

**DOE PROCESS FOR RADIOLOGICAL, NUCLEAR,  
AND PROCESS SAFETY REGULATION OF THE  
RPP WASTE TREATMENT PLANT  
CONTRACTOR**



**U.S. Department of Energy  
Office of River Protection  
Richland, Washington**

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## Preface

As directed by Congress in Section 3139 of the *Strom Thurmond National Defense Authorization Act for Fiscal Year 1999*, the U.S. Department of Energy (DOE) established the Office of River Protection (ORP) at the Hanford Site to manage the River Protection Project (RPP), formerly known as the Tank Waste Remediation System. ORP is responsible for the safe storage, retrieval, treatment, and disposal of the high level nuclear waste stored in the 177 underground tanks at Hanford.

The initial concept for treatment and disposal of the high level wastes at Hanford was to use private industry to design, construct, and operate a Waste Treatment Plant (WTP) to process the waste. The concept was for DOE to enter into a fixed-price contract for the Contractor to build and operate a facility to treat the waste according to DOE specifications. In 1996, DOE selected two contractors to begin design of a WTP to accomplish this mission. In 1998, one of the contractors was eliminated, and design of the WTP was continued. However, in May 2000, DOE chose to terminate the privatization contract and seek new bidders under a different contract strategy. In December 2000, a team led by Bechtel National, Inc. was selected to continue design of the WTP and to subsequently build and commission the WTP.

A key element of the River Protection Project Waste Treatment Plant (RPP-WTP) is DOE regulation of safety through a specifically chartered, dedicated Office of Safety Regulation (OSR). The OSR reports directly to the ORP Manager. The regulation by the OSR is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of the River Protection Project Waste Treatment Plant Contractor* (DOE/RL-96-25) (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, Process Safety Regulation of the RPP-WTP Contractor* (DOE/RL-96-26) (referred to as the MOA). These two documents provide the basis for the safety regulation of the RPP-WTP at Hanford.

The foundation of both the Policy and the MOA is that the mission of removal and immobilization of the existing large quantities of tank waste by the RPP-WTP Contractor must be accomplished safely, effectively, and efficiently.

The Policy maintains the essential elements of the regulatory program established by DOE in 1996 for the privatization contracts. The MOA clarifies the DOE organizational relationships and responsibilities for safety regulation of the RPP-WTP. The MOA provides a basis for key DOE officials to commit to teamwork in implementing the policy and achieve adequate safety of RPP-WTP activities.

The Policy, the MOA, the RPP-WTP Contract and the four documents incorporated in the Contract define the essential elements of the regulatory program being executed by the OSR. The four documents incorporated into the Contract (and also in the MOA) are as follows:

*Concept of the DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor*, DOE-96-0005,

*DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor*, DOE/RL-96-0003,

*Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, DOE/RL-96-0006, and

*Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor*, DOE/RL-96-0004.

DOE patterned its safety regulation of the RPP-WTP Contractor to be consistent with the concepts and principles of good regulation (stability, clarity, openness, efficiency, and independence) used by the Nuclear Regulatory Commission (NRC). In addition, the DOE principles of integrated safety management were built into the regulatory program for design, construction, operation, and deactivation of the facility. The regulatory program for nuclear safety permits waste treatment services to occur on a timely, predictable, and stable basis, with attention to safety consistent with that which would occur from safety regulation by an external agency. DOE established OSR as a dedicated regulatory organization to be a single point of DOE contact for nuclear safety oversight and approvals for the WTP Contractor. The OSR performs nuclear safety review, approval, inspection, and verification activities for ORP using the NRC principles of good regulation while defining how the Contractor shall implement the principles of standards-based integrated safety management.

A key feature of this regulatory process is its definition of how the standards-based integrated safety management principles are implemented to develop a necessary and sufficient set of standards and requirements for the design, construction, operation, and deactivation of the RPP-WTP facility. This process closely parallels the DOE necessary and sufficient closure process (subsequently renamed Work Smart Standards process) in DOE Policy 450.3, *Authority for the Use of the Necessary and Sufficient Process for Standards-based Environment, Safety and Health Management*, and is intended to be a DOE approved process under DOE Acquisition Regulations, DEAR 970.5204-78, *Laws, Regulations and DOE Orders*, Section (c). DOE approval of the contractor-derived standards is assigned to the OSR.

The RPP-WTP Contractor has direct responsibility for WTP safety. DOE requires the Contractor to integrate safety into work planning and execution. This integrated safety management process emphasizes that the Contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. DOE, through its safety regulation and management program, verifies that the Contractor achieves adequate safety by complying with approved safety requirements.

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# **DOE PROCESS FOR RADIOLOGICAL, NUCLEAR, AND PROCESS SAFETY REGULATION OF THE RPP WASTE TREATMENT PLANT CONTRACTOR**

## **1.0 PURPOSE**

The purpose of this document is to describe the process that the U.S. Department of Energy (DOE) Office of River Protection (ORP) will use to regulate the radiological, nuclear, and process safety of the River Protection Project-Waste Treatment Plant (RPP-WTP) Contractor (Contractor). This regulation will be achieved through a definitive and formalized process in which the Contractor obtains authorizations from DOE to undertake facility design, construction, operation, and deactivation activities. Once the bases for the authorizations are approved, authorization agreements will be negotiated between the DOE and the Contractor, and oversight by DOE will ensure that the Contractor's operations are in continued compliance with the agreements. This regulatory process is intended to be predictable, effective, unambiguous, and consistent with the regulatory concepts and principles of the U.S. Nuclear Regulatory Commission.

This document provides details of the six primary regulatory actions that are the essence of the regulatory process for the radiological, nuclear, and process safety regulation of the RPP-WTP Contractor. It specifies documentation required from the Contractor to support the six regulatory actions as well as DOE-specific activities to accomplish each regulatory action, including review and approval schedules. The documentation requirements contained herein are considered by DOE to be generally complete in scope but flexible in the details of format and content in order to permit tailoring of the documentation to the nature and level of the hazards associated with the Contractor's activities. However, it is the Contractor's responsibility to ensure that within this flexibility all relevant information is provided to the Office of Safety Regulation (OSR) that could materially affect the decisions and actions of the Safety Regulation Official (SRO).

## **2.0 SCOPE**

The regulatory process described herein applies to the radiological, nuclear, and process safety regulation of the Contractor during design, construction, operations, and deactivation of the RPP-WTP. While the scope of the regulation is predominantly limited to the Contractor's activities from initial design through deactivation, it also must include the Contractor's consideration of site characteristics, its use of site services, and its coordination with DOE Richland Operation Office's integrated emergency response.

### **3.0 GENERAL SAFETY REGULATION STRUCTURE**

#### **3.1 Safety Regulation Organization**

The organization responsible for radiological, nuclear, and process safety regulation of the RPP-WTP Contractor is a specifically chartered, dedicated unit within the ORP, designated the OSR. The OSR will have the authority, on behalf of the ORP, to approve the Contractor's recommended safety standards and integrated safety management plan. The ORP Manager will have authority to authorize construction, operation, and deactivation (following approval/concurrence from the Office of Environmental Management [EM]); to suspend operations; and to recommend enforcement actions upon recommendation of the SRO. The SRO will be responsible for the following:

1. All important-to-safety regulatory interactions with the RPP-WTP Contractor
2. All safety reviews
3. Safety review schedules
4. Performance of the safety regulation functions in a disciplined and responsive manner
5. Documentation of all safety regulation actions and interactions
6. Quality assurance of the safety regulation functions
7. All interactions with independent safety oversight organizations
8. All safety regulation interactions with the public
9. The protection of the Contractor-submitted proprietary information.

Upon recommendation from the SRO, the ORP Manager will formally issue authorizations for construction, operations, and deactivation. The SRO will approve all Standards Approval documents (see Section 3.3.1) and changes thereto. The SRO will also exercise approval authority on behalf of DOE for formally approving Contractor-generated items specified in the applicable regulations, such as in 10 CFR 820, "Procedural Rules for DOE Nuclear Activities"; 10 CFR 830, "Nuclear Safety Management"; and 10 CFR 835, "Occupational Radiation Protection."

The OSR within ORP will use internally specified review procedures and acceptance criteria appropriate to the regulatory function. A full-time staff will manage and lead the reviews; will manage and lead the preparation of evaluation reports, recommendations for regulatory action, and authorization agreements; and will perform inspections to support the safety regulatory oversight function. This full-time staff will be supported by on-call technical experts from other DOE organizations and support contractors, as appropriate.

#### **3.2 Comprehensive Safety Regulation Process**

The comprehensive safety regulation process is shown in Figure 1 and consists of six regulatory actions. In approximate chronological order, these actions are as follows:

1. Standards Approval
2. Initial Safety Evaluation
3. Authorization for Construction

4. Authorization for Production Operations
5. Oversight Process Determination
6. Authorization for Deactivation.

This comprehensive regulatory process is intended to ensure that the Contractor’s safety program achieves adequate radiological, nuclear, and process safety through requirements that are properly defined, implemented, and maintained. As indicated in Figure 1, the Contractor and the OSR will have an intensely interactive relationship for each of the periods of the six regulatory actions.

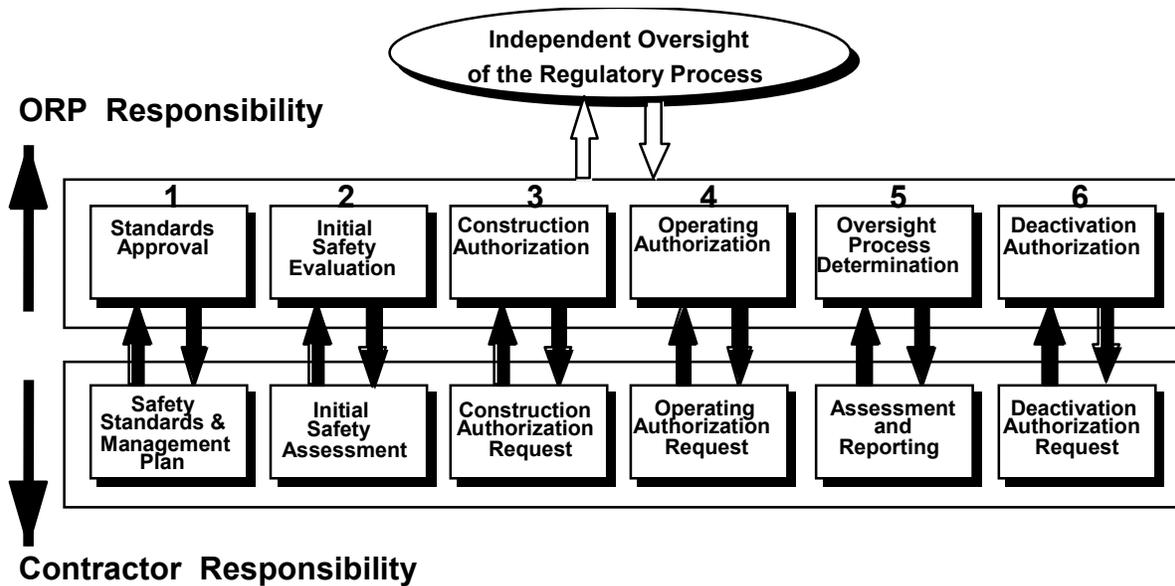


Figure 1. Comprehensive Safety Regulation Process

Oversight functions, independent from the OSR, will also exist. These functions will ensure that the ORP regulatory process is implemented effectively. Independent oversight of the radiological, nuclear, and process safety regulation shall be performed by the DOE Office of Environment, Safety, and Health (EH) consistent with their responsibilities for independent oversight of DOE programs and activities, departmental policy, and enforcement of nuclear safety rules. In addition, the Office of Environmental Management (EM) will have line-management responsibility for oversight of safety consistent with the requirements of DOE Policy 450.5, "Line Environmental, Safety, and Health Oversight."

### 3.3 Regulatory Actions

#### 3.3.1 Standards Approval

The purpose of Standards Approval regulatory action is to approve the Contractor-recommended set of radiological, nuclear, and process safety standards and requirements documented in a Safety Requirements Document (SRD) and to approve the Contractor's standards-based

integrated safety management program documented in an Integrated Safety Management Plan (ISMP). This action will provide assurance to the Contractor that its safety basis (safety technical approach and safety management practices) for the design and the projected construction, operation, and deactivation is adequate and acceptable, thereby providing a firm safety basis for services to be provided under the Contract.

The SRD shall include the Contractor's recommended standards for the format and content of information to be submitted by the Contractor for subsequent regulatory actions and shall include standards for nuclear safety management features required by DOE regulations, particularly 10 CFR 830.

The approval of the Contractor's recommended set of radiological, nuclear, and process safety standards and requirements will be issued upon determination by the SRO that

1. The set documented in the SRD includes all requirements of applicable laws and regulations.
2. The set documented in the SRD conforms to the top-level radiological, nuclear, and process standards and principles contained in the DOE-provided DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Standards and Principles for the RPP Waste Treatment Plant Contractor*.
3. The hazards associated with the proposed facility and its operation are appropriately assessed.
4. The set documented in the SRD was generated through the appropriate implementation of the standards process specified by DOE in the document titled DOE/RL-96-0004, *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor*.
5. Appropriate expertise was employed in the standards selection and confirmation processes.
6. The set documented in the SRD will provide adequate safety if properly implemented.

Approval of the Contractor's proposed ISMP will be issued upon determination by the SRO that

1. The program documented in the ISMP complies with all applicable laws and regulations.
2. The program documented in the ISMP conforms to the top-level radiological, nuclear, and process standards and principles contained in DOE/RL-96-0006.
3. The selected safety management processes documented in the ISMP are standards based and are appropriately tailored to the hazards associated with the Contractor's proposed facility, its operation, and its deactivation.
4. The selected safety management processes documented in the ISMP properly and adequately address management of process hazards.

5. The program documented in the ISMP contains appropriate features of integrated safety management (i.e., integration among safety, design, and operations interests; integration over the life cycle of the activities; and integration into work planning and performance).
6. The interfaces among regulatory regimes are appropriately addressed to ensure that adequate protection is fully achieved.
7. Safety documentation processes delineated in the ISMP provide for appropriate document control and maintenance.
8. Scheduling of the important-to-safety activities as described in the ISMP, including generation of regulatory submittals, is consistent with Figure 2 of this document.<sup>1</sup>
9. Self-assessment elements documented in the ISMP are appropriate.
10. Safety definition, implementation, and maintenance roles, responsibilities, and authorities defined in the ISMP are clear and appropriate.

The approvals of the SRD and ISMP will be based on the information provided by the Contractor (SRD, ISMP, and supplemental information described in Section 4.1.2). Approval will be issued by the SRO after a specified review and discussion period. This period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the reviews or if open issue resolution is not effectively supported by the Contractor.

During Part A of the TWRS Privatization (TWRS-P) Project (see Figure 2), both privatization Contractors submitted SRDs and ISMPs. The SRDs and the ISMPs were thoroughly reviewed by the OSR, using a pre-determined formal review process, and approved. Approval of these submittals by the OSR was based on (1) the sufficiency of the set of subordinate radiological, nuclear, and process safety standards recommended by the contractors to ensure adequate safety for the workers and the public, and (2) execution of the standards identification process as defined in DOE/RL-96-0004. Following approval of the set of standards by the SRO, the set was incorporated into the Contracts as mandatory safety requirements with which the TWRS privatization contractors were to comply.

At the end of Part A of TWRS-P, a single Contractor, BNFL Inc. (BNFL), was selected to proceed with Part B. BNFL continued to maintain the SRD and ISMP as part of the authorization basis as specified in its Contract. The approved SRD and ISMP were subsequently adopted with minor alterations by the interim Contractor, CH2M Hill Hanford Group, Inc. (CHG), and by the design, construct, and commission contractor, Bechtel National, Inc. (BNI), as part of the authorization basis. It is expected that BNI, and any subsequent Contractor, will continue to maintain the SRD and ISMP as part of the authorization basis and will use the documented OSR process to make subsequent changes to the documents.

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<sup>1</sup> Part of Figure 2, specifically the time line prior to Authorization for Construction, refers to historical evolution of the project and is currently of no significance to the RPP-WTP contract. It is included here only to maintain the historical continuity of this document.

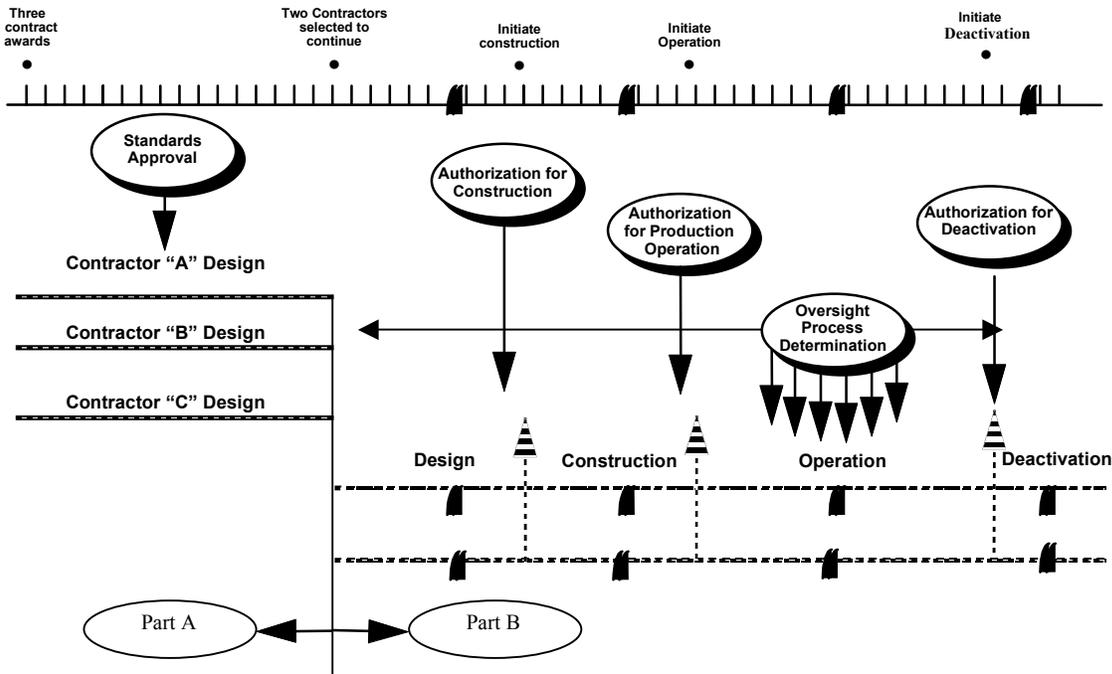


Figure 2. Overall Timeline for Regulatory Actions

### 3.3.2 Initial Safety Evaluation

The purpose of the Initial Safety Evaluation regulatory action was to assess the capability of the Contractor's waste processing approach to achieve subsequent authorizations for construction, operation, and deactivation. This evaluation also provided a perspective on the regulatory risks associated with the Contractor's proposal. The Initial Safety Evaluation addressed the following:

1. The degree to which the Contractor's proposed important-to-safety activities were being performed or could be performed in compliance with the approved SRD.
2. The degree to which the Contractor's proposed important-to-safety activities were being performed or could be performed in compliance with the approved ISMP.
3. The adequacy with which the hazards, including process hazards, attendant to the Contractor's proposed activities have been assessed and controlled.
4. The adequacy of the selection and definition of design basis events for the proposed facilities.
5. The acceptability of the results of analysis of representative design basis events.
6. The adequacy of the categorization of systems, structures, and components that are important to safety.
7. The adequacy of the projected safety basis for the facility and its operation.

8. The adequacy of the outlines of various plans, programs, and requests that will be generated and implemented under the Contract.
9. The confidence associated with important-to-safety aspects of constructability, operability, reliability, availability, maintainability, and inspectability.
10. The resolvability of open issues.
11. The adequacy of the draft deactivation plan.

The initial safety evaluation of the TWRS-P Contractor submittals was based on the Initial Safety Assessment (ISA) submitted by the Contractors, which included an Initial Safety Analysis Report and the supplemental information described in Section 4.2.2. The format and content for these Contractor submittals were determined as part of the process for producing the SRD and were approved in the Standards Approval regulatory action described in Section 3.3.1.

Initial Safety Evaluation Reports (ISER) were issued by the SRO after the specified review and discussion period for both TWRS-P Contractors. The review and approval process assessed the viability and sufficiency of the Contractor's approaches to achieve and maintain adequate safety through their proposed design and management practices. The fundamental aspects of design described in the ISA remains as part of the authorization basis until superseded by an approved authorization basis revision, or approval of the construction authorization request. The Initial Safety Assessment will not be repeated by the design, construct, and commission Contractor (BNI).

### **3.3.3 Authorization for Construction**

The purpose of the Authorization for Construction regulatory action is to authorize the Contractor to begin construction of its facility for processing high-level radioactive waste. A construction authorization will be issued by the ORP Manager (following approval/concurrence from EM), based upon the determination and recommendation of the SRO that:

1. The Contractor's important-to-safety activities are being conducted in accordance with its approved SRD.
2. That proposed changes to the SRD and the ISMP are acceptable.
3. The Contractor's design complies with the design-related part of the updated SRD.
4. The Contractor's design properly accounts for the natural and man-made external events associated with the designated site.
5. The Contractor is qualified by reason of experience and training to perform the proposed construction.
6. The Contractor's construction and pre-operational testing procedures are adequate to ensure that the construction-related part of the SRD will be properly implemented.

7. The Contractor's quality assurance plan is adequate and has been implemented such that the intended quality will be assured in the important-to-safety portions of the design, construction, and pre-operational testing and that the quality assurance records will attest thereto.
8. The radiological, nuclear, and process hazards associated with facility operation, including those from postulated accidents, have been adequately assessed, sufficiently controlled/mitigated, and adequately documented in a formally controlled Preliminary Safety Analysis Report (PSAR) to establish a basis for safe operation and an unambiguous definition of the safe-operating envelope.
9. The draft deactivation plan is acceptable.
10. The drafts of plans and programs to be finalized as elements of the operating authorization request and implemented during operation are adequate and acceptable.
11. The Contractor has made a commitment to comply with the conditions of the authorization agreement associated with the construction authorization.

Based on the recommendation of the SRO and following approval/concurrence of EM, the ORP Manager will issue a construction authorization agreement. The SRO will make a recommendation based on a determination that the Construction Authorization Request, which includes a PSAR and the supplemental information described in Section 4.3.2, submitted by the Contractor under oath and affirmation, is acceptable. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

The construction authorization, which will be in the form of a construction authorization agreement, will be issued by the ORP Manager, upon recommendation of the SRO and approval/concurrence from EM, after a specified review and discussion period, culminating in the issuance of a Preliminary Safety Evaluation Report (PSER). This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the above defined determinations or if open issue resolution is not effectively supported by the Contractor.

#### **3.3.4 Authorization for Production Operations**

The purpose of the Authorization for Production Operations regulatory action is to authorize the Contractor to begin introducing significant quantities of high-level radioactive waste into its facility. The authorization will be issued by the ORP Manager (following approval/concurrence from EM), based on a determination and recommendation of the SRO that

1. The Contractor's important-to-safety activities are being conducted in accordance with its approved ISMP.
2. The proposed changes to the SRD and ISMP are acceptable.

3. The Contractor's as-built facility complies with the design-related, construction-related, and testing-related parts of the final SRD.
4. The Contractor's as-built facility properly accounts for the natural and man-made external events associated with the designated site.
5. The Contractor is qualified by reason of experience and training to conduct the proposed operation.
6. The Contractor's operating procedures are adequate to ensure safe operation of the facility and ensure that all operations are conducted within the approved/proposed operating authorization basis.
7. The Contractor's quality assurance plan is adequate and has been implemented such that the intended quality has been achieved in the important-to-safety portions of the design, construction, and pre-operational testing, and the quality assurance records attest thereto.
8. The Contractor's physical protection provisions are adequate to prevent unauthorized access to structures, systems, and components important to safety.
9. The Contractor's personnel training and certification are adequate for the safe operation of the plant.
10. The Contractor's deactivation plan is adequate to protect the health and safety of the public and the workers, and adequate financial arrangements have been made to ensure its implementation.
11. The radiological, nuclear, and process hazards associated with as-built facility operation, including those from postulated accidents, have been adequately assessed, sufficiently controlled/mitigated, and adequately documented in a formally controlled Final Safety Analysis Report (FSAR) to ensure safe operation and an unambiguous definition of the safe-operating envelope.
12. Adequate Technical Safety Requirements (TSRs) have been established to ensure that operations are conducted well within the safe-operating envelope.
13. The startup test program has been successfully completed and confirms the intended safety characteristics of the facility.
14. An adequate emergency plan is in place and operational.
15. All other plans and programs required to be finalized and implemented in support of production operations are acceptable.
16. The Contractor has made a commitment to comply with the conditions of the authorization agreement associated with the operating authorization.

17. The Contractor has made a commitment to comply with the provisions of the regulatory oversight program defined in Section 3.3.5 and Section 4.5 of this document.
18. The Contractor's conduct of operations program for the operations phase is adequate, and it is fully implemented.
19. A formal operational readiness review has been successfully completed and documented.

Based on the recommendation of the SRO and following approval/concurrence of EM, the ORP Manager will issue an operating authorization agreement. The SRO will base the recommendation on the determination that the Operating Authorization Request, which includes a FSAR and supplemental information, described in Section 4.4.2 and submitted by the Contractor under oath and affirmation, is acceptable. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

The operating authorization, which will be in the form of an operating authorization agreement, will be issued by the ORP Manager, upon recommendation of the SRO and approval/concurrence from EM, after a specified review and discussion period, culminating in the issuance of a Final Safety Evaluation Report (FSER). This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the above defined determinations or if open issue resolution is not effectively supported by the Contractor.

### **3.3.5 Oversight Process Determination**

The purpose of this regulatory action is to monitor the operation of the Contractor's facility to ensure that the authorization basis and the conditions in the authorization agreement are not violated. The regulatory oversight program of the RPP-WTP Contractor will consist of the following elements:

1. Annual review and assessment of physical, process, and operational changes.
2. Annual review and assessment of site-related changes.
3. Annual review and assessment of changes to equipment and structures, particularly those that are important to safety.
4. Annual review and assessment of changes in the regulations that form the authorization basis and the conditions in the authorization agreement.
5. Annual review of the Contractor's analysis of the effects of the changes noted in items 1-4 above, including any analyses and determinations associated with potential Unreviewed Safety Questions (USQs).
6. Review and assessment of event reports.

7. Review and assessment of the effectiveness of emergency response actions and drills.
8. Review and assessment of the effectiveness of the Contractor's assessments of its conduct of operations.
9. Onsite inspections of records, premises, and activities, particularly those associated with conduct of operations.
10. Consideration of amendments to the authorization to operate or to the authorization agreement, including review and approval of changes to the FSAR.
11. Review and approval of proposed changes to the SRD and ISMP.
12. Review and approval of proposed changes to the TSRs.
13. Consideration of corrective actions, including suspension of operations.
14. Communication of noncompliances to the DOE Enforcement and Inspection staff for enforcement consideration under 10 CFR 820.

This oversight function will be performed based on information submitted by the Contractor under oath and affirmation, on direct inspections, and on other reliable, documented information. The format and content for the information to be submitted by the Contractor will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

Amendments to the operating authorization or to the operating authorization agreement will be issued after an agreed upon review and discussion period. This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the review and approval of the amendments or if open issue resolution is not effectively supported by the Contractor.

### **3.3.6 Authorization for Deactivation**

The purpose of the Authorization for Deactivation regulatory action is to authorize deactivation of the Contractor's facility following a stipulation by the Contractor to cessation of the waste processing activities at the facility. The authorization will be issued by the ORP Manager (following approval/concurrence from EM), based on the determination and recommendation of the SRO that:

1. The Contractor has submitted a final plan for deactivation.
2. The plan adequately addresses the current conditions at the facility and associated site.
3. The selected approach for deactivation is adequate given the facility and site conditions.

4. The controls and limits on procedures and equipment to protect worker and public health and safety are adequate.
5. The proposed final radiation surveys are adequate.
6. The arrangements are adequate to complete the deactivation activities, to perform final radiation surveys, and to properly dispose of the wastes generated.
7. The schedule for performing the deactivation activities is consistent with assuring no undue radiological, nuclear, and hazardous chemical risks to the public, or the workers.

The SRO will make this recommendation to the ORP Manager, based upon a determination that the Deactivation Authorization Request, which includes a Deactivation Safety Assessment and supplemental information described in Section 4.6, submitted by the Contractor under oath and affirmation, is acceptable. The format and content for this Contractor submittal will have been determined as part of the process for producing the SRD and will have been approved in the Standards Approval regulatory action described in Section 3.3.1.

The deactivation authorization, which will be in the form of a deactivation authorization agreement, will be issued by the ORP Manager, upon recommendation of the SRO and approval/concurrence of EM. The SRO will make a recommendation after a specified review and discussion period, culminating in the issuance of a Deactivation Safety Evaluation Report. This review and discussion period may be extended if the information submitted by the Contractor is insufficient in scope or depth to facilitate the above defined determinations or if open issue resolution is not effectively supported by the Contractor.

#### **4.0 DETAILED REGULATORY IMPLEMENTATION**

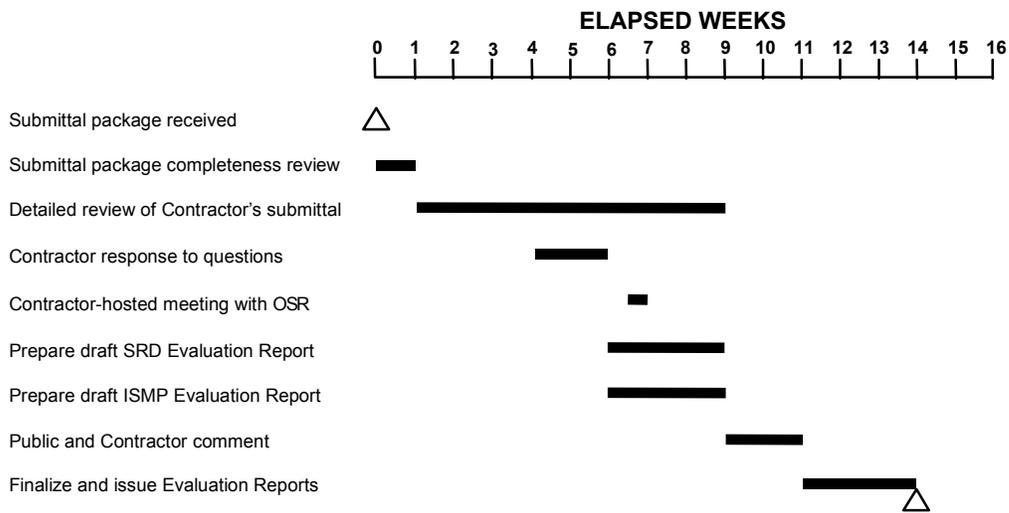
Figure 2 shows the overall time-line for accomplishing the safety regulatory actions described in Section 3.0. This is not intended as a detailed schedule for the safety regulatory actions, but rather, it provides the general time frames in which these actions must occur. The Contractor shall define the detailed schedule for submittal of its documentation to support these actions, taking into account the review and approvals.

The first two regulatory actions described below, Standards Approval and the Initial Safety Evaluation, were completed during Part A of the TWRS-P Project. Portions of the Standards Approval Package (SRD, significant and bounding hazards described in the Hazard Analysis Report [HAR], and implementing standards from the SRD described in the ISMP or ISA) and the fundamental aspects of design described in the Initial Safety Evaluation remain as part of the authorization basis. The Standards Approval and Initial Safety Evaluation descriptions are maintained below to show the process that was used by the Contractors and by the OSR for these regulatory submittals.

## 4.1 Standards Approval

### 4.1.1 Review Process

The reference review and approval schedule for the Standards Approval regulatory action is shown in Figure 3. As shown previously in Figure 2, it is expected that the Contractor's submittal package for this action will be delivered to OSR about midway through Part A. If the submittal package is sufficient to proceed with the review process and if the Contractor supports the process with written responses to prepared questions and a discussion meeting, according to the reference schedule, the SRD and ISMP approvals will be issued by the SRO in a total elapsed time of 14 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.



**Figure 3. Reference Schedule for Standards Approval**

### 4.1.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Standards Approval submittal package 30 days prior to delivery. The Standards Approval submittal package shall consist of the following documentation:

1. The Contractor's recommended set of radiological, nuclear, and process standards for design; construction; operation; deactivation; and safety regulation submittals in the form of a SRD
2. The Contractor's certification that the set of radiological, nuclear, and process standards in the SRD will, when properly implemented, provide adequate safety, because the integrated safety management process, which includes following the contractually prescribed process for requirements and standards selection, has been applied; there is

- compliance with all applicable laws and regulations; and there is conformance to the DOE-specified top-level safety standards and principles
3. The hazards assessment used to facilitate the selection of the standards
  4. The hazards control strategy implemented in the design and proposed operations
  5. Description of the process and facility design and its proposed operation
  6. The Contractor's treatment of the top-level radiological, nuclear, and process safety standards and principles
  7. The rationale for the selection of the standards and the adequacy of the set
  8. The standards identification process used and the credentials of the participants
  9. The standards confirmation process used and the credentials of the participants
  10. The Contractor's approval process used for the set of standards and the basis for the approval
  11. The Contractor's ISMP, which shall do the following:
    - a. Define the key important-to-safety activities to be performed by the Contractor.
    - b. Specify the standards-based management processes to be used by the Contractor to ensure that radiological, nuclear, and process safety is adequately defined (i.e., tailored to the nature and level of hazards, including process hazards), implemented, and maintained.
    - c. Ensure that the Contractor is in compliance with DOE nuclear safety regulations, in conformance with the DOE-specified top-level safety standards and principles, and in compliance with the SRD.
    - d. Define the Contractor's interfaces with other regulatory regimes such as environmental protection, occupational safety, and safeguards and security and define the processes for resolving conflicting requirements at these interfaces and for ensuring safety adequacy at these interfaces (i.e., ensuring that safety "gaps" do not occur).
    - e. Specify the expected flow and schedule of the Contractor's important-to-safety work and deliverables, including interactions with the OSR.
    - f. Describe the self-assessment functions to be employed by the Contractor.
    - g. Describe the Contractor's approach for tailoring its radiological, nuclear, and process safety deliverables and actions commensurate with the nature and level of hazards associated with its waste processing activities.

- h. Identify roles, responsibilities, and authorities for defining, implementing, and maintaining safety.
- 12. ISMP compliance with applicable laws and regulations.
- 13. ISMP conformance to the top-level radiological, nuclear, and process standards and principles contained in DOE/RL-96-0006.

The Contractor shall also prepare written responses to review questions and shall participate in a discussion meeting with the OSR hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the SRO to approve the SRD and the ISMP.

#### **4.1.3 OSR Actions**

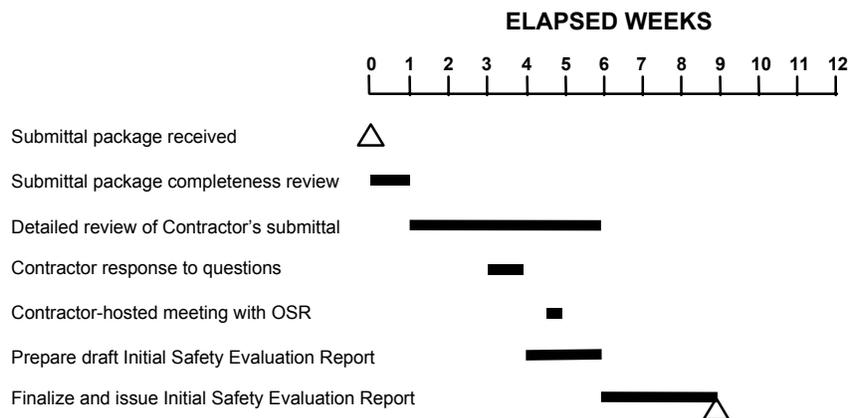
The OSR will conduct the review in the following manner:

1. Assign a review manager from the OSR to direct the reviews of the SRD and ISMP.
2. Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence.
3. Review the Standards Review submittal package for completeness and adequacy within one week from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the OSR may request additional information from the Contractor to clarify or supplement material in the package.
4. Request public comments on the Standards Approval Package.
5. Perform the reviews in accordance with review plans previously developed by the OSR.
6. Further clarify previously provided Contractor information and responses to additional information requests at a Contractor/OSR meeting. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review.
7. Disposition public comments on the Standards Approval Package.
8. Prepare a draft SRD Evaluation Report and a draft approval letter (may be conditional).
9. Prepare a draft ISMP Evaluation Report and a draft approval letter (may be conditional).
10. Issue the final SRD Evaluation Report, final ISMP Evaluation Report and final approval letters.

## 4.2 Initial Safety Evaluation

### 4.2.1 Review Process

The reference schedule for the Initial Safety Evaluation regulatory action is shown in Figure 4. As shown previously in Figure 2, it is expected that the Contractor's submittal package for this action, the ISA, will be delivered to the OSR late in Part A. If the submittal package is sufficient to proceed with the standards review process and if the Contractor supports the process with written responses to prepared questions and a discussion meeting, according to the reference schedule, the Initial Safety Evaluation Report will be issued by the SRO in nine weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached. Rescheduling the review may not permit a full review of the ISA because of the constraints of the overall procurement schedule. If so, the partial review and associated results will be summarized in the ISER along with all open issues.



**Figure 4. Reference Schedule for the Initial Safety Review**

### 4.2.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Initial Safety Assessment submittal package 30 days prior to delivery. This submittal package shall consist of the following documentation:

1. Description of the design developed during Part A and the proposed facility operations.
2. Description of the Contractor's site and its location within the Hanford Site.
3. An assessment of compliance to the approved SRD and the ISMP.
4. Description of hazards, including process hazards, and hazards controls implemented in the design and operations.

5. Description of potential design-basis events.
6. Analysis of the potential design-basis events.
7. Preliminary safety acceptance criteria against which the consequences of the potential design-basis events are compared for acceptability.
8. Description of structures, systems, and components designated as important to safety and the rationale for their selection.
9. The Contractor's evaluations of constructability, operability, reliability, availability, maintainability, and inspectability.
10. An Initial Safety Analysis Report that does the following:
  - a. Defines the projected safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, representative off-normal internal events, representative external events, representative safety analyses and results, major uncertainties in data and analyses.
  - b. Describes how the facility should perform such that the radiological, nuclear, and process safety standards and requirements in the SRD and in applicable regulations are met.
  - c. Describes how adequate protection of the public, the workers, and the environment should be achieved.
11. Draft deactivation plan.
12. Outlines of the following:
  - a. Emergency Response Plan
  - b. USQ Plan
  - c. Conduct of Operations Plan
  - d. TSRs
  - e. Training and Qualification Plan
  - f. Maintenance Implementation Plan
  - g. Occurrence Reporting Procedures
  - h. Environmental Radiological Protection Program
  - i. Radiation Protection Program
  - j. Operational Assessment Reports.

The Contractor shall also prepare written responses to review questions and shall participate in a discussion meeting with OSR hosted by the Contractor. The Contractor shall also submit any other information that could materially affect this evaluation by OSR.

### **4.2.3 OSR Actions**

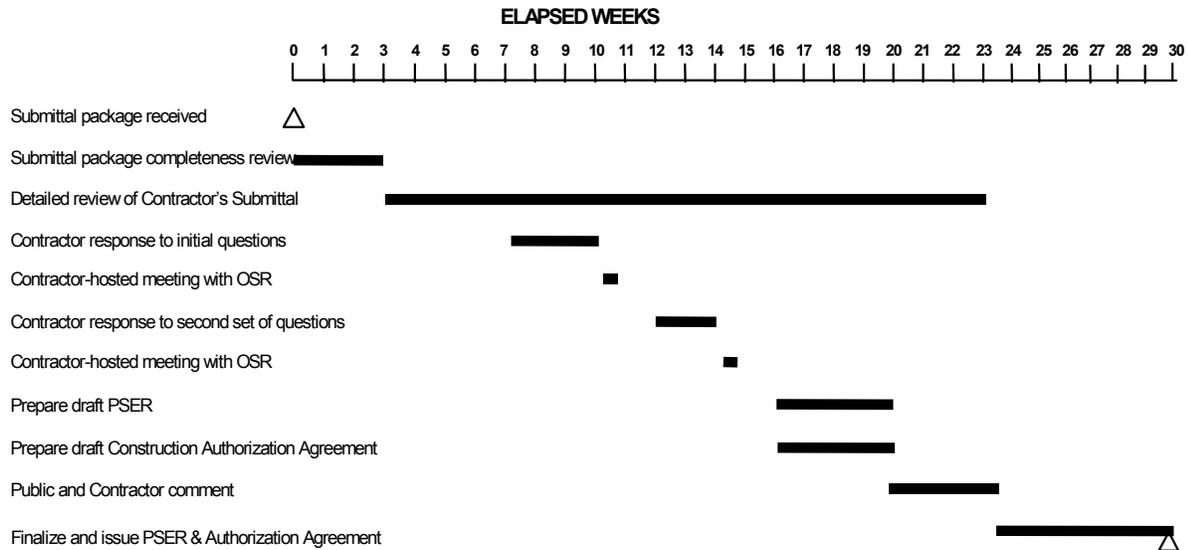
The OSR will conduct the review in the following manner:

1. Assign a review manager from the OSR to direct the initial safety evaluation.
2. Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence.
3. Review the submittal package for completeness and adequacy within one week from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the OSR may request additional information from the Contractor to clarify or supplement material in the package.
4. Request public comments on the Initial Safety Assessment submittal.
5. Perform the review in accordance with a review plan previously developed by the OSR.
6. Further clarify previously provided Contractor information and responses to additional information requests at a Contractor/OSR meeting. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review.
7. Disposition public comments on the Initial Safety Assessment.
8. Prepare and issue a final ISER.

## **4.3 Authorization for Construction**

### **4.3.1 Review Process**

The reference review and approval schedule for the Authorization for Construction regulatory action is shown in Figure 5. As shown previously in Figure 2, it is expected that the Contractor's submittal package for this action, the Construction Authorization Request, will be delivered to the OSR before substantial construction involving important-to-safety features has been initiated. If the submittal package is sufficient to proceed with the review process and if the Contractor supports the process with written responses to prepared questions and with scheduled discussion meetings according to the reference schedule, the construction authorization will be issued by the ORP Manager, upon recommendation by the SRO and approval/concurrence of EM, in a total elapsed time of 30 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.



**Figure 5. Reference Schedule for Issuing a Construction Authorization**

### 4.3.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Construction Authorization Request submittal package four months prior to delivery. This submittal package shall consist of the following documentation:

- A. A PSAR containing the following:
  1. Description of the Contractor's site and its location within the Hanford Site.
  2. Description of natural-phenomena and man-made external hazards at the Contractor's site, the selected design-basis external events, and the rationale for their selection.
  3. Description of high-level radioactive waste handling and treatment processes.
  4. Description of planned facility operations.
  5. Description of facility structures, systems, and components including those designated as important to safety.
  6. Description of the decontamination and deactivation features provided in the design and draft deactivation plan.
  7. Design data and design drawings to support descriptions in 5, above.
  8. Analysis of radiological, nuclear, and process hazards for the design.
  9. Description of facility features and functions provided to control the radiological, nuclear, and process hazards.

10. Description of the range of off-normal events and postulated accidents that could initiate internal to the Contractor's facility, the selected design-basis internal events, and the rationale for their selection.
  11. Analysis of hazards-control features during all expected facility operating modes, off-normal conditions, and design basis internal and external events.
  12. Potential safety limits and the justification for their selection.
  13. Description of planned important-to-safety testing to be performed, including the purpose of each test, expected data, and a description of the test and associated equipment.
  14. Description of quality assurance program employed during the design and to be employed during construction, important-to-safety testing, and pre-operational testing.
  15. An analysis of the safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, off-normal internal events considered, external events considered, assumptions made, uncertainties in data and analyses, safety limits, and operating limits.
  16. A demonstration that the facility should perform such that the radiological, nuclear, and process safety requirements in the SRD and in applicable regulations should be met.
  17. A demonstration that adequate protection of the public, the workers, and the environment should be achieved.
  18. Drafts of the
    - a. USQ Plan
    - b. Conduct of Operations Plan
    - c. TSRs
    - d. Training and Qualifications Plan
    - e. Maintenance Implementation Plan
    - f. Occurrence Reporting Procedures
    - g. Environmental Radiological Protection Program.
- B. The Contractor's technical and experience qualifications to construct the plant.
- C. The approach to be used to implement the construction and pre-operational testing portions of the SRD and the ISMP.

- D. The current SRD and the ISMP and an assessment of compliance to the SRD and the ISMP (note the changes relative to the SRD and the ISMP approved by the regulatory action of Section 4.1).
- E. The draft Emergency Response Plan.
- F. The draft Radiation Protection Program.

The Contractor shall also prepare written responses to review questions and shall participate in up to three discussion meetings with the OSR hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the OSR to recommend a construction authorization.

Note: During the construction activities, the RPP-WTP Contractor shall support regulatory oversight aimed at assuring that the construction authorization agreement is not violated or that formal amendment processes are facilitated.

### **4.3.3 OSR Actions**

The OSR will conduct the review in the following manner:

1. Assign a review manager from the OSR to direct the Construction Authorization Request review.
2. Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence.
3. Review the submittal package for completeness and adequacy within two weeks from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the OSR may request additional information from the Contractor to clarify or supplement material in the package.
4. Request public comment on the Construction Authorization Request.
5. Perform the review in accordance with a review plan previously developed by the OSR.
6. Further clarify previously provided Contractor information and responses to additional information requests during three Contractor/OSR meetings. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review.
7. Disposition public comments on the Construction Authorization Request.
8. Prepare a draft PSER and draft construction authorization agreement.

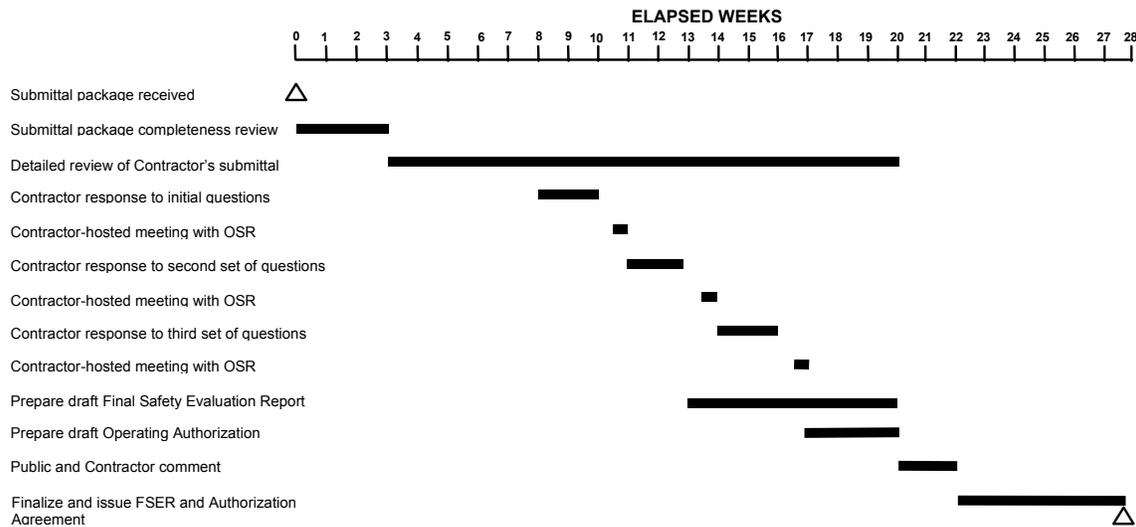
9. Issue the final PSER.
10. Recommend to the ORP Manager that a construction authorization agreement be issued to the Contractor.

Note: During the construction activities, the OSR will perform regulatory oversight aimed at assuring that the construction authorization agreement is not violated and that formal amendment processes are executed.

#### 4.4 Authorization for Production Operations

##### 4.4.1 Review Process

The reference review and approval schedule for the Authorization for Production Operations regulatory action is shown in Figure 6. As shown previously in Figure 2, it is expected that the Contractor's submittal package for this action, the Operating Authorization Request, will be delivered to the OSR near the end of the construction/pre-operational testing period. If the submittal package is sufficient to proceed with the review process for an operating authorization and if the Contractor supports the process with written responses to prepared questions and with scheduled discussion meetings according to the reference schedule, the authorization will be issued by the ORP Manager, based upon the recommendation by the SRO in a total elapsed time of 28 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.



**Figure 6. Reference Schedule for Issuing an Operating Authorization**

#### 4.4.2 Contractor Input

The Contractor shall provide written notice of the intent to submit the Operating Authorization Request submittal package 12 months prior to delivery. This submittal package shall consist of the following documentation:

- A. An FSAR containing the following:
1. Final description of the Contractor's site and its location within the Hanford Site (emphasize changes from the construction authorization basis).
  2. Final description of the natural-phenomena and man-made external hazards at the Contractor's site, selected design-basis external events, and rationale for their selection (emphasize changes from the construction authorization basis).
  3. Final description of the high-level radioactive waste handling and treatment processes (emphasize changes from the construction authorization basis).
  4. Final description of the planned facility operations (emphasize changes from the construction authorization basis).
  5. Final description of the facility structures, systems, and components including those designated as important to safety (emphasize changes from the construction authorization basis).
  6. Final design data and design drawings that clearly indicate the safety features of the plant and their characteristics (emphasize changes from the construction authorization basis).
  7. Final analysis of radiological, nuclear, and process hazards as controlled by the engineered safety features (emphasize changes from the construction authorization basis).
  8. A fully defined, analyzed safety basis for the facility (safety envelope) in terms of physical design, structures with prescribed safety functions, systems with prescribed safety functions, equipment with prescribed safety functions, operating modes, operating conditions, off-normal internal events considered, external events considered, assumptions made, uncertainties in data and analyses, safety limits, and operating limits.
  9. A demonstration that the facility will perform such that the radiological, nuclear, and process safety requirements in the SRD and in applicable regulations will be met.
  10. A demonstration that adequate protection of the public, the workers, and the environment will be achieved.

11. Final description of the decontamination and deactivation features provided in the design and the deactivation plan, including financial arrangements that have been made to ensure its implementation (emphasize changes from the construction authorization basis).
  12. Proposed TSRs and the rationale for their selection.
  13. A Quality Assurance Program for operations.
  14. Final description of the expected radiological effluents from the facility and the associated monitoring and reporting programs.
  15. Final description of the expected radioactive wastes (non-product wastes) from facility operations and the associated storage, handling, and disposal programs.
  16. Final Conduct of Operations Plan to be implemented during the facility operations.
- B. Final Training and Qualification Plan.
- C. The final SRD and ISMP, and an assessment of the compliance to the SRD and ISMP (emphasize changes from the construction authorization basis).
- D. The Contractor's technical and experience qualifications to operate the facility.
- E. Description of the important-to-safety testing program, including pre-operational facility and equipment tests, including all associated acceptance criteria.
- F. Documentation of the effectiveness of the QA program implementation in assuring that the facility is constructed as intended.
- G. Final submissions of the following:
- a. USQ Plan
  - b. Maintenance Implementation Plan
  - c. Occurrence Reporting Procedures
  - d. Environmental Radiological Protection Program
  - e. Radiation Protection Program
  - f. Emergency Response Plan and procedures.
- H. Evidence that the intended emergency response capability is qualified and functional.
- I. Final description of the physical protection program and associated physical and administrative features.
- J. The Contractor's understanding of and commitment to comply with the provisions of the regulatory oversight program during the operations phase.

Two months prior to the planned date for start of operations involving radioactive material, the Contractor shall complete a formal review for operational readiness and shall document this review process and the results thereof. This shall include certification that operations personnel are ready and able to perform their intended functions. The Contractor may perform separate facility reviews of operational readiness if it is seeking authority to operate one or more facilities before other facilities are ready for operation.

The Contractor shall also prepare written responses to review questions, and participate in up to three discussion meetings with the OSR hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the ORP Manager to grant an operating authorization.

#### **4.4.3 OSR Actions**

The OSR will conduct the review in the following manner:

1. Assign a review manager from the OSR to direct the Operating Authorization Request review.
2. Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence.
3. Review the submittal package for completeness and adequacy within three weeks from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the OSR may request additional information from the Contractor to clarify or supplement material in the package.
4. Request public comments on the Operating Authorization Request.
5. Perform the review in accordance with a review plan previously developed by the OSR.
6. Further clarify previously provided Contractor information and responses to additional information requests during three Contractor/OSR meetings. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review.
7. OSR's obligation for operational readiness determination (within OSR scope) shall be achieved through inspection.
8. Disposition public comments on the Operating Authorization Request.
9. Prepare a draft FSER and draft operating authorization agreement.
10. Issue the final FSER.

11. Recommend to the ORP Manager that an operating authorization agreement be issued to the Contractor.

#### **4.5 Oversight Process Determination**

##### **4.5.1 Ongoing Oversight Process**

The oversight process for determining that the authorization basis and the authorization agreement are not violated during all phases of the RPP-WTP facility will consist of the following elements:

1. Review of annual Contractor reports and self-assessments
2. Unscheduled evaluations of unusual occurrences
3. Unscheduled intermittent reviews of authorization amendments and USQs
4. Continuous in-facility inspections
5. Corrective actions.

The oversight process begins with the start of design following approval of the Standards Approval Package and ends at the point in time that the operating authorization is terminated.

The focus of the oversight process will be on the following:

1. In-facility verification of the completeness and correctness of the information provided by the Contractor to the OSR.
2. Assurance that changes to the facility structures, systems, equipment, processes, procedures, etc., are properly assessed and, if necessary, addressed promptly with the OSR.
3. Potential challenges to the authorization agreement.
4. The nature and frequency of off-normal conditions and occurrences.

##### **4.5.2 Contractor Input**

The Contractor shall do the following:

1. Maintain a listing of Authorization Basis Change Notices that catalog significant physical, procedural, and administrative changes over a given year.
2. Submit unusual occurrence reports describing the event or condition, the Contractor's assessment of implications and causes, and the Contractor's recommended corrective actions.

3. Support in-facility regulatory inspections of operations; tests; maintenance activities; records; facility, system, and equipment status; operating and administrative procedures; unusual occurrences; and log-books.
4. Provide written notice of intent to submit a request to amend the authorization agreement 30 days prior to the request. (Note: The 30 day notice requirement may be waived by the SRO for good cause shown.)
5. Submit all necessary information to support the review and evaluation of any such requested amendments.
6. Support requests for additional information and discussions during the reviews associated with requested amendments.
7. Maintain the FSAR, SRD, TSR, and key supporting documents that are materially part of the authorization basis in a current state (annual updates unless circumstances warrant otherwise).
8. Support the resolution of USQs.
9. Perform back-fit assessments as requested.
10. Support annual safety performance meetings in which the facility safety record is presented, safety performance is discussed, and safety plans are described.

The Contractor and the SRO may agree to establish other reporting and submittal requirements at a later date.

#### **4.5.3 OSR Actions**

The OSR will perform the oversight in the following manner:

1. Assign an oversight manager from the OSR to direct the oversight process.
2. Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence.
3. Review proposed amendments to the authorization agreement.
4. Recommend approval of amendments to the authorization agreement to the ORP Manager.
5. Review and disposition USQs.
6. Review all change reports, self-assessment reports, and unusual occurrence reports submitted by the Contractor and in-facility inspection reports to determine needs for

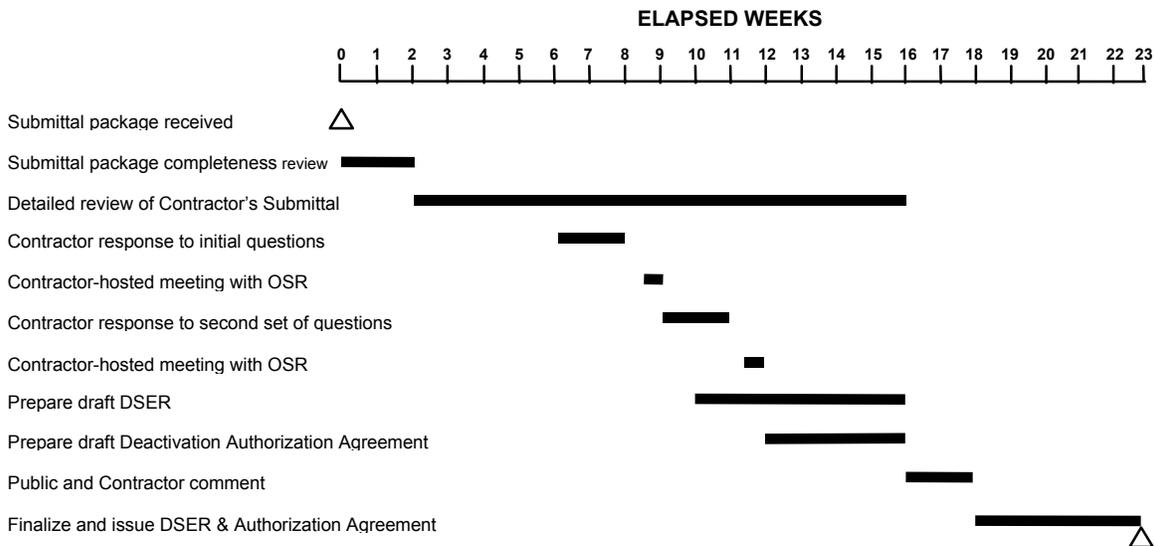
modifications to the authorization basis and associated controlled documents or amendments to the operating authorization agreement.

7. Issue back-fit requirements, as necessary, based on reviews of Contractor's back-fit assessments.
8. Perform in-facility inspections.
9. Formulate and issue corrective actions.
10. Communicate regulatory noncompliances to DOE Enforcement and Investigation staff.

#### 4.6 Authorization for Deactivation

##### 4.6.1 Review Process

The reference review and approval schedule for the Authorization for Deactivation regulatory action is shown in Figure 7. As shown previously in Figure 2, it is expected that the Contractor's submittal package for this action, the Deactivation Authorization Request, will be delivered to the OSR one year before the end of the production operations period. If the submittal package is sufficient to proceed with the review process for deactivation authorization and if the Contractor supports the process with written responses to prepared questions and with scheduled discussion meetings, the deactivation authorization will be issued by the ORP Manager, based upon the recommendation of the SRO and approval/concurrence from EM, in a total elapsed time of 23 weeks. If the package is rejected, the review process will be rescheduled. The insufficiency of the information will be explained in a letter of rejection transmitted to the Contractor within one week after the rejection decision has been reached.



**Figure 7. Reference Schedule for Issuing a Deactivation Authorization**

#### **4.6.2 Contractor Input**

The Contractor shall provide written notice of the intent to submit the Deactivation Authorization Request submittal package 60 days prior to delivery. This submittal package shall consist of the following documentation:

1. A final deactivation plan
2. Description of the post-operations conditions of the facility and the associated site
3. Rationale for the selection of the deactivation approach
4. The hazards assessment for the selected deactivation approach and the results
5. Description of the controls and limits that will be imposed through procedures and on equipment to protect worker and public health and safety
6. Description of the final radiation survey to be performed
7. A Quality Assurance Program for deactivation
8. The adequacy of arrangements for the deactivation activities, including final radiation survey and disposal of wastes
9. The proposed schedule for the deactivation and providing an assessment of the risks associated with any delays in performing the deactivation.

The Contractor shall also prepare written responses to review questions and shall participate in a discussion meeting with the OSR hosted by the Contractor. The Contractor shall also submit any other information that could materially affect the determination by the OSR to recommend a deactivation authorization.

Note: During the deactivation activities, the RPP-WTP Contractor shall support regulatory oversight aimed at assuring that the deactivation authorization agreement is not violated and that formal amendment processes are executed.

#### **4.6.3 OSR Actions**

The OSR will conduct the review in the following manner:

1. Assign a review manager from the OSR to direct the Deactivation Authorization Request review.
2. Prepare and maintain a public records file, with due consideration of proprietary information, with all information received, the basis for all review findings, copies of meeting minutes, and all correspondence.

3. Review the submittal package for completeness and adequacy within one week from the day of its receipt. Upon completing the review, issue a notice to the Contractor in writing of the acceptability of the package. If the package is rejected, list the reasons for the rejection and the necessary corrective actions. After the package is accepted for review, the OSR may request additional information from the Contractor to clarify or supplement material in the package.
4. Request public comments on the Deactivation Authorization Request.
5. Perform the review in accordance with a review plan previously developed by the OSR.
6. Further clarify previously provided Contractor information and responses to additional information requests during two Contractor/OSR meetings. Any resulting agreements, understandings, and new information shall be documented and submitted by the Contractor as additional information submitted for review.
7. Disposition public comments on the Deactivation Authorization Request.
8. Prepare a draft Deactivation Safety Evaluation Report (DSER) and draft deactivation authorization agreement.
9. Issue the final DSER.
10. Recommend to the ORP Manager that a deactivation authorization agreement be issued to the Contractor.

Note: During the deactivation activities, the OSR will perform regulatory oversight aimed at assuring that the deactivation authorization agreement is not violated and that formal amendments processes are executed.

#### **4.7 Proprietary Information**

The OSR, including any associated technical support teams, and review and oversight bodies, will adopt and implement procedures and processes necessary to protect the Contractor's proprietary information. The procedures and processes will be reviewed and approved by the Contractor prior to any interactions between the Contractor and the OSR involving the Contractor's proprietary information.

#### **4.8 Back-fit**

As used in this section, back-fit means the addition, elimination, or modification of (1) structures, systems, or components of the facility or (2) procedures or organizations required to operate the facility after the construction authorization has been issued. Upon recommendation of the SRO, the ORP Manager will require a back-fit if the OSR determines, and an independent review concurs, that such action is necessary for the following reasons:

1. Ensure adequate protection of worker or public health and safety.
2. Bring the facility and its operation into compliance with the operating authorization and the conditions attached thereto.
3. Bring the facility and its operation into compliance with current federal, state, and local regulations.
4. Bring the facility and its operation into compliance with any compliance orders issued under Subpart C of 10 CFR 820.
5. Achieve a substantial increase in overall protection of worker or public health and safety, and the associated implementation costs are justified.

In support of the implementation of this back-fit policy, the Contractor shall provide assessments of proposed back-fits, including implementation approaches and associated safety, cost, and operational impacts and shall submit alternative approaches, if any, to achieve the expressed purpose of a particular back-fit.

#### **4.9 Authorization Revocation**

Upon the recommendation of the SRO, the operating authorization may be revoked or suspended in whole or in part by the ORP Manager for any of the following reasons:

1. A material false statement in the request for an authorization or associated material presented under oath and affirmation as the authorization basis.
2. A revelation of conditions or statements of fact that would have been a basis for refusal to grant an authorization had such conditions or facts been known by the SRO at the time the authorization was granted.
3. Failure to operate the facility in accordance with the operating authorization agreement.
4. Failure to comply with applicable laws and regulations.
5. Failure to comply with compliance orders issued under Subpart C of 10 CFR 820.

To ensure adequate protection to worker or public health and safety, a revocation of the operating authorization and associated cessation of operation (treatment of high-level waste) shall be a planned event. The Contractor shall ensure that the facility is placed and maintained in a safe state that is fully restartable using approved operating procedures.

#### **4.10 Suspension of Operation**

The SRO may order the suspension of facility operation if a clear and present danger to the workers or the public is evidenced. Such an action will be taken only after specified procedures

have been followed. To ensure adequate protection to worker or public health and safety, an ordered suspension of operation (treatment of high-level waste) shall be a planned event. The Contractor shall ensure that the facility is placed and maintained in a safe state that is fully restartable using approved operating procedures.

#### **4.11 Issue Resolution**

In general, issues will be addressed by the OSR based on factual information and objective standards or expectations. However, factual information can have subjective aspects: its quality, its interpretation, its applicability, its sufficiency, etc., and use of standards is not without subjective elements. Therefore, disagreements between the OSR and the Contractor may occur. To ensure that issues involving subjective elements are expeditiously resolved, a definitive resolution process will be developed and implemented by the ORP Manager after consultation with the Contractor. The elements of this process will include the following:

1. Development of a clear statement of the issue
2. Delineation of the facts versus subjective elements
3. Establishment of agreement on the root cause of the disagreement
4. Development of an action plan to address (remove) the root cause
5. Development of alternatives to avoid the root-cause
6. Formulation of definitive alternatives for issue resolution with implications of each (cost, schedule, safety margins, etc.)
7. Independent review input
8. Ruling on the matter by the SRO
9. Appeal to the ORP Manager.

#### **4.12 Formal Review/Comment Process for OSR Guidance Documents**

On occasion, the OSR will prepare interpretative guidance documents, review guidance, position papers, or other regulatory documents related to the interpretation and application of requirements and standards within its jurisdiction. Such documents will be made available for contractor and public review and comments before such documents are finalized. In finalizing such documents, the OSR will make publicly available its disposition of comments received, including the reasons for accepting or rejecting such comments.

## 5.0 REFERENCES

10 CFR 820, “Procedural Rules for DOE Nuclear Activities,” *Code of Federal Regulations*, as amended.

10 CFR 830, “Nuclear Safety Management,” *Code of Federal Regulations*, as amended.

10 CFR 835, “Occupational Radiation Protection,” *Code of Federal Regulations*, as amended.

DOE/RL-96-0004, *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

## 6.0 LIST OF TERMS

DOE	U.S. Department of Energy
DSER	Deactivation Safety Evaluation Report
FSAR	Final Safety Analysis Report
FSER	Final Safety Evaluation Report
HAR	Hazard Analysis Report
ISA	Initial Safety Assessment
ISER	Initial Safety Evaluation Report
ISMP	Integrated Safety Management Plan
ORP	Office of River Protection
OSR	Office of Safety Regulation
PSAR	Preliminary Safety Analysis Report
PSER	Preliminary Safety Evaluation Report
RPP-WTP	River Protection Project Waste Treatment Plant
SRD	Safety Requirements Document
SRO	Safety Regulation Official
TSRs	Technical Safety Requirements
USQs	Unreviewed Safety Questions

## 7.0 GLOSSARY<sup>2</sup>

**acceptable release:** The release of radioactive material, within acceptable limits, to the environment.

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<sup>2</sup> Certain terms used in this document and listed in this glossary have origins in radiological and nuclear safety. Extension of their use to process safety may be useful but is not specified herein. It is expected that the extension of their use to process safety will be considered as part of the standards and requirements identification process.

**anticipated operational occurrences:** Conditions of normal operation expected to occur one or more times during the life of the facility and include, but are not limited to, loss of offsite power to the process activity within the facility.

**Authorization Agreement:** The document mutually agreed upon by the Office of River Protection Manager and a Contractor that specifies authorization terms and conditions.

**authorization basis:** 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 the Contractor permission to perform regulated activities.

**back-fit:** The addition, elimination, or modification of (1) structures, systems, or components of the facility or (2) procedures or organizations required to operate the facility after the construction authorization has been issued.

**catastrophic release:** A major uncontrolled chemical emission, fire, or explosion that presents serious danger to employees in the workplace.

**co-located worker:** 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:** 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:** 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.

**Contractor:** The company or companies selected to contract with DOE for construction and operation of the technologies and facilities necessary to retrieve, process tank waste, and deliver treated waste products to DOE for storage or disposal.

**Contractor Representative(s):** The organization manager(s), or duly appointed designee(s), who have direct Contract responsibility, accountability, and authority for directing or performing the River Protection Project Waste Treatment Plant work subject to the set of standards.

**Contractor Representative(s) recommended set of standards and requirements:** Those standards and requirements identified through a DOE-specified process and recommended by the Contractor Representative(s) as necessary assurance that work will be performed in a manner that protects the workers, the public, and the environment from the actual hazards identified for the specific work activities of the River Protection Project Waste Treatment Plant Contractor. (Also see the definition for "requirements.") The recommended set serves as a basis for DOE review and approval by the Safety Regulation Official and the issuance of the Safety Requirements Document.

**control strategy:** A set of generally described provisions (barriers, dilution/dispersal, physical limitations on material quantities, administrative material controls, confinement, ventilation of flammable gas, etc.) and/or approaches (defense in depth, use of passive features, prevention, mitigation, etc.) which are intended to ensure adequate control of a specific hazard and associated accidents in the context of the work.

**controlled area:** 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 Safety Evaluation Report:** The document approved and issued by the Safety Regulation Official that addresses the adequacy of the authorization basis for deactivation.

**defense in depth:** The fundamental principle underlying the safety technology of the facility centered on several levels of protection including successive barriers preventing the release of radioactive materials to the workplace or environment. Human aspects of defense in depth are considered to protect the integrity of the barriers, such as quality assurance, administrative controls, safety reviews, operating limits, personnel qualification and training, and safety program. Design provisions, including both those for normal facility systems and those for systems important to safety help to (1) prevent undue challenges to the integrity of the physical barriers; (2) prevent failure of a barrier if it is challenged; (3) where it exists, prevent consequential damage to multiple barriers in series; and (4) mitigate the consequences of accidents. Defense in depth helps to assure that two basic safety functions (controlling the process flow and confining the radioactive material) are preserved and that radioactive materials do not reach the worker, public, or the environment.

**design basis:** The information that identifies the specific functions to be performed by structures, systems, or components of the facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

**design-basis events:** Postulated events providing bounding conditions for establishing the performance requirements of structures, systems, and components that are necessary to (1) ensure the integrity of the safety boundaries protecting the worker; (2) place and maintain the facility in a safe state indefinitely; or (3) prevent or mitigate the event consequences so that the radiological exposures to the general public or the workers would not exceed appropriate limits. The design-basis events also establish the performance requirements of the structures, systems and components whose failure under design-basis event conditions could adversely affect any of the above functions.

**documented safety analysis:** A documented analysis of the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.

**DOE-customer:** A DOE employee who has knowledge of the equipment, facilities, and processes necessary for performance by the Contractor of the work activities to deliver the contracted services.

**environment, safety, and health standards experts:** Individuals with knowledge and expertise relevant to the radiological, nuclear, or process standards and requirements in a particular environment, safety, and health discipline.

**facility:** Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

**Final Safety Evaluation Report:** The document approved and issued by the Safety Regulation Official that addresses the adequacy of the authorization basis for operation.

**hazard:** A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation).

**hazards assessment experts:** Individuals with the knowledge, skills, and abilities to identify, based on examination of the work activities defined, the hazards associated with the work activities, as well as the risk to the workers, public, and environment attributable to those hazards.

**hazards control experts:** Individuals with knowledge, skills, and abilities to identify, based on examination of the work activities and associated hazards, the controls necessary to mitigate the hazards to an acceptable level.

**highly hazardous chemical:** A substance possessing toxic, reactive, flammable, or explosive properties, which can lead to a catastrophic release.

**important to safety:** 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 oversight:** Authorized oversight by bodies or groups having no financial, programmatic, or other direct interest in the activities or organizations under review and which are totally free of management relationships with those activities or organizations.

**independent oversight bodies:** Independent oversight bodies are those established organizations that have no financial, programmatic, or other direct interest in and are outside the management structure of the Contractor and the Office of Safety Regulation (OSR). The independent oversight bodies include personnel qualified and skilled to critique, evaluate, and recommend that the safety regulatory oversight provided by the OSR of the Contractor is effective.

**Independent Review Team:** A group of individuals with the appropriate knowledge and expertise to review the recommended standards set for completeness, credibility, and adequacy before the standards are recommended by the Contractor Representative(s) to the Safety Regulation Official.

**Initial Safety Evaluation Report:** The document, approved and issued by the Safety Regulation Official, that addresses the capability or potential for obtaining future authorizations for construction, operation, and deactivation.

**Integrated Safety Management Plan Evaluation Report:** The document, approved and issued by the Safety Regulation Official, that addresses the adequacy of the Contractor's Integrated Safety Management Program as reflected in its Integrated Safety Management Plan.

**Integrated Safety Management Program:** A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

**limiting conditions for operations:** The limits that represent the lowest functional capability or performance level of important-to-safety structures, systems, and components required for safe operations.

**limiting control settings:** The settings on important-to-safety systems that control process variables to prevent exceeding a safety limit.

**margin of safety:** 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.

**normal operation:** 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.

**Office of Safety Regulation:** The organization that executes safety regulatory authority for the River Protection Project Waste Treatment Plant Contractor.

**offsite:** The area outside the perimeter of the Hanford Site.

**onsite:** The area within the Hanford Site control perimeter that is under the jurisdiction of the DOE.

**operating limits:** Those limits required to ensure the safe operation of a nuclear facility, including limiting control settings and limited conditions of operation.

**oversight safety determination:** The oversight of the Contractor performed by the Office of Safety Regulation to ensure continuing compliance to an authorization agreement.

**postulated accidents:** Events, including the design-basis events, that would have an adverse affect on the facility process but which do not have a significant probability of occurrence during the life of the facility and include, but are not limited to, pipe or tank failures.

**Preliminary Safety Evaluation Report:** The document, approved and issued by the Safety Regulation Official, that addresses the adequacy of the authorization basis for construction.

**process:** 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 manager:** A person, designated by the Contractor Representative(s), responsible for ensuring that the process steps are accomplished.

**Process Management Team:** A group of individuals designated by the Contractor Representative(s) to approve specified actions proposed by the process manager and to monitor their implementation.

**process safety:** The operation of facilities that handle, use, process, or store chemicals or hazardous materials in a manner free of episodic or catastrophic releases. However, the handling, use, processing, and storage of chemicals or 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:** The application of management systems to the identification, understanding, and control of process hazards to prevent process-related injuries and incidents.

**public:** Individuals who are not occupationally engaged at the Hanford Site.

**radiation worker:** A worker who has qualifications and training to work in a restricted area of the facility where radiation or radioactive material is present.

**reliability targets:** Quantified probabilistic expectations that a component, equipment, or system will perform its intended function satisfactorily under given circumstances, such as environmental conditions, limitations as to operation time, and frequency and thoroughness of maintenance for a specified period of time. Identified important-to-safety items are expected to perform their function satisfactorily through all design basis accident conditions.

**requirements:** Standards that are mandated by an authority through statute, regulation, or contract.

**restricted area:** 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 analysis:** The development of a qualitative or quantitative estimate of risk based on engineering evaluation and techniques for considering estimates of incident consequences and frequency.

**safe state:** 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:** 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 assurance:** Established confidence that adequate protection of worker and public health and safety have been provided.

**safety basis:** The combination of information relating to the control of hazards at a nuclear facility (including design, engineering analyses, and administrative controls) upon which the DOE depends for its conclusion that activities at the facility can be conducted safely.

**safety function:** Any function that is necessary to ensure (1) the integrity of the boundaries retaining the radioactive materials, (2) the capability to place and maintain the facility in a safe state, or (3) the capability to prevent or mitigate the consequences of facility conditions that could result in radiological exposures to the general public or workers in excess of appropriate limits.

**safety limits:** 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.

**Safety Regulation Official:** An individual who has been delegated the authority to execute the radiological, nuclear, and process safety regulation of the River Protection Project Waste Treatment Plant Contractor.

**Safety Requirements Document:** 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.

**Safety Requirements Document Evaluation Report:** The document approved and issued by the Safety Regulation Official that addresses the adequacy of the set of radiological, nuclear, and process safety standards that a Contractor proposes to implement to ensure adequate protection of worker and public health and safety.

**safety setpoints:** Physical parameters set in the control equipment by an operator for equipment that controls the process or process flow to maintain the process within the systems design safety limits. A safety setpoint represents a process characteristic, such as pressure, temperature, or material level, that is monitored by a control system to restrict the process characteristic within a system's design operating range. These setpoints are identified in the design as levels above which a process physical parameter would exceed a design operating range of a process component or system leading to its failure and risk to the safety of the worker, public, or the environment. Several setpoints may be used to initiate alarm levels or control the process to a safe state.

**significantly new safety information:** Either (1) a safety requirement newly mandated by the Office of Safety Regulation, (2) a safety item newly identified by the Contractor as an item not included in the Safety Analysis Report for the facility; or (3) a determination that an unresolved safety question exists.

**stakeholder:** Any individual other than federal employees or DOE contractor employees who will be materially affected by, or can materially affect, the outcome of the work, either favorably or unfavorably.

**standards:** The expressed expectation for the performance of work.

**state-of-the-art human factors:** The most effective design approaches established for use at the start of the final design phase.

**technical safety requirements:** The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and hazards identified in the documented safety analysis for the facility: safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

**Unreviewed Safety Question:** A situation where (1) the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analyses could be increased; (2) the possibility of an accident

or malfunction of a different type than any evaluated previously in the documented safety analyses could be created; (3) a margin of safety could be reduced; or (4) the documented safety analysis may not be bounding or may be otherwise inadequate. (Also see definition for "margin of safety.")

**work:** Functional description of a set of activities (e.g., process operations) that will produce the intended outcome or objective (such as achieving a mission in terms of specified functional requirements).

**worker:** Worker means an individual within the controlled area of the facility performing work for or in conjunction with the Contractor or utilizing Contractor facilities.

**work activities:** All activities associated with performing the work, including design, construction, operation, and deactivation.

**work activity experts:** Individuals with knowledge and expertise relevant to the work, site, and activities addressed by the standards set.

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