and evaluating proposed changes to administrative procedures related to facility operation
12) Ensuring operation of support systems (e.g., electrical, instrument air, and steam)
13) Performing analysis of feed material, product, and process chemicals
14) Developing procedures for hazardous material handling, packaging, labeling, storage, and shipping practices
15) The packaging and manifesting of dangerous waste
16) Evaluating proposed changes to the radioactive startup program

Environment, Safety, & Health Manager

The ES&H Manager is a member of the PSC and serves as the PSC alternate chairperson. In addition, for the operating project the ES&H organization has the following roles:

1) Developing the emergency plan and the emergency plan implementing procedures
2) Managing emergency drills and exercises
3) Modifying plans and procedures to address internal safety and oversight functions for the deactivation phase
4) Developing deactivation safety performance measures, modification of plans and procedures, and confirmation the facility meets the safe storage criteria on completion of deactivation
5) Managing occupational health and safety
6) Obtaining monitoring, sampling, and record keeping information on facility discharges
7) Maintaining state and federal environmental permits

8) Maintaining the environmental database
9) Keeping environmental regulators informed on current status, concerns, and new data
10) Identifying critical aspects of facility deactivation that would affect environmental regulatory compliance
11) Developing the USQ identification and evaluation process
12) Developing TSR surveillance testing and evaluation program
13) Monitoring compliance to the authorization basis
14) Updating authorization basis documentation including the FSAR
15) Directing incident investigations including reporting, root cause analyses, identification of corrective actions, and tracking of effectiveness of corrective actions and applying lessons learned from relevant facilities
16) Developing a process for evaluating deficiencies to nuclear safety requirements subject to 10 CFR 820, "Procedural Rules for DOE Nuclear Activities"
17) Preparing a deactivation safety analysis report
18) Developing and implementing the Radiation Protection Program for operations that is compliant with 10 CFR 835, "Occupational Radiation Protection"
19) Performing radiation and contamination surveys and maintaining personnel exposure records
20) Informing management of conditions that could lead to exceeding radiation limits established for radiation areas or exceeding administrative limits for personnel radiological exposure
21) Monitoring deactivation activities to ensure personnel exposure meets as low as reasonably achievable (ALARA) objectives

Quality Assurance Manager

The QA Manager is a member of the PSC. Roles of the QA Organization include the following:

1) Establishing a Quality Assurance Program for operations
2) Performing independent assessments and program compliance audits
3) Reviewing the project quality procedures and documenting compliance with applicable QAP requirements
4) Modifying and implementing quality assurance plans and procedures for the for deactivation process
5) Verifying implementation of corrective action measures and determining that the solutions for quality problems are effective

The QA Manager has the authority and responsibility to stop project work when the work, if allowed to continue, would result in activities or documents being in noncompliance with stated requirements. The QA Manager is responsible for determining when appropriate corrective or preventative actions have been taken and for lifting the stop work order to allow work to proceed.

Engineering Manager

The Engineering Manager a member of the PSC. Roles of the Engineering organization include the following:

1) Evaluating startup test results and comparing the results to acceptance criteria
2) Developing and evaluating proposed design improvements and changes to engineered features
3) Supporting resolution of production problems
4) Developing the surveillance and maintenance criteria for facility operations
5) Identifying measures that minimize hazards associated with treating and storing radioactive waste, and for the safe handling of fissionable materials
6) Performing a job hazard analysis and participating with ES&H to update HAR
7) Updating the process hazards analysis (PHA) to support permit and authorization basis updates
8) Preparing and implementing a deactivation management plan that includes:
   - updating the HAR
   - defining surveillance and maintenance criteria for deactivation and safe storage
   - developing facility modifications to facilitate performance of surveillance tests
   - implementing measures that minimize hazards associated with treating and storing radioactive materials

Maintenance Manager

The Maintenance Manager oversees the activities of the Maintenance organization. Roles of the Maintenance organization include:

1) Defining and implementing a maintenance program that includes preventive, predictive, and corrective maintenance practices and incorporates vendor-recommended maintenance activities and equipment history
2) Performing TSR surveillances assigned to maintenance and supporting those TSR surveillances assigned to operations
3) Implementing facility modifications
4) Developing and modifying operating and maintenance instructions for post-deactivation operational equipment
5) Writing maintenance procedures
6) Collecting and processing baseline data for system and component performance monitoring and maintenance planning

Procurement and Property Manager

The Procurement and Property Manager's safety related roles, responsibilities, and authorities include:

1) Providing the processes and procedures for procuring items and services important to safety.
2) Providing full support to the Quality Assurance Program described in the *Quality Assurance Manual* (QAM), thereby assuring that all work performed under his or her cognizance will conform to and support the requirements of the QAM.

Startup Manager

The Startup organization manages the startup testing program. Additional roles of the Startup Manager include the following:

1) Evaluating proposed changes to the startup program
2) Verifying and validating operation and maintenance procedures during performance of testing
3) Providing information from the startup program to the operations, training, and procedures groups, and maintenance for verification and validation of operating administrative controls

Configuration Management Manager

The Configuration Management Manager oversees the activities of the Configuration Management organization. Roles of the Configuration Management organization include the following:

1) Continued implementation of the operational configuration management program
2) Maintaining the facility operating history to facilitate deactivation of the facility

Administration and Controls Manager

The Administration and Controls Manager continues those activities started by the DC&C contractor Business and Project Controls Organization

12.0 Definitions

In the following list, the parenthetical information following the term being defined is the source of the definition. However, for sources other than DOE/RL-96-0006 (DOE 1996b) or the BNFL Inc./DOE contract (DOE-RL 1996c), the wording provided may be tailored to the Project use and therefore may not be exactly as contained in the referenced source.

Accident Risk Goal (DOE/RL-96-0006 [DOE-RL 1996b]). The risk, to an average individual in the vicinity of the Contractor's facility, of prompt fatalities that might result from an accident should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population generally are exposed.

By footnote 14 of DOE/RL-96-0006, for evaluation purposes, individuals are assumed to be located within 1 mile of the contractor's controlled area.

Acute Hazard (AIChE 1992). The potential for injury or damage to occur as a result of an instantaneous or short duration exposure to the effects of an accident.

Administrative Controls. Provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of the facility.

As Low as Reasonably Achievable (10 CFR 835). The approach to radiation protection to manage and control exposures (both individual and collective) to the work force and to the general public to as low as is reasonable, taking into account social, technical, economic, practical, and public policy considerations. The ALARA approach is not a dose limit but a process that has the objective of attaining doses as far below the applicable limits of this part (10 CFR 835) as is reasonably achievable.

Authorization Basis (DOE/RL-96-0006 [DOE-RL 1996b]). The composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the Director of the Regulatory Unit grants permission to perform regulated activities.

Changes (RL/REG-97-13). Changes to the facility design and administrative controls that are described in the authorization basis or are relied upon by the Contractor to ensure conformance to the authorization basis. Included within the scope of "Changes" are those items that may not be explicitly described in the authorization basis, but where Changes would cause a deviation from commitments contained in the authorization basis.

As used above, "facility" refers to the physical facility, the hazards and safety analysis of the facility, and the work at the facility that is enveloped by the analyses. The facility is described in the authorization basis by information such as: the site description, design information, hazard analysis information, safety analysis information, and descriptions of facility operations, tests, and experiments.

As used above, "administrative controls" refers broadly to the management and administrative processes associated with managing, designing, building, or operating the facility. Administrative controls are described in the authorization basis by information such as the descriptions of procedures, programs, plans, and management processes.

Codes and Standards. Document containing expressed expectations for the performance of work; normally refers to those practices issued by consensus organizations (e.g., American National Standards Institute, American Society of Mechanical Engineers, and National Fire Protection).

Co-located Worker (DOE/RL-96-0006 [DOE-RL 1996b]). An individual within the Hanford Site, beyond the Contractor-controlled area, performing work for or in conjunction with DOE or utilizing other Hanford Site facilities.

Common-Cause Failures (DOE/RL-96-0006 [DOE-RL 1996b]). Dependent failures that are caused by a condition external to a system or set of components that make system or multiple component failures more probable than multiple independent failures.

Common-Mode Failures (DOE/RL-96-0006 [DOE-RL 1996b]). Dependent failures caused by susceptibilities inherent in certain systems or components that make their failures more probable than multiple independent failures due to those components having the same design or design conditions that would result in the same level of degradation.

Consequence (AIChE 1992). The direct, undesirable result of an accident sequence usually involving a fire, explosion, or release of toxic material. Consequence descriptions may be qualitative or quantitative estimates of the effects of an accident in terms of factors such as radiological exposure, health impacts, economic loss, and environmental damage.

Consequence Analysis (AIChE 1992). The analysis of the effects of incident outcome cases independent of frequency or probability.

Controlled Area (DOE/RL-96-0006 [DOE-RL 1996b]). The physical area enclosing the facility by a common perimeter (security fence). Access to this area can be controlled by the contractor. The controlled area may include identified restricted areas.

Deactivation (Contract, Section J, Attachment 9 [DOE-RL 1996c]). The process of permanently ceasing active operation at a facility in a planned and controlled manner to support follow-on decontamination and decommissioning activities. A process whereby non-essential systems and/or equipment in a shut down facility are de-energized, drained and flushed, isolated, or removed to minimize the long-term costs of maintaining the facility in a physically safe and environmentally secure condition. Includes the removal of fuel and stored radioactive and/or hazardous waste from the facility and implementation of appropriate facility safety requirements.

Deterministic Analysis. A non-probabilistic approach to accident analysis that begins with the establishment of a specific set of credible accident initiating events expected to represent a range of possible challenges to the safety of the facility and some of which are expected to define the design requirements for the facility. The design of the facility is then evaluated to this set of events using conservative inputs and assumptions to account for uncertainties, to ensure that adequate controls exist to protect the public and workers such that radiological and chemical exposure standards are satisfied. In the evaluation of public and worker safety, the most limiting random single active failure of a system or component is assumed and credit is taken only for those structures, systems, and components that meet Safety Design Class requirements. Other than selecting credible events to account for accident likelihood, this is a consequence-oriented rule-followed approach (i.e., assume worst single failure) to establish the design of the facility.

Regulatory Unit (DOE/RL-96-0006 [DOE-RL 1996b]). The organization reporting to the Director of the Regulatory Unit dedicated to supporting the Director in executing regulatory authority.

Double-shell Tank (Contract, Section J, Attachment 9 [DOE-RL 1996c]). A reinforced concrete underground vessel with two inner steel liners to provide containment and backup containment of liquid wastes; annulus is instrumented to permit detection of leaks from the inner liner. At the Hanford Site, there are 28 double-shell tanks.

Emergency Response Planning Guidelines (AIChE 1992). A system of guidelines for airborne concentrations of toxic materials prepared by the American Industrial Hygiene Association (AIHA).

Engineered Feature. A structure, system, or component that contributes to the safe operation of the facility.

Episodic Event (AIChE 1992). An unplanned event of limited duration, usually associated with an accident.

ERPG-2 (AIHA 1988). The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms that could impair their abilities to take protective action.

External Event. An event external to the RPP-WTP caused by (1) a natural hazard (e.g., earthquake, flood, lightning, or range fire) or (2) a human-induced event (e.g., transportation or nearby industrial activity).

Facility Worker. An individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities. This is the same as the definition of 'worker' in DOE/RL-96-0006 which is "Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities".

Final Safety Evaluation Report (DOE/RL-96-0006 [DOE-RL 1996b]). The document approved and issued by the Director of the Regulatory Unit that addresses the adequacy of the authorization basis for operation.

Graded Approach (10 CFR 830.3). A process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this part (i.e., 10 CFR Part 830) are commensurate with:

1) Relative importance to safety, safeguards, and security
2) Magnitude of any hazard involved
3) Life cycle stage of a facility
4) Programmatic mission of a facility
5) Particular characteristics of a facility
6) Any other relevant factor

Hanford Site. A 1,450 km^2 reservation in southeast Washington State owned by the Federal Government. Established in 1943 as part of the Manhattan Project, the initial activity on the Hanford Site was to produce plutonium for use in nuclear weapons for the nation's defense. The Hanford Site has had nine production reactors and four chemical separation plants. The current mission on the Hanford Site is environmental cleanup and development of related technologies.

Hazard (DOE/RL-96-0006 [DOE-RL 1996b]). A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel, damage to an operation, or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation).

Hazard and Operability Analysis (AIChE 1992). A systemic method in which process hazards and potential operating problems are identified using a series of guide words to investigate process deviations.

Hazardous Material. A solid, liquid, or gaseous material that is toxic, explosive, flammable, corrosive, or otherwise physically or biologically threatening to health.

High-Level Waste (Contract, Section J, Attachment 9 [DOE-RL 1996c]). The highly radioactive waste material that results from the operation of the first-cycle solvent extraction system or equivalent and subsequent extraction cycles or equivalent that contains a combination of transuranic waste and fission products in concentrations requiring permanent isolation.

High Radiation Area (10 CFR 835). Any area, accessible to individuals, in which radiation levels could result in an individual receiving a deep dose equivalent in excess of 0.1 rem (0.001 sievert) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Highly Hazardous Chemical (DOE/RL-96-0006 [DOE-RL 1996b]). A substance possessing toxic, reactive, flammable, or explosive properties as defined by 29 CFR 1910.119.

Human Factors (AIChE 1992). A discipline concerned with designing machines, operations, and work environments to match human capabilities, limitations, and needs. Among human factors specialists, this general term includes any technical work (engineering, procedure writing, worker training, worker selection) related to the person in operator-machine systems.

Important-to-Safety (DOE/RL-96-0006 [DOE-RL 1996b]). Structures, systems, and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the workers and the public. It encompasses the broad class of facility features addressed (not necessarily explicitly) in the top-level radiological, nuclear, and process safety standards and principles that contribute to the safe operation and protection of workers and the public during all phases and aspects of facility operations (i.e., normal operation as well as accident mitigation).

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety class, safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction (i.e., support systems, subsystems, or components). Thus, these latter structures, systems, and components would be subject to applicable top-level radiological, nuclear, and process safety standards and principles to a degree commensurate with their contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort all significant systems interactions may not be identified and only the traditional interpretation of important to safety (i.e., safety-related may be practical). However, as the design matures and results from risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components should be considered for inclusion within this definition.

Independent Safety Review Team. A group of individuals with the demonstrated knowledge and expertise to confirm the completeness, credibility, and adequacy of the Project radiological, nuclear, process safety documents, and recommend their approval to the Project Manager.

Initial Safety Evaluation Report (DOE/RL-96-0006 [DOE-RL 1996b]). The document, approved and issued by the Director of the Regulatory Unit, that addresses the capability or potential for obtaining future authorizations for construction, operation, and deactivation.

Initiating Event (AIChE 1992). The first event in an event sequence. Can result in an accident unless engineered protection systems or human actions intervene to prevent or mitigate the accident.

Internal Event. An occurrence related to structure, system, and component performance or human action, or an occurrence external to the system but within the RPP-WTP that causes upset of a structure, system, or component.

Likelihood (AIChE 1992). A measure of the expected probability or frequency of an event's occurrence.

Limiting Conditions for Operations (DOE/RL-96-0006 [DOE-RL 1996b]). The lowest functional capability or performance level of equipment required for safe operation of the facility.

Low-Activity Waste (Contract, Section J, Attachment 9 [DOE-RL 1996c]). Low-level tank waste that has not yet received NRC concurrence as incidental.

Margin of Safety (DOE/RL-96-0006 [DOE-RL 1996b]). The level of confidence that is assigned to the integrity of radiological control measures such as confinement barriers. It is defined as the range between the design acceptance limits and the design failure point of the control feature. The design acceptance limits for radiological control measures such as confinement barriers are established during the design of the facility. These criteria are given in terms of those physical parameters that define their performance. Whenever the values of the design acceptance limits are exceeded, the margin of safety, and therefore the confidence in the integrity of the control feature, is decreased.

Major Accident. Relative to implementation of the incident investigation and reporting requirements of 29 CFR 1910.119(m), a major accident is a major uncontrolled emission, fire, or explosion, involving one or more highly hazardous chemicals or radioactive materials, that presents serious danger to facility workers.

Mitigative Feature. A structure, system, component, or administrative control that serves to reduce the consequences of a hazardous situation or accident.

Normal Operation (DOE/RL-96-0006 [DOE-RL 1996b]). Steady-state operation and those departures from steady-state operation that are expected frequently or regularly in the course of facility operation, system testing, and maintenance. It includes conditions such as startup, shutdown, standby, anticipated operational occurrences, operation with specific equipment out of service as permitted by the approved operational constraints, and routine inspection, testing, and maintenance of components and systems during any of these conditions if it is consistent with the approved operational constraints.

Operations Risk Goal (DOE/RL-96-0006 [DOE-RL 1996b]). The risk, to the population (public and workers) in the area of the Contractor's facility, of cancer fatalities that might result from facility operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks to which members of the U.S. population generally are exposed.

By Footnote 13 to DOE/RL-09-0006, for evaluation purposes, individuals are assumed to be located within 10 miles of the controlled area.

Preventative Feature. A structure, system, component, or administrative control that serves to preclude the occurrence of a hazardous situation or accident.

Probabilistic Analysis. An approach to accident analysis that addresses all credible initiating events and that is risk-based in that it considers both the likelihood and consequences of accidents to determine overall risks. Mitigating system and component reliability as well as human performance are assessed probabilistically to support risk-informed decision making. The probabilistic analysis goes beyond the single failure requirements of the deterministic approach in that it assesses the probabilities of multiple failures. This is a "best-estimate" analysis in that realistic input and modeling assumptions are used and all of the available structures, systems, and components are considered that can prevent or mitigate the event. The evaluation of the availability and reliability of structures, systems, and components considers failure to start and failure to run as well as maintenance-caused unavailabilities.

Process (DOE/RL-96-0006 [DOE-RL 1996b]). Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the onsite movement of such chemicals, or a combination of these activities.

Process Hazards Analysis. The identification of hazards and the analysis of the significance of hazardous situations associated with a process or activity. It includes preliminary hazard analysis and Hazard and Operability Analysis (HAZOP).

Process Safety DOE/RL-96-0006 [DOE-RL 1996b]). The operation of facilities that handle, use, process, or store hazardous materials in a manner free of episodic or catastrophic incidents. However, the handling, use, processing, and storage of materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition towards which one strives.

Process Safety Management DOE/RL-96-0006 [DOE-RL 1996b]). The application of management systems to the identification, understanding, and control of process hazards to prevent process-related injuries and incidents.

Public DOE/RL-96-0006 [DOE-RL 1996b]). Individuals who are not occupationally engaged at the Hanford Site.

Radiation Exposure. Radiation exposure, as used in Project documents, is the exposure of people (public, facility workers, collocated workers) to ionizing radiation produced by radioactive material. Unless otherwise specified, radiation exposure means the total effective dose equivalent (TEDE), that is, the sum of external and internal exposures. External exposures are assessed as the resulting effective dose equivalent; internal exposures as the resulting committed effective dose equivalent. Other terms used in Project documents, such as radiological exposure, dose, radiation dose, and the like, are taken as synonymous to radiation exposure.

Radiological, Nuclear, and Process Safety (Contract, Section J, Attachment 9 [DOE-RL 1996c]). Those actions taken to control the hazards incident to possession, use and disposal of radioactive and nuclear material, and the processing of hazardous chemicals.

Radiological Worker (10 CFR 835). A general employee whose job assignment involves operation of radiation-producing devices, or working with radioactive materials, or who is likely to be routinely occupationally exposed above 0.1 rem (0.001 sievert) per year total effective dose equivalent (TEDE).

Regulatory Guides. Documents that describe methods acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for implementing specific portions of NRC regulations. Some regulatory guides lay out steps taken by the staff in evaluating specific situations. Others provide guidance to applicants concerning information needed by staff in its review of applications for permits and licenses, or refer to or endorse national standards.

Reportable Occurrence. An incident that shall be reported to the DOE incident reporting and process system and other federal or state agencies. The threshold for reporting will be provided in the RPP-WTP incident reporting procedure to be developed in Part B.

Requirements. Standards that are mandated by an authority through statute, regulations, and contract.

Restricted Area (DOE/RL-96-0006 [DOE-RL 1996b]). An area identified by the Contractor to which access is limited for the purposes of protecting individuals against undue risk from exposure to radiation and radioactive materials. Only a radiation worker is allowed into this area.

Risk (AIChE 1992). The combination of the expected frequency (events/year) and consequence (effects/event) of a single accident or a group of accidents.

Risk Assessment (AIChE 1992). The systematic application of management policies, procedures, and practices to the tasks of analyzing and controlling risk in order to protect employees, the general public, the environment, and company assets.

Safe State (DOE/RL-96-0006 [DOE-RL 1996b]). A situation in which the facility process has been rendered safe and no pressurized material flow occurs in the process lines. Any active, energy generating, process reactions are in controlled or passive equipment. The structures, systems, and components necessary to reach and maintain this condition are functioning in a stable manner, with all process parameters within normal safe state ranges.

Safety Analysis Report (DOE/RL-96-0006 [DOE-RL 1996b]). A document that fully describes the analyzed safety basis for the facility (safety envelope), fully demonstrates that the facility will perform and will be operated such that radiological, nuclear, and process safety requirements are met, and fully demonstrates adequate protection of the public, the workers, and the environment.

Safety Criterion. A measurable and/or demonstrable statement of an expected condition that ensures adequate protection of the public and workers. In satisfying the full set of Safety Criteria, the Project ensures that an acceptable status or condition protecting the public and/or workers has been achieved and/or maintained.

Safety Design Class. Structures, systems, or components that, by performing their specified safety function, prevent workers or the maximally exposed member of the public from receiving a radiological or chemical exposure that exceeds the accident exposure standards defined in the SRD. Those features credited for the prevention of a criticality event are also designated as Safety Design Class.

Safety Design Significant. Structures, systems, and components needed to achieve compliance with the radiological or chemical exposure standards for the public and workers during normal operation; and SSCs that can, if they fail or malfunction, place frequent demands on, or adversely affect the function of, Safety Design Class SSCs.

Safety Limits (DOE/RL-96-0006 [DOE-RL 1996b]). Limits on process variables associated with those physical barriers, generally passive, that are necessary for the intended facility safety functions and that are found to be required to prevent release of unacceptable levels of radioactive material to workers or the general public.

Specified Safety Function. That attribute of a Safety Design Class or Safety Design Significant engineered control credited for maintaining public or worker safety within exposure standards.

Safety Requirements Document (SRD)(DOE/RL-96-0006 [DOE-RL 1996b]). A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor's facilities.

Start of Cold-Testing. That point in the construction phase of each facility of the RPP-WTP during start-up testing but prior to admitting any significant quantities of radioactive waste or process chemicals into the facility. This milestone will be established in the Construction Agreement.

Tailoring (DOE G 450.4-1). Adapting something, such as a safety program, practice, or requirement to suit the need or purposes of a particular operation or activity, taking into account the type of work and associated hazards and hazardous situations.

Technical Safety Requirements (DOE/RL-96-0006 [DOE-RL 1996b]). Those requirements that define the conditions, the safe boundaries, and the management or administrative controls necessary to ensure the safe operation of the facility, reduce the potential risk to the public and facility workers from uncontrolled releases of radioactive materials, and from radiation exposures due to inadvertent criticality.

Unreviewed Safety Question (USQ) (DOE/RL-96-0006 [DOE-RL 1996b]). A safety question where any of the following conditions are satisfied: 1) the probability of occurrence or the radiological consequences of an accident or malfunction of equipment important to safety, previously evaluated in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility analysis, may be increased; 2) a possibility for an accident or equipment malfunction of a different type than any evaluated previously in the facility safety analyses or other related safety analysis and evaluations not yet included in the updated facility safety analysis may be created; or 3) any margin of safety is reduced. (Also see definition for “Margin of Safety”.)

Validation. As applied to procedures, validation is the process that ensures an administrative control provides sufficient and understandable guidance and direction to the craft person and that it is compatible with the equipment or system being maintained. Validation is typically performed in the field prior to initial procedure use.

Verification. As applied to procedures, verification is the review to ensure the proper format and technical accuracy of a new or revised procedure. This review also ensures that the format incorporates human factors principles and other appropriate administrative policies.

Worker (DOE/RL-96-0006 [DOE-RL 1996b]). Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

13.0 References

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10 CFR 820, "Procedural Rules for DOE Nuclear Activities", *Code of Federal Regulations*, as amended.

10 CFR 830.120, "Quality Assurance Requirements", *Code of Federal Regulations*, as amended.

10 CFR 835, "Occupational Radiation Protection", *Code of Federal Regulations*, as amended.

10 CFR 1021.216, "Procurement, Financial Assistance, and Joint Ventures", *Code of Federal Regulations*, as amended.

29 CFR 1910, "Occupational Safety and Health Standards", *Code of Federal Regulations*, as amended.

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