

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF PAGES 1 87
2. CONTRACT (Proc. Inst. Ident.) NO. DE-EM0004943/1087-17-702030		3. EFFECTIVE DATE 09/01/2017	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. See Schedule	
5. ISSUED BY ORP U.S. Department of Energy Office of River Protection P.O. Box 450 MS H6-60 Richland WA 99352	CODE 02701	6. ADMINISTERED BY (If other than Item 5) CODE		

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code) See Schedule		8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)
		9. DISCOUNT FOR PROMPT PAYMENT NET 30
		10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM Section G

11. SHIP TO/MARK FOR Office of River Protection US Department of Energy P.O.Box 450 Richland WA 99352	CODE 00603	12. PAYMENT WILL BE MADE BY OR for ORP U.S. Department of Energy Oak Ridge Financial Service Center P.O. Box 6017 Oak Ridge TN 37831	CODE 00524
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13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION <input type="checkbox"/> 10 U.S.C. 2304 (c) () <input checked="" type="checkbox"/> 41 U.S.C. 253 (c) ()	14. ACCOUNTING AND APPROPRIATION DATA See Schedule
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15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued					
15G. TOTAL AMOUNT OF CONTRACT					\$1,530,000.00

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	2	X	I	CONTRACT CLAUSES	31
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	6	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	8	X	J	LIST OF ATTACHMENTS	32
X	D	PACKAGING AND MARKING	9	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	10	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	12	L	INSTRS., CONDS. AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	14	M	EVALUATION FACTORS FOR AWARD		
X	H	SPECIAL CONTRACT REQUIREMENTS	24				

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return <u>1</u> copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.) 18A. NAME AND TITLE OF SIGNER (Type or print) <i>Bradley W. Teast CFO</i>	18. <input type="checkbox"/> AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any condition sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.
19A. NAME OF CONTRACTOR <i>[Signature]</i>	20A. NAME OF CONTRACTING OFFICER Margit Larriou
19B. NAME OF CONTRACTOR	20B. UNITED STATES OF AMERICA
19C. DATE SIGNED <i>8-8-17</i>	20C. DATE SIGNED 08/08/2017

2. CONTRACT (Proc. Inst. Ident.) NO. DE-EM0004943/1087-17-702030	3. EFFECTIVE DATE 09/01/2017	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. See Schedule
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19A. NAME AND TITLE OF SIGNER (Type or print)

19B. NAME OF CONTRACTOR

BY _____
(Signature of person authorized to sign)

20A. NAME OF CONTRACTING OFFICER
Margit Larrieu

20B. UNITED STATES OF AMERICA

BY Signature on File
(Signature of the Contracting Officer)

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
DE-EM0004943/1087-17-702030

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NAME OF OFFEROR OR CONTRACTOR
See Schedule

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
00001	<p>Tax ID Number: 80-0651341 DUNS Number: 965502193</p> <p>Small Business Administration</p> <p>965502193 North Wind Solutions, LLC Attn: JOHN BUKOWSKI 1425 HIGHAM STREET IDAHO FALLS ID 834021513 2085219143</p> <p>Delivery: 08/31/2020 FOB: Destination Period of Performance: 09/01/2017 to 08/31/2020</p> <p>IGF::OT::IGF The purpose of this contract is to procure support services for Environmental Remediation, Technical and Program Management Support to support the US DOE Office of River Protection (ORP) by providing qualified assistance in the planning, directing, and overseeing of design, construction, environmental remediation, cleanup, and operation of ORP facilities.</p> <p>Nuclear waste treatment plant support contract. Requisition No: 17EM002112, 17EM002203</p>				1,530,000.00

SECTION B

SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 TYPE OF CONTRACT-SERVICES BEING ACQUIRED

This is a labor hour contract to provide environmental remediation, and related technical and administrative program management support expertise and assistance in carrying out responsibilities to plan, direct and oversee design, construction, environmental remediation, cleanup and operation of government facilities to support the US DOE Office of River Protection (ORP). The Contractor shall provide the personnel, materials, supplies, services (except as may be expressly set forth in this Contract as furnished by the Government), and do all things necessary and incident to providing the services specified in Section C - Statement of Work.

B.2 CEILING PRICE

- (a) The ceiling price for each contract year does not represent, nor shall it be construed as a guarantee or minimum amount. The ceiling price shall not be exceeded by Contractor, to do so will be at its own risk. The Contractor shall not incur any costs in excess of the amount obligated in the contract and each task assignment will have a not-to-exceed dollar amount, which the Contractor may not exceed. Should the Contractor exceed the task assignment ceiling price, it does so at its own risk.
- (b) The ceiling price for each contract year does not represent, nor shall it be construed as a guarantee or minimum amount. The ceiling price is provided in the summary table below.

Year	Description	Ceiling Price
1	Base Period	\$8,500,000.00
2	Year 2	\$8,500,000.00
3	Year 3	\$7,500,000.00
	Total	\$24,500,000.00

- (c) **BASE YEAR:** The Contractor shall provide the engineering, environmental, and related technical and administrative support services specified in Section C, at the applicable hourly labor rates and Other Direct Cost limit specified in Sections B.3 and B.4 for the applicable period of performance specified in Section F.1.

Funds Obligated to Base Year:

Year	Accounting & Appropriation Data	Obligation Amount*
1	See Section A	\$ 8,500,000.00

* Subject to Section I Clause FAR 52.232-22 entitled, *Limitation of Funds (APR 1984)*, the cumulative amount identified in this column is the total amount presently available for payment under this Base Year. The contractor shall not incur any costs in excess of the amount obligated to this contract.

- (d) **YEAR 2:** The Contractor shall provide the engineering, environmental, and related technical and administrative support services specified in Section C, at the applicable hourly labor rates and Other Direct Cost limit specified in Sections B.3 and B.4 for the applicable period of

performance specified in Section F.1.

Funds Obligated to Year 2:

Year	Accounting & Appropriation Data	Obligation Amount*
2	See Section A	TBD

* Subject to Section I Clause FAR 52.232-22 entitled, *Limitation of Funds (APR 1984)*, the cumulative amount identified in this column is the total amount presently available for payment under this Year 2. The contractor shall not incur any costs in excess of the amount obligated to this contract.

- (e) YEAR 3: The Contractor shall provide the engineering, environmental, and related technical and administrative support services specified in Section C, at the applicable hourly labor rates and Other Direct Cost limit specified in Sections B.3 and B.4 for the applicable period of performance specified in Section F.1.

Funds Obligated to Year 3:

Year	Accounting & Appropriation Data	Obligation Amount*
3	See Section A	TBD

* Subject to Section I Clause FAR 52.232-22 entitled, *Limitation of Funds (APR 1984)*, the cumulative amount identified in this column is the total amount presently available for payment under this funding year. The contractor shall not incur any costs in excess of the amount obligated to this contract.

B.3 DIRECT PRODUCTIVE LABOR HOURS AND FIXED LABOR RATES

- (a) Direct Productive Labor Hours (DPLH) are defined as actual work hours exclusive of vacation, holiday, sick leave, and other absences. The maximum required DPLH will be specified in Task Assignments (Attachment J) in accordance with the Task Assignment Procedures in Section H. The Contractor shall provide all required DPLH to perform approved Task Assignments which will be derived from Section C Statement of Work.
- (b) The following labor categories, and corresponding fully burdened hourly labor rates (maximum, not reflecting discount) , and skill levels meeting the qualifications in Section J, Attachment J-5 and corresponding fully burdened hourly labor rates are applicable to work performed under this contract for the applicable period of performance:

Fully Burdened Hourly Labor Rates (On Site)			
Labor Category	9/01/2017 - 8/31/2018	9/01/2018 - 8/31/2019	9/01/2019 - 8/31/2020
Executive Consultant III			
Executive Consultant II			
Executive Consultant I			
Management Consultant III			
Management Consultant II			
Management Consultant I			
Consultant III			
Consultant II			
Consultant I			
Program Manager III			
Program Manager II			
Program Manager I			
Project Manager III			
Project Manager II			
Project Manager I			
Technical Specialist III			
Technical Specialist II			
Technical Specialist I			
Analyst III			
Analyst II			
Analyst I			
Engineer III			
Engineer II			
Engineer I			
Quality Specialist III			
Quality Specialist II			
Quality Specialist I			
Safety Specialist III			
Safety Specialist II			
Safety Specialist I			
Designer III			
Designer II			
Designer I			
Technical Editor			
Technical Editor Associate			
Administrative Specialist III			
Administrative Specialist II			
Administrative Specialist I			
Administrative Support			
Clerk/Typist/Data Entry			

- (c) The labor categories and corresponding fully burdened hourly labor rates listed above, are applicable to work performed pursuant to FAR 52.217-8 Option to Extend Services.

B.4 OTHER DIRECT COSTS

In addition to transition and HLAN costs that are direct billed to the contract, the Contractor may need to procure miscellaneous non-labor items such as local travel and supplies. The estimated dollar amount of such Other Direct Costs (ODCs), including G&A on ODCs, are included in the ceiling price, for each year, subject to the provisions in Section B.2. The estimated ODC dollar amount is \$200,000 for the term of the contract. All travel shall be specified in Task Assignments in accordance with the Task Assignment Procedures in Section H.

SECTION C

STATEMENT OF WORK

ENVIRONMENTAL REMEDIATION SERVICES, TECHNICAL AND PROGRAM MANAGEMENT SUPPORT

C.1 BACKGROUND

The U.S. Department of Energy (DOE) Office River Protection (ORP) was established by the U.S. Congress in 1998, as an independent office at the DOE Site in eastern Washington State with the exclusive focus of remediating and solving the DOE's tank cleanup challenges. ORP's mission is to protect the Columbia River by safely cleaning up hazardous and radioactive waste contained in underground storage tanks located at the DOE Site. The nuclear waste at the DOE Site is the result of more than four decades of reactor operations and plutonium production for national defense and includes 53 million gallons of highly toxic, radioactive waste stored in 177 underground tanks located within 7 miles of the Columbia River, including 149 single steel liner tanks that are decades beyond their design life. The cleanup of this legacy waste is now a national priority and part of closing the circle on the nation's nuclear weapons production cycle.

The Waste Treatment and Immobilization Plant Project (WTP), which is currently being built at the DOE Site is the largest construction project within DOE, occupying 65 acres of land and is the cornerstone of the River Protection Project. The purpose of this Project is to reduce to an acceptable level the environmental risk from DOE's radioactive tank waste, which together comprise 56 percent of the nation's tank-stored radioactive waste. The Project includes the design, construction, startup, commissioning, and operation of a chemical processing plant to treat and immobilize (i.e., vitrify) high-level and low-activity radioactive waste for long-term storage and final disposal. The Project entails the construction of a facility to treat and separate the radioactive hazardous tank waste into low-activity and high-level waste streams, immobilize the high-level waste fraction for shipment to a national high-level nuclear waste repository, and immobilize the low-activity waste for onsite disposal.

In conducting its WTP management and oversight responsibilities, ORP requires various types of short-term and long-term Technical, Environmental Remediation, and Program Management Support expertise and assistance in carrying out its responsibilities to plan, direct, and oversee design, construction, environmental remediation, cleanup, and operation of government facilities. The general purpose of this support is directly to assist in the restoration and remediation of a contaminated environment and will also include related technical support activities involving engineering services, management consulting services, and hazardous waste collection and treatment.

C.2 SCOPE OF WORK

The River Protection Project at the DOE Site in eastern Washington has been under construction for over a decade now and has encountered numerous technical difficulties, which are in the process of being overcome. Some parts of the Project are expected to become operational over the near term, bringing an evolving scope. Thus, the Scope of Work of the support activities for the next few years will differ significantly from the Scope that existed over the past few years, as

facility designs are finalized, construction is completed, and remedial start-up operations are initiated and the facilities are made to work as designed.

- (a) The Contractor shall provide ORP with a broad array of expert Technical, Environmental Remediation, and Program Management Support resources, at times on very short notice, to perform a wide array of services, including but not limited to technical studies, environmental remediation, management support, preliminary assessment, site inspection, testing, remedial investigation, feasibility studies, regulatory compliance, remedial design, remediation services, quality assurance and design reviews, containment, nuclear remediation, removal of contaminated materials, and security and site closeouts to be specified in written Task Assignments issued by the Contracting Officer.
- (b) The Contractor shall provide highly qualified subject matter experts and technical specialists capable of providing high quality services, in areas of remediation, engineering, management support, advisory and assistance, hazardous and other waste collection, laboratory testing, assessments and evaluations, studies and analyses, guidance, counseling, training, support for policy development and decision-making, support for project management and administration; support to improve the efficiency and effectiveness of ORP processes and procedures; support for logistics management, project monitoring and reporting, data collection, budgeting, accounting, performance auditing, and administrative technical support for environmental remediation related programs.
- (c) The Contractor shall provide highly qualified subject matter experts and technical experts, as needed, to meet support services needs as stated in (c) perform a broad array of Environmental Remediation, Technical and Program Management Support services including, but not limited to, may be separately defined in each Task Assignment for specific functional areas. Labor category requirements with specific educational and work related experience requirements are stated in Attachment J-6.
- (d) All required Environmental Remediation, Technical, and Program Management Support services will be separately detailed and issued using written Task Assignments in accordance with the Task Assignment Procedures outlined in Section H.
- (e) The Contractor shall maintain electronic copies of all Task Assignments, Task Plans/Proposals, Contracting Officer Approvals, Work Authorizations, Monthly Task Status Reports, Monthly Task Assignment Tracking Reports, Monthly Accruals Reports, and all related documentation in an ORP shared drive location accessible to the Contracting Officer and other CPM contracting staff as necessary.

C.3 DELIVERABLES

- (a) The Contractor shall provide deliverables in the form of reports, analyses, evaluation recommendations, training, day-to-day support of ORP staff for the successful performance of ongoing ORP contract management, safety oversight, and project integration operations. When applicable, deliverables will be specified in each Task Assignment issued by the Contracting Officer.
- (b) The Contractor shall provide an accurate, complete, and timely contract budget/cost report accompanying each invoice which provides the budget and cost status of each Task Assignment and of the overall contact, in a format approved by the Contracting Officer.

SECTION D

PACKAGING AND MARKING

D.1 PACKAGING

Preservation, packaging, and packing for shipment or mailing of all work delivered hereunder shall be in accordance with good commercial practice and adequate to ensure acceptance by common carrier and safe transportation at the most economical rate(s).

D.2 MARKING

Each package, report, or other deliverable shall be accompanied by a letter or other document which:

- (a) Identifies the Contract by number under which the item is being delivered.
- (b) Identifies the deliverable Item Number or Report Requirement that requires the delivered item(s).

SECTION E

INSPECTION AND ACCEPTANCE

E.1 NOTICE LISTING CONTRACT CLAUSES INCORPORATED BY REFERENCE

The following contract clauses pertinent to this section are hereby incorporated by reference (by Citation Number, Title, and Date) in accordance with the clause at FAR "52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)" in Section I of this contract.

<u>NUMBER</u>	<u>TITLE</u>
FAR 52.246-6	INSPECTION OF SERVICES – TIME-AND-MATERIAL AND LABOR-HOUR (MAY 2001)

E.2 INSPECTION AND ACCEPTANCE

Inspection and acceptance shall be accomplished by the Contracting Officer or the Contracting Officer's Representative acting within the scope of his/her authority.

SECTION F

DELIVERIES OR PERFORMANCE

F.1 PERIOD OF PERFORMANCE

(a) The total period of performance for the work specified in Section C, Statement of Work, is three (3) years (assuming the subsequent annual periods are performed). The period of performance durations for the base and subsequent annual periods are specified below.

(1) YEAR 1 – One-Year Base Period from the contract effective date (9/01/2017 - 8/31/2018).

(2) YEAR 2 – One-Year 2nd Contract Year (9/01/2018 - 8/31/2019).

(3) YEAR 3 – One-Year 3rd Contract Year (9/01/2019 - 8/31/2020)

(b) In addition, the Government may extend the base period or any subsequent annual periods for up to six (6) additional months pursuant to FAR 52.217-8, Option to Extend Services (NOV 1999).

F.2 PRINCIPAL PLACE OF PERFORMANCE

The principal place of performance for this contract is at the Department of Energy, Office of River Protection and other facilities in Richland, WA as directed by the Contracting Officer.

F.3 FAR 52.242-15 STOP-WORK ORDER (AUG 1989) -- ALTERNATE I (APRIL 1984)

(a) The Contracting Officer may, at any time, by written order to the Contractor, require the Contractor to stop all, or any part, of the work called for by this Contract for a period of 90 days after the order is delivered to the Contractor, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this Clause. Upon receipt of the order, the Contractor shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allowable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work order is delivered to the Contractor, or within any extension of that period to which the parties shall have agreed, the Contracting Officer shall either-

(1) Cancel the stop-work order; or

(2) Terminate the work covered by the order as provided in the Termination clause of this Contract.

(b) If a stop-work order issued under this clause is canceled or the period of the order or any extension thereof expires, the Contractor shall resume work. The Contracting Officer shall make an equitable adjustment in the delivery schedule, the estimated cost, the fee, or a combination thereof, and in any other terms of the contract that may be affected and the contract shall be modified, in writing, accordingly, if--

- (1) The stop-work order results in an increase in the time required for, or in the Contractor's cost properly allowable to, the performance of any part of this contract;
and
 - (2) The Contractor asserts a claim for the adjustment within 30 days after the end of the period of work stoppage; provided that if the Contracting Officer decides the facts justify the action, the Contracting Officer may receive and act upon the claim asserted at any time before final payment under this Contract.
- (c) If a stop-work order is not canceled and the work covered by the order is terminated for the convenience of the Government, the Contracting Officer shall allow reasonable costs resulting from the stop-work order in arriving at the termination settlement.
- (d) If a stop-work order is not canceled and the work covered by the order is terminated for default, the Contracting Officer shall allow, by equitable adjustment or otherwise, reasonable costs resulting from the stop-work order.

SECTION G

CONTRACT ADMINISTRATION DATA

G.1 CORRESPONDENCE PROCEDURES

To promote timely and effective administration, correspondence submitted under this Contract shall include the Contract number and be subject to the following procedures:

- (a) Technical Correspondence. Technical correspondence (as used herein, excludes technical correspondence where patent or technical data issues are involved and correspondence which proposes or otherwise involves waivers, deviations, or modifications to the requirements, terms, or conditions of this Contract) shall be addressed to the U.S. Department of Energy (DOE) Office of River Protection (ORP) Contracting Officer's Representative (COR) or Technical Monitor, with an information copy addressed to the DOE-ORP Contracting Officer and DOE-ORP Correspondence Control.
- (b) Other Correspondence. All other correspondence shall be addressed to the Contracting Officer with information copies of the correspondence to the COR and/or Technical Monitor, DOE-ORP Correspondence Control, and the U.S. Department of Energy, Richland Operations Office (RL) Patent Counsel (when patent or technical data issues are involved).

G.2 CONTRACT ADMINISTRATION

The ORP Contracting Officer (CO) is:

U. S. Department of Energy
Office of River Protection, MS H6-60
Margit Larrieu, Contracting Officer
P.O. Box 450
Richland, WA 99352

Tele: (509) 376-4504
Fax: (509) 376-0570
E-mail: Margit_Larrieu@orp.doe.gov

G.3 CONTRACTING OFFICER REPRESENTATIVE (COR)

By separate letter, a COR may be designated this Contract. The COR will represent the CO in the technical phases of the work. The COR is not authorized to change any of the terms and conditions of this Contract. The CO, through properly written modification(s) to the Contract, is the only person authorized to make changes to the work scope.

G.4 BILLING INSTRUCTIONS

- (a) The contractor shall submit vouchers electronically through the Oak Ridge Financial Service Center's (ORFSC) Vendor Inquiry Payment Electronic Reporting System (VIPERS). VIPERS allows vendors to submit vouchers, attach supporting documentation, and check the payment status of any voucher submitted to the DOE. To obtain access to and use VIPERS, please visit the web page at <http://finweb.oro.doe.gov/vipers.htm>. Detailed instructions on how to enroll and use the system are provided on the web page. The submission of vouchers electronically will reduce correspondence and other causes for delay to a minimum and will

- facilitate prompt payment to the Contractor. Electronic and/or hard copies of supporting documents may also be requested by the Contracting Officer.
- (b) The voucher must provide Direct Productive Labor Hours (DPLH) multiplied by the hourly labor rate specified in Section B, both for the current billing period and cumulatively for the entire contract. The voucher shall also include the total cost of Other Direct Costs such as HLAN support, travel costs, etc. The contractor shall provide supporting documentation for DPLH and Other Direct Costs incurred, in a format requested by the Contracting Officer. The contractor shall provide a full and detailed narrative explanation of all travel costs, and shall include all supporting documentation (receipts, etc) for all travel expenses regardless of the cost of the travel.
 - (c) Each invoice shall provide cumulative summary data which demonstrates the extent of compliance with FAR 52.219-14, Limitations on Subcontracting (NOV 2011).

G.5 DELIVERY DESTINATION FOR CORRESPONDENCE AND CONTRACT DELIVERABLES

The following delivery points apply to technical correspondence and deliverables described in Section C, Statement of Work:

- (a) Contracting Officer (CO)
U. S. Department of Energy
Office of River Protection
Acquisition Management Division
MS H6-60
Attn: Margit Larrieu
P.O. Box 450 (for U.S. Mail delivery) or 2440 Stevens Drive (for hand delivery)
Richland, WA 99352
- (b) DOE-ORP Correspondence Control
U. S. Department of Energy
Office of River Protection
DOE-ORP Correspondence Control
MS H6-60
P.O. Box 450 (for U.S. Mail delivery) or 2440 Stevens Drive (for hand delivery)
Richland, WA 99352
- (c) Contracting Officer Representative (COR)
U. S. Department of Energy
Office of River Protection
MS H6-60
Attn: TBD
P.O. Box 450 (for U.S. Mail delivery) or 2440 Stevens Drive (for hand delivery)
Richland, WA 99352

SECTION H

SPECIAL CONTRACT REQUIREMENTS

H.1 MODIFICATION AUTHORITY

Notwithstanding any of the other clauses of this Contract, the Contracting Officer shall be the only individual authorized to:

- (a) Accept nonconforming work,
- (b) Waive any requirement of this contract, or
- (c) Modify any term or condition of this contract.

H.2 SECTION 8(a) DIRECT AWARD (FAR 52.219-11, Special 8(a) Contract Conditions (FEB 1990))

- (a) This contract is issued as a direct award between the contracting activity and the 8(a) Contractor pursuant to the Partnership Agreement (PA) between the U.S. Small Business Administration (SBA) and the U.S. Department of Energy. SBA does retain responsibility for 8(a) certification, 8(a) eligibility determinations and related issues, and providing counseling and assistance to the 8(a) Contractor under the 8(a) program. The cognizant SBA district office is:

U.S. Small Business Administration
Boise District Office
380 East Parkcenter Blvd., Suite 330
Boise, ID 83706
SBA Requirement No. 1087-17-702030

- (b) The contracting activity is responsible for administering the contract and taking any action on behalf of the Government under the terms and conditions of the contract. However, the contracting activity shall give advance notice to the SBA before it issues a final notice terminating performance, either in whole or in part, under the contract. The contracting activity shall also coordinate with SBA prior to processing any novation agreement. The contracting activity may assign contract administration functions to a contract administration office.
- (c) The Contractor agrees:
 - (1) To notify the Contracting Officer, simultaneous with its notification to SBA (as required by SBA's 8(a) regulations), when the owner or owners upon whom 8(a) eligibility is based plan to relinquish ownership or control of the concern. Consistent with 15 U.S.C. 637(a)(21), transfer of ownership or control shall result in termination of the contract for convenience, unless SBA waives the requirement for termination prior to the actual relinquishing of ownership and control.
 - (2) It will adhere to the requirements of FAR 52.219-14, Limitations on Subcontracting (NOV 2011).
 - (3) To provide the Government with a complete list of simultaneous services being performed by Contractor's employees or subcontracted employees for similar or

overlapping services for the duration of their employment with the Contractor and under this contract. This list is to be updated and maintained by the Contractor and provided to the Contracting Officer.

- (4) To provide the Government with the greatest supply and direct alignment of its own direct labor force, limiting the utilization of subcontractors to 75-85% utilization level in compliance with SBA guidelines.

H.3 REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF THE OFFEROR

The Representations, Certifications, and Other Statements of the Offeror submitted with the offer for this Contract are, by reference, hereby incorporated in and made a part of this Contract.

H.4 HEALTH AND SAFETY REQUIREMENTS

- (a) The Contractor shall take all reasonable precautions in the performance of the work to protect the safety and health of employees and the public.
- (b) The Contractor shall comply with Hanford Site requirements for work performed on the Hanford Site, including requirements for activities conducted in areas that may contain chemical, biological, physical, and/or radiological hazards.
- (c) Contractor employees who require access to Hanford Site radiologically controlled areas are required to use Hanford Site dosimetry and shall comply with Hanford Site dosimetry requirements. Dosimetry will be provided to these employees at no charge to the Contractor.
- (d) The Contractor is responsible for compliance by its employees and subcontractors with the health and safety requirements of this Contract. DOE reserves the right to direct in writing that the Contractor remove any employee and/or subcontractor employee from the Hanford Site who fails to comply with health and safety requirements of this Contract. If the Contractor fails to comply, DOE may cause removal of the employee from the Hanford Site.
- (e) The Contractor and its employees shall comply with the DOE Integrated Safety Management (ISM) Order, Policy and Guide (DOE O 450.4A; DOE P 450.1 and DOE G 450.4-1C); the DOE/ORP Worker Safety and Health Program (10 CFR 851) and the Occupational Radiation Protection Program (10 CFR 835).
- (f) The Contractor shall comply with the requirements in TRS-QSH-IP-12 R2 Federal Employees Occupational Safety and Health Program for support services (Attachment J-2) including site-specific worker protection programs (Employee Job Task Analysis (EJTA) reporting requirements).
- (g) Failure by the Contractor to comply with any of the health and safety requirements set forth in this Contract shall constitute a material breach of Contract.

H.5 SECURITY REQUIREMENTS

- (a) Citizenship. Each Contractor and subcontractor employee who requires authorization to have access to the Hanford Site must be a citizen of the United States or a foreign national with proper, advance ORP authorization.
- (b) Property Passes. Property passes are necessary for the movement of Government property and/or prohibited articles into and out of limited and/or protected areas of the Hanford Site. The DOE Richland Operations Office will advise the Contractor of procedures applicable to this Contract.

- (c) Employee Access. Contractor employees will require security escort when access to Limited and/or Protected Areas of the Hanford Site is required.
- (d) Picture Security Badges.
- (1) Each Contractor and subcontractor employee must have a picture (photo) security badge for access to any area within the Hanford Site. Picture badges are not required for visitors whose stay is for 30 days or less; in such cases, badges without photos are required. Security badges shall be worn in plain view, above the waist. Each employee must appear in person to obtain a badge. Badge applicants must provide adequate information to the issuing office to properly identify themselves.
 - (2) Security badges will be valid only for the duration of a specific contract or for the current calendar year, whichever ends first.
 - (3) If a contract performance period extends beyond expiration of Contractor security badge, new security badges must be obtained before that date.
 - (4) A new security badge must be obtained whenever there is a significant change in facial appearance, e.g., growth or removal of facial hair, changes resulting from surgery, etc.
 - (5) Each Contractor and subcontractor employee is responsible for his or her badge and for returning the badge to the issuing office whenever one of the following occurs, but in any event, before final payment:
 - i. Contract work is completed;
 - ii. Badge is no longer needed; and
 - iii. Badge becomes void for any reason.
 - (6) A charge of \$250.00 will be assessed to the Contractor for each security badge not returned within the times specified above. Such charges will be deducted from payments otherwise due the Contractor.
 - (7) Lost security badges shall be reported to the issuing office as soon after the loss as possible.
- (e) Safety and Security Orientation. Each employee of the Contractor and subcontractor must receive a safety and security orientation briefing before being issued a security badge.
- (f) Prohibited Articles. The following items can only be brought onto the Hanford Site under strict controls: 1) weapons including but not limited to firearms, explosives, or incendiary devices; 2) nonprescription narcotics or dangerous drugs and/or controlled substances; 3) alcoholic beverages; and 4) other items similar in effect or purpose to any of the above.
- (1) Employees who transport, possess, or use prohibited articles within either a controlled access or administratively controlled area (including Limited and Protected Areas of the Hanford Site) are required to have in their possession a valid Prohibited Articles Pass. In addition, a Prohibited Articles Pass is required for cameras and camera equipment when used inside the 100, 200, 300, and 400 Limited Areas.
 - (2) Upon notification that an employee of the Contractor or subcontractors is found to possess or is suspected of possessing narcotics, dangerous drugs, and/or controlled substances on the Hanford Site, the company for whom the individual works shall be notified that the employee's security badge is to be returned to Safeguards and Security

and that the employee's worksite access is being temporarily suspended pending identification, through laboratory analysis, of the items in question.

- (3) Upon receipt of positive identification, through laboratory analysis, of narcotics, dangerous drugs, and/or controlled substances, the individual and employing company representative, if applicable, shall be informed that the individual's access to the Hanford Site will be denied for a minimum of one (1) year.

H.6 REQUIRED INSURANCE

- (a) The Contractor shall procure at its expense and maintain during the entire period of performance under this Contract the following minimum insurance coverage:
 - (1) Comprehensive General Liability: \$500,000.00;
 - (2) Automobile Liability: \$200,000.00 per person, \$500,000.00 per occurrence of bodily injury, and \$50,000.00 for property damage;
 - (3) Worker's Compensation: as required by Federal and State workers' compensation and occupational disease statutes; and
 - (4) Other insurance as required by State Law.
- (b) Before commencement of work, the Contractor shall furnish to the Contracting Officer a certified copy of the certificate or written statement of the above required insurance. The policies evidencing required insurance shall contain an endorsement to the effect that cancellation or any material change in the policies adversely affecting the interests of the Government in such insurance shall not be effective for such period as may be prescribed by the laws of the State in which this Contract is to be performed and in no event less than thirty (30) days after written notice to the Contracting Officer.
- (c) The Contractor shall include the requirements of this clause in all contracts with subcontractors.
- (d) Nothing herein shall relieve or limit the liability of the Contractor for losses and damages to person or property as a result of its operation. The Contractor shall indemnify and hold harmless the Government from any and all liability associated with its operation.

H.7 RESPONSIBILITY FOR LOSS OR DAMAGE TO CONTRACTOR PROPERTY

The Government's responsibility for loss or damage to the property of the Contractor shall be determined solely under the provisions of the Federal Tort Claims Act, 28 U.S.C. Section 2671, et seq., and relevant judicial decisions thereunder.

H.8 ENVIRONMENTAL LAWS

The Contractor shall comply with all applicable Federal, State, and local environmental laws and regulations, including but not limited to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), 42 U.S.C. section 9601, et seq., the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. section 6901, et seq., the Clean Air Act, 42 U.S.C. section 7401, et seq., Clean Water Act, 33 U.S.C. section 1251, et seq., Emergency Planning and Community Right-to-Know Act (EPCRA), 42 USC section 11001, et seq., Safe Drinking Water Act (SDWA), 42 USC section 300f, et seq., National Environmental Policy Act (NEPA), 42 USC sections 4321, et seq., National Historic Preservation Act (NHPA), , 16 USC section 470, as amended, Endangered Species Act (ESA), 16 USC section 1531, et seq., Toxic Substances Control Act (TSCA), 15 USC section 2601, et seq., Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), 7 USC section 136, et seq., State and local equivalents, and their implementing rules and regulations.

H.9 CONFIDENTIALITY OF INFORMATION

- (a) To the extent that the work under this contract requires that the Contractor be given access to confidential or proprietary business, technical, or financial information belonging to the Government or other companies, the Contractor shall, after receipt thereof, treat such information as confidential and agree not to appropriate such information to its own use or to disclose such information to third parties unless specifically authorized by the Contracting Officer in writing. The foregoing obligations, however, shall not apply to:
- (1) Information which, at the time of receipt by the Contractor, is in the public domain;
 - (2) Information which is published after receipt thereof by the Contractor or otherwise becomes part of the public domain through no fault of the Contractor;
 - (3) Information which the Contractor can demonstrate was in its possession at the time of receipt thereof and was not acquired directly or indirectly from the Government or other companies;
 - (4) Information which the Contractor can demonstrate was received by it from a third party that did not require the Contractor to hold it in confidence.
- (b) The Contractor shall obtain the written agreement (using the form provided by the Contracting Officer) of each employee permitted access, whereby the employee agrees that he or she will not discuss, divulge or disclose any such information or data to any person or entity except those persons within the Contractor's organization directly concerned with the performance of the contract.
- (c) The Contractor agrees, if requested by the Government, to sign an agreement identical, in all material respects, to the provisions of this clause, with each company supplying information to the Contractor under this contract, and to supply a copy of such agreement to the Contracting Officer. From time to time upon request of the Contracting Officer, the Contractor shall supply the Government with reports itemizing information received as confidential or proprietary and setting forth the company or companies from which the Contractor received such information.
- (d) The Contractor agrees that upon request by DOE it will execute a DOE-approved agreement with any party whose facilities or proprietary data it is given access to or is furnished, restricting use and disclosure of the data or the information obtained from the facilities. Upon request by DOE, such an agreement shall also be signed by Contractor personnel.
- (e) This clause shall flow down to any subcontractors or consultants.

H.10 TASK ASSIGNMENT PROCEDURES

- (a) Although the general nature of the work is outlined in the statement of work, the contract will be managed through individual task assignments. Therefore, no work may commence under the contract until the Contracting Officer issues a written task assignment which provides (a) details of the work to be performed, (b) applicable labor category and corresponding contract labor rate, (c) quantity of labor hours, (d) total not-to-exceed task price, (e) period of performance, (f) and other information to give a clear understanding of the effort. Some details may only be known as the work materializes at which time the Contractors proposal is reviewed and approved.

- (b) All work under this contract will be managed with written Task Assignments (For template, see Attachment J-1) to be issued by the Contracting Officer as requirements materialize.
- (c) Upon receipt of a Task Assignment from the Contracting Officer, the contractor shall develop and submit to the Contracting Officer a Task Plan/Proposal outlining the task details, deliverables, staff resource(s), period of performance, applicable contract labor category, DPLH required to perform the work, and the total not-to-exceed dollar amount of the task. The Task Plan will be reviewed by the ORP technical monitor to ensure the Task Plan will accomplish the intent of the Task Assignment and that the proposed skills mix and/or contract labor category is appropriate for the work. The ORP technical monitor will also determine whether the proposed staff resource should be qualified to perform assessments of contractor and/or ORP activities in accordance with ORP procedures. The Contracting officer will verify the fixed labor rate matches the proposed labor category, ensure funding program official concurrence is received, ensure all Task Assignments are within the contract ceiling in compliance with Section B.2, and ensure sufficient funds are obligated to the contract.
- (d) To avoid any conflicts of interest, contractor employees shall not develop Task Assignments or revisions thereto. In addition, each Task Plan/Proposal submitted by the Contractor shall include the conflict of interest disclosure statement in DEAR 952.209-8(c).
- (e) Task Assignments may only be revised in writing by the Contracting Officer. All Task Assignment revisions shall provide a cumulative recap of all previous revision actions.
- (f) The Contractor shall only commence performance of a Task Assignment and any revisions thereto after receiving written approval from the Contracting Officer.
- (g) The Contractor shall provide the Contracting Officer with an accounting that lists other government contracts for which the Contractor's employee is performing services during the same period of performance as this contract.
- (h) The Contractor shall submit monthly invoices and provide the Contracting officer or CS with labor hour reports that are being expended on individual task assignments. The reports will show the monthly and cumulative quantities of labor hours, any direct costs or subsequent charges to the original ceiling price shall be documented.
- (i) The Contractor shall obtain approval for any telework. A report of telework activities shall be submitted by the Contractor employee to the ORP Technical Monitor specific to the corresponding Task Assignment for each day telework is performed. The ORP Technical Monitor shall submit the report to the Contracting Officer and Contracting Officer Representative (COR) by the end of each telework day.

H.11 PROHIBITION OF PERSONAL SERVICES

In accordance with FAR 37.104, Personal Services Contracts, the Contractor shall have policies and procedures to ensure their employees guard against any actions that are of the nature of personal services, or give the perception of personal services. If the Contractor believes that any actions constitute or are perceived to constitute personal services, the Contractor shall immediately notify the Contracting Officer in writing explaining the circumstances including Contractor corrective actions taken.

H.12 WITHDRAWAL OF WORK

- (a) ORP reserves the unilateral right to have any of the work contemplated by Section C, Statement of Work performed by another Contractor or ORP employees.

- (b) Work may be withdrawn from the Contractor for any reason in the best interests of the Government, including, but not limited to:
 - (1) Facilitate transition of work, or ORP pilot programs,
 - (2) The Contractor's estimated costs are considered unreasonable,
 - (3) The Contractor's performance is deemed to be less than satisfactory.

H.13 CONTRACTOR IDENTIFICATION

- (a) The contractor shall ensure all contractor employee e-mail messages including out-of-office messages include a signature block to clearly indicate identity as contractor support service staff. Example:

Mary Smith
 XYZ Corp., Contractor to the
 US DOE Office of River Protection
 Richland WA 99354

- (b) The contractor shall ensure all contractor employee phone greetings (including recorded voicemail greetings) clearly indicate identity as contractor support service staff.
- (c) The contractor shall ensure all contractor employee offices have signage that clearly indicates identity as contractor support service staff.

H.14 OFFICE SPACE

The Government will provide office space and cubicles at: 2440 Stevens Center Place, Richland WA, 2435 Stevens Center Place, Richland WA. The office space will be equipped with computer(s) and phone(s) at the Government's expense; however, the Contractor is responsible for obtaining HLAN support which shall be invoiced directly to the contract as an Other Direct Cost along with documentation listing the name of the employee having HLAN access and the office location.

H.15 CONTRACTOR TRAINING

- (a) The contractor shall be responsible for all contractor employee access badge requirements including ensuring contractor employee completion of Hanford General Education Training (HGET). The government will bear the cost of HGET training required by the contractor to attend HGET and/or to acquire a Hanford site access badge.
- (b) The contractor shall provide qualified trained employees with demonstrated skills to perform the work including a working knowledge of commercially available word processing, spreadsheet, slide presentation, e-mail/calendar, and related office software applications. DOE will not be responsible for providing this training, and will not reimburse the contractor for such commercially available non-DOE site specific training.
- (c) DOE will reimburse the contractor for any other **required DOE site-specific training** only if the training is approved in advance by the Contracting Officer.

H.16 EXTRAORDINARY LEAVE

Presidential, Secretarial, or Other Official Release from Work: Occasionally, federal employees are granted administrative leave for various reasons, including, but not limited to early release prior to holidays, an unanticipated day off, a day of mourning for a Presidential funeral, and so

forth. When such administrative leave is granted to federal employees, the Contractor may also grant its employees administrative time off (workload permitting) only on a non-reimbursable basis. Therefore, DOE will not reimburse the Contractor for any Contractor employee hours not worked when federal employees are granted administrative leave for any reason.

H.17 INDEMNIFICATION

The contractor shall indemnify and hold the Government harmless of any obligation to pay outstanding invoices submitted by the Contractor on behalf of Contractor's employee after 90 calendar days from the date of the employee's final day of service.

H.18 QUALITY ASSURANCE (QA) FOR WORK AFFECTING NUCLEAR SAFETY

The Contractor shall implement a Department of Energy (DOE) approved Quality Assurance Program (QAP) in accordance with the current revision of EM-QA-001, *Environmental Management (EM) Quality Assurance Program (QAP)*, prior to commencement of work. The EM QAP provides the basis to achieve quality across the EM complex for all mission-related work while providing a consistent approach to Quality Assurance (QA).

EM requires American Society of Mechanical Engineers (ASME) NQA-1-2008, "*Quality Assurance Requirements for Nuclear Facility Applications*," and addenda through 2009 to be implemented as part of the Contractor's QA Program or approval be granted for using a consensus standard other than NQA-1-2008/2009a. When using NQA-1-2008/2009a, the required portions to be implemented include: 1) Introduction; 2) Part I; and 3) Part II. NQA-1 Parts III and IV are to be used as guidance for the Contractor's QAP and implementing procedures.

In order to use a QAP that is not based on NQA-1-2008/2009a, the contractor must get specific approval from DOE. For facilities, activities, or operations that meet the definition of a nonreactor nuclear facility in 10 CFR 830 (QA Rule), the requesting contractor must perform a risk-informed evaluation that clearly demonstrates that any identified gaps between the site or project's current QAP and NQA-1-2008.2009a do not represent any additional risks to quality of EM work, products, or services. This risk informed evaluation must be submitted to the DOE site office Contracting Officer and forwarded to the EM Headquarters (HQ) Safety, Security, and Quality Assurance Programs office for review and approval.

For facilities, activities, or operations that do not meet the definition of a nonreactor nuclear facility in the QA Rule, the requesting site or project must prepare a justification to demonstrate why the nonreactor nuclear facility definition does not apply, including identification of the differing chosen consensus standard, and why the differing chosen consensus standard is deemed appropriate. The justification must be submitted to the appropriate approval authority (e.g., the DOE site office if the authority is delegated) for review and approval. This justification may be provided in the contract scope and approved via approval or the contract or may be a separate submittal as deemed necessary by the approval authority.

Contractors conducting EM work have four options for complying with this contract requirement:

- 1) Develop and submit for DOE approval a new QAP;
- 2) Adopt the prior Contractor's DOE-approved QAP;
- 3) Modify the prior Contractor's DOE-approved QAP and submit it for DOE approval; or
- 4) Implement the QAP of the Buyer.

Development of a new QAP, adoption of an existing or modified version of a QAP from a prior contractor, or use of the Buyer's QAP, does not alter a Contractor's legal obligation to comply with 10 CFR 830, other regulations affecting QA and DOE Order 414.ID.

The Contractor shall, at a minimum, annually review and update as appropriate, their QAP. The review and any changes shall be submitted to DOE for approval. Changes shall be approved before implementation by the Contractor.

Consistent with the approved QAP, the Contractor shall develop/adopt and implement, or use the Buyer's comprehensive Issues Management System for the identification, assignment of significance category, and processing of issues identified within the Contractor's organization.

The contractor shall comply with all requirements applicable to DOE Quality Assurance (QA) requirements for work Affecting Nuclear Safety in accordance with DOE/ORP approved Quality Assurance Program Description, MGT-PM-04 (current version), (Section J-5) and in compliance with 10 CFR 830, Subpart A-Quality Assurance Requirements and DOE O 414.1D, Quality Assurance (2011). (See Attachment J-5)

H.19 FEDERAL HOLIDAY AND OTHER CLOSURES (DOE-H-2047, OCT 2014)

(a) Designated Federal holidays. Federal employees observe the following Federal holidays:

1. New Year's Day
2. Birthday of Martin Luther King, Jr.
3. Washington's Birthday
4. Memorial Day
5. Independence Day
6. Labor Day
7. Columbus Day
8. Veterans Day
9. Thanksgiving Day
10. Christmas Day

Generally, Federal holidays that fall on Saturday are observed on the preceding Friday; and holidays that fall on Sunday are observed on the following Monday. The exact calendar day and/or date on which any of the listed holidays are observed may change year to year.

(b) Other Federal Holidays. In addition to the holidays specified above in paragraph (a), Federal employees may observe other holidays designated by Federal Statute, Executive Order, or Presidential Proclamation as a one-time, day-off such as Inauguration Day for the President of the United States.

(c) Unscheduled closures. Occasionally, an individual Federally-owned or-controlled site or facility will be closed or have an early closure on a normal work day for other reasons such as inclement weather or facility conditions. If an unplanned closure occurs, the Contractor will be notified as soon as possible after the determination that the Federally-owned or –controlled site or facility will be closed.

(d) The Contractor shall provide the services required by the contract at Federally- owned or – controlled sites or facilities on all regularly scheduled Federal work days and other days as may be required by the contract. The Contractor shall not provide the services required by the contract on those days, or portions thereof, specified in paragraphs (a), (b) and (c), except as required under paragraph (e). Accordingly, the Contractor's employees, whose regular duty station in performance of this contract is a Federally-owned or controlled site or facility, shall not be granted access to the facility during those times specified in paragraphs (a), (b) and (c), unless required by paragraph (e) below.

- (e) There may be times that the Contractor is required to perform the services required by the contract on a Federal holiday or other closure times. In the event that such performance is required, the Contracting Officer will notify the Contractor, in writing, and specify the extent to which performance of the contract will be required. The Contractor shall provide sufficient personnel to perform the contractually-required work on those days, as directed by the Contracting Officer.
- (f) In accordance with the payment and other applicable clauses of the contract, the Government will not pay the Contractor for its employees' regularly scheduled work hours not actually provided directly in performance of the contract due to an unscheduled closure as contemplated in paragraphs (b) and (c) above.

H. 20 ORP SPECIFIC ATTENDANCE DIRECTIVE FOR CONTRACTOR EMPLOYEES IN FEDERALLY OWNED FACILITIES

- (a) Contractor employees attending ORP All-Hands Meetings, training sessions or other government-sponsored functions or activities, unless specifically approved in advance by the Contracting Officer and the ORP Task Monitor, may not charge any time for these and similar activities and the Contractor may not request payment for employee time spent on these and similar activities described herein. Contractor is to provide specific guidelines or policies to their non-federal work force employees in alignment and compliance to ORP's directives.
- (b) Contractor employees may not conduct work on any designated Federal Holiday or on any weekend day and must refer to the Contractor's guidelines for instructions.
- (c) Contractor employees may not report to federally owned facilities during periods of unplanned Site closures on normal working days due to inclement weather or facility conditions, and shall not report to work. Information regarding unplanned Site closures is distributed through the Hanford Hotline (509-376-9999), e-mail notifications, and web-site updates.
- (d) Contractor is responsible to alert his employees of conditions stated in this Section H and shall assure that each Contractor employee will be trained, informed and will agree to comply with these directives.

H. 21 DEPARTMENT OF ENERGY AD HOC OR SITUATIONAL TELEWORK DIRECTIVES

- (a) The Federal telework program and policies do not cover Federal Contractors and their employees. However, this does not prohibit and should not prevent Contractor employees from teleworking as appropriate. This provision authorizes telework in the event of hazardous road conditions during winter months, office moves, Continuity of Operations (COOP) exercises, emergency or other similar circumstances, as warranted.
- (b) Telework arrangements shall be negotiated with the Contractor employee's own employer, with the ORP Technical Monitor and the Contracting Officer so policies and procedures are in agreement with all parties. Contractor shall have the final decision making authority.
- (c) Telework agreements must be coordinated on a task by task basis as needed. Teleworking must be approved by the Contracting Officer. A report of telework activities shall be submitted by the Contractor employee to the ORP Task Monitor for each day telework is performed. The ORP Task Monitor shall submit the report to the Contracting Officer and the Contracting Officer Representative (COR) by the end of each telework day.
- (d) Contractor shall assure each Contractor employee will be trained, informed and will agree to comply with these directives.

H. 22 DEPARTMENT OF LABOR WAGE DETERMINATIONS

In the performance of this Contract the Contractor and/or subcontractor shall comply with the requirements of the U.S. Department of Labor Wage Determinations (DLWD)) located in Section

J-3 of the Contract and subcontracts are covered by the Service Contract Act. Each contractor and subcontractor must be paid at least the pay and benefits set forth in the DLWD.

H. 23 DEPARTMENT OF ENERGY CYBER SECURITY PROGRAM

As applicable, in the performance of this Contract the Contractor and/or subcontractor shall comply with requirements stated in applicable sections of U.S. Department of Energy DOE Order 205.1B (Department of Energy Cyber Security Program) (Chg 3 dated 4-29-2014), as periodically updated.

- (a) DOE information and information systems must be protected in a manner commensurate with impact to mission, national security, risk and magnitude of harm. (Sec. 4)
- (b) The Contractor must establish a process to ensure that users acknowledge and consent to site privacy and monitoring policies. (Attachment Contractor Requirements Document, Sec. 6)

PART II – CONTRACT CLAUSES

SECTION I

CONTRACT CLAUSES

I.1 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far>

<u>NUMBER</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	NOV 2013	DEFINITIONS
52.203-3	APR 1984	GRATUITIES
52.203-5	MAY 2014	COVENANT AGAINST CONTINGENT FEES
52.203-6	SEP 2006	RESTRICTIONS ON SUBCONTRACTOR SALES TO THE GOVERNMENT
52.203-7	MAY 2014	ANTI-KICKBACK PROCEDURES
52.203-8	JAN 1997	CANCELLATION, RESCISSION, AND RECOVERY OF FUNDS FOR ILLEGAL OR IMPROPER ACTIVITY
52.203-10	JAN 1997	PRICE OR FEE ADJUSTMENT FOR ILLEGAL OR IMPROPER ACTIVITY
52.203-12	OCT 2010	LIMITATION ON PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS
52.204-2	AUG 1996	SECURITY REQUIREMENTS
52.204-4	MAY 2011	PRINTED OR COPIED DOUBLE-SIDED ON RECYCLED PAPER
52.204-7	OCT 2016	CENTRAL CONTRACTOR REGISTRATION
52.204-9	JAN 2011	PERSONAL IDENTITY VERIFICATION OF CONTRACTOR PERSONNEL
52.209-6	OCT 2015	PROTECTING THE GOVERNMENT'S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT
52.215-2	OCT 2010	AUDIT AND RECORDS - NEGOTIATION
52.215-8	OCT 1997	ORDER OF PRECEDENCE - UNIFORM CONTRACT FORMAT

52.215-10	AUG 2011	PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA
52.215-12	OCT 2010	SUBCONTRACTOR COST OR PRICING DATA
52.215-19	OCT 1997	NOTIFICATION OF OWNERSHIP CHANGES
52.217-2	OCT 1997	CANCELLATION UNDER MULTI-YEAR CONTRACTS
52.219-14	JAN 2017	LIMITATIONS ON SUBCONTRACTING
52.219-28	JUL 2013	POST-AWARD SMALL BUSINESS PROGRAM REPRESENTATION
52.222-1	FEB 1997	NOTICE TO THE GOVERNMENT OF LABOR DISPUTES
52.222-3	JUN 2003	CONVICT LABOR
52.222-21	APR 2015	PROHIBITION OF SEGREGATED FACILITIES
52.222-26	SEP 2016	EQUAL OPPORTUNITY
52.222-35	OCT 2015	EQUAL OPPORTUNITY FOR SPECIAL DISABLED VETERANS, VETERANS OF THE VIETNAM ERA, AND OTHER ELIGIBLE VETERANS
52.222-36	JUL 2014	AFFIRMATIVE ACTION FOR WORKERS WITH DISABILITIES
52.222-37	FEB 2016	EMPLOYMENT REPORTS ON SPECIAL DISABLED VETERANS, VETERANS OF THE VIETNAM ERA, AND OTHER ELIGIBLE VETERANS
52.222-41	MAY 2014	SERVICE CONTRACT LABOR STANDARDS
52.222-42	MAY 2014	STATEMENT OF EQUIVALENT RATES FOR FEDERAL HIRES
52.222-43	MAY 2014	AIR LABOR STANDARDS ACT AND SERVICE CONTRACT LABOR STANDARDS – PRICE ADJUSTMENT (MULTIPLE YEAR AND OPTION CONTRACTS)
52.223-6	MAY 2001	DRUG-FREE WORKPLACE
52.224-1	DEC 2016	PRIVACY ACT NOTIFICATION
52.224-2	APR 1984	PRIVACY ACT
52.225-13	JUN 2008	RESTRICTIONS ON CERTAIN FOREIGN PURCHASES
52.227-3	APR 1984	PATENT INDEMNITY
52.227-14	MAY 2014	RIGHTS IN DATA--GENERAL
52.228-7	MAR 1996	INSURANCE - LIABILITY TO THIRD PERSONS
52.232-7	AUG 2012	PAYMENTS UNDER TIME-AND-MATERIALS AND LABOR-HOUR CONTRACTS

52.232-17	MAY 2014	INTEREST
52.232-19	APR 1994	AVAILABILITY OF FUNDS FOR THE NEXT FISCAL YEAR
52.232-22	APR 1984	LIMITATION OF FUNDS
52.232-23	MAY 2014	ASSIGNMENT OF CLAIMS
52.232-25	JAN 2017	PROMPT PAYMENT
52.232-33	JUL 2013	PAYMENT BY ELECTRONIC FUNDS TRANSFER – CENTRAL CONTRACTOR REGISTRATION
52.233-1	MAY 2014	DISPUTES-ALTERNATE I (DEC 1991)
52.233-3	SEP 2006	PROTEST AFTER AWARD- ALTERNATE I (JUN 1985)
52.233-4	OCT 2004	APPLICABLE LAW FOR BREACH OF CONTRACT CLAIM
52.242-1	APR 1984	NOTICE OF INTENT TO DISALLOW COSTS
52.242-13	JUL 1995	BANKRUPTCY
52.243-3	SEP 2000	CHANGES – TIME-AND-MATERIALS OR LABOR-HOURS
52.244-2	OCT 2010	SUBCONTRACTS
52.244-5	DEC 1996	COMPETITION IN SUBCONTRACTING
52.244-6	JAN 2017	SUBCONTRACTS FOR COMMERCIAL ITEMS
52.249-6	MAY 2004	TERMINATION-(COST REIMBURSEMENT)-ALTERNATE IV (SEP 1996)
52.249-14	APR 1984	EXCUSABLE DELAYS
52.253-1	JAN 1991	COMPUTER GENERATED FORMS

I.2 FAR 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor at least 30 days before the contract expires.

I.3 FAR 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

- (a) The Government may extend the term of this contract by written notice to the Contractor within 30 days of contract expiration, provided that the Government gives the Contractor a

- preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option clause
 - (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed three (3) years.

I.4 DEAR 952.203-70 WHISTLEBLOWER PROTECTION FOR CONTRACTOR EMPLOYEES (DEC 2000)

- (a) The Contractor shall comply with the requirements of "DOE Contractor Employee Protection Program" at 10 CFR part 708 for work performed on behalf of DOE directly related to activities at DOE-owned or-leased sites.
- (b) The Contractor shall insert or have inserted the substance of this clause, including this paragraph (b), in subcontracts at all tiers, for subcontracts involving work performed on behalf of DOE directly related to activities at DOE-owned or leased sites.

I.5 DEAR 952.204-75 PUBLIC AFFAIRS (DEC 2000)

- (a) The Contractor must cooperate with the Department in releasing unclassified information to the public and news media regarding DOE policies, programs, and activities relating to its effort under the contract. The responsibilities under this clause must be accomplished through coordination with the Contracting Officer and appropriate DOE public affairs personnel in accordance with procedures defined by the Contracting Officer.
- (b) The Contractor is responsible for the development, planning, and coordination of proactive approaches for the timely dissemination of unclassified information regarding DOE activities onsite and offsite, including, but not limited to, operations and programs. Proactive public affairs programs may utilize a variety of communication media, including public workshops, meetings or hearings, open houses, newsletters, press releases, conferences, audio/visual presentations, speeches, forums, tours, and other appropriate stakeholder interactions.
- (c) The Contractor's internal procedures must ensure that all releases of information to the public and news media are coordinated through, and approved by, a management official at an appropriate level within the Contractor's organization.
- (d) The Contractor must comply with DOE procedures for obtaining advance clearances on oral, written, and audio/visual informational material prepared for public dissemination or use.
- (e) Unless prohibited by law, and in accordance with procedures defined by the Contracting Officer, the Contractor must notify the Contracting Officer and appropriate DOE public affairs personnel of communications or contacts with Members of Congress relating to the effort performed under the contract.
- (f) In accordance with procedures defined by the Contracting Officer, the Contractor must notify the Contracting Officer and appropriate DOE public affairs personnel of activities or situations that may attract regional or national news media attention and of non-routine inquiries from national news media relating to the effort performed under the contract.

- (g) In releases of information to the public and news media, the Contractor must fully and accurately identify the Contractor's relationship to the Department and fully and accurately credit the Department for its role in funding programs and projects resulting in scientific, technical, and other achievements.

I.6 DEAR 952.204-77 COMPUTER SECURITY (AUG 2006)

- (a) Definitions.
 - (1) Computer means desktop computers, portable computers, computer networks (including the DOE Network and local area networks at or controlled by DOE organizations), network devices, automated information systems, and or other related computer equipment owned by, leased, or operated on behalf of the DOE.
 - (2) Individual means a DOE Contractor or subcontractor employee, or any other person who has been granted access to a DOE computer or to information on a DOE computer, and does not include a member of the public who sends an e-mail message to a DOE computer or who obtains information available to the public on DOE Web sites.
- (b) Access to DOE computers. A Contractor shall not allow an individual to have access to information on a DOE computer unless—
 - (1) The individual has acknowledged in writing that the individual has no expectation of privacy in the use of a DOE computer; and
 - (2) The individual has consented in writing to permit access by an authorized investigative agency to any DOE computer used during the period of that individual's access to information on a DOE computer, and for a period of three years thereafter.
- (c) No expectation of privacy. Notwithstanding any other provision of law (including any provision of law enacted by the Electronic Communications Privacy Act of 1986), no individual using a DOE computer shall have any expectation of privacy in the use of that computer.
- (d) Written records. The Contractor is responsible for maintaining written records for itself and subcontractors demonstrating compliance with the provisions of paragraph (b) of this section. The Contractor agrees to provide access to these records to the DOE, or its authorized agents, upon request.
- (e) Subcontracts. The Contractor shall insert this clause, including this paragraph (e), in subcontracts under this contract that may provide access to computers owned, leased or operated on behalf of the DOE.

I.7 DEAR 952.209-72 ORGANIZATIONAL CONFLICT OF INTEREST (AUG 2009)

- (a) Purpose. The purpose of this clause is to ensure that the Contractor (1) is not biased because of its financial, contractual, organizational, or other interests which relate to the work under this contract, and (2) does not obtain any unfair competitive advantage over other parties by virtue of its performance of this contract.
- (b) Scope. The restrictions described herein shall apply to performance or participation by the Contractor and any of its affiliates or their successors in interest (hereinafter collectively referred to as "Contractor") in the activities covered by this clause as a prime Contractor, subcontractor, cosponsor, joint venturer, consultant, or in any similar capacity. For the

purpose of this clause, affiliation occurs when a business concern is controlled by or has the power to control another or when a third party has the power to control both.

(1) Use of Contractor's Work Product.

- (i) The Contractor shall be ineligible to participate in any capacity in Department contracts, subcontracts, or proposals therefore (solicited and unsolicited) which stem directly from the Contractor's performance of work under this contract for a period of (Contracting Officer see 48 CFR 909.507-2 and enter specific term) years after the completion of this contract. Furthermore, unless so directed in writing by the Contracting Officer, the Contractor shall not perform any advisory and assistance services work under this contract on any of its products or services or the products or services of another firm if the Contractor is or has been substantially involved in their development or marketing. Nothing in this subparagraph shall preclude the Contractor from competing for follow-on contracts for advisory and assistance services.
- (ii) If, under this contract, the Contractor prepares a complete or essentially complete statement of work or specifications to be used in competitive acquisitions, the Contractor shall be ineligible to perform or participate in any capacity in any contractual effort which is based on such statement of work or specifications. The Contractor shall not incorporate its products or services in such statement of work or specifications unless so directed in writing by the Contracting Officer, in which case the restriction in this subparagraph shall not apply.
- (iii) Nothing in this paragraph shall preclude the Contractor from offering or selling its standard and commercial items to the Government.

(2) Access to and use of information.

- (i) If the Contractor, in the performance of this contract, obtains access to information, such as Department plans, policies, reports, studies, financial plans, internal data protected by the Privacy Act of 1974 (5 U.S.C. 552a), or data which has not been released or otherwise made available to the public, the Contractor agrees that without prior written approval of the Contracting Officer it shall not—
 - (A) use such information for any private purpose unless the information has been released or otherwise made available to the public;
 - (B) compete for work for the Department based on such information for a period of six (6) months after either the completion of this contract or until such information is released or otherwise made available to the public, whichever is first;
 - (C) submit an unsolicited proposal to the Government which is based on such information until one year after such information is released or otherwise made available to the public; and
 - (D) release such information unless such information has previously been released or otherwise made available to the public by the Department.
- (ii) In addition, the Contractor agrees that to the extent it receives or is given access to proprietary data, data protected by the Privacy Act of 1974 (5 U.S.C. 552a), or other confidential or privileged technical, business, or financial information under this contract, it shall treat such information in accordance with any restrictions imposed on such information.

- (iii) The Contractor may use technical data it first produces under this contract for its private purposes consistent with paragraphs (b)(2)(i) (A) and (D) of this clause and the patent, rights in data, and security provisions of this contract.
- (c) Disclosure after award.
 - (1) The Contractor agrees that, if changes, including additions, to the facts disclosed by it prior to award of this contract, occur during the performance of this contract, it shall make an immediate and full disclosure of such changes in writing to the Contracting Officer. Such disclosure may include a description of any action which the Contractor has taken or proposes to take to avoid, neutralize, or mitigate any resulting conflict of interest. The Department may, however, terminate the contract for convenience if it deems such termination to be in the best interest of the Government.
 - (2) In the event that the Contractor was aware of facts required to be disclosed or the existence of an actual or potential organizational conflict of interest and did not disclose such facts or such conflict of interest to the Contracting Officer, DOE may terminate this contract for default.
- (d) Remedies. For breach of any of the above restrictions or for nondisclosure or misrepresentation of any facts required to be disclosed concerning this contract, including the existence of an actual or potential organizational conflict of interest at the time of or after award, the Government may terminate the contract for default, disqualify the Contractor from subsequent related contractual efforts, and pursue such other remedies as may be permitted by law or this contract.
- (e) Waiver. Requests for waiver under this clause shall be directed in writing to the Contracting Officer and shall include a full description of the requested waiver and the reasons in support thereof. If it is determined to be in the best interests of the Government, the Contracting Officer may grant such a waiver in writing.
- (f) Subcontracts.
 - (1) The Contractor shall include a clause, substantially similar to this clause, including this paragraph (f), in subcontracts expected to exceed the simplified acquisition threshold determined in accordance with 48 CFR part 13 and involving the performance of advisory and assistance services as that term is defined at 48 CFR 2.101. The terms "contract," "Contractor," and "Contracting Officer" shall be appropriately modified to preserve the Government's rights.
 - (2) Prior to the award under this contract of any such subcontracts for advisory and assistance services, the Contractor shall obtain from the proposed subcontractor or consultant the disclosure required by 48 CFR 909.507-1, and shall determine in writing whether the interests disclosed present an actual or significant potential for an organizational conflict of interest. Where an actual or significant potential organizational conflict of interest is identified, the Contractor shall take actions to avoid, neutralize, or mitigate the organizational conflict to the satisfaction of the Contractor. If the conflict cannot be avoided or neutralized, the Contractor must obtain the approval of the DOE Contracting Officer prior to entering into the subcontract.

I.8 DEAR 952.242-70 TECHNICAL DIRECTION (DEC 2000)

- (a) Performance of the work under this contract shall be subject to the technical direction of the DOE Contracting Officer's Representative (COR). The term "technical direction" is defined to include, without limitation:

- (1) Providing direction to the Contractor that redirects contract effort, shift work emphasis between work areas or tasks, require pursuit of certain lines of inquiry, fill in details, or otherwise serve to accomplish the contractual Statement of Work.
 - (2) Providing written information to the Contractor that assists in interpreting drawings, specifications, or technical portions of the work description.
 - (3) Reviewing and, where required by the contract, approving, technical reports, drawings, specifications, and technical information to be delivered by the Contractor to the Government.
- (b) The Contractor will receive a copy of the written COR designation from the Contracting Officer. It will specify the extent of the COR's authority to act on behalf of the Contracting Officer.
- (c) Technical direction must be within the scope of work stated in the contract. The COR does not have the authority to, and may not, issue any technical direction that—
- (1) Constitutes an assignment of additional work outside the Statement of Work;
 - (2) Constitutes a change as defined in the contract clause entitled "Changes;"
 - (3) In any manner causes an increase or decrease in the total estimated contract cost, the fee (if any), or the time required for contract performance;
 - (4) Changes any of the expressed terms, conditions or specifications of the contract; or
 - (5) Interferes with the Contractor's right to perform the terms and conditions of the contract.
- (d) All technical direction shall be issued in writing by the COR.
- (e) The Contractor must proceed promptly with the performance of technical direction duly issued by the COR in the manner prescribed by this clause and within its authority under the provisions of this clause. If, in the opinion of the Contractor, any instruction or direction by the COR falls within one of the categories defined in (c)(1) through (c)(5) of this clause, the Contractor must not proceed and must notify the Contracting Officer in writing within five (5) working days after receipt of any such instruction or direction and must request the Contracting Officer to modify the contract accordingly. Upon receiving the notification from the Contractor, the Contracting Officer must—
- (1) Advise the Contractor in writing within thirty (30) days after receipt of the Contractor's letter that the technical direction is within the scope of the contract effort and does not constitute a change under the Changes clause of the contract;
 - (2) Advise the Contractor in writing within a reasonable time that the Government will issue a written change order; or
 - (3) Advise the Contractor in writing within a reasonable time not to proceed with the instruction or direction of the COR.
- (f) A failure of the Contractor and Contracting Officer either to agree that the technical direction is within the scope of the contract or to agree upon the contract action to be taken with respect to the technical direction will be subject to the provisions of the clause entitled "Disputes."

SECTION J
ATTACHMENTS

- J-1 Task Assignment Template
- J-2 Federal Employees Occupational Safety and Health Program
- J-3 Washington State Wage Determination
- J-4 QADP – Full text provided in RFP attachment
- J-5 Labor Categories - Associated Minimum Qualification Requirements

NORTH WIND SOLUTIONS, LLC

DOE ORP Contract No. DE-EM000XXXX

Proposal TA 00X - Revision 0

TASK TITLE

DATE

Purpose of This Task

Revisions

Revision No.	Description of Change
00	

Statement of Work

Work Locations

Limitations on Teleworking from Off-Site Locations

Period of Performance

Revision No.	Period of Performance Associated With This Revision	Task Period of Performance
00	Original POP.	

Estimated Labor Hours

Revision No.	Estimated Hours for this Revision	Total Estimated Task Hours
00		
Totals		

Funding Source/Charge Code

Estimated Travel Costs

Revision No.	Estimated Travel Expenses
00	
Total	

Proposed Resource

Organizational Conflict of Interest [DEAR 952.209-8(c)]

Non-Disclosure Agreement

Proposed Labor Category and Rate

Program Management Costs

Revision No.	PM/HLAN/Phone Costs
00	
Total	

Estimated Total Cost

Revision No.	Labor	Travel	Program Management	Total
00				
Total				

Deliverables

Deliverable(s) Due Date(s)



U.S. DEPARTMENT OF ENERGY
OFFICE OF RIVER PROTECTION

**TITLE: FEDERAL EMPLOYEES OCCUPATIONAL
SAFETY AND HEALTH PROGRAM**

Number: TRS-QSH-IP-12 R2
 Issued: 04/17/2015
 Effective Date: 04/17/2015
 Page: 1 of 24
 POC: Ronald J. Koll
 Approved by: Robert G. Hastings

1.0 PURPOSE

The Federal Employee Occupational Safety and Health (FEOSH) Program emphasizes a place of employment free from recognized uncontrolled occupational safety and health hazards that cause, or are likely to cause, physical harm or death. Furthermore, the program integrates the pertinent requirements of Section 19 of the Occupational Safety and Health Act (OSHA); Executive Order 12196, [Occupational Safety and Health Programs for Federal Employees](#); DOE O 440.1B, Admin Chg 1 [Worker Protection Management for DOE Federal \(Including the National Nuclear Security Administration\) Federal Employees](#); 29 CFR 1960, “[Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters](#)”; and site-specific worker protection programs (e.g., Employee Job Task Analyses [EJTA], personal protective equipment [PPE], etc.). The purpose of this program is to prevent accidental injuries and illnesses to U.S. Environmental Energy (DOE), Office of River Protection (ORP) employees by providing a safe and healthful workplace.

2.0 CANCELLATION OR RECORD OF CHANGE

Revision	Revision Description
0	New Implementing Procedure
1	Editorial changes including revision of ESQ to TRS organization, revised acronyms, and revised references.
2	Editorial changes regarding emergency preparedness within 2440 Stevens Center Place

3.0 APPLICABILITY

This implementing procedure applies to ORP federal staff and support services contractors that utilize ORP’s FEOSH program as their de facto company safety program.

4.0 DEFINITIONS

4.1 ACRONYMS

AMTRS assistant manager, technical and regulatory support
 CBDPP Chronic Beryllium Disease Prevention Program
 DOE U.S. Department of Energy
 DOL U.S. Department of Labor

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EAP	Employee Assistance Program
EJTA	Employee Job Task Analysis
FEOSH	Federal Employee Occupational Safety and Health Program
HGET	Hanford General Employee Training
IRT	Incident Response Team
MOU	memorandum of understanding
ORP	U.S. Department of Energy, Office of River Protection
OSHA	Occupational Safety and Health Act
PPE	personal protective equipment
SME	subject matter expert
SHD	Safety and Health Division
SOMC	site occupational medicine contractor

4.2 DEFINITION OF TERMS

Abatement – A process where a health and safety hazard or condition is reduced. This reduction is based on the amount, degree, and intensity of the hazard(s). Abatement implies that a path forward is established to put an end to the hazard or condition.

Assessment – An introspective analysis process that looks for management issues within the total picture. It is a process conducted by qualified personnel within an organization and involves direct or close management involvement to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Beryllium – Elemental beryllium and any insoluble beryllium compound or alloy containing 0.1 percent beryllium or greater that may be released as an airborne particulate.

Beryllium Article – A manufactured item that is formed to a specific shape or design during manufacture that has end-use functions that depend in whole or in part on its shape or design during end use and that does not release beryllium or otherwise result in exposure to airborne concentrations of beryllium under normal conditions of use.

Beryllium-Affected Worker – A current worker who is or was exposed, or potentially exposed to, airborne concentrations of beryllium at a DOE facility. This individual may be a DOE Federal or contractor worker, an employee of a subcontractor to a DOE contractor, or a visitor.

Beryllium-Associated Worker – A current worker who is or was exposed, or potentially exposed to, airborne concentrations of beryllium at a DOE facility including:

- Beryllium worker
- Current worker whose work history shows that the worker may have been exposed to airborne concentrations of beryllium at a DOE facility
- Current worker who exhibits signs or symptoms of beryllium exposure
- Current worker who is receiving medical removal protection benefits.

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FEOSH Committee – Employees that management appoints to monitor and assist in the implementation of the ORP FEOSH Program.

Hazard – Workplace condition that can result in injury, illness, or fatality.

Imminent Danger – Any conditions or practices in any workplace such that a danger exists, which could reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through normal procedures consistent with the DOE-0343, *Hanford Site Stop Work Procedure*. Manager/Management – ORP employees identified as supervisors, division directors, deputy assistant managers, assistant managers, ORP Deputy Manager, and ORP Manager.

ORP Supervisor – An employee having authority in the interest of the agency to hire, direct, assign, promote, reward, transfer, furlough, layoff, recall, suspend, discipline, or remove employees, to adjust their grievances, or to effectively recommend such action. This includes supervisors, division directors, and higher levels positions. Managers are also supervisors.

Reprisal – Any act of restraint, interference, coercion, or discrimination against an employee for exercising his or her rights under Executive Order 12196 and 29 CFR 1960, or for participating in ORP’s FEOSH Program.

Safety and Health Specialist – A safety and/or occupational health specialist or other person authorized pursuant to Executive Order 12196, Section 1-201(g), who carries out inspections consistent with Subpart D of 29 CFR 1960. This person has equipment and competence to recognize safety and/or health hazards in the workplace.

Site Occupational Medicine Contractor – The physician responsible for the overall direction and operation of the site occupational medicine program at the Hanford Site.

Stop Work – Stopping the specific task or activity that poses danger to human health and/or the environment.

Serious Conditions – Any conditions or practices in any workplace such that there is a substantial probability that death or serious physical harm could result.

Union – The bargaining unit identified as the American Federation of Government Employees, Local 788.

Workplace – A physical location, area, room, or establishment where ORP employees perform assigned job functions or operations.

5.0 RESPONSIBILITIES

5.1 ASSISTANT MANAGER, TECHNICAL AND REGULATORY SUPPORT RESPONSIBILITIES

The assistant manager, technical and regulatory support (AMTRS) is responsible for administering the FEOSH Program, monitoring the implementation of the program, and verifying adequate closure of

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corrective actions performed by management/supervisors identified in the course of implementing the FEOSH Program. Responsibilities for managing the FEOSH program are listed in MGT-PM-PL-02, *Safety Management Functions Responsibilities and Authorities (FRA) for the U.S. Department of Energy, Office of River Protection*. Effective implementation of the FEOSH Program will be accomplished by the combined efforts of management, supervisors, and employees by meeting the minimum responsibilities outlined in the program. Supervisors and employees are key elements in achieving this objective, along with management leadership. The AMTRS organization provides technical support in this effort utilizing safety subject matter experts (SME).

5.2 OFFICE OF RIVER PROTECTION MANAGEMENT RESPONSIBILITIES

ORP management leads, directs, and provides resources as specified in 29 CFR 1960 to effectively implement the FEOSH Program, including establishment of the ORP FEOSH Committee. ORP management demonstrates commitment to the FEOSH Program by accepting the following responsibilities:

- Provide a safe and healthy working environment
- Establish program goals and objectives
- Provide adequate budget and staff
- Welcome employees to express safety concerns without fear of reprisal
- Resolve safety issues promptly
- Know, understand, and comply with safety rules.

5.3 SUPERVISOR RESPONSIBILITIES

ORP supervisors are responsible for maintaining safe working conditions within his/her area of authority and responsibility, and for directly implementing this program. Supervisors' primary FEOSH responsibilities are as follows:

- Monitor the workplace to identify actual or potential hazards and inform employees of hazardous condition(s).
- Ensure that employees follow appropriate work practices.
- Furnish generic (e.g., hard hats, safety shoes, etc.) PPE and enforce its use.
- Observe work restrictions imposed by medical providers on staff members.
- Track employee radiation exposures to ensure administrative limits are not exceeded.
- Administer appropriate and consistent disciplinary action when health and safety rules are violated.
- Provide access to appropriate safety and health training.
- Complete employee EJAs and review/update annually.
- Ensure appropriate abatement actions are taken to mitigate any unsafe or unhealthy condition.
- Support accident/incident investigations.
- Ensure employees have full access to the contractors' safety and health programs.

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- Participate in and encourage workers to participate in the FEOSH Program.
- Comply with this document and other safety rules, regulations, and/or orders issued by the ORP Manager.
- Report unsafe/hazardous conditions, accidents, injuries, and fatalities.
- Immediately report all employee work related injuries and illnesses to the FEOSH program manager for screening to determine OSHA recordability.
- Advocate behaviors that minimize conflicts in the workplace that could precipitate violent actions.
- Respond to reported incidents of actual or potential violence or threats in a timely manner.
- Notify the next level of management, the director of the human resources office, or security office upon receipt of allegation of workplace violence or upon observation of behavior, verbal exchanges, etc. that indicates workplace violence may occur or has occurred.

5.4 EMPLOYEE RESPONSIBILITIES AND RIGHTS

5.4.1 Employee Responsibilities

ORP management will provide a workplace free of recognized, uncontrolled hazards for employees covered by this FEOSH Program. It is ORP management’s expectation that staff maintain an adequate understanding of occupational safety and health, as well as an awareness of the potential hazards and unsafe conditions at their workplace.

ORP employees have the responsibility and authority to stop work if they believe unsafe conditions exist as identified in DOE-0343.

Actionee	Step	Action
Employee	1.	Stop work when employees believe that a situation exists that places them, their coworker(s), contracted personnel, or the public at risk or in danger; could adversely affect the safe operation or cause damage to the facility; or result in a release of radiological or chemical effluents to the environment above regulatory requirements or approvals; to clarify work instructions; or to propose additional controls.
	2.	Place the work/activity in a safe condition and <u>immediately</u> notify supervision/management and affected workers when you stop work or decline to perform an activity.
Manager	3.	Resolve any issues that have resulted in an employee stopping work or an activity. Provide feedback to individuals or their appropriate safety representatives (e.g., Union safety representative, Occupational Safety and Health safety professional, etc.) who initiated the stop work in case the individual is not available.

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Actionee	Step	Action
		Be sure any necessary corrective or compensatory actions are taken before resuming an activity and documented in accordance with contractor procedure (logbook or other established method of reporting/tracking safety issues).
Employees	4.	If you have a “Stop Work” issue that has not been resolved to the mutual agreement of manager and employee, then the stop work remains in place and the supervisor will notify the appropriate company management, safety representative, and union safety representative. Resolution of the stop work resides with the safety representative and company management to resolve and/or propose actions necessary to return to work. Work may be resumed when the safety representation and management agree that the issue has been resolved. The objective is to reach resolution at the lowest levels of engagement.
Managers	5.	Notify senior management and the U.S. Department of Energy facility representative if the stop work action meets the stop work criteria defined in Contract Section H, “Stop-Work and Shutdown Authorization,” or resulted from an unresolved issue.

In order to maintain a workplace free of uncontrolled hazards, employees have the following responsibilities:

- Report job-related injuries or illnesses to supervisors and ensure prompt treatment of these conditions.
- Employee may request an accommodation when a personal illness/injury condition exists. The DOE sites highly encourage employees to request an accommodation if their personal condition warrants such.
- Report unsafe conditions to supervisors.
- Maintain workplaces free from tripping hazards, loose items overhead, and excess fire loading.
- Stop work if it is believed that unsafe conditions exist.
- Use equipment and furniture appropriately (e.g., do not use chairs as step stools, etc.).
- Comply with this program description and standards, rules, regulations, orders, and procedures.
- Notify the supervisor or next higher-level supervisor when the employee is a target of workplace violence or threats of violence, or when the employee observes or has firsthand knowledge of violent behavior against others.
- Use safety equipment, PPE, and other devices as required ensuring personal protection.
- Comply with contractors’ safety programs and other pertinent instructions while conducting activities in contractor-operated facilities.

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- Maintain an adequate understanding of occupational safety and health.
- Maintain an adequate awareness of the potential unsafe conditions and potential hazards at the workplace, including administrative restrictions on exposures to radiation and other hazardous materials.
- Review personal EJTA on an annual basis.
- Maintain an awareness of exposures to radiation and other hazardous substances.

5.4.2 Employee Rights

ORP employees, including management, supervisors, and staff, have the right to work in an environment that is free from recognized, uncontrolled hazards that may cause physical harm or death. In addition, ORP employees also have the right to information, in a timely manner, about recognized occupational hazards and measures to protect the employee. Thirdly, ORP employees have a right to access any exposure information previously collected that is representative of their own exposure in the workplace (as governed by 29 CFR 1910.1020, “Access to Employee Exposure and Medical Records”). ORP employees may obtain medical records and radiological records by contacting the site occupational medicine contractor (SOMC) and Mission Support Alliance, LLC, respectively. ORP staff may contact the ORP safety representatives (e.g., industrial hygiene, occupational safety, radiation protection, etc.) for assistance. Also, ORP employees working in the field have a right to full access to the contractors’ safety programs, including the use of appropriate PPE and other safety equipment where required. Furthermore, ORP employees have the right to express concerns about occupational safety and health issues to appropriate officials, with the expectation that those issues will be addressed and no adverse action will be taken against them as a result of voicing concerns. ORP employees have access to records documenting safety and health observations and/or results of exposure monitoring through safety organizations. ORP employees have access to their personnel, medical, and FEOSH training records through the human resources organization, the SOMC, or the training office, respectively.

5.5 OFFICE OF RIVER PROTECTION SAFETY AND HEALTH DIVISION RESPONSIBILITIES

The ORP Safety and Health Division (SHD) organization is responsible for the following:

- Administer the ORP FEOSH Program
- Monitor implementation of the FEOSH Program
- Assist the FEOSH Committee in the accomplishment of its assigned tasks
- Coordinate the inspection of space occupied by ORP employees at least annually
- Maintain a staff of adequately trained safety specialists for implementing the ORP FEOSH Program
- Assist supervisors with completion of EJTA's
- Track and trend safety and health data for the federal workforce
- Verify adequacy of corrective action closures

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- Investigate and report unsafe/hazardous conditions
- Assist management and supervisors in the implementation of the Chronic Beryllium Disease Prevention Program
- Develop memoranda of understanding (MOU) with external organizations (e.g., General Services Administration, General Support Service Contractors, etc.) and address FEOSH concerns with building conditions
- Provide SMEs in radiation protection, industrial hygiene, or occupational safety in the execution of the ORP FEOSH Program.

5.6 FEDERAL EMPLOYEE OCCUPATIONAL SAFETY AND HEALTH COMMITTEE RESPONSIBILITIES

The FEOSH Committee is responsible for the following:

- Oversee the implementation of the FEOSH Program
- Develop FEOSH goals for ORP
- When requested, provide periodic status reports to ORP management on the effectiveness of the FEOSH Program
- Review internal/external evaluation reports and make recommendations as necessary.

5.7 DISCIPLINARY STATEMENT

As stated in DOE O 3750.1, *Work Force Discipline*, and the ORP Collective Bargaining Agreement (where appropriate), disciplinary action may be taken if ORP employees fail to carry out safety responsibilities or fail to work in a safe manner including complying with safety requirements.

Disciplinary actions can range from oral admonishment to removal. See the *Disciplinary and Adverse Actions* procedure on the DOE Richland Operations Office RL Information Management System (RIMS) Web site under Human Resources Management System, Employee Relations.

5.8 PERFORMANCE EVALUATION

The Performance Management Program (located on the DOE Richland Operations Office Web site under human resources) is maintained by human resources staff and applies the requirements of 29 CFR 1960. Specifically, the performance evaluation of ORP managers and supervisors includes occupational safety and health factors consistent with assigned responsibilities and authority, taking into consideration applicable human resource regulations.

5.9 REPRISALS

ORP employees are protected from any act of restraint, interference, coercion, or discrimination for exercising rights under Executive Order 12196 and 29 CFR 1960, or for participating in ORP's FEOSH Program. ORP employees should seek relief when it is perceived that reprisal or retaliation has occurred. Experience has shown that many situations leading to reprisal or the appearance of reprisal are generated by a breakdown in communications. Most situations can and should be resolved

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by open, forthright dialogue between affected parties. ORP employees are encouraged to first address situations of potential reprisal or retaliation through their existing management system informally.

ORP employees can also raise the issue through human resources staff, the FEOSH Safety and Health Committee, and the Employee Concerns Program. Additional options are defined in DOE O 342.1, *Grievance Policy and Procedures*. Further options for bargaining employees are in the ORP Collective Bargaining Agreement. Where the employee believes that reprisal or retaliation has occurred and no previous option has been satisfactory, legal relief is available through the DOE Headquarters Office of General Counsel.

6.0 FEDERAL EMPLOYEE OCCUPATIONAL SAFETY AND HEALTH COMMITTEE

The FEOSH Committee is established to assist in providing, promoting, and developing a culture that promotes safe and healthful work practices by Federal employees. An ORP FEOSH Committee charter was created by the members to further define the FEOSH Committee's processes, procedures, and functions. The FEOSH Committee will meet at least quarterly and will issue minutes of each meeting. Copies of the minutes will be made available to ORP management and employees.

The ORP FEOSH Committee is organized and maintained to oversee and assist in implementing ORP's FEOSH Program. The purpose of the FEOSH Committee is to assist in maintaining an open channel of communication between ORP employees and management concerning occupational safety and health matters in workplaces occupied by ORP employees. The FEOSH Committee will also recommend safety and health program goals to senior management for approval and track ORP progress on achieving those goals. The FEOSH Committee provides a method by which ORP employees can use their knowledge of workplace operations to assist agency management in improving policies, conditions, and practices.

The FEOSH Committee also evaluates the effectiveness of the FEOSH Program at ORP. The FEOSH Committee makes recommendations for changes to the program, as needed, to improve its effectiveness. The ORP FEOSH Committee meets the provisions of Executive Order 12196, Section 1-3, and 29 CFR 1960.

6.1 MEMBERSHIP

The ORP FEOSH Committee will have equal representation of management and non-management employees who will be members of record. The ORP managers will select and designate, in writing, FEOSH Committee members from a list of volunteer employees representing management, non-management, and bargaining personnel. The exclusive bargaining representative will have the right to recommend bargaining employees for appointment to the FEOSH Committee.

ORP management will select from the pool nominated by the bargaining unit. FEOSH Committee members should serve overlapping terms of at a least two year duration. The FEOSH Committee chairperson will be nominated from the FEOSH Committee's members and will be elected by the FEOSH Committee members. Management and non-management FEOSH Committee members should serve alternate terms. Maximum service time as FEOSH Committee chairperson will be two consecutive years.

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6.2 SAFETY AND HEALTH PROGRAMS

6.2.1 Safety, Health, and Return-to-Employment Initiative

On January 9, 2004, President Bush announced the Safety, Health, and Return-to-Employment initiative directing federal agencies to establish goals and track performance in four major areas. Federal agencies are charged with lowering workplace injury and illness case rates, lowering lost-time injury and illness case rates, timely reporting of injuries and illnesses, and reducing lost days resulting from work injuries and illnesses.

Goals and performance targets have been set by each agency through collaboration with the U.S. Department of Labor (DOL) Office of Workers' Compensation Programs and OSHA. The DOL measures and tracks the performance of each agency. The DOL also works with Federal agencies to improve safety and health at high injury rate sites, to improve the timeliness of reporting claims through electronic and other means, and to guide agencies in providing suitable work.

The FEOSH Committee will monitor performance against the goals and keep ORP management informed if ORP is not achieving the goals. Should ORP fail to meet these goals, the FEOSH Committee will be responsible for developing an action plan for implementing compensatory measures.

6.2.2 Surveillances/Assessments, Abatement, and Accident Investigations

FEOSH safety and health specialists assist management in ensuring workplaces are free from recognized hazards and to verify compliance with standards, rules, and regulations. Inspections of space occupied by ORP employees will be conducted and documented at least annually by employees and/or FEOSH safety and health specialists qualified to recognize and evaluate hazards of the working environment and to suggest general abatement procedures. This would include inspecting contractor spaces where federal staffs are located (e.g., facility representative office space). These surveillances or assessments will be conducted using TRS-OA-IP-01, *Integrated Assessment Process*.

Representatives of management and employees for a specific workplace (including a union representative, where appropriate) may accompany FEOSH safety and health specialists during the physical inspection of any workplace, including monitoring and measuring hazardous agents, to aid the inspection and to provide facility knowledge. FEOSH safety and health specialists are authorized to deny the right of accompaniment to any person whose participation interferes with a fair and orderly inspection.

FEOSH safety and health specialists should consult with employees concerning matters of safety or health to the extent deemed necessary for the conduct of an effective and thorough inspection. During the course of an inspection, employees will be afforded an opportunity to bring to the attention of the FEOSH safety and health specialist any unsafe or unhealthful working condition, which they have reason to believe exists in the workplace. FEOSH safety and health specialists must maintain proficiency in their safety and health training. FEOSH safety and health specialists will use the nearest OSHA office for interpretations as needed. Where there are workplaces containing information classified in the interest of national security or special nuclear material, access must be provided to FEOSH safety and health specialists who have obtained the appropriate security clearance.

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Many federal employees have offices in contractor-owned/operated facilities that are inspected for life safety/fire protection under the contractor's fire protection and safety programs. Other federal employees occupy facilities (e.g., Richland Federal Building) that are not covered by the contractor's fire protection and safety programs. The ORP fire protection SME supports the FEOSH Program Manager in life safety inspections through surveillances of these facility spaces.

Abatement of hazards identified during the course of FEOSH inspections will be assigned to the appropriate entity during the course of the inspection. Abatement actions may range from an employee removing an unapproved appliance (e.g., space heater, ungrounded coffeepot, etc.) to the facility landlord performing facility modifications. The FEOSH safety representative will determine the appropriate abatement action and the cognizant supervisor will be responsible for initiating abatement. Abatement activities will be documented and closed out using the ORP Issues Management System.

DOE O 225.1B, *Accident Investigations*, defines the criteria for the different levels of accident investigations to be conducted for accidents involving DOE contractor personnel, equipment, and property. The same criteria applies to accidents involving federal employees.

6.2.3 Employee Job Task Analysis

ORP employees are required to have an EJTA that reflects hazard(s) the employee either is, or is likely to be, exposed to during routine work activities. In addition, the EJTA identifies essential job functions. It is completed by an employee's supervisor with the assistance of the industrial hygienist and reviewed with the employee. ORP supervisors should download the EJTA software from Software Distribution and obtain assistance from the SOMC in completing this responsibility.

Each supervisor should meet with their employees and a representative from the ORP safety organization and complete the electronic forms. After filling in required data and electronically signing the form(s), the form(s) goes to the SOMC, electronically. The SOMC determines what medical qualification and monitoring programs, if any, the employee must be in to comply with applicable regulations. It is recommended that supervisor and employee print out, review, and sign the EJTA annually. Retain copies of the signed EJTA.

EJTAs should be reviewed within 90 days of job transfers. An EJTA must be completed during the first month of employment and should be validated as soon as practicable after job assignment changes. EJTA data must be reviewed during the annual performance appraisal to ensure that the data is current. The human resources office advises ORP industrial hygienists of individuals who are no longer employed by ORP so they can revise the EJTA data. Access to the EJTA program can be obtained through the SOMC.

6.2.4 Health Evaluations

ORP employees are required to have a complete health evaluation prior to any job-related exposures to hazardous materials or environments. The purpose of the examination is to determine the employee's current health status, the employee's physical capabilities, and any required accommodations necessary for safe and healthy job performance. The SOMC conducts these examinations at no cost to the employee. The SOMC will schedule the examination based upon EJTA input to determine the scope of the examination.

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ORP employees age 45 and over are offered complete health evaluations annually at no cost to the employee. Employees under age 45 are offered health evaluations on a space available basis. Employees who may have had exposures to hazardous materials during employment by DOE prior to 1998 are encouraged to complete the DOE Historic Health Exposure Questionnaire and submit it to the SOMC. During the next examination, the physician will review this information to determine if the voluntary periodic health maintenance examination frequency should be adjusted.

ORP employees who are absent from work for more than three consecutive workdays due to an occupational illness or injury are expected to submit either a health status report from a personal physician (obtained at the employee's expense) to the employee's supervisor stating that the employee is fit to work, or the employee must undergo a health evaluation at the SOMC at no cost to the employee. Employee may ask for an accommodation when a personal illness/injury condition exists. ORP highly encourages employees to request an accommodation if their personal condition warrants. Employees who are retiring or separating from a position where there is an associated health hazard will receive a separation exam at no cost to the employee. If the employee wishes to decline this examination, it is his/her responsibility to cancel the SOMC exam and notify his/her supervisor and human resources of this decision.

6.2.5 Employee Assistance Program

ORP recognizes employees as their most valuable resources. An Employee Assistance Program (EAP) is available to employees to assist with a wide range of personal situations. The EAP provides services to all federal employees, especially those whose job performance is impaired as a result of a medical-behavioral problem (e.g., alcoholism, drug abuse, mental health disorders, and personal crises). The service is free and confidential. The EAP is provided by the site occupational health contractor.

6.2.6 Vehicle Safety

6.2.6.1 Transportation Policy

If transportation is required to perform government business a general services administration pool vehicle is the preferred mode of transportation. If the general services administration car is not available, employees may voluntarily use their personally owned vehicle with prior management approval, and will be reimbursed for mileage at the prevailing rate. Alternate arrangements, such as conference calls or rescheduling, should be discussed with the employee's manager if motor vehicle transportation is not available.

Employees should not use bicycles, jogging, or other methods of transportation that might increase their risk of injuries to travel to other locations.

ORP employees will comply with the following safety requirements when operating government vehicles:

- Applicable laws and regulations, including having a valid driver's license and using safety belts
- Prior to starting a vehicle, inspect the area for hazards and the vehicle for observable damage.

Drivers must pull off the roadway to use cell phone unless using a hands free device and not a speaker phone. Employees who observe unsafe driving acts on the Hanford Site should report these acts, including license number or vehicle description, to the Patrol Operations Center at 509-373-3800.

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6.2.7 Emergency Preparedness

All occupants working in the 2440 Stevens Center Place Building (building occupants) have a responsibility to know their proper course of action in the event of an emergency impacting the 2440 Stevens Center Place Building. Prompt and correct action during emergencies is essential to minimize injuries, illnesses, and perhaps loss of life. Consistent with other aspects of the FEOSH Program, building occupants are responsible for knowing and following the 2440 Stevens Center Place Building emergency response procedures. The procedures are posted in the 2440 Stevens Center Place Building and available on the ORP intranet site. Under these procedures, building occupants may be requested, through their respective management, to fill roles in the emergency response organization (i.e., personnel accountability aids [PAA]). In addition, building occupants will be offered the option to attend first aid training at no personal expense. The rendering of first aid in the workplace is at the personal discretion of the trained building occupants and is not an expectation or condition of employment.

When at offsite locations, such as contractor-controlled workspaces (e.g., field sites and offices; the Hammer Facility) or other DOE facilities, such as the Richland Federal Building, building occupants are responsible for following that location’s emergency response procedures.

6.2.8 Chronic Beryllium Disease Prevention Program for Office of River Protection Employees

6.2.8.1 Purpose

10 CFR 850, “Chronic Beryllium Disease Prevention Program” (CBDPP), published December 8, 1999, requires employers to implement a program to manage and control worker beryllium exposures in order to reduce the number of exposures and ensure early detection of chronic beryllium disease.

6.2.8.2 Applicability

ORP employees might conduct activities at Hanford facilities that present the potential for exposure to airborne beryllium particles. ORP employees may have been previously exposed to beryllium during work at Hanford or other DOE sites.

6.2.8.3 Status of Beryllium Facilities at Hanford

Several years ago, a baseline inventory of beryllium was conducted at Hanford facilities where beryllium articles were handled or where beryllium-related activities were conducted. Hanford beryllium facilities were identified through a review of industrial hygiene records and employee interviews. For each potential beryllium facility, a responsible Hanford contractor was established. The facility owner is responsible for samples and analysis to determine if beryllium is present in the facility, hazard assessments, and warning signs on the facility, if necessary. Sampling and analysis were conducted or are being conducted in facilities where beryllium was potentially used during past operations.

6.2.8.4 General Requirements

The ORP SHD organization is responsible for assisting employees in implementing the CBDPP and keeping track of CBDPP documentation and records. Assessments are periodically conducted by ORP to evaluate implementation of this plan by ORP employees and provide results of assessment(s) to line managers; safety and health staff; employees; and the American Federation of Government Employees, Local 788, upon request.

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ORP managers are responsible for minimizing the potential that employees will be exposed to beryllium above the action level (i.e., no greater than 0.1 µg/m³, calculated as an 8-hour time-weighted average exposure as measured in the worker’s breathing zone by personal monitoring), limiting the number of employees potentially exposed to beryllium, and minimizing the opportunity for exposure to beryllium. Supervisors must review their employees’ job assignments to prevent ORP employees from being exposed to beryllium at or above the action level.

In the unlikely event that an exposure level for an ORP employee occurs at or above the action level, the responsible supervisor must prepare an exposure reduction and minimization plan for the next fiscal year in accordance with Section 25(b) of 10 CFR 850. This plan must be reviewed and approved by the AMTRS. ORP employees are expected to limit the time spent in any facility that has the potential for resulting in inhalation of beryllium in excess of background levels.

6.2.8.5 Beryllium Facility Inspections and/or Visits

ORP employees must comply with the “owning” contractor’s CBDPP and facility-specific requirements for any suspect beryllium facility that is to be inspected and/or visited. Furthermore, ORP employees must not take or cause any actions to be performed by a Hanford contractor that are inconsistent with the requirements of 10 CFR 850.

6.2.8.6 Specific Program Requirements

Many of the specific program requirements of 10 CFR 850 do not apply or have limited applicability to ORP due to the type of activities performed by ORP employees (e.g., management, oversight, etc.). ORP employees must comply with the requirements of a Hanford contractor-approved CBDPP that must be in compliance with the requirements of 10 CFR 850. These requirements include, but are not limited to, Section 850.22 (permissible exposure limit), Section 850.23 (action level), Section 850.24 (exposure monitoring), Section 850.25 (exposure reduction and minimization), Section 850.26 (regulated areas), Section 850.27 (hygiene facilities), Section 850.28 (respiratory protection), Section 850.29 (protective clothing and equipment), Section 850.37 (training and counseling), and Section 850.38 (warning signs and labels).

ORP employees must comply with the requirements of Section 850.34 (medical surveillance), Section 850.35 (medical removal), Section 850.36 (medical consent), Section 850.37 (counseling), and Section 850.30 (beryllium registry) by using the services of the SOMC.

SOMC maintains medical records generated as a result of implementing the requirements of 10 CFR 850. The SOMC will update the beryllium registry as required by 10 CFR 850.39 on behalf of ORP.

6.2.8.7 Medical Surveillance Program

ORP employees who believe they may have been exposed to beryllium during DOE employment are encouraged to contact the SOMC to obtain additional information on beryllium sensitization and chronic beryllium disease and to determine the need for a medical evaluation. The SOMC maintains a list of beryllium-associated workers (i.e., workers who may have been exposed to beryllium).

Medical surveillance as specified in 10 CFR 850.34 will be performed by the SOMC for ORP beryllium-associated workers who voluntarily participate in the program. The SOMC, on behalf of ORP, will implement the medical consent (10 CFR 850.36) and provide counseling to ORP employees who are sensitized or have chronic beryllium disease (10 CFR 850.37). ORP safety and health

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organizations will provide information to the SOMC specified in 10 CFR 850.34(a)(5) for beryllium sensitized employees when the information is known.

The quantity of the specified information available for historical exposures of ORP employees is limited. ORP safety organizations are responsible for reporting beryllium sensitization, chronic beryllium disease, or any other abnormal condition or disorder caused or aggravated by occupational exposure to beryllium on the applicable OSHA reporting form.

6.2.8.8 Work Assignments

If the Site Occupational Medical Director determines that an ORP employee should not be exposed to beryllium because the employee is sensitized, has chronic beryllium disease, or has other signs or symptoms, then the employee’s supervisor is responsible for assigning work to the individual that will not result in exposure to beryllium above the limits established in the work restriction.

6.3 OFFICE OF RIVER PROTECTION WORKPLACE VIOLENCE PREVENTION PROGRAM

Workplace violence is a problem in today’s workforce. It can have devastating effects on organizational productivity and on the quality of life of employees and their families. Additionally, businesses are beginning to realize the high cost of even one violent incident and that no one is immune to acts of violence. Workplace violence, at times, is the result of gradually escalating behavior that is not challenged and stopped early. Violent, abusive, or threatening behavior will not be tolerated in the workplace. ORP will make every effort to prevent violent incidents in order to protect employees, the public, and federal property.

6.3.1 Purpose and Scope

The purpose of the Workplace Violence Prevention Program is to identify responsibilities and actions to be taken to help prevent workplace violence and to report and respond to incidents of workplace violence. The provisions of this program apply to ORP employees in their day-to-day dealings with each other, as well as with contractor or subcontractor employees, or visitors.

6.3.2 What Constitutes Violent Behavior

Violence is defined as the deliberate and wrongful violation, damage, or abuse of other persons, self, or property, and includes threats of violence. Acts of violence and threats thereof include, but are not limited to verbal (e.g., threats, harassment, abuse, and intimidation); nonverbal (e.g., gestures and intimidation); physical assault (e.g., hitting, pushing, shoving, kicking, and unwanted touching, or any other offensive physical contact); and other threats (e.g., written threats, arson, sabotage, vandalism, and stalking). It is important to note that all threats will be taken seriously.

6.3.3 Prevention

ORP supervisors, as well as employees, should be aware of abnormal behaviors exhibited by others that could be precursors to violent acts. Violence or the potential for violence can be mitigated if early signs of potential violence are dealt with effectively. Example reasons employees could make threats are as follows:

- Perception of being isolated or have difficulty forming bonds with people

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- Frustration with job or personal life
- Changes in the degree of cooperation with coworkers or supervisors
- Belief that the employer is treating them unfairly or singling them out
- Blames a specific individual for their problems
- Volatility, impulsivity, little emotional control, and failure to consider the consequences of their actions
- Over sensitivity to perceived insults or threats
- Tendency to use violence to solve problems and to threaten when they feel threatened.

Supervisors should address these symptoms in a timely manner with the assistance of human resource staff. Employees are expected to provide initial notification in a timely manner to their supervisor or human resource representative of any incidents that they believe may constitute workplace violence or are a precursor to a violent act.

6.3.4 Investigations

Once an incident of alleged workplace violence is reported (verbal and/or written), the designated human resources and safeguards and security representatives will:

- Immediately evaluate the severity of a reported issue
- Identify and manage the Incident Response Team (IRT)/Investigation Team and review the team’s report
- Recommend appropriate action and/or disciplinary measures to management
- Support and assist individuals, coworkers, and families following an incident.

The IRT represents management during the full investigation process and collects facts from sources in order to assist the agency in reaching a conclusion. See the *Violence in the Workplace* procedure on the Richland Operations Office RIMS Web site under Human Resources Management System, Employee Relations for further reporting requirements.

6.4 RADIATION PROTECTION PROGRAM

ORP employees must follow the applicable contractor’s radiological control requirements, including using PPE provided by the contractor for radiation protection when working in radiological areas and radiologically controlled areas. Radiological areas and radiologically controlled areas are identified on the Hanford Site by posted yellow signs with the standard magenta radiation-warning trefoil. Contractors establish radiological controls and manage the radiation hazards in accordance with their DOE approved Radiation Protection Program.

The requirements of 10 CFR 835, “Occupational Radiation Protection,” identify how the contractor will control radiation hazards and occupational dose from ionizing radiation. ORP employees’ occupational dose from ionizing radiation is monitored when working in radiological areas in accordance with the applicable contractor’s Radiation Protection Program. Dosimetry requirements

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may include monitoring for external and/or internal dose. Dosimetry requirements are identified in the contractor’s radiological work permits. Dosimetry requirements for federal staff are in the dosimetry services crosscutting process.

Management determines the need to place employees in the bioassay program based on work activities as determined by the contractor’s Radiation Protection Program or radiological work permit. ORP employees, who in an official capacity visit a radiological site outside of DOE, must arrange to have all pertinent occupational radiological exposure data reported to the Hanford dose tracking service at Mission Support Alliance, LLC, within 30 days after determination of the dosimetry results.

ORP employees who have questions regarding radiation protection programs, monitoring requirements, dosimetry, or the contractors radiation protection programs may contact the ORP SHD radiation protection SME.

6.5 MUSCULOSKELETAL DISORDER PROGRAM (ERGONOMICS)

ORP management has established a process to evaluate ergonomic adequacy of workplace settings to identify any potential negative impact to the comfort or long-term health of the employee. Assessments may be made of workstations, required movements, environment, and other factors that may be present in the employee’s immediate workplace. ORP employees who want an ergonomic evaluation of their workstation should complete the “Authorization for Ergonomic Assessment” and obtain their supervisor’s approval. The employee’s supervisor will forward the request to the SOMC. The SOMC will perform the evaluation for ORP employees. The supervisor is responsible for determining and implementing appropriate corrective actions based on results of the SOMC evaluation. Basic information on this subject is included in standard first aid training classes offered at Hanford. Employees and supervisors shall follow requirements in CPM-AAM-IP-16, *Government Purchase Card Use and Administration*, to order appropriate workstation equipment recommended from the ergonomic assessment.

6.6 BLOODBORNE PATHOGENS PROGRAM

ORP employees are not assigned duties requiring contact with blood or other potentially infectious materials. Nevertheless, first aid training is encouraged, and trained ORP employees voluntarily rendering first aid to victims should be aware of the hazards of bloodborne pathogens and precautionary measures.

6.7 PERSONAL PROTECTIVE EQUIPMENT

PPE includes clothing and other work accessories designed to create a barrier against workplace hazards. The primary protective equipment used by ORP employees consists of eye, head, hearing, and foot protection. The employee’s supervisor is responsible for ensuring appropriate protective equipment is available (e.g., safety shoes, prescription safety glasses, etc.) Safety equipment is not required for activities normally performed by Federal employees in office locations. ORP employees will be trained in the proper use of protective equipment when required. ORP employees will use equipment consistent with training and work assignment.

When employees need safety rated footwear or prescription safety glasses to perform their jobs safely, they are to be purchased locally by the division/organization needing the item(s) using the Government

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p-card (CPM-AAM-IP-16). Additional specialty PPE (e.g., cold-weather gear, special hearing protection, etc.) is to be purchased in this manner as well. When employees need any such PPE, the employee must initiate the “U.S. Department of Energy – Hanford Purchase Authorization Form for Personal Protective Equipment” (ORP version) and follow the form steps, including complying with the limitations and requirements included on the form.

The use of PPE is mandatory when such protective equipment has been specified for certain work activities or areas. ORP employees are responsible for complying with the PPE requirements of the specific contractor responsible for the area, operation, or facility being visited. ORP exceeds Waste Treatment and Immobilization Plant and tank farm contractor site requirements with respect to protective footwear. Federal employees performing fieldwork are required to wear safety-rated footwear certified as ASTM F2413-11, *Standard Specification for Performance Requirements for Protective (Safety) Toe Cap Footwear* or ANSI Z41 PT 99, *Protective Footwear Standards*. Substantial footwear is not acceptable. Areas requiring specific PPE are identified by posting or by contractor’s activity level hazard analysis (i.e., job hazard analysis, job safety analysis, etc.). ORP employees must exercise caution when approaching any barrier/warning.

The requirements for a respiratory protection program are included in 29 CFR 1910.134, “Respiratory Protection.” ORP implements these requirements by requiring ORP employees to medically qualify to wear a respirator as determined by the SOMC, have a fit test in accordance with Hanford contractor processes, and receive training to wear a respirator by participating in Hanford contractor training classes. The ORP safety organizations perform the respiratory protection program administrative functions for their respective organizations to ensure regulatory compliance with 29 CFR 1910.134 by performing periodic oversight of the contractor’s respiratory protection program.

6.8 SAFETY AND HEALTH TRAINING

Safety and health training is designed to meet the requirements of 29 CFR 1960, Subpart H, “Training”; DOE O 440.1B; and ultimately to improve ORP employees’ knowledge so that they can perform their assigned functions safely. Safety awareness training that satisfies the requirements of 29 CFR 1960 for federal employees is available at the Energy Online Learning Center. Federal employees whose job requires entry into areas with radiological, industrial safety or health hazards will take Hanford General Employee Training (HGET) as a minimum. Employees and their supervisors using the EJTA process will determine the appropriate training based on the employees’ job duties. HGET is required if it is determined that the employee needs unescorted access to contractor controlled facilities.

6.9 REPORTING, RECORDS, AND INTERFACES

6.9.1 Reporting Hazardous or Unsafe Working Conditions

Federal employees have several avenues for reporting hazardous conditions. If the hazardous conditions are in their work areas, they should report the hazards to their supervisor. Alternative methods include input to the Issues Management System, notifying the safety official identified on the poster located in the work area, notifying the ORP safety organization representative, or following ORP’s dispute resolution or employee concerns program crosscutting processes. ORP employees are expected and encouraged to raise concerns through their supervision as the preferred channel.

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Upon receipt of reports of hazardous or unsafe conditions, the supervisor should notify the ORP safety organization within eight working hours. An unsafe condition report should be entered into the log maintained by the ORP safety organization. Copies of the reports should be provided to the FEOSH Committee. The log includes a sequentially numbered case file, coded for identification, date, time, location of condition, brief description of the condition, classification (i.e., imminent danger, serious, or other) and date, and nature of actions taken.

An ORP safety representative must conduct an inspection within 24 hours for employee reports of imminent danger (defined in 29 CFR 1960) conditions, within three working days for potentially serious conditions and within 20 working days for other than serious safety and health conditions. Qualified safety and health personnel should conduct these inspections. An inspection may not be necessary if the hazardous condition can be abated immediately through normal management action. An inspection or investigation report must be made available to the employee making the report within 15 days after completion of the inspection for safety violations or within 30 days for health violations, unless there are compelling reasons. ORP safety organizations will be made aware of any safety and health concerns involving federal employees expressed through the employee concerns processes.

If the hazardous condition is in a Hanford contractor-managed facility, the ORP safety staff will notify the appropriate facility representative and contractor representative (e.g., facility manager, safety manager) that an unsafe condition exists. Typically posters in contractor facilities will include the name of an individual to contact or advise your contractor point of contact. ORP safety staff can be contacted for assistance and resolution of safety concerns in contractor facilities.

Assessments that identify occupational hazards and deficiencies (e.g., the control of hazards or validations of compliance) must be documented as to what was observed and actions taken. Findings identified in surveillances or assessments must be documented in accordance with ORP approved procedures (e.g., TRS-OA-IP-01).

6.9.2 Reporting Accident/Injury or Vehicle Loss/Damage

ORP employees sustaining a work-related injury, illness, or vehicle accident are required to notify their supervisor as soon as possible. Employee supervisors, with assistance from the employee when possible, are required to document work-related fatalities, injuries, illnesses, and vehicle accidents within six working days of injury/incident on the “Individual Accident/Incident Report” (form DOE F 5484.3, available on Hanford Site Forms by typing CAIRS in the ‘Title’ box). The supervisor is required to immediately report all work related injuries and illnesses to the FEOSH program manager for screening to determine OSHA recordability.

The threshold for reporting vehicle damage is greater than \$1,000 and includes privately owned vehicles operated while on official business, and government owned, rented, or leased vehicles. Copies of the completed form must be provided to the ORP safety organization.

In addition, for work-related injuries, the supervisor and employee are required to complete a “Federal Employee’s Notice of Traumatic Injury and Claim for Continuation of Pay/Compensation” (CA-1) form to record work-related injuries or a “Federal Employee’s Notice of Occupational Disease and Claim for Compensation” (CA-2) form to record work-related diseases. For work-related employee death, the supervisor is required to complete “Official Superior’s Report of Employee’s Death” (CA-6) form. These forms are available through human resources.

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The employee is required to submit the completed CA-1 or CA-2 form to their immediate supervisor within 30 days following injury or disease diagnosis. The supervisor must submit the form within 10 working days following receipt of form from the employee. The CA-6 form is required to be completed within 10 working days after knowledge by supervisor of an employee's work-related death. The supervisor submits the completed forms to the human resources organization for processing.

Note: Employees with musculoskeletal disorder or carpal tunnel syndrome should complete the CA-2 form when a physician has diagnosed the condition.

6.9.3 Accident/Incident Reports and Log and Summary of Occupational Injuries and Illnesses

For accident/incident reports and log and summary of occupational injuries and illnesses (OSHA No. 200 or 300) the ORP staff should contact the SHD FEOSH Program Manager.

6.9.4 Records Maintenance

Records are maintained in accordance with DOE O 200.1, *Information Management Program*. See Chapter 8.0 for further information.

6.9.5 Workplace Violence Reports

Reports of workplace violence and investigations thereof must be kept confidential to the extent possible in accordance with the *Privacy Act of 1974*. Confidentiality is provided to parties involved in the incident, where appropriate. Reports and investigations of workplace violence will be restricted to those with a need to know. Records of incidents, IRT reports, and investigation team results will be maintained by human resources staff in accordance with DOE O 200.1.

6.9.6 Information Dissemination

ORP employees are made aware of their occupational safety and health rights and responsibilities through a conspicuous posting of the DOE worker protection poster in each building routinely occupied by five or more federal employees. Information included on the poster includes management responsibilities, employee responsibilities, and rights of employees and their representatives. ORP safety organizations periodically verify that the posters have not been altered, defaced, or covered with other material.

6.9.7 Interface with General Services Administration, Other Federal Agencies, and Site Contractors

In those situations where ORP employees occupy workspaces that are under the management of the General Services Administration or other management entities including site contractors, ORP safety organizations should develop MOUs, letters of direction, or other contracting vehicles to clearly describe each organizations' safety and health responsibilities. These agreements will allow for proper hazard communications, and periodic inspections by ORP FEOSH safety and health specialists, and provide for the repair and renovation of occupied facilities when appropriate. Similar MOUs should be developed with General Services Administration if safety and health responsibilities are not clearly defined in contracts.

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7.0 REFERENCES

- 10 CFR 835, "Occupational Radiation Protection," *Code of Federal Regulations*, as amended.
- 10 CFR 850, "Chronic Beryllium Disease Prevention Program," *Code of Federal Regulations*, as amended.
- 29 CFR 1910.35, "Compliance with Alternate Exit-Route Codes," *Code of Federal Regulations*, as amended.
- 29 CFR 1910.134, "Respiratory Protection," *Code of Federal Regulations*, as amended.
- 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records," *Code of Federal Regulations*, as amended.
- 29 CFR 1960, "Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters," *Code of Federal Regulations*, as amended.
- ANSI Z41 PT 99, 2005, *Protective Footwear Standards*, American National Standards Institute, Washington, District of Columbia, <<http://www.ansi.org>> (February 2014).
- ASTM F2413-11, *Standard Specification for Performance Requirements for Protective (Safety) Toe Cap Footwear*, ASTM International, West Conshohocken, Pennsylvania, <<http://www.astm.org>>, May 2013.
- CPM-AAM-IP-15, 2012, *Motor Vehicles (Government)*, Rev. 3, U.S. Department of Energy, Office of River Protection, Richland, Washington, October 24.
- CPM-AAM-IP-16, 2013, *Government Purchase Card Use and Administration*, Rev. 2, U.S. Department of Energy, Office of River Protection, Richland, Washington, March 5.
- DOE-0343, 2013, *Hanford Site Stop Work Procedure*, Rev. 3, U.S. Department of Energy, Office of River Protection, Richland, Washington, November 21.
- DOE O 200.1A, 2008, *Information Technology Management*, U.S. Department of Energy, Washington D.C., December 23.
- DOE O 225.1B, 2011, *Accident Investigations*, U.S. Department of Energy, Washington D.C., March 4.
- DOE O 342.1, 2006, *Grievance Policy and Procedures*, U.S. Department of Energy, Washington D.C., February 2.
- DOE O 440.1B, 2007, *Admin Chg 1 Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees*, U.S. Department of Energy, Washington, D.C., May 17.
- DOE O 3750.1, 1983, *Work Force Discipline*, Chg 6, U.S. Department of Energy, Washington D.C., March 23.

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Executive Order 12196, 1980, *Occupational Safety and Health programs for Federal Employees*, Presidential Documents, National Archives, February 26.

Labor-Management Relations, 5 USC 71, et seq., as amended.

MGT-PM-PL-02, 2013, *Safety Management Functions Responsibilities and Authorities (FRA) for the U.S. Department of Energy, Office of River Protection*, Rev. 6, U.S. Department of Energy, Office of River Protection, Richland, Washington, February 27.

United States Office of Workplace Management, 1998, *Office of Personnel Management's Dealing with Workplace Violence – A Guide for Agency Planners*, Office of Workforce Relations, February.

Privacy Act of 1974, 5 USC 552a, Public Law 93-579, 88 Stat. 1896, as amended.

TRS-OA-IP-01, 2014, *Integrated Assessment Process*, Rev. 8, U.S. Department of Energy, Office of River Protection, Richland, Washington, February 5.

TRS-QSH-IP-08, 2015, *Records Management*, Rev. 3, U.S. Department of Energy, Office of River Protection, Richland, Washington, Feb 26.

U.S. Department of Energy, Richland Operations Office, *Disciplinary and Adverse Actions*, Employee Relations, Human Resources Management System, RL Information Management System (RIMS) Web site, <http://www5.rl.gov/rw_DOE/DOERL/> (February 2014)

U.S. Department of Energy, Richland Operations Office, *Violence in the Workplace* procedure, Employee Relations, Human Resources Management System, DOE Richland Operations Office RL Information Management System (RIMS) Web site, <http://www5.rl.gov/rw_DOE/DOERL/> (February 2014).

U.S. Department of Energy, Richland Operations Office/Office of River Protection and the American Federation of Government Employees, Local 788, Collective Bargaining Agreement.

8.0 RECORDS

The following records generated by this procedure will be controlled and maintained by the generating organization.

Table 1. Records Table. (2 pages)

Record Description	QA Record Y/N	QA Record Retention L/NP	Responsibility For Submittal
Training and Qualification Records	Y	L	TRS
Employee Job Task Analysis	N	N/A	Supervisor
Memorandum of Understanding	N	N/A	TRS

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Table 1. Records Table. (2 pages)

Record Description	QA Record Y/N	QA Record Retention L/NP	Responsibility For Submittal
Status Report to Management	N	N/A	FEOSH Chair
FEOSH Charter	N	N/A	FEOSH Chair
FEOSH Minutes	N	N/A	FEOSH Chair
Action Plan	N	N/A	FEOSH Chair
Exposure Reduction and Minimization Plan	N	N/A	Supervisor
OSHA Reporting Forms	N	N/A	TRS
Unsafe Condition Report	N	N/A	TRS
Investigation Report	N	N/A	TRS
Individual Accident/Incident Report	N	N/A	TRS
Notice of Traumatic Injury (CA-1 form)	N	N/A	TRS
Claim for Compensation (CA-2 form)	N	N/A	TRS
Supervisor's Report of Employee Death	N	N/A	TRS
Letter of Direction, Other Vehicles	N	N/A	TRS

- FEOSH = Federal Employee Occupational Safety and Health
- L = lifetime.
- NP = nonpermanent.
- ORP = U.S. Department of Energy, Office of River Protection.
- OSHA = Occupational Safety and Health Act

The identified records shall be processed and maintained in accordance with TRS-QSH-IP-08, *Records Management*.

WD 15-5527 (Rev.-1) was first posted on www.wdol.gov on 01/17/2017

REGISTER OF WAGE DETERMINATIONS UNDER THE SERVICE CONTRACT ACT		U.S. DEPARTMENT OF LABOR EMPLOYMENT STANDARDS ADMINISTRATION
By direction of the Secretary of Labor		WAGE AND HOUR DIVISION WASHINGTON D.C. 20210

Daniel W. Simms Director		Division of Wage Determinations		Wage Determination No.: 2015-5527 Revision No.: 1 Date Of Revision: 01/12/2017
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Note: Under Executive Order (EO) 13658, an hourly minimum wage of \$10.20 for calendar year 2017 applies to all contracts subject to the Service Contract Act for which the contract is awarded (and any solicitation was issued) on or after January 1, 2015. If this contract is covered by the EO, the contractor must pay all workers in any classification listed on this wage determination at least \$10.20 per hour (or the applicable wage rate listed on this wage determination, if it is higher) for all hours spent performing on the contract in calendar year 2017. The EO minimum wage rate will be adjusted annually. Additional information on contractor requirements and worker protections under the EO is available at www.dol.gov/whd/govcontracts.

State: Washington

Area: Washington Counties of Benton, Franklin

****Fringe Benefits Required Follow the Occupational Listing****

OCCUPATION CODE - TITLE	FOOTNOTE	RATE
01000 - Administrative Support And Clerical Occupations		
01011 - Accounting Clerk I		14.97
01012 - Accounting Clerk II		16.80
01013 - Accounting Clerk III		18.79
01020 - Administrative Assistant		24.65
01035 - Court Reporter		18.59
01041 - Customer Service Representative I		11.64
01042 - Customer Service Representative II		13.09
01043 - Customer Service Representative III		14.28
01051 - Data Entry Operator I		14.72
01052 - Data Entry Operator II		16.06
01060 - Dispatcher, Motor Vehicle		18.77
01070 - Document Preparation Clerk		12.94
01090 - Duplicating Machine Operator		12.94
01111 - General Clerk I		13.10
01112 - General Clerk II		14.30
01113 - General Clerk III		16.05
01120 - Housing Referral Assistant		20.52
01141 - Messenger Courier		11.95
01191 - Order Clerk I		13.68
01192 - Order Clerk II		14.93
01261 - Personnel Assistant (Employment) I		17.21
01262 - Personnel Assistant (Employment) II		19.25
01263 - Personnel Assistant (Employment) III		21.47
01270 - Production Control Clerk		26.54
01290 - Rental Clerk		15.00
01300 - Scheduler, Maintenance		16.45
01311 - Secretary I		16.45
01312 - Secretary II		18.40
01313 - Secretary III		20.52
01320 - Service Order Dispatcher		18.84
01410 - Supply Technician		24.65
01420 - Survey Worker		17.33
01460 - Switchboard Operator/Receptionist		13.51
01531 - Travel Clerk I		14.84
01532 - Travel Clerk II		15.95

01533 - Travel Clerk III	17.09
01611 - Word Processor I	15.07
01612 - Word Processor II	16.91
01613 - Word Processor III	18.91
05000 - Automotive Service Occupations	
05005 - Automobile Body Repairer, Fiberglass	18.71
05010 - Automotive Electrician	19.58
05040 - Automotive Glass Installer	18.28
05070 - Automotive Worker	18.28
05110 - Mobile Equipment Servicer	15.82
05130 - Motor Equipment Metal Mechanic	20.88
05160 - Motor Equipment Metal Worker	18.28
05190 - Motor Vehicle Mechanic	20.88
05220 - Motor Vehicle Mechanic Helper	14.82
05250 - Motor Vehicle Upholstery Worker	16.99
05280 - Motor Vehicle Wrecker	18.28
05310 - Painter, Automotive	19.58
05340 - Radiator Repair Specialist	18.28
05370 - Tire Repairer	14.84
05400 - Transmission Repair Specialist	20.88
07000 - Food Preparation And Service Occupations	
07010 - Baker	17.23
07041 - Cook I	13.97
07042 - Cook II	15.66
07070 - Dishwasher	10.60
07130 - Food Service Worker	11.22
07210 - Meat Cutter	17.51
07260 - Waiter/Waitress	12.54
09000 - Furniture Maintenance And Repair Occupations	
09010 - Electrostatic Spray Painter	22.59
09040 - Furniture Handler	14.80
09080 - Furniture Refinisher	22.59
09090 - Furniture Refinisher Helper	17.79
09110 - Furniture Repairer, Minor	20.17
09130 - Upholsterer	22.59
11000 - General Services And Support Occupations	
11030 - Cleaner, Vehicles	11.95
11060 - Elevator Operator	13.15
11090 - Gardener	17.89
11122 - Housekeeping Aide	14.75
11150 - Janitor	16.03
11210 - Laborer, Grounds Maintenance	13.45
11240 - Maid or Houseman	10.71
11260 - Pruner	11.97
11270 - Tractor Operator	16.40
11330 - Trail Maintenance Worker	13.45
11360 - Window Cleaner	18.02
12000 - Health Occupations	
12010 - Ambulance Driver	18.51
12011 - Breath Alcohol Technician	18.94
12012 - Certified Occupational Therapist Assistant	26.16
12015 - Certified Physical Therapist Assistant	26.70
12020 - Dental Assistant	18.66
12025 - Dental Hygienist	43.92
12030 - EKG Technician	28.90
12035 - Electroneurodiagnostic Technologist	28.90
12040 - Emergency Medical Technician	18.51
12071 - Licensed Practical Nurse I	17.04
12072 - Licensed Practical Nurse II	19.06
12073 - Licensed Practical Nurse III	21.26
12100 - Medical Assistant	15.12
12130 - Medical Laboratory Technician	17.61
12160 - Medical Record Clerk	14.92
12190 - Medical Record Technician	16.70
12195 - Medical Transcriptionist	18.70
12210 - Nuclear Medicine Technologist	40.24
12221 - Nursing Assistant I	10.62

12222 - Nursing Assistant II	11.94
12223 - Nursing Assistant III	13.03
12224 - Nursing Assistant IV	14.63
12235 - Optical Dispenser	19.06
12236 - Optical Technician	17.90
12250 - Pharmacy Technician	17.24
12280 - Phlebotomist	14.63
12305 - Radiologic Technologist	28.22
12311 - Registered Nurse I	29.51
12312 - Registered Nurse II	36.10
12313 - Registered Nurse II, Specialist	36.10
12314 - Registered Nurse III	43.68
12315 - Registered Nurse III, Anesthetist	43.68
12316 - Registered Nurse IV	52.36
12317 - Scheduler (Drug and Alcohol Testing)	23.47
12320 - Substance Abuse Treatment Counselor	13.55
13000 - Information And Arts Occupations	
13011 - Exhibits Specialist I	22.42
13012 - Exhibits Specialist II	27.79
13013 - Exhibits Specialist III	33.99
13041 - Illustrator I	22.42
13042 - Illustrator II	27.79
13043 - Illustrator III	33.99
13047 - Librarian	30.76
13050 - Library Aide/Clerk	15.60
13054 - Library Information Technology Systems Administrator	27.77
13058 - Library Technician	19.91
13061 - Media Specialist I	20.04
13062 - Media Specialist II	22.44
13063 - Media Specialist III	25.00
13071 - Photographer I	18.05
13072 - Photographer II	20.20
13073 - Photographer III	25.01
13074 - Photographer IV	30.59
13075 - Photographer V	37.02
13090 - Technical Order Library Clerk	15.49
13110 - Video Teleconference Technician	17.69
14000 - Information Technology Occupations	
14041 - Computer Operator I	19.45
14042 - Computer Operator II	21.76
14043 - Computer Operator III	24.28
14044 - Computer Operator IV	26.98
14045 - Computer Operator V	29.87
14071 - Computer Programmer I	(see 1) 22.85
14072 - Computer Programmer II	(see 1)
14073 - Computer Programmer III	(see 1)
14074 - Computer Programmer IV	(see 1)
14101 - Computer Systems Analyst I	(see 1)
14102 - Computer Systems Analyst II	(see 1)
14103 - Computer Systems Analyst III	(see 1)
14150 - Peripheral Equipment Operator	19.45
14160 - Personal Computer Support Technician	26.98
14170 - System Support Specialist	30.75
15000 - Instructional Occupations	
15010 - Aircrew Training Devices Instructor (Non-Rated)	30.62
15020 - Aircrew Training Devices Instructor (Rated)	37.04
15030 - Air Crew Training Devices Instructor (Pilot)	44.39
15050 - Computer Based Training Specialist / Instructor	30.62
15060 - Educational Technologist	37.11
15070 - Flight Instructor (Pilot)	44.39
15080 - Graphic Artist	22.27
15085 - Maintenance Test Pilot, Fixed, Jet/Prop	41.71
15086 - Maintenance Test Pilot, Rotary Wing	41.71
15088 - Non-Maintenance Test/Co-Pilot	41.71
15090 - Technical Instructor	30.03
15095 - Technical Instructor/Course Developer	35.79

15110 - Test Proctor	23.64
15120 - Tutor	23.64
16000 - Laundry, Dry-Cleaning, Pressing And Related Occupations	
16010 - Assembler	11.99
16030 - Counter Attendant	11.99
16040 - Dry Cleaner	13.76
16070 - Finisher, Flatwork, Machine	11.99
16090 - Presser, Hand	11.99
16110 - Presser, Machine, Drycleaning	11.99
16130 - Presser, Machine, Shirts	11.99
16160 - Presser, Machine, Wearing Apparel, Laundry	11.99
16190 - Sewing Machine Operator	14.71
16220 - Tailor	15.67
16250 - Washer, Machine	12.60
19000 - Machine Tool Operation And Repair Occupations	
19010 - Machine-Tool Operator (Tool Room)	26.35
19040 - Tool And Die Maker	31.91
21000 - Materials Handling And Packing Occupations	
21020 - Forklift Operator	16.37
21030 - Material Coordinator	26.54
21040 - Material Expediter	26.54
21050 - Material Handling Laborer	13.19
21071 - Order Filler	13.22
21080 - Production Line Worker (Food Processing)	16.37
21110 - Shipping Packer	14.51
21130 - Shipping/Receiving Clerk	14.51
21140 - Store Worker I	11.73
21150 - Stock Clerk	16.73
21210 - Tools And Parts Attendant	16.37
21410 - Warehouse Specialist	16.37
23000 - Mechanics And Maintenance And Repair Occupations	
23010 - Aerospace Structural Welder	28.36
23019 - Aircraft Logs and Records Technician	22.23
23021 - Aircraft Mechanic I	26.95
23022 - Aircraft Mechanic II	28.36
23023 - Aircraft Mechanic III	30.04
23040 - Aircraft Mechanic Helper	19.58
23050 - Aircraft, Painter	25.26
23060 - Aircraft Servicer	22.23
23070 - Aircraft Survival Flight Equipment Technician	25.26
23080 - Aircraft Worker	23.60
23091 - Aircrew Life Support Equipment (ALSE) Mechanic I	23.60
23092 - Aircrew Life Support Equipment (ALSE) Mechanic II	26.95
23110 - Appliance Mechanic	24.60
23120 - Bicycle Repairer	15.88
23125 - Cable Splicer	37.57
23130 - Carpenter, Maintenance	22.89
23140 - Carpet Layer	20.75
23160 - Electrician, Maintenance	33.10
23181 - Electronics Technician Maintenance I	28.84
23182 - Electronics Technician Maintenance II	30.89
23183 - Electronics Technician Maintenance III	32.95
23260 - Fabric Worker	22.22
23290 - Fire Alarm System Mechanic	27.31
23310 - Fire Extinguisher Repairer	20.49
23311 - Fuel Distribution System Mechanic	27.97
23312 - Fuel Distribution System Operator	21.00
23370 - General Maintenance Worker	20.48
23380 - Ground Support Equipment Mechanic	26.95
23381 - Ground Support Equipment Servicer	22.23
23382 - Ground Support Equipment Worker	23.60
23391 - Gunsmith I	20.49
23392 - Gunsmith II	23.91
23393 - Gunsmith III	27.31
23410 - Heating, Ventilation And Air-Conditioning	23.73

Mechanic	
23411 - Heating, Ventilation And Air Contditioning Mechanic (Research Facility)	24.97
23430 - Heavy Equipment Mechanic	25.42
23440 - Heavy Equipment Operator	25.97
23460 - Instrument Mechanic	29.27
23465 - Laboratory/Shelter Mechanic	25.62
23470 - Laborer	12.98
23510 - Locksmith	22.50
23530 - Machinery Maintenance Mechanic	25.56
23550 - Machinist, Maintenance	22.78
23580 - Maintenance Trades Helper	18.56
23591 - Metrology Technician I	29.27
23592 - Metrology Technician II	30.80
23593 - Metrology Technician III	32.62
23640 - Millwright	33.04
23710 - Office Appliance Repairer	22.32
23760 - Painter, Maintenance	19.88
23790 - Pipefitter, Maintenance	31.14
23810 - Plumber, Maintenance	29.19
23820 - Pneudraulic Systems Mechanic	27.31
23850 - Rigger	27.31
23870 - Scale Mechanic	23.91
23890 - Sheet-Metal Worker, Maintenance	27.79
23910 - Small Engine Mechanic	21.55
23931 - Telecommunications Mechanic I	25.57
23932 - Telecommunications Mechanic II	26.91
23950 - Telephone Lineman	26.33
23960 - Welder, Combination, Maintenance	22.67
23965 - Well Driller	27.31
23970 - Woodcraft Worker	27.31
23980 - Woodworker	20.49
24000 - Personal Needs Occupations	
24550 - Case Manager	14.78
24570 - Child Care Attendant	10.60
24580 - Child Care Center Clerk	13.63
24610 - Chore Aide	11.35
24620 - Family Readiness And Support Services Coordinator	14.78
24630 - Homemaker	14.78
25000 - Plant And System Operations Occupations	
25010 - Boiler Tender	30.04
25040 - Sewage Plant Operator	25.62
25070 - Stationary Engineer	30.04
25190 - Ventilation Equipment Tender	21.51
25210 - Water Treatment Plant Operator	25.62
27000 - Protective Service Occupations	
27004 - Alarm Monitor	24.21
27007 - Baggage Inspector	17.55
27008 - Corrections Officer	23.96
27010 - Court Security Officer	27.65
27030 - Detection Dog Handler	22.01
27040 - Detention Officer	23.96
27070 - Firefighter	25.75
27101 - Guard I	17.55
27102 - Guard II	22.01
27131 - Police Officer I	31.54
27132 - Police Officer II	35.02
28000 - Recreation Occupations	
28041 - Carnival Equipment Operator	15.64
28042 - Carnival Equipment Repairer	16.71
28043 - Carnival Worker	11.72
28210 - Gate Attendant/Gate Tender	14.01
28310 - Lifeguard	12.43
28350 - Park Attendant (Aide)	15.66
28510 - Recreation Aide/Health Facility Attendant	11.39
28515 - Recreation Specialist	19.33

28630 - Sports Official	12.47
28690 - Swimming Pool Operator	22.22
29000 - Stevedoring/Longshoremen Occupational Services	
29010 - Blocker And Bracer	30.59
29020 - Hatch Tender	30.59
29030 - Line Handler	30.59
29041 - Stevedore I	28.40
29042 - Stevedore II	32.76
30000 - Technical Occupations	
30010 - Air Traffic Control Specialist, Center (HFO) (see 2)	36.92
30011 - Air Traffic Control Specialist, Station (HFO) (see 2)	25.46
30012 - Air Traffic Control Specialist, Terminal (HFO) (see 2)	28.04
30021 - Archeological Technician I	16.14
30022 - Archeological Technician II	18.43
30023 - Archeological Technician III	24.07
30030 - Cartographic Technician	25.48
30040 - Civil Engineering Technician	27.26
30051 - Cryogenic Technician I	24.09
30052 - Cryogenic Technician II	26.61
30061 - Drafter/CAD Operator I	16.14
30062 - Drafter/CAD Operator II	18.43
30063 - Drafter/CAD Operator III	20.55
30064 - Drafter/CAD Operator IV	24.77
30081 - Engineering Technician I	16.35
30082 - Engineering Technician II	18.35
30083 - Engineering Technician III	20.53
30084 - Engineering Technician IV	25.43
30085 - Engineering Technician V	31.11
30086 - Engineering Technician VI	38.46
30090 - Environmental Technician	24.57
30095 - Evidence Control Specialist	21.76
30210 - Laboratory Technician	26.29
30221 - Latent Fingerprint Technician I	24.09
30222 - Latent Fingerprint Technician II	26.61
30240 - Mathematical Technician	22.36
30361 - Paralegal/Legal Assistant I	17.77
30362 - Paralegal/Legal Assistant II	22.02
30363 - Paralegal/Legal Assistant III	26.94
30364 - Paralegal/Legal Assistant IV	32.59
30375 - Petroleum Supply Specialist	26.61
30390 - Photo-Optics Technician	22.36
30395 - Radiation Control Technician	26.61
30461 - Technical Writer I	23.24
30462 - Technical Writer II	28.43
30463 - Technical Writer III	34.40
30491 - Unexploded Ordnance (UXO) Technician I	23.46
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Note: Executive Order (EO) 13706, Establishing Paid Sick Leave for Federal Contractors, applies to all contracts subject to the Service Contract Act for which the contract is awarded (and any solicitation was issued) on or after January 1, 2017. If this contract is covered by the EO, the contractor must provide employees with 1 hour of paid sick leave for every 30 hours they work, up to 56 hours of paid sick leave each year. Employees must be permitted to use paid sick leave for their own illness, injury or other health-related needs, including preventive care; to assist a family member (or person who is like family to the employee) who is ill, injured, or has other health-related needs, including preventive care; or for reasons resulting from, or to assist a family member (or person who is like family to the employee) who is the victim of, domestic violence, sexual assault, or stalking. Additional information on contractor requirements and worker protections under the EO is available at www.dol.gov/whd/govcontracts.

ALL OCCUPATIONS LISTED ABOVE RECEIVE THE FOLLOWING BENEFITS:

HEALTH & WELFARE: \$4.27 per hour or \$170.80 per week or \$740.13 per month

VACATION: 2 weeks paid vacation after 1 year of service with a contractor or successor; 3 weeks after 5 years, 4 weeks after 10 years, and 5 weeks after 20 years.

Length of service includes the whole span of continuous service with the present contractor or successor, wherever employed, and with the predecessor contractors in the performance of similar work at the same Federal facility. (Reg. 29 CFR 4.173)

HOLIDAYS: A minimum of ten paid holidays per year: New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day. (A contractor may substitute for any of the named holidays another day off with pay in accordance with a plan communicated to the employees involved.) (See 29 CFR 4.174)

THE OCCUPATIONS WHICH HAVE NUMBERED FOOTNOTES IN PARENTHESES RECEIVE THE FOLLOWING:

1) COMPUTER EMPLOYEES: Under the SCA at section 8(b), this wage determination does not apply to any employee who individually qualifies as a bona fide executive, administrative, or professional employee as defined in 29 C.F.R. Part 541. Because most Computer System Analysts and Computer Programmers who are compensated at a rate not less than \$27.63 (or on a salary or fee basis at a rate not less than \$455 per

week) an hour would likely qualify as exempt computer professionals, (29 C.F.R. 541.400) wage rates may not be listed on this wage determination for all occupations within those job families. In addition, because this wage determination may not list a wage rate for some or all occupations within those job families if the survey data indicates that the prevailing wage rate for the occupation equals or exceeds \$27.63 per hour conformances may be necessary for certain nonexempt employees. For example, if an individual employee is nonexempt but nevertheless performs duties within the scope of one of the Computer Systems Analyst or Computer Programmer occupations for which this wage determination does not specify an SCA wage rate, then the wage rate for that employee must be conformed in accordance with the conformance procedures described in the conformance note included on this wage determination.

Additionally, because job titles vary widely and change quickly in the computer industry, job titles are not determinative of the application of the computer professional exemption. Therefore, the exemption applies only to computer employees who satisfy the compensation requirements and whose primary duty consists of:

(1) The application of systems analysis techniques and procedures, including consulting with users, to determine hardware, software or system functional specifications;

(2) The design, development, documentation, analysis, creation, testing or modification of computer systems or programs, including prototypes, based on and related to user or system design specifications;

(3) The design, documentation, testing, creation or modification of computer programs related to machine operating systems; or

(4) A combination of the aforementioned duties, the performance of which requires the same level of skills. (29 C.F.R. 541.400).

2) AIR TRAFFIC CONTROLLERS AND WEATHER OBSERVERS - NIGHT PAY & SUNDAY PAY: If you work at night as part of a regular tour of duty, you will earn a night differential and receive an additional 10% of basic pay for any hours worked between 6pm and 6am.

If you are a full-time employed (40 hours a week) and Sunday is part of your regularly scheduled workweek, you are paid at your rate of basic pay plus a Sunday premium of 25% of your basic rate for each hour of Sunday work which is not overtime (i.e. occasional work on Sunday outside the normal tour of duty is considered overtime work).

**** HAZARDOUS PAY DIFFERENTIAL ****

An 8 percent differential is applicable to employees employed in a position that represents a high degree of hazard when working with or in close proximity to ordnance, explosives, and incendiary materials. This includes work such as screening, blending, dying, mixing, and pressing of sensitive ordnance, explosives, and pyrotechnic compositions such as lead azide, black powder and photoflash powder.

All dry-house activities involving propellants or explosives. Demilitarization, modification, renovation, demolition, and maintenance operations on sensitive ordnance, explosives and incendiary materials. All operations involving re-grading and cleaning of artillery ranges.

A 4 percent differential is applicable to employees employed in a position that represents a low degree of hazard when working with, or in close proximity to ordnance, (or employees possibly adjacent to) explosives and incendiary materials which involves potential injury such as laceration of hands, face, or arms of the employee engaged in the operation, irritation of the skin, minor burns and the like; minimal damage to immediate or adjacent work area or equipment being used. All operations involving, unloading, storage, and hauling of ordnance, explosive, and incendiary ordnance material other than small arms ammunition. These differentials are only applicable to work that has been specifically designated by the agency for ordnance, explosives, and incendiary material differential pay.

**** UNIFORM ALLOWANCE ****

If employees are required to wear uniforms in the performance of this contract (either by the terms of the Government contract, by the employer, by the state or local law, etc.), the cost of furnishing such uniforms and maintaining (by laundering or dry cleaning) such uniforms is an expense that may not be borne by an

employee where such cost reduces the hourly rate below that required by the wage determination. The Department of Labor will accept payment in accordance with the following standards as compliance:

The contractor or subcontractor is required to furnish all employees with an adequate number of uniforms without cost or to reimburse employees for the actual cost of the uniforms. In addition, where uniform cleaning and maintenance is made the responsibility of the employee, all contractors and subcontractors subject to this wage determination shall (in the absence of a bona fide collective bargaining agreement providing for a different amount, or the furnishing of contrary affirmative proof as to the actual cost), reimburse all employees for such cleaning and maintenance at a rate of \$3.35 per week (or \$.67 cents per day). However, in those instances where the uniforms furnished are made of "wash and wear" materials, may be routinely washed and dried with other personal garments, and do not require any special treatment such as dry cleaning, daily washing, or commercial laundering in order to meet the cleanliness or appearance standards set by the terms of the Government contract, by the contractor, by law, or by the nature of the work, there is no requirement that employees be reimbursed for uniform maintenance costs.

** SERVICE CONTRACT ACT DIRECTORY OF OCCUPATIONS **

The duties of employees under job titles listed are those described in the "Service Contract Act Directory of Occupations", Fifth Edition (Revision 1), dated September 2015, unless otherwise indicated.

** REQUEST FOR AUTHORIZATION OF ADDITIONAL CLASSIFICATION AND WAGE RATE, Standard Form 1444 (SF-1444) **

Conformance Process:

The contracting officer shall require that any class of service employee which is not listed herein and which is to be employed under the contract (i.e., the work to be performed is not performed by any classification listed in the wage determination), be classified by the contractor so as to provide a reasonable relationship (i.e., appropriate level of skill comparison) between such unlisted classifications and the classifications listed in the wage determination (See 29 CFR 4.6(b)(2)(i)). Such conforming procedures shall be initiated by the contractor prior to the performance of contract work by such unlisted class(es) of employees (See 29 CFR 4.6(b)(2)(ii)). The Wage and Hour Division shall make a final determination of conformed classification, wage rate, and/or fringe benefits which shall be paid to all employees performing in the classification from the first day of work on which contract work is performed by them in the classification. Failure to pay such unlisted employees the compensation agreed upon by the interested parties and/or fully determined by the Wage and Hour Division retroactive to the date such class of employees commenced contract work shall be a violation of the Act and this contract. (See 29 CFR 4.6(b)(2)(v)). When multiple wage determinations are included in a contract, a separate SF-1444 should be prepared for each wage determination to which a class(es) is to be conformed.

The process for preparing a conformance request is as follows:

- 1) When preparing the bid, the contractor identifies the need for a conformed occupation(s) and computes a proposed rate(s).
- 2) After contract award, the contractor prepares a written report listing in order the proposed classification title(s), a Federal grade equivalency (FGE) for each proposed classification(s), job description(s), and rationale for proposed wage rate(s), including information regarding the agreement or disagreement of the authorized representative of the employees involved, or where there is no authorized representative, the employees themselves. This report should be submitted to the contracting officer no later than 30 days after such unlisted class(es) of employees performs any contract work.
- 3) The contracting officer reviews the proposed action and promptly submits a report of the action, together with the agency's recommendations and pertinent information including the position of the contractor and the employees, to the U.S. Department of Labor, Wage and Hour Division, for review (See 29 CFR 4.6(b)(2)(ii)).

4) Within 30 days of receipt, the Wage and Hour Division approves, modifies, or disapproves the action via transmittal to the agency contracting officer, or notifies the contracting officer that additional time will be required to process the request.

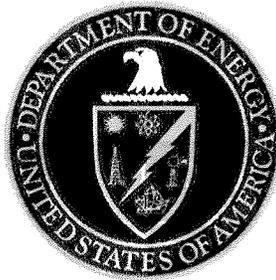
5) The contracting officer transmits the Wage and Hour Division's decision to the contractor.

6) Each affected employee shall be furnished by the contractor with a written copy of such determination or it shall be posted as a part of the wage determination (See 29 CFR 4.6(b)(2)(iii)).

Information required by the Regulations must be submitted on SF-1444 or bond paper.

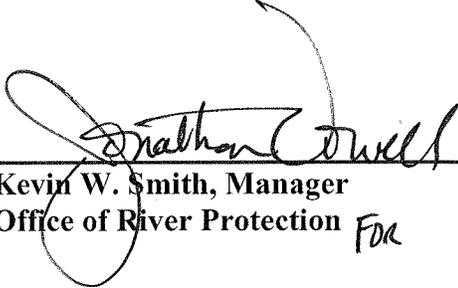
When preparing a conformance request, the "Service Contract Act Directory of Occupations" should be used to compare job definitions to ensure that duties requested are not performed by a classification already listed in the wage determination. Remember, it is not the job title, but the required tasks that determine whether a class is included in an established wage determination. Conformances may not be used to artificially split, combine, or subdivide classifications listed in the wage determination (See 29 CFR 4.152(c)(1)).

QUALITY ASSURANCE PROGRAM DESCRIPTION



U.S. Department of Energy
Office of River Protection

Approved:


Kevin W. Smith, Manager
Office of River Protection *FOR*

8/20/14
Date

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EXECUTIVE SUMMARY

This document defines the U.S. Department of Energy (DOE), Office of River Protection (ORP) Quality Assurance (QA) Program. The QA Program was prepared to comply with DOE O 414.1D, *Quality Assurance*; EM-QA-001, *EM Quality Assurance Program*, Rev. 1; the national consensus standard, ASME NQA-1-2008 with the ASME NQA-1a-2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*; and DOE/RW-0333P, *Quality Assurance Requirements and Description*. Effective implementation of the QA Program provides processes and tools to support the principles and functions of DOE P 450.4A, *Integrated Safety Management System Policy*.

The QA Program is part of the management system used by ORP to ensure work is performed safely and in compliance with requirements. QA Program requirements apply to ORP and its direct support contractors. Management is responsible for ensuring the requirements of the ORP QA Program are implemented and followed by employees. Individuals are responsible for the quality of their work and for doing the work in compliance with the requirements as implemented in ORP procedures.

The scope, depth, and rigor of the management system application of requirements to a specific activity are determined using a graded approach. The purpose of this graded approach, or “grading,” is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.

MGT-PM-PL-02, *Safety Management Functions, Responsibilities, and Authorities*, describes the ORP organizational structure and levels of responsibility and authority. This document describes organizational interfaces and the methods used by ORP for planning, performing, and assessing the adequacy of a job, including work assigned outside of the organization, for implementing the ORP QA Program.

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REVISION HISTORY

Revision	Revision Description
0	Revised entire document to replace ORP M 414.1, <i>ORP Quality Assurance Program Description</i> , Rev. 2 and to be in line with the requirements of ASME NQA-1-2004 and DOE/RW-0333P, <i>Quality Assurance Requirements and Description</i> , Rev. 21.
1	<ul style="list-style-type: none"> • Revised Chapter 1.0, first paragraph, by adding “and addenda through 2007.” • Revised Chapter 1.0, third paragraph, by clarifying that Appendix A constitutes the Quality Assurance Implementation Plan. • Revised Chapter 1.0, Section 1.3, by adding the word “implemented” and deleting the word “issued.” • Revised Chapter 2.0, Section 2.3 A, C, and D, to clarify the responsibilities of management per 2007 addenda of ASME NQA-1 and the U.S. Department of Energy, Office of Environmental Management (EM) Quality Assurance Plan (QAP). • Revised Chapter 2.0, Section 2.4, to distinguish between independent quality assurance (QA) assessments and independent QA audits. • Revised Chapter 2.0, Section 2.4 B, to clarify the Quality Assurance Team (QAT) authorities per 2007 addenda of ASME NQA-1. • Revised Chapter 3.0, Section 3.1, first paragraph to add “and addenda through 2007” and to delineate the parts of ASME NQA-1 implemented by the U.S. Department of Energy, Office of River Protection (ORP) QA Program. • Revised Chapter 3.0, Section 3.1, last paragraph, to delete the word “independent.” • Revised Chapter 3.0, Section 3.5.1, per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 3.0, Section 3.5.6, per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 3.0, Section 3.6, per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 4.0, Section 4.1, to clarify the procurement document control requirements per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 5.0, Section 5.3, by adding 5.3 D and clarifying 5.4 B1 per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 5.0, Section 5.5, to correct the number of the subparagraph. • Revised Chapter 6.0, Sections 6.1 and 6.3 B and J, to clarify document control requirements per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 7.0, Section 7.1, to clarify the control of purchased items and services requirements per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 7.0, Section 7.2.4, to clarify and add new paragraphs per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 7.0, Section 7.2.5 by adding Section A per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 8.0, Sections 8.1, 8.2.3, 8.2.4.2, 8.2.4.5, and 8.2.4.6, to clarify and address the requirements of 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 9.0, Sections 9.1, 9.2.2, 9.2.3, 9.2.5, 9.2.6, and 9.2.7, to clarify records requirements per 2007 addenda of ASME NQA-1 and the EM QAP. • Revised Chapter 10.0, Sections 10.1, 10.2, 10.3, and 10.6, to clarify the differences between assessments, independent assessments, audits, and surveillances. Revised Section 10.2.1 to add requirement pertaining to the experience and training of independent auditors and auditors. • Revised Chapter 11.0, Section 11.1, to revise the name of the ORP tracking system.

Revision	Revision Description
	<ul style="list-style-type: none"> • Revised Appendix A to reflect the format of a Quality Assurance Implementation Plan as required by the EM QAP. • Revised the definitions of assessment, audit, independent assessment, and training.
2	<p>Editorial/minor change:</p> <ul style="list-style-type: none"> • Revised Figure 1-1, “U.S. Department of energy, Office of River Protection Organization,” to reflect current, approved organization. • Revised Appendix B, definitions for assessment, audit, and independent assessment, to clarify the definitions and to bring them into alignment with the implementation expectations. • Editorial changes throughout for clarification.
3	<p>Major change:</p> <ul style="list-style-type: none"> • Revised entire document to bring ORP’s QA Program into compliance with DOE O 414.1D, <i>Quality Assurance</i>; EM-QA-001, <i>Office of Environmental Management (EM) Quality Assurance Program</i>; the national consensus standard, ASME NQA-1-2008 with the ASME NQA-1a-2009 addenda, <i>Quality Assurance Requirements for Nuclear Facility Applications</i>; and DOE/RW-0333P, <i>Quality Assurance Requirements and Description</i>.
4	<p>Changes:</p> <ul style="list-style-type: none"> • Revised organization chart to reflect the newly approved ORP organization and change QAT to Quality Assurance Division (QAD). • Revised QAT supervisor to QAD director. • Minor changes to clarify the term “implementing procedure” as compared to “procedures, desk instructions, plans, and guides. • Deleted the explanation of Priority Level One findings since this is fully explained in the implementing procedure. • Added QARD requirements of Chapter 14 “Qualification of Existing Data” of the QAPD. • Changed should to shall for multiple requirements throughout plan.

QUALITY ASSURANCE POLICY

The U.S. Department of Energy (DOE), Office of River Protection (ORP) was created by the *Strom Thurmond National Defense Authorization Act for Fiscal Year 1999*. The ORP mission is to remove waste from the past production of nuclear materials stored in underground tank farms, treat the waste to standards that are protective of human health and the environment, and close the tanks and treatment facilities. ORP is committed to safely and cost effectively retrieving, treating, immobilizing, storing, and dispositioning the waste so that it no longer poses an environmental concern. This effort is the largest and most complex environmental cleanup project within the DOE.

ORP personnel continuously seek to perform work safely, effectively implement applicable rules and regulations, increase productivity, and enhance work efficiencies. As such, ORP is committed to achieving quality in accomplishing ORP's mission by having a comprehensive Quality Assurance (QA) Program in place for those activities that can impact safety and quality. This *Quality Assurance Program Description (QAPD)* is the upper tier document of the ORP QA Program, which implements the QA requirements contained in DOE O 414.1D, *Quality Assurance*. This QAPD establishes QA requirements applicable to ORP work and provides the framework for developing lower tier procedures and instructions that implement the QAPD. The QAPD, combined with procedures, desk instructions, plans, and/or guides, constitute the ORP QA Program.

As required by DOE O 414.1D and EM-QA-001, *EM Quality Assurance Program*, Rev. 1, ORP has adopted ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, with the ASME NQA-1a-2009 addenda, as the consensus standard that forms the basis for its QA Program. Where necessary, QA requirements contained in ASME NQA-1 have been supplemented with QA requirements from DOE O 414.1D and DOE/RW-0333P, *Quality Assurance Requirements and Description*, for immobilized high-level waste.

ORP's QA philosophy endorses the belief that there are four levels of defense of quality and that each level of defense has a unique makeup and contributions to quality. The four levels of defense are:

1. Individuals and work groups
2. Supervision and management
3. Internal oversight
4. External oversight.

The first level of defense is provided by individual and work group activities. Individual staff members, integrated project teams, audit teams, and assessment teams are examples of this first level of defense for ORP. Individual staff members, audit teams, and assessment teams are responsible for performing oversight of ORP work activities and of the ORP contractors. The primary function of the integrated project team is to support the federal project director in managing ORP contractors. This is the only level of defense that provides a real-time, complete opportunity to detect conditions adverse to quality (CAQ). Every individual owns their own first level of defense and can ensure staying within the quality envelope by adhering to procedures, attending training, conducting meticulous and systematic self-checking, ensuring implementation of the QA Program, and providing feedback to management.

The second level of defense is made up of all levels of supervision and management from the task leader to senior management. A CAQ detected by the second level of defense is usually indicative of at least two CAQs: the detected condition and a self-assessment weakness in the first level of defense.

The third level of defense, internal oversight, provides sampling checks of the processes, programs, products, and services of the first and second levels of defense of quality, and assesses the effectiveness of self-assessment efforts. Any CAQ detected by the third level of defense is usually indicative of at least three CAQs: the detected condition and self-assessment weaknesses in the first two levels of defense.

The fourth level of defense is made up of non-ORP organizations, such as DOE Headquarters and the Defense Nuclear Facilities Safety Board. These organizations assess the first three levels, especially with respect to the effectiveness of self-assessment efforts, and provide feedback. Any CAQ detected by the fourth level of defense is usually indicative of at least four CAQs: the detected condition and self-assessment weaknesses in the first three levels of defense.

The level of defense at which a problem is identified directly affects the cost associated with resolution of the problem. CAQs are most safely and economically addressed when identified at the first level of defense by the individuals or work groups accountable during the initial review. CAQs identified by external observation or by an adverse event that results in damage or organizational disruption, are the most expensive to address and resolve. Adverse conditions not identified by the person accountable on the first pass are “downstream-identified” adverse conditions. Every downstream-identified adverse condition is handled as two or more problems: the problem itself (i.e., the adverse condition), and all of the problems related to, or stemming from the adverse condition, not having been identified by the accountable person on the initial review.

ORP’s basic philosophy about quality includes the following:

- The credibility of ORP is dependent on the ability of individuals, managers, clients, and regulators to regard our words as meeting the highest standards of reliability. Staff at all levels must exemplify a high level of integrity and professionalism in everything they do.
- Transparency is doing business in such a way that others can easily tell what has gone wrong in a certain instance, and that the causal factors of potential future events are easy to recognize or see. Opacity is doing business in such a way that it is hard to see what went wrong.
- Self-assessment is the continuing evaluation of one’s own performance and the resources, processes, and performance of one’s own organization. ORP recognizes that important and valuable contributions can be made by others; however, self-assessment must be done by the individual.
- Most audits and assessments will uncover weaknesses ranging in significance from limiting weaknesses to minor opportunities for improvement. Limiting weaknesses are those that hold the organization back. ORP expects all audits, assessments, and self-assessments to clearly address the limiting weakness in the topic of the audit or assessment.

- ORP is sensitive to the implementation of change. New personnel, shifted responsibilities, new contractors, new and revised regulatory requirements, and new and revised procedures, have all been precursors of quality problems. ORP encourages controlling change so that all changes are made with appropriate foresight and with a questioning attitude.
- The quality system will not function properly unless management is accountable for establishing requirements, including quality requirements.
- ORP's approach to procedural adherence is congruent with its commitment to ASME NQA-1-2008 with the ASME NQA-1a-2009 addenda, which states, "Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished."
- Work activities are prescribed by documented instructions, procedures, or drawings and are followed as written, or the work is suspended until the appropriate document is corrected. Anything else is a violation of the ORP QA Program.
- Quality is inherently cost beneficial and contributes to optimal safety and reliability. The cost of quality is what it takes to prevent, detect, and respond to quality problems. It also includes the spinoff cost of quality problems, such as lost availability and regulatory penalties. The cost of quality should be as low as reasonably achievable.
- Problems should be characterized according to associated quality and risk impacts so resources can be applied prudently in a manner commensurate with the potential impact on ORP's mission.
- Management has the responsibility to expend or reduce resources consistent with the value added. It is a function of management to decide, within the bounds of its regulatory commitments, which risks it will and will not accept.
- Quality cannot be assessed into or inspected into a process, program, product, or service.
- Management commitment to corrective actions is the key to their effectiveness. Correcting a symptom only corrects the symptom, while correcting a causal factor and its underlying causes prevents similarly caused problems from recurring. Corrective actions must also address the broader (generic) implications of the identified symptoms and causal factors.
- The identification and elimination or control of CAQs must be emphasized, but quality is not achieved merely by the correction of identified CAQs and their causal factors. Corrective actions must address the pervasiveness of conditions as well as their underlying causes.
- Truly isolated CAQs are rare. Seldom does anything go wrong due to a single causal factor. Causal factors of CAQs can be contributors to potentially serious events. The causal factors of significant events are the same as the causal factors of nonsignificant events. The greater the significance of an event, the larger the number of independent

causal factors that could have contributed to it, and the larger the number of precursors that should have alerted the accountable personnel.

- Management is expected to use precursors, observations, adverse operational events, and regulatory shortcomings as triggers to reexamine the effectiveness of their self-assessment processes.
- Personnel want to do the job right, free of errors. Human performance problems generally occur due to underlying causal factors. Some of these underlying causal factors have to do with the work situation and some are brought to the work situation by the individual. ORP expects management to seek out and eliminate the causal factors that result in personal error and/or lapse in judgment.
- It is the job of every responsible professional to define the right job, to do each job right the first time, to determine all valid requirements for the job, and to identify the clients and their needs.
- Objective, emotionally neutral language must be used when reporting adverse observations and conclusions. It is ORP's responsibility to exercise reasonable tact and diplomacy so that the intended message is communicated and not obscured or diluted by the chosen language.
- Every adverse event is an opportunity for improvement. ORP approaches these events with a questioning attitude in looking for ways the event could have been prevented. Less than adequate quality assessment practices contribute to almost every adverse event.
- Operational experience review(s) is part of the planning for every one of ORP's audits and assessments.
- Work suspension is appropriate when continued work would be unsafe, would be likely to create rework, and when safety or quality is indeterminate.

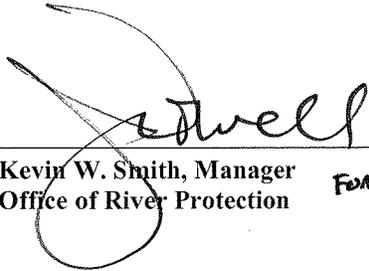
ORP's work environment reflects the following:

- QA Program effectiveness is dependent on continuous and involved management support.
- ORP regards obstructing access to known CAQs or concealing them in any way to be a serious breach of professional ethics and a violation of law. Any suspected examples are promptly brought to the attention of senior management.
- ORP believes that raising standards of excellence is one of the strategies for enhancing quality.
- ORP's effectiveness demands that we communicate internally to make sure everyone understands that there is one program and one standard.
- When any person within ORP cannot in good conscience abide by the operational philosophy of the organization or a specific quality decision, that person should make those differences known through the chain of command.
- Any attempt to discourage or inhibit the discussion of valid quality concerns is intimidation. Intimidation is not acceptable.

- ORP's processes for resolving employee concerns and differing professional opinions assure that the concerns and viewpoints of all employees are appropriately addressed and resolved.

The ORP QA Program requirements, as described in this QAPD, have my full endorsement and complete support. Implementation of the applicable QAPD requirements, responsibilities, and authorities is mandatory for all ORP personnel.

In support of this policy statement, all ORP personnel are expected to demonstrate their personal commitment to the achievement of quality through their active involvement in the implementation of the ORP QA Program.



Kevin W. Smith, Manager
Office of River Protection

For

8/20/14

Date

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ABBREVIATIONS AND ACRONYMS

AM	assistant manager
ASME	American Society of Mechanical Engineers
BNI	Bechtel National, Inc.
CAP	corrective action plan
CAQ	condition adverse to quality
CGD	commercial grade dedication
CIO	Chief Information Officer
DEAR	<i>Department of Energy Acquisition Regulation</i>
DOE	U.S. Department of Energy
EM	U.S. Department of Energy, Office of Environmental Management
email	electronic mail
HLW	high-level waste
IHLW	immobilized high-level waste
IMS	Issues Management System
LMSI	Lockheed Martin Services, Inc.
M&TE	measuring and test equipment
MSC	Mission Support Contractor
ORP	U.S. Department of Energy, Office of River Protection
PAAA	<i>Price-Anderson Amendments Act</i>
QA	quality assurance
QAPD	<i>Quality Assurance Program Description</i>
QARD	<i>Quality Assurance Requirements and Description</i>
QAD	Quality Assurance Division
R&D	research and development
RL	U.S. Department of Energy, Richland Operations Office
RPP	River Protection Project
S/CI	suspect/counterfeit item
SCAQ	significant condition adverse to quality
SNF	spent nuclear fuel
SSC	systems, structures, and components
TRS	Technical and Regulatory Support
WRPS	Washington River Protection Solutions LLC
WTP	Waste Treatment and Immobilization Plant

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1.0 GENERAL

This Quality Assurance Program Description (QAPD) implements those requirements of ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, with ASME NQA-1a-2009 addenda; DOE O 414.1D, *Quality Assurance*; EM-QA-001, Rev. 1, *EM Quality Assurance Program*; and DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD) that are applicable to work performed by the U.S. Department of Energy (DOE), Office of River Protection (ORP).

ORP has limited work associated with the QARD. This work only applies to waste-affecting activities and represents a relatively small subset of ORP's activities. ORP has evaluated the applicability of these requirements to ORP work and appropriately related them to those specific items and services that affect quality.

ORP's primary function is to manage the contracts for the River Protection Project (RPP). ORP does not perform any industrial activity or operate any facilities; this work is performed by the RPP contractors working under their own quality assurance (QA) programs. Therefore, many of the requirements of ASME NQA-1-2008 with ASME NQA-1a-2009 addenda do not apply to ORP work and are not addressed within this QAPD.

Table 1-1 compares the basic requirements of ASME NQA-1-2008 with ASME NQA-1a-2009 addenda to the requirements of DOE O 414.1D and EM-QA-001 Rev. 1, and to DOE/RW-0333P, and identifies those requirements applicable to ORP work.

This QAPD does not address ASME NQA-1-2008 requirements 3, 8, 9, 10, 11, 12, 13, 14, or 15 because those activities do not apply to the ORP work scope. As a result, the layout of this QAPD does not correlate directly to the requirements of ASME NQA-1-2008.

Appendix A identifies the ORP procedures, desk instructions, and plans that directly implement this QAPD and, therefore, the ORP QA Program. As such, Appendix A constitutes the ORP *Quality Assurance Implementation Plan* as required by EM-QA-001.

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Table 1-1. Quality Assurance Requirements. (3 pages)

ASME NQA-1-2008 with ASME NQA-1a-2009 Addenda		DOE O 414.1D and EM-QA-001, Rev. 1		DOE/RW-0333P		Applicable to ORP Activities QAPD Chapter No.
Requirements	Title	Criterion	Title	Section	Title	
1	Organization	1	Management/Program	1	Organization	Yes – 2
2	Quality Assurance Program	2	Management/Personnel Training and Qualification	2	Quality Assurance Program	Yes – 3
		9	Assessment/Management Assessment			
3	Design Control	6	Performance/Design	3	Design Control	No
4	Procurement Document Control	7	Performance/Procurement	4	Procurement Document Control	Yes – 4
5	Instructions, Procedures and Drawings	5	Performance/Work Processes	5	Procedures, Instructions, and Drawings	Yes – 5
6	Document Control	4	Management/Documents and Records	6	Document Control	Yes – 6
7	Control of Purchased Items and Services	7	Performance/Procurement	7	Control of Purchased Material, Equipment and Services	Yes – 7
8	Identification and Control of Items	5	Performance/Work Processes	8	Identification and Control of Materials, Parts, and Components	No
9	Control of Special Processes	5	Performance/Work Processes	9	Control of Special Processes	No
10	Inspection	8	Performance/Inspection and Acceptance Testing	10	Inspection	No
11	Test Control	8	Performance/Inspection and Acceptance Testing	11	Test Control	No
12	Control of Measuring and Test Equipment	8	Performance/Inspection and Acceptance Testing	12	Control of Measuring and Test Equipment	No
13	Handling, Storage, and Shipping	5	Performance/Work Processes	13	Handling, Storage, and Shipping	No

Table 1-1. Quality Assurance Requirements. (3 pages)

ASME NQA-1-2008 with ASME NQA-1a-2009 Addenda		DOE O 414.1D and EM-QA-001, Rev. 1		DOE/RW-0333P		Applicable to ORP Activities QAPD Chapter No.
Requirements	Title	Criterion	Title	Section	Title	
14	Inspection, Test, and Operating Status	8	Performance/Inspection and Acceptance Testing	14	Inspection, Test, and Operating Status	No
15	Control of Nonconforming Items	3	Management/Quality Improvement	15	Control of Nonconforming Material, Parts, or Components	No
16	Corrective Action	3	Management/Quality Improvement	16	Corrective Action	Yes – 8
		Attachment 3	Suspect/Counterfeit Items Prevention			
17	Quality Assurance Records	4	Management/Documents and Records	17	Quality Assurance Records	Yes – 9
				Supplement V	Control of the Electronic Management of Information	
18	Audits	—	—	18	Audits	Yes – 10
—	—	10	Assessment/Independent Assessment	—	—	Yes – 11
Subpart 2.14	Quality Assurance Requirements for Commercial Grade Items and Services	—	—	7	Control of Purchased Material, Equipment and Services	Yes – 12.4 (CGD of Quality-Affecting Software)
Subpart 2.7	Software	Attachment 4	Safety Software QA Requirements for Nuclear Facilities	Supplement I	Software	Yes – 12
Subpart 3.1	Guidance on Qualification of Existing Data	—	—	Supplement III	Scientific Investigation	Yes – 14

Table 1-1. Quality Assurance Requirements. (3 pages)

ASME NQA-1-2008 with ASME NQA-1a-2009 Addenda		DOE O 414.1D and EM-QA-001, Rev. 1		DOE/RW-0333P		Applicable to ORP Activities QAPD Chapter No.
Requirements	Title	Criterion	Title	Section	Title	
Subpart 4.2	Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development	—	—	—	—	Yes – 13
—	—	—	—	Supplement II	Sample Control	No
—	—	—	—	Supplement III	Scientific Investigation	No
—	—	—	—	Supplement IV	Field Surveying	No
—	—	—	—	Supplement V	Control of the Electronic Management of Information	Yes – 9
—	—	—	—	Appendix A	Waste Custodian Interface	Yes – All
—	—	—	—	Appendix B	Not Used	No
—	—	—	—	Appendix C	Storage and Transportation	No

ASME NQA-1-2008, 2008, *Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.

ASME NQA-1a-2009, 2009, *Addenda to ASME NQA-1-2008: Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.

DOE O 414.1D, 2011, *Quality Assurance*, U.S. Department of Energy, Washington, D.C.

DOE/RW-0333P, 2008, *Quality Assurance Requirements and Description*, Rev. 21, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Washington, D.C., December.

EM-QA-001, 2012, *EM Quality Assurance Program*, Rev. 1, U.S. Department of Energy, Washington, D.C.

CGD = commercial grade dedication.

QA = Quality Assurance.

ORP = U.S. Department of Energy, Office of River Protection.

QAPD = Quality Assurance Program Description.

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1.1 INTEGRATED SAFETY MANAGEMENT SYSTEM

- A. ORP complies with regulations and implements management systems consistent with DOE P 450.4A, *Integrated Safety Management Policy*; DOE O 414.1D; DOE O 420.1C, *Facility Safety*; DOE P 470.1A, *Safeguards and Security Program*; and DOE O 151.1C, *Comprehensive Emergency Management System*.
- B. DOE P 450.4A is a policy document that describes how to systematically integrate safety within an organization. MGT-PM-PL-03, *Integrated Safety Management System Description*, describes how ORP integrates environmental, safety, and health requirements and controls within all organizational levels of ORP. MGT-PM-PL-03 encompasses the seven guiding principles and five core functions that are the basis for requirements that implement integrated safety management as defined in DOE P 450.4A.
- C. DOE P 450.4A defines DOE expectations regarding DOE employees' responsibilities for safety management. MGT-PM-PL-02, *Safety Management Functions, Responsibilities, and Authorities (FRA) for the U.S. Department of Energy Office of River Protection*, succinctly defines ORP's organization, including safety management functions, responsibilities, and lines of authority to ensure that work is performed safely and efficiently.
- D. ORP's safety management functions, responsibilities, and authorities for ensuring adequate protection and safe operations cannot be delegated to contractors.
- E. The ORP QA Program implements the Integrated Safety Management System requirements and the Environmental Management System objectives through the implementation of this QAPD as described in Table 1-2.
- F. Each "Requirements" section identifies the QA requirements and any methods necessary to ensure consistent implementation for the requirements associated with each specific QA element that ORP must implement when conducting activities.
- G. Each "QARD Requirements" section shall identify the immobilized high-level waste (IHLW) requirements that are in addition to those contained in the "Requirements" section. The additional requirements are based on the QARD (DOE/RW-0333P), including Appendix A, "Waste Custodians," and are applicable when performing oversight of IHLW activities.

Table 1-2. Correlation of Environmental Management System and Quality Assurance to Integrated Safety Management.

ISMS Guiding Principles	ISM Core Functions	Quality Assurance Criterion	EMS Programmatic Components
1. Line Management Responsibility for Safety	All five core functions	<ul style="list-style-type: none"> Quality Assurance Program 	EMS provides a systematic management process for identifying and addressing environmental consequences of an ORP action. Processes within the EMS encompass a continuous cycle of planning, implementing, and evaluating to ensure the safety of the workers and the public, and protection of the environment.
2. Clear Roles and Responsibilities		<ul style="list-style-type: none"> Personnel training and qualification 	
3. Competence Commensurate with Responsibilities			
4. Balanced Priorities	1. Define the Scope of Work	<ul style="list-style-type: none"> Instructions, procedures, and drawings Document control Records management Procurement 	Permit management
	2. Analyze the Hazards		<ul style="list-style-type: none"> NEPA analysis Radiation protection and radioactive waste management Watershed management Cultural resource management
5. Identification of Safety Standards and Requirements 6. Hazard Controls Tailored to Work Being Performed	3. Develop and Implement Hazard Controls		Pollution prevention
	7. Operations Authorization		4. Perform Work Within Controls
5. Provide Feedback and Continuous Improvement			<ul style="list-style-type: none"> Corrective action Management assessment Independent assessment

ISMS = Integrated Safety Management System.
 ISM = Integrated Safety Management.
 EMS = Environmental Management System.

NEPA = *National Environmental Policy Act*.
 ORP = U.S. Department of Energy, Office of River Protection.

1.2 REQUIREMENTS SECTION FORMAT AND CONTENT

- A. Each requirement portion of this QAPD contains, at a minimum, the following sections:
1. Description.
 2. Requirements.
 3. QARD Requirements.
- B. Each “Description” section contains a brief overview of the ORP activities and topics associated with the specific QA element.

1.3 CONTROL OF THE QUALITY ASSURANCE PROGRAM

- A. Revisions to DOE O 414.1D, EM-QA-001, and the QARD shall be reviewed for changes and their impact on this QAPD.
- B. A matrix will be maintained that is both consistent with the scope of work and provides the relationship between the QARD and the implementing documents.
- C. Changes to procedures, desk instructions, plans, and/or guides or the need to prepare new procedures, desk instructions, plans, and/or guides resulting from changes to this QAPD, or organizational changes shall be implemented within 180 days of the issuance of this QAPD, unless an interim action plan is defined and approved by the ORP Manager. This QAPD shall be revised within 180 days of any organizational change that impacts or effects Figure 1-1 of this manual.

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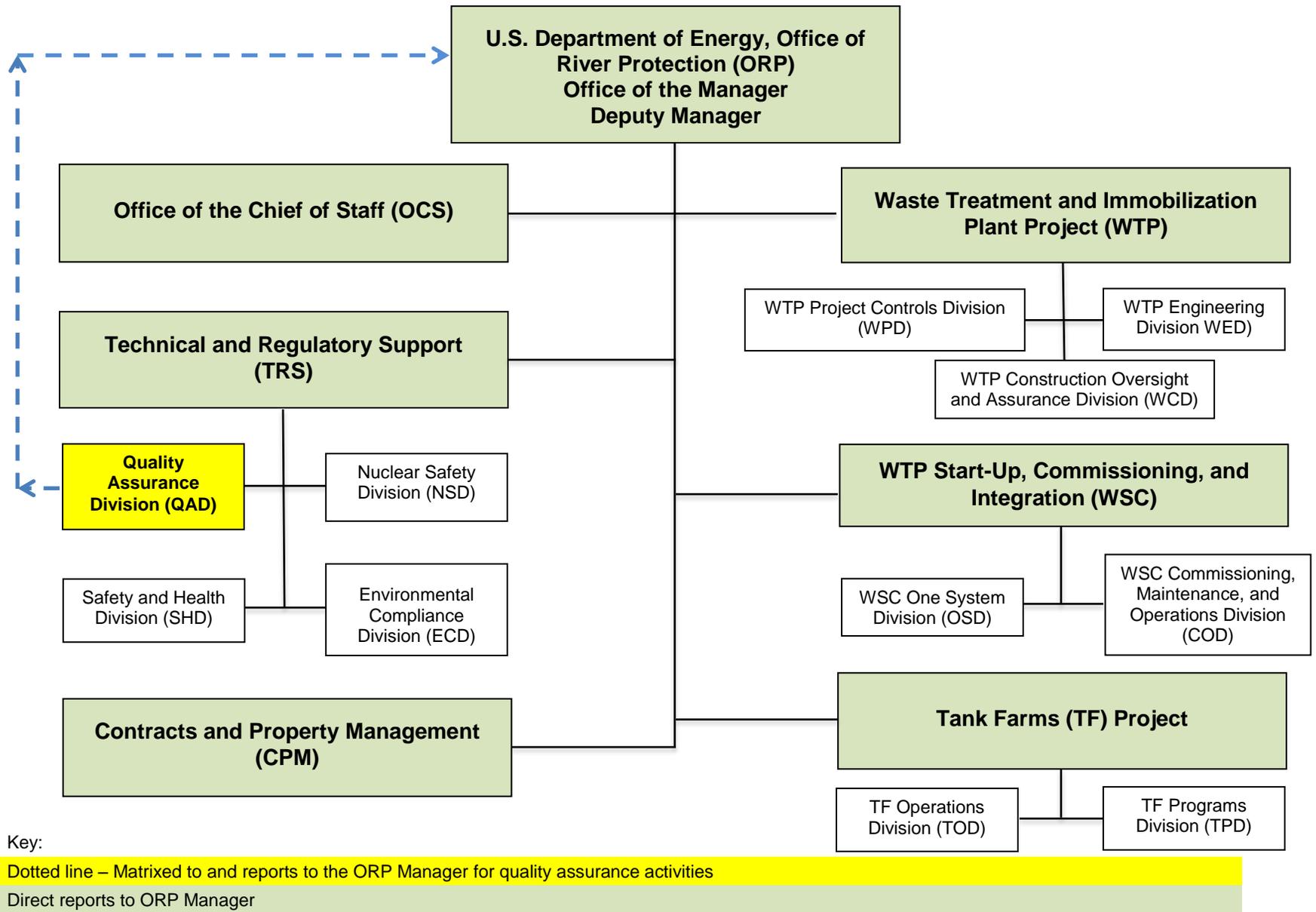


Figure 1-1. U.S. Department of Energy, Office of River Protection Organization.

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2.0 ORGANIZATION

2.1 DESCRIPTION

ORP's mission is to remove waste from the past production of nuclear materials stored in underground tank farms, treat the waste to standards that are protective of human health and the environment, and close the tanks and treatment facilities. This will ultimately serve to protect the Columbia River. The cleanup of the Hanford Site must occur in an environmentally sound, safe, and cost-effective manner and in compliance with Federal and State regulations. Cleanup must also comply with the agreement between DOE, the U.S. Environmental Protection Agency, and the Washington State Department of Ecology—the *Hanford Federal Facility Agreement and Consent Order* (Ecology et al. 1989), also known as the Tri-Party Agreement. This is an agreement for achieving compliance with remedial action provisions of the *Comprehensive Environmental Response, Compensation, and Liability Act of 1980*, and treatment, storage, and disposal unit regulations and corrective action provisions of the *Resource Conservation and Recovery Act of 1976*.

ORP is responsible for planning, integrating, and managing the RPP, which is executed by contractors performing work under ORP overall management. Currently, the following three prime contractors are involved in the RPP:

- A. Bechtel National, Inc., responsible for executing the design, construction, and commissioning of the Hanford Tank Waste Treatment and Immobilization Plant (WTP) Project (Contract DE-AC27-01RV14136).
- B. Washington River Protection Solutions LLC (WRPS), responsible for safely retrieving highly radioactive and hazardous waste stored in underground tanks for treatment and future vitrification as well as executing the Tank Operations Contract (Contract DE-AC27-08RV14800).
- C. Advanced Technologies and Laboratories International, Inc., responsible for performing the analytical services production functions of receiving, handling, analyzing, and storing samples; performing special tests; and reporting the results of these analyses and tests to the contractors of DOE offices at Hanford (Contract DE-AC27-10RV15051).

A WTP operations contract will be awarded when the plant becomes operational.

To execute the RPP mission, ORP receives direction, guidance, and input from Congress, DOE Headquarters, and stakeholders. These sources of input are called external drivers. The RPP management team (ORP, WTP Contractor [Bechtel National, Inc.], Tank Farms Contractor [WRPS], and future WTP operator) executes the mission.

The interface between ORP and the Defense Nuclear Facilities Safety Board is defined in DOE M 140.1-1B, *Interface with the Defense Nuclear Facilities Safety Board*. Review and approval guidance for environmental compliance and cleanup agreements for the DOE Office of Environmental Management (EM) defines interfaces among ORP and Federal and State environmental regulatory entities. Interfaces between ORP and the DOE Richland Operations Office (RL) are defined in memoranda of agreement. Interfaces between ORP and its prime contractors are defined in their respective contracts.

2.2 ORGANIZATION REQUIREMENTS

This section describes the requirement for the organizational structure, primary interfaces, functional responsibilities, and levels of authority required to implement the ORP QA Program.

Effective implementation of the ORP QA Program is dependent upon effort and cooperation at all levels of the organization. The organizational structures and the responsibility assignments within ORP shall be such that those organizations assigned responsibility for performing the work are thus responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, and supporting the staff in pursuit of quality.

ORP's organizational structure and responsibilities can be summarized as follows:

- A. Senior management establishes overall expectations for effective implementation of the QA Program and is responsible for obtaining the desired end result
- B. Line management is responsible for implementation of quality achieved and maintained by those assigned responsibility for performing work.
- C. Quality achievement is verified by those not directly responsible for performing the work.

The ORP Quality Assurance Division (QAD) is responsible for verifying the achievement of quality in the implementation of the ORP QA Program.

Figure 1-1 depicts the ORP organization responsible for implementing the requirements of this QAPD.

2.3 MANAGEMENT RESPONSIBILITIES

For the purpose of this QAPD, "management" refers to the ORP Manager, ORP Deputy Manager, and all direct reports to the ORP Manager.

- A. Management has overall responsibility for successfully accomplishing activities subject to this QAPD and is responsible for obtaining the desired results. Management provides the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Management is responsible for planning, performing, and approving ORP work.
- B. Management is responsible for establishing and implementing procedures, desk instructions, plans, and/or guides that control the quality of work, consistent with the provisions of this QAPD.
- C. Management quality responsibilities include:
 - 1. Ensuring that an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work are established.
 - 2. Identifying and approving the QA Program scope and appropriate quality levels.
 - 3. Identifying and approving characteristics to be verified and the acceptance criteria to be used.
 - 4. Identifying and approving actions to resolve quality problems.

5. Identifying and approving the determination of the validity and disposition of nonconforming items and services.
 6. Ensuring that management processes, including planning, scheduling, and providing resources for work, are established.
 7. Ensuring that adequate technical and QA training is provided for personnel performing activities subject to this QAPD.
 8. Ensuring compliance with all applicable regulations; DOE orders and requirements; and applicable federal, state, and local laws.
 9. Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of records.
 10. Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override quality, environmental, safety, or health considerations.
 11. Developing, implementing, and maintaining procedures, desk instructions, plans, and/or guides that implement this QAPD in a controlled manner.
 12. Identifying, investigating, reporting, and correcting quality problems.
 13. Performing management assessments and self-assessments, and ensuring audits or assessments of contractor activities are performed.
- D. Quality achievement and maintenance is the responsibility of those performing the work. Thus management/line organizations are responsible for achieving quality in their areas.

2.4 QUALITY ASSURANCE ORGANIZATION

The ORP QAD has the authority and overall responsibility to independently audit ORP's implementation of the QA Program to verify the achievement of quality. Quality is achieved and maintained by those assigned responsibility for performing work, and quality achievement is verified by those not directly responsible for performing the work. The QAD develops, administers, and coordinates implementation of the ORP QA Program.

The QAD reports directly to the assistant manager (AM), Technical and Regulatory Support (TRS), and is matrixed to and reports to the ORP Manager. This ensures independence from cost, schedule, and production considerations, along with consistency and objectivity in process and product QA evaluations. Objectivity is achieved by both independence and the use of approved and documented criteria. The QAD is matrixed to and reports to the ORP Manager to ensure differing opinions are accepted/evaluated without any hindrances or organizational bias.

A. The QAD has the following responsibilities:

1. Ensures requirements documents have been incorporated into the contractors' contracts and that the contractors have appropriately implemented the requirements into plans, policies, and procedures.
2. Identifies and interprets quality requirements. Develops quality policies and procedures and ensures RPP work is performed compliant with applicable quality requirements, laws, standards, and statutes.

3. Administers, interprets, and monitors effective implementation of ORP QA policies and associated documents, including the QARD, for those portions of the ORP QA Program that could affect IHLW.
4. Reviews and assesses WTP contractor IHLW acceptance-affecting activities to ensure ORP IHLW activities are in accordance with requirements specified in the waste acceptance systems requirements documents.
5. Acts as liaison to EM on issues associated with implementation of each contractor's QA and IHLW QA Program.
6. Reviews the contractors' programs for identifying, reporting, correcting, and tracking *Price-Anderson Amendment Act* (PAAA) noncompliances.
7. Provides oversight of RPP contractors' QA programs. Reviews these programs and recommends approval or rejection to the ORP Manager.
8. Provides technical subject matter support on quality issues to ORP line organizations.
9. Conducts audits, independent assessments, surveillances, and other oversight activities to verify contractor compliance with contractual and regulatory QA requirements.
10. Conducts internal audits, independent assessments, surveillances, and other oversight activities to assure all ORP organizations comply with DOE quality requirements.
11. Maintains the QAPD and assigned procedures, desk instructions, plans, and/or guides for ORP.
12. Provides programmatic support to the Assessment Program Committee, overseeing ORP's Integrated Assessment Program and participates in the screening of issues from the IMS.
13. Provides advisory support to the ORP Manager and other ORP organizations on QA issues.
14. Assists ORP organizations as needed with quality planning, documentation, quality measurement, and problem identification and resolution.
15. Provides guidance to applicable organizations concerning identification, control, and protection of records.
16. Conducts supplier pre-award evaluations and followup audits as necessary to provide coverage, consistency, and coordination with ongoing work.
17. Maintains procedures for and operates the ORP suspect/counterfeit items (S/CI) program.
18. Maintains liaison responsibilities between ORP and various DOE Headquarters entities on software QA issues.
19. Conducts reviews and concurs with causal analysis of conditions adverse to quality (CAQ) and significant conditions adverse to quality (SCAQ).
20. Maintains the qualifications and certifications of QAD staff.
21. Coordinates all activities pertaining to PAAA investigations and violations. Serves as the point of contact for all PAAA issues with DOE Headquarters Office of Enforcement, ORP line organizations, and contractor PAAA coordinators.

- B. The QAD Director is responsible for assuring that an appropriate QA program has been established that complies with regulatory and management requirements and is effectively implemented. The QAD verifies activities affecting quality, and shall have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to allow its members to perform this function. The QAD Director must report to a management level so that the required authority and organizational freedom, provides sufficient independence from cost and schedule when opposed to safety function considerations and direct access to responsible management at a level where appropriate action can be affected. The QAD Director must have no other assigned duties that would prevent full attention to QA-related responsibilities and have the authority to stop work when an SCAQ warrants such action. These verification functions include the following:
1. Verifying activities affecting quality.
 2. Identifying quality problems.
 3. Initiating, recommending, or providing solutions to quality problems through designated channels.
 4. Verifying implementation of solutions.
 5. Assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.
 6. Verifying the adequacy and implementation (i.e., compliance and effectiveness) of the ORP QA Program and the ORP contractor QA programs, and report the results to senior management.

2.5 COMMUNICATION AND INTERFACE RESPONSIBILITIES

- A. Organizations at all management levels shall establish communication channels that provide timely and organization-wide dissemination of information pertinent to quality performance, such as:
1. Status of development and implementation of the QA Program.
 2. Status and resolution of significant quality problems.
 3. Lessons learned from significant quality problems and adverse conditions.
 4. Quality management practices and improvements.
 5. Trend analysis results.
- B. Where more than one organization is involved in the execution of activities covered by this QAPD, the following requirements apply:
1. The responsibility and authority of each organization shall be clearly established, defined, and documented.
 2. The external interfaces between organizations, the internal interfaces between organizational units, and interface changes shall be documented.
 3. Interface responsibilities shall be defined and documented; and shall include the requirements for management, performance, and assessment.

2.6 DELEGATION OF WORK

Individuals or organizations responsible for establishing, planning, accomplishing, and assessing the work may delegate work to other individuals or organizations in writing. However, the individuals or organizations making the delegation shall retain overall responsibility for the delegated work.

2.7 RESOLUTION OF DISPUTES

Disputes concerning interpretations involving the definition and implementation of QA Program requirements will be brought to the attention of the ORP QAD and the responsible manager. If not resolved, the issues will be elevated progressively to successively higher levels of management as necessary for resolution.

2.8 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to the requirements previously described.

2.8.1 Requirements

ORP shall prepare one or more controlled documents that describe(s) their responsibilities and authorities; including the management positions responsible for achieving and maintaining quality, internal, and external organizational interfaces, organizational structures, and responsibilities for their scope of work. These documents shall be revised upon any reorganization that impacts responsibilities associated with the implementation of QARD-related activities.

2.8.2 Resolution of Quality Disputes

ORP does not have a direct line relationship regarding the QARD; therefore, disputes within ORP concerning the QARD program shall be addressed through EM.

3.0 QUALITY ASSURANCE PROGRAM

3.1 DESCRIPTION

ORP's QA Program implements the requirements of DOE O 414.1D; 10 CFR 830, "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements"; EM-QA-001; and the QARD for oversight activities of IHLW activities. ORP has selected the national consensus standard ASME NQA-1-2008, with the ASME NQA-1a-2009 addenda, to form the basis for ORP's QA Program for nuclear-related activities. ORP implements Parts I, II, III, and IV, of ASME NQA-1, in a graded approach, as applicable to the activities performed by ORP. Appendix B provides a definition of terms used within ORP's QA Program.

The QARD Requirements section shall identify the IHLW requirements that are in addition to those contained in the Requirements section. The additional requirements are based on the QARD and are applicable when performing ORP IHLW activities and QAD oversight of IHLW contractor activities.

Figure 3-1 shows the hierarchy of QA documents for ORP.

A graded approach, based on the relative importance of safety, safeguards and security, and other pertinent areas of management consideration, is used in applying the requirements of this QAPD.

The success of any organization, including ORP, requires members of the organization to be skilled in their work processes and capable of performing their assigned work. RL Human Resources assists in these efforts by screening potential applicants against the education, skills, and experience requirements for the position and ensuring only qualified applicants are considered.

The AMTRS provides training on the ORP QA Program. Training will be provided to all employees involved in QA Program implementation to ensure personnel are capable of performing their assigned work. Individual managers ensure personnel are qualified before being placed in their positions. ORP uses the RL Office of Employee and Organizational Development for selected staff training.

Training includes education in principles, enhancement of skills and practices, and the training required to meet DOE-wide technical qualification standards for functional areas. The extent of training is commensurate with the scope, complexity, and nature of the respective task. Methods of training include reading assignments, observation and performance of activities, briefings, formal training classes, and/or verbal and written tests.

Training and qualification of technical personnel are accomplished in accordance with DOE O 426.1, *Federal Technical Capability*. Managers with federal technical employees whose duties and responsibilities require them to provide assistance, guidance, direction, oversight, or evaluation of contractor activities that could impact the safe operation of a defense nuclear facility are qualified in accordance with the ORP Technical Qualification Program. The ORP Technical Qualification Program includes the Safety System Oversight Program, Facility Representative Program, Technical Staff Program, or Project Manager Program, and Senior Technical Safety Manager Program. The managers of these technical employees are required to make sure employees are qualified in accordance with this program plan. Programmatic and administrative support for ORP training is provided by RL Human Resources.

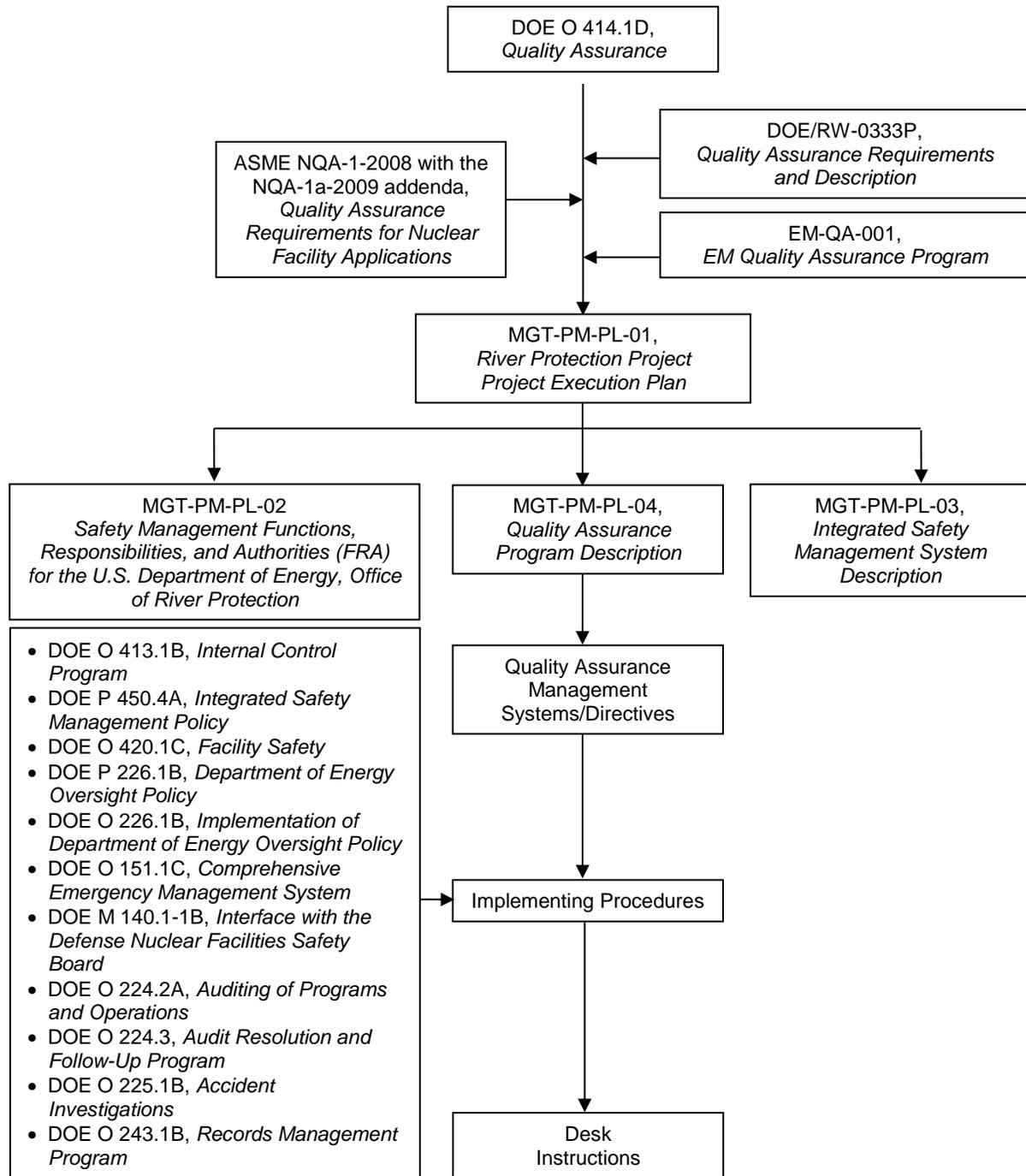


Figure 3-1. Quality Assurance Document Hierarchy.

Federal QAD Personnel are directly responsible for the oversight of quality requirements governing defense nuclear facilities must be qualified in accordance with DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard*.

Federal QAD personnel are directly responsible for oversight of safety software QA activities of defense nuclear facilities must be qualified in accordance with DOE-STD-1172-2011, *Safety Software Quality Assurance Functional Area Qualification Standard*.

ORP staff members directly responsible for independent QA oversight (audits) are qualified in accordance with ASME NQA-1-2008 with the ASME NQA-1a-2009 addenda, Part I, Requirement 2, “Quality Assurance Program,” Section 300 “Qualification Requirements,” and Part III, Nonmandatory Appendix 2.A-3, “Guidance on the Education and Experience of Lead Auditors.”

Staff members, who perform oversight, including assessments and management assessments, are trained to the assessment procedures. In addition, ORP management documents the qualification status of the assigned facility representatives. Other ORP divisions document an individual’s qualifications by minimum education requirements, work experience, and professional certifications.

ORP facility representatives are qualified by completing a process that begins with the required education and experience. It then includes completion of core knowledge requirements to perform facility representative duties, facility-specific requirements determined by the field element, and verbal and written examinations.

ORP AMs and directors review the status, adequacy, effectiveness, and compliance aspects of the QA Program on a continuing basis. These reviews are accomplished through direct observation of ORP activities in the field during management assessments, self-assessments, and assessments.

3.2 IMPLEMENTATION OF QUALITY ASSURANCE PROGRAM REQUIREMENTS

This section describes the basic elements of the QA Program and their applicability.

3.2.1 Quality Assurance Program Documents

ORP organizations shall develop and follow plans and procedures that effectively implement the requirements described in this QAPD when performing ORP activities. In addition, ORP will effectively implement the requirements described in DOE O 414.1D.

3.2.2 Applicability of Quality Assurance Program Description Requirements

- A. ORP conducts oversight of the design, construction, inspection, testing, and operation of nuclear facilities associated with the RPP. This QAPD is applicable, in a graded approach manner, to all personnel performing work for ORP.
- B. ORP work that involves nuclear-related research and development shall be performed in accordance with the requirements of this QAPD.

3.3 GRADED APPROACH FOR ITEMS AND ACTIVITIES AND THE APPLICATION OF MANAGEMENT CONTROLS

- A. Obtaining a “Quality” product applies to all quality-related activities performed by ORP. The graded approach is a process used to determine the level of analysis, controls, documentation, and verification necessary to mitigate hazards and risks for these activities. In addition, grading is applied to activities consistent with their importance to safety, cost,

schedule, and success of mission. The graded approach processes necessary to comply with QA Program requirements are developed commensurate with the following factors:

1. Relative importance of an item or activity with respect to safety, safeguards, security, and regulatory compliance.
 2. Magnitude of a hazard, the risk involved with the consequences of failure, and the probability of the occurrence of the postulated consequences that include natural phenomena hazards.
 3. Life-cycle stage of a facility, item, or activity.
 4. Performance history or standardization of a facility, item, or activity.
 5. Impact/consequences on the programmatic mission of a facility.
 6. Particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, difficulty to perform services, the necessity for special controls or processes, or oversight of processes and performance).
 7. Nuclear safety classification or hazard category of the item or activity.
 8. Adequacy of existing safety documentation.
 9. Relative importance of radiological and nonradiological hazards.
 10. Complexity of products, items, or services involved.
 11. Difficulty and impact on the results of performance audits, assessments, and engineering analyses.
 12. Importance of the data to be generated.
 13. Need to demonstrate compliance with specific regulatory design and QA requirements, including special controls and oversight.
- B. The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility, item, or activity. ORP shall develop a method to determine that the defined grading process is effective. The use of the graded approach shall determine the appropriate level of controls necessary to manage the items, systems, and activities necessary to achieve ORP's mission.
- C. Grading methods for ORP shall provide for:
1. Assignment of management and QA control levels that ensure the grading methods do not grade the QA criterion to zero for safety-related and mission critical activities.
 2. Activities such as administrative systems or activities that do not contain quality-related functions requiring DOE O 414.1D and ASME NQA-1 implementation, such as accounting, human resources, scheduling, responding to requests for information, procurement of office supplies, attending meetings, and other similar activities are not considered activities governed under the requirements of this QAPD.
 3. Definitive criteria used in selecting the grading levels.

4. Detailed descriptions of the management and QA control provisions corresponding to those levels, based on these requirements.

3.4 PLANNING WORK

Work is defined as a task or activity necessary to accomplish the ORP mission and meet regulatory requirements. Work activities consist of a series of actions planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls to achieve an end result. All ORP staff shall perform work activities by following approved procedures written to accomplish the ORP mission and meet regulatory requirements.

3.5 PERSONNEL QUALIFICATION AND TRAINING

3.5.1 Qualification Requirements

Qualification requirements for ORP positions or job functions will be established and documented in procedures, desk instructions, plans, and/or guides. The level of qualification complexity will be determined based on the position responsibilities such as job hazards, risks, safety functions, and/or critical to mission success. At a minimum, these positions include managers, engineers, scientists, and independent assessment personnel. The responsible manager shall:

- A. Analyze each job position to determine the task responsibilities of the position subject to this QAPD, commensurate with the scope, complexity, and nature of the work. The analysis shall identify minimum education, experience, and training. It shall also identify required highly technical or specialized skills, and required prerequisites or specialized certification, for each position involved in the planning, performance, or verification of activities subject to this QAPD.
- B. Ensure the analysis of each job position determines whether competency or qualification shall be demonstrated prior to the performance of work, which requires the specific competency or qualification, within a specified timeframe after entering the position. When a specified timeframe is established, all work performed by the assigned personnel shall be reviewed by personnel that are competent or qualified prior to use of the work product.
- C. Ensure personnel performing or managing activities receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, the requirements of applicable codes and standards, regulatory requirements, ORP procedures, and QA Program requirements.
- D. Ensure personnel selected to perform or verify activities subject to this QAPD have education, experience, and training commensurate with the minimum requirements specified. The qualification of an individual shall be based on evaluation of education, experience, and formal or on-the-job training, which is compared to the established requirements for the position and may include a practical and/or written examination process.

3.5.2 Assessor Qualification

Staff members who lead or perform assessments shall be trained and qualified as assessors in accordance with procedures or desk instructions that implement the criteria described in Sections 3.5.1 and 11.2.

3.5.3 Lead Auditor and Auditor Qualification for Quality Assurance Audits Performed Under this Quality Assurance Program Description (ASME NQA-1 or the Quality Assurance Requirements and Description Requirements)

A lead auditor for ASME NQA-1 or QARD-based QA audits shall be capable of planning, organizing, and directing audits, reporting audit results, and evaluating planned and implemented corrective actions. Prospective lead auditors/auditors shall have effective written and verbal communication skills relative to performing audits. Lead auditors/auditors also shall be certified as meeting the requirements provided in this section for education and experience, communication skills, training, assessment participation, and the successful completion of a lead auditor/auditor examination.

A. Lead Auditor Education and Experience:

The prospective lead auditor shall have verifiable evidence that a minimum of 10 credits have been accumulated under the following scoring system; or the prospective auditor shall have verifiable evidence that a minimum of seven credits have been accumulated under the following scoring system:

1. Education (four credits maximum)

- a. An associate's degree from an accredited institution scores one credit. If the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits.
- b. A bachelor's degree from an accredited institution scores two credits. If the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits. Score one additional credit for a master's degree (or higher) in engineering, physical sciences, business management, or QA from an accredited institution.

2. Experience (nine credits maximum)

The prospective lead auditor shall have participated in a minimum of five QA audits within 3 years prior to the date of certification, one of which shall be a nuclear QA audit within the year prior to qualification.

Participation in independent assessments, including team assessments and regulatory inspections/surveys by the prospective lead auditor, may be used to satisfy up to four of the five required QA audits, provided that the activities can demonstrate the following:

- a. Independence from the functional areas being assessed.
- b. Planning that establishes the scope of the activities and associated evaluation criteria.
- c. Performance by technically qualified and experienced personnel.
- d. Results that are documented and reported to management.
- e. Appropriate corrective action(s) initiated and tracked to resolution.

The prospective auditor shall have participated in at least one QA audit within 3 years of the date of qualification.

Such participation shall be subject to review and acceptance by ORP TRS prior to their use for qualification.

In addition, for technical experience in such areas as engineering, manufacturing, construction, operation, or maintenance, or experiences applicable to the assessment of an organization's area of responsibility, score one credit for each full year, with a maximum of five credits. If 2 years of this experience have been in:

- a. A nuclear field, score one additional credit
- b. QA, score two additional credits
- c. Auditing or assessment, score three additional credits
- d. Nuclear-related QA, score three additional credits
- e. Nuclear-related QA auditing or assessment, score four additional credits.

3. Professional Competence (two credits maximum)

For certification of competency in engineering, science, or QA specialties, issued and approved by a State agency or national professional or technical society, score two credits.

4. Rights of Management (two credits maximum)

When determined appropriate, the organization performing the qualification may grant up to two credits for other performance factors applicable to audits that are not explicitly called out in this section (e.g., leadership, sound judgment, maturity, analytical ability, tenacity, past performance, completed QA training courses).

B. Lead Auditor/Auditor Communication Skills:

The prospective lead auditor/auditor shall have the capability to communicate effectively both verbally and in writing. These skills shall be attested to in writing by the candidate's supervisor.

C. Lead Auditor/Auditor Training:

Prospective lead auditors/auditors shall be trained to the extent necessary to ensure their competence in skills as established by the organization responsible for performing assessments. Training in the following areas shall be accomplished and its completion verified based on a management evaluation of the particular needs of each prospective lead auditor/auditor:

1. Knowledge and understanding of the participant organization's QA Program and other program-related procedures, codes, standards, regulations, DOE orders, and regulatory guides, as applicable.
2. General structure of QA plans and implementation procedures as a whole.
3. Assessment techniques of examining, questioning, evaluating, reporting, and methods of identifying, following up, and closing corrective actions.
4. Assessment planning in functional areas of nuclear QA.

D. Lead Auditor/Auditor Examination:

The prospective lead auditor/auditor shall pass an examination that evaluates his or her comprehension of, and ability to apply, the assessment knowledge described in this section. The examination may be verbal, written, practical, or any combination thereof.

The development and administration of the examination for a lead auditor/auditor is the responsibility of the organization responsible for the audit program. This organization shall:

1. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctor examinations.
2. Develop and maintain objective evidence regarding the type and content of the examination.

E. Lead Auditor/Auditor Certification:

Lead auditors/auditors shall be certified by the organization responsible for the audit program as being qualified to lead audits. This certification will document the following:

1. Name of the organization performing the certification.
2. Name of the lead auditor.
3. Date of certification or recertification.
4. Basis of certification (e.g., education, indoctrination, experience, capability demonstration, test results, communication skills, training).
5. Signature of the designated representative of the organization responsible for the certification.

F. Lead Auditor/Auditor Proficiency Maintenance:

1. Lead auditors/auditors shall maintain their proficiency through one or a combination of the following:
 - a. Regular and active participation in the audit process.
 - b. Review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA Program audits.
 - c. Participation in training programs.
2. Management of the audit organization shall evaluate the proficiency of lead auditors/auditors annually. Based on the evaluation, management shall choose to extend the qualification, require retraining, or require requalification. Management evaluations shall be documented.
3. Lead auditors/auditors who fail to maintain their proficiency for a 2-year period shall require requalification to the requirements of this section of this QAPD. However, participation in only one nuclear assessment is required.

3.5.4 Technical Specialists

Staff members who perform duties as technical specialists shall be trained and qualified in accordance with procedures and desk instructions that implement the criteria described in Section 3.5.1.

3.5.5 Subject Matter Experts

Staff members who perform duties as subject matter experts shall be trained and qualified in accordance with procedures and desk instructions that implement the criteria described in Section 3.5.1.

3.5.6 Training Requirements

ORP personnel performing activities important to the mission of ORP shall receive related training in accordance with the following requirements. Training shall emphasize the correct performance of work, describe why the applicable quality and nuclear safety requirements exist, and describe the fundamentals of the work and the context in which the training will relate to the work to be performed. Training shall be subject to ongoing review to determine instruction and training program effectiveness and shall be upgraded whenever needed improvements or enhancements are identified. Training shall be made available to improve knowledge or skills specific to the job and/or organization. Management shall:

- A. Ensure personnel receive indoctrination and training, including on-the-job and hands-on training, as needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology; methods of performing the work; job responsibilities; and QA procedures, desk instructions, plans, and/or guides, prior to performing any tasks subject to this QAPD.
- B. Ensure personnel receive indoctrination in the following:
 1. General criteria, including applicable QA plans, codes, regulations, and standards.
 2. Specific criteria, including procedures, desk instructions, plans, and/or guides.
- C. Ensure personnel are trained to the extent that is commensurate with the scope, complexity, and nature of the respective task, thus ensuring they are capable of performing the assigned work and are fully qualified for their positions.
- D. Provide continuing training to personnel to maintain job proficiency, develop new skills, maintain or improve job performance, and enhance existing skills.
- E. Ensure specific training is documented and updated as required to maintain competence and qualification required by the position.
- F. Ensure records generated during qualification, general indoctrination and training, or specific skill training activities are collected and maintained as records.
- G. Ensure technical qualification records are maintained separately from other training records.
- H. Records of indoctrination and training shall include one or more of the following:
 1. Attendance sheets.
 2. Training logs.
 3. Personnel training records.

3.6 MANAGEMENT ASSESSMENT

Management assessment is a method used to achieve continuous improvement and/or to identify barriers that hinder improved performance. ORP managers shall periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. These evaluations are performed periodically and also in response to identified issues. Management assessments include verifying roles and responsibilities are known and understood, processes and procedures are effectively implemented, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, the staff is complying with procedures, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied.

Managers shall periodically assess their management processes, including the performance of their organization in comparison with their mission, responsibilities, and priorities. Management assessments determine the effectiveness of program provisions that enable the organization to meet customer requirements and expectations, and identify and correct problems that hinder the organization from achieving its objectives. The assessment(s) should emphasize the use of human and material resources to achieve organizational goals and objectives and identify areas needing correction and/or improvement.

- A. The management assessment shall include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals.
- B. Managers shall retain overall responsibility for management assessments. Direct participation by senior management is essential to the success of the process because management is in the position to view the organization as a total system.
- C. Management assessments shall be performed by managers knowledgeable in the subject area and trained in assessment techniques.
- D. Management assessments shall focus on the identification and resolution of both systemic and management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives shall be identified so that meaningful action can be taken to improve quality.
- E. Management processes being assessed include the performance of manager's organization in comparison with their mission, responsibilities and priorities. Other areas to consider are safety, quality, mission completion, performance against technical and financial goals and objectives, strategic planning, organizational interfaces, use of performance indicators, trend analysis data, staff training and qualifications, and supervisory oversight and support.
- F. Management assessments include verifying roles and responsibilities are known and understood, processes and procedures are effective, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied.
- G. Effective management assessments evaluate such conditions as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers and organizations; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.
- H. Management assessments of the program shall be scheduled and conducted regularly by ORP division directors and all direct reports to the ORP Manager, and reported at least annually to the ORP Manager.
- I. Management assessment results shall be used as input to the organizational continuous improvement process.
- J. Management assessments shall be documented in a management assessment report, and deficiencies identified and tracked in accordance with the ORP Issues Management System (IMS).

3.7 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW QARD requirements that are in addition to those previously described.

3.7.1 Quality Assurance Program

3.7.1.1 Quality Assurance Program Applicability and Related Activities

The QARD shall be applied to the following ORP work:

- A. Systems, structures, and components (SSC) important to safety.
- B. Activities related to SSCs and barriers described in QARD Subsections 2.2.2A, 2.2.2B, and 2.2.2C, which include facility and equipment design and construction (i.e., designing, purchasing, fabricating, handling, packaging, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying).
- C. The controls applied to activities related to SSCs described in QARD Subsection 2.2.2C using a graded approach. These SSCs and related activities are not within the scope of 10 CFR 63.142, "Quality Assurance Criteria." However, if duplicate or conflicting requirements exist between 10 CFR 63.142 and DOE O 414.1D, 10 CFR 63.142 shall govern.
- D. Activities related to DOE high-level waste (HLW) waste forms (i.e., waste form development through qualification, waste form production, and waste form acceptance).
- E. Activities related to DOE spent nuclear fuel (SNF) (i.e., SNF characterization, conditioning, treatment, and/or canisterization and acceptance).

3.7.1.2 Classifying Structures, Systems, and Components

EM waste custodians and their contractors shall identify their items and/or activities that are subject to the QARD. This identification does not have to be in the form of a quality item list (Q-list) (e.g., it may be more appropriate for some EM waste custodians or their contractors to maintain an items and activities list).

3.7.1.3 Surveillances

Surveillances shall be:

- A. Scheduled in a manner to provide coverage, consistency, and coordination of ongoing work, and at a frequency commensurate with the status and importance of work.
- B. Performed by personnel who are knowledgeable about, and not directly responsible for, the work under surveillance.
- C. Documented in a report to appropriate management.

3.7.1.4 Readiness Reviews

The need for readiness reviews shall be approved by ORP for major programmatic, organizational, or process changes, to ensure QARD program objectives are met. Where needed, readiness reviews shall be conducted for the planned scope of work to ensure objective evidence exists demonstrating that:

- A. Work prerequisites have been satisfied
- B. Personnel have been suitably trained and qualified
- C. Appropriate implementing documents and management controls are available and approved.

3.7.1.5 Quality Assurance Program Self-Assessments

Management of each organization with QARD-related work scope regularly assesses the scope, status, adequacy, and compliance aspects of the QA Program they are executing to ensure its effective implementation. These assessments shall include frequent reviews of the QA Program status through reports, meetings, audits, surveillance, and observations. Management shall receive, as a minimum, audit reports, surveillance reports, trend reports, and management audit reports. Self-assessments are documented. Identified CAQs shall be documented in accordance with Chapter 8.0. ORP implements self-assessments in accordance with Section 3.6.

3.7.1.6 Personnel Indoctrination, Training, Qualification, and Certification

Personnel indoctrination, training, and qualification processes shall be implemented in a manner that ensures the appropriate indoctrination, training, and qualification have been provided before independently performing activities within the scope of the QA Program. Personnel performing these activities are indoctrinated, trained, qualified, and certified.

- A. Personnel shall be indoctrinated and trained as follows:
 - 1. Document formal training, including the objective and content of the training, attendees, and the date of attendance.
 - 2. Personnel that require certification are given proficiency tests. Acceptance criteria are developed to determine whether individuals are properly trained and qualified.
 - 3. Evaluate and assess the need for additional indoctrination and training as assignments, positions, or implementing documents change.
 - 4. Ensure personnel are indoctrinated in the following topics as they relate to a particular function:
 - a. QA practices, concepts, and requirements.
 - b. Job responsibilities and authority.
- B. Personnel performing as technical specialists shall be trained and qualified in accordance with procedures, desk instructions, plans, and/or guides that implement the criteria described in QARD Section 3.5.1.

3.7.1.7 Scheduled Frequency Tolerance

Activities addressed in the QARD that specify a scheduled frequency for the performance of an activity may be extended by 25 percent at the discretion of the manager responsible for

performing the activity. This flexibility shall not be used to circumvent the next scheduled performance.

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4.0 PROCUREMENT DOCUMENT CONTROL

4.1 DESCRIPTION

The ORP procurement document control process includes establishing technical, administrative, performance, and quality requirements.

An effective procurement program requires a cooperative and integrated acquisition strategy to ensure work is accomplished in compliance with applicable laws, acquisition regulations, State and Federal regulations, and DOE orders and directives. The acquisition strategy requires an effort by multiple ORP organizations, with quality achieved by clearly defining the requirements for items and services, adhering to the *Federal Acquisition Regulation* and *Department of Energy Acquisition Regulation*, and implementing cost-effective procurement strategies. Management controls exist for DOE procurement and subcontracts through applicable DOE orders; DEAR 909, “Contractor Qualifications”; and FAR 1, “Federal Acquisition Regulations System.” Within those regulations, FAR 46, “Quality Assurance,” defines requirements related to QA.

Each ORP AM and director requiring an item or service to be purchased by contract establishes performance requirements in the statement of work to ensure services meet established requirements and perform as specified. The requirements are established according to FAR 11, “Describing Agency Needs.”

ORP AMs and directors coordinate with the contracting officer to state requirements with respect to an acquisition of supplies or services in terms of functions performed, performance-required QA requirements, and essential physical characteristics. Statements of work specify that applicable requirements will be passed down to subcontractors. In addition, the contracting officer defines requirements in terms that enable and encourage contractors to supply commercial items when appropriate.

4.2 PROCUREMENT DOCUMENTS CONTENT

Procurement documents prepared by ORP organizations shall include the following, as applicable to the item or service being procured:

- A. Scope of work shall be clearly defined.
- B. Technical requirements, including the following:
 1. Design bases shall be identified or referenced.
 2. Specific documents (e.g., drawings, codes, standards, regulations, DOE orders, procedures, instructions) that describe the technical requirements of the items or services to be furnished shall be identified. The revision level or change status of these documents shall also be identified.
 3. Tests, inspections, hold points, or acceptance criteria that the purchaser shall use to monitor and evaluate the performance of the supplier shall be specified.

C. QA provisions shall be specified by the purchaser's QAD and shall include:

1. The requisite QA and other documentation requirements, depending on the control level of the item or service being procured, as well as a supplier QA Program that is pertinent to the intended scope of work.
2. The pass down requirements that the supplier shall incorporate into any subtier procurement document.
3. When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the ORP QA Program, provided the requirements are adequately implemented. In these cases, procurement documents shall specify that ORP's QA procedures, desk instructions, plans, and/or guides are applicable to the supplier and that the purchaser shall provide the applicable documents to the supplier.
4. The right of access to supplier facilities and records for inspection and assessment by ORP or other designee authorized by ORP.
5. The records requirements of Chapter 9 and provisions for disposition for all records the supplier is required to maintain.
6. The requirements for the supplier to report nonconformances and obtain ORP approval of supplier-recommended dispositions.
7. For procurements that involve nuclear-related research and development, the procurement document must incorporate the requirements of Chapter 12.

4.3 PROCUREMENT DOCUMENT REVIEW AND APPROVAL

- A. A review of the procurement documents and any changes thereto, shall be made to verify that documents include appropriate provisions to ensure items or services meet the prescribed requirements. Procurement document changes shall be subject to the same degree of control as the original documents.
- B. Procurement document reviews and their subsequent approval shall be performed and documented before the document is issued to the supplier.
- C. Reviews shall be performed by personnel who have access to pertinent information; and who have adequate understanding of the requirements and scope of the procurement.
- D. Procurement document reviews shall include representatives from technical specialties and the QAD and shall be approved by responsible management.
- E. Changes shall be subject to the same degree of control as is used in the preparation of the original documents.

4.4 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described previously.

4.4.1 Procurement Document Control

4.4.1.1 Procurement Document Preparation

Procurement documents shall include the following provisions to ensure quality, as applicable to the item(s) (including spare parts and replacements) or service(s) being procured:

- A. Procurement documents shall require suppliers to have a QA program consistent with the applicable requirements of this document, to the extent necessary, depending on the type and use of the item or service being procured. A supplier's QA program description document shall comply with this QAPD. The extent of the QA program shall depend on the scope, nature, type, use, and/or complexity of the item or service being procured.
- B. Provisions for establishing hold points beyond which work cannot proceed without ORP authorization.
- C. Identification of the schedule for submittal of documents to ORP for information, review, and/or approval.
- D. Instructions relative to the performance of special processes.
- E. A requirement for suppliers to establish controls to mitigate the procurement and installation of counterfeit or fraudulent items.

4.4.1.2 Procurement Document Review and Approval

Reviews shall ensure that all applicable requirements delineated in Section 4.4.1.1 are correctly stated, can be inspected, and are controlled; that there are adequate acceptance and rejection criteria; and that the procurement document has been prepared, reviewed, and approved in accordance with the requirements of this section.

4.4.1.3 Procurement Document Changes

Changes made as a result of proposal/bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The evaluation of these changes and the resulting impact(s) shall be completed before the contract is awarded. The evaluation shall consider:

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

4.4.1.4 Quality Assurance Program Requirements

- A. As an alternative to requiring a documented QA program for the procurement of analytical services to support scientific investigation, procurement of data, or commercial calibration services, the procurement may be controlled in accordance with QARD Subsections 7.2.12B, 7.2.12C, and 7.2.12D, respectively (see QARD Subsection 4.2.4B.1).

4.4.2 Procurement Document Preparation

- A. Provisions shall be included for identifying that the procurement is subject to the provisions of 10 CFR 21, "Reporting of Defects and Noncompliance."

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5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 DESCRIPTION

Work performed by ORP focuses on completing the ORP mission through effective contract management. Work is performed in accordance with regulations, DOE orders and directives, and established technical standards using approved manuals, procedures, and instructions.

ORP performs multidisciplined oversight of contractor work performance. ORP AMs and directors are delegated the responsibility for ensuring contractor performance is in accordance with the program/acquisition requirements and contract documents. AMs and directors use project controls and oversight activities to monitor contractor performance and ensure the production of quality products.

Work processes and required process controls (e.g., procedures and instructions) are prepared and documented to implement the requirement documents, (e.g., laws, regulations, DOE orders) applicable to the work ORP performs. The level of detail in the required procedures, desk instructions, plans, and guides is commensurate with the complexity of the work activity and the risk associated should the work be performed incorrectly.

Those performing work are responsible for achieving and maintaining quality. Those performing work have the goal of doing work correctly the first time. To ensure those doing the work achieve that goal, management is responsible for establishing processes and procedures to ensure all work is planned and performed under controlled conditions by personnel who are knowledgeable of the work requirements. These individuals must be capable of accomplishing the work in accordance with the requirements of this QAPD.

ORP management is involved in the work processes through their interactions with personnel performing the work and through their review and assessment of ongoing and completed work. This helps to ensure the definition of “acceptable work performance” is clearly communicated and personnel are provided the necessary training, resources, and administrative controls to properly accomplish their tasks.

The responsibilities of the directors and AMs for implementing this QAPD are defined in MGT-PM-PL-02.

5.2 INSTRUCTIONS, PROCEDURES, AND DRAWING REQUIREMENTS

- A. Work shall be performed in accordance with established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means.
- B. Individuals performing work shall comply with procedures, desk instructions, plans, and/or guides. When work cannot be accomplished as described in procedures, desk instructions, plans, and/or guides or the accomplishment of such work would result in an undesirable situation, a CAQ, or an unacceptable safety risk, the work shall be suspended until appropriate procedure change provisions are implemented.

5.3 WORK

- A. Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel shall be knowledgeable of the requirements for work they perform and the capability of the tools and processes they use.
- B. Managers will ensure personnel working under their supervision are qualified and are provided the necessary training, resources, and administrative controls to accomplish their assigned tasks. Managers shall define the criteria describing acceptable work performance for the worker.
- C. Managers will review both in-process and completed work documentation, as well as any related information, to ensure the desired quality is achieved and to identify areas needing improvement.
- D. Employees shall identify opportunities for improvement in work processes or procedures.
- E. Work shall be planned, authorized, and performed under controlled conditions using technical standards, QA requirements, and procedures, desk instructions, plans, and/or guides commensurate with applicable control levels.

5.4 PROCEDURES, DESK INSTRUCTIONS, PLANS, AND/OR GUIDES

- A. Procedures, desk instructions, plans, and/or guides shall be developed, reviewed, and approved by technically competent personnel.
- B. Procedures and desk instructions shall include the following information, as appropriate to the work to be performed:
 - 1. Roles and responsibilities of the organizations and employees affected by the document.
 - 2. Technical, regulatory, QA, or other program requirements.
 - 3. Special qualification and training requirements.
 - 4. Methods for demonstrating that the work was performed as required (e.g., provisions for documenting results, check off lists, or signoff blocks).
 - 5. Identification and classification of records to be generated by the procedure and desk instruction.
 - 6. Quantitative and/or qualitative acceptance criteria for determining prescribed activities have been satisfactorily accomplished and prescribed results have been satisfactorily attained.

5.5 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described above.

No additional requirements are identified.

6.0 DOCUMENT CONTROL

6.1 DESCRIPTION

All ORP documents are prepared, reviewed, approved, issued, used, and revised in accordance with prescribed procedures. The purpose of these procedures is to ensure the content of documents is correct and reflects ORP management policies, and documents are distributed (paper copy or electronic copy) to the location where needed.

Incoming documents are reviewed, distributed to persons who need them to perform their jobs, and filed.

Documents in ORP's document control system include procedures, letters, memoranda, forms, and reports. All ORP-generated external letters and business-related internal memoranda are identified using correspondence numbers (i.e., a unique set of alphanumeric characters). Electronic mail (email) and non-business-related internal memoranda are not assigned correspondence numbers. Individuals who need the information in these documents to perform their jobs, are identified in controlled distribution lists.

ORP uses the Integrated Document Management System for document control activities. Before internal procedures or reports are issued, a review and approval process takes place. The review process verifies that the information contained in the document is correct and consistent with higher level documents. The completed approval page provides objective evidence of the review process and is retained with the record copy of the document.

Revisions to documents are reviewed and approved by the same organizations that approved the original document, unless another organization with equivalent technical capabilities is designated. Individuals on the distribution list are notified when a document is revised. When appropriate, an "all ORP employees" notice is sent out to advise ORP staff of significant revisions to important documents.

Outgoing ORP documents are transmitted to the recipient after the document goes through the approval process (i.e., concurrence ladder). The concurrence ladder provides final verification that ORP documented work products are correct and consistent with other requirements.

Procedures for outgoing ORP project management documents include the *U.S. Department of Energy, Office of River Protection Correspondence Manual* (ORP 2006), which describes preparation and formatting of external correspondence.

6.2 DOCUMENT CONTROL REQUIREMENTS

- A. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.
- B. Documents that specify requirements, prescribe processes, or establish design criteria important to nuclear safety, environmental protection, and the ORP mission, shall be controlled according to the requirements listed below to ensure that the correct documents are being used. Examples of these include instructions, procedures, drawings, test plans, management plans, technical reports, and performance reports.

6.3 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

- A. Documents shall be reviewed for accuracy, adequacy, completeness, compliance, and correctness with established requirements prior to issuance. The documents shall then be approved prior to release. The individuals or organizations responsible for the preparation, review, approval, and issuance of controlled documents shall be identified.
- B. During the preparation or revision of documents, an analysis shall be performed of all new or revised requirements to determine their potential impact.
- C. Pertinent background information or data shall be made available by the organization requesting the document review if the information is not readily available to the reviewer.
- D. Individuals other than the originator will perform the review.
- E. Reviewers will be technically competent in the subject area of all documents being reviewed.
- F. Organization or technical discipline affected by the document shall review the document according to the established review criteria.
- G. QAD shall review documents that interpret QAPD requirements.
- H. Review comment documentation shall be resolved in accordance with approved procedures. Evidence of review comment resolution shall be maintained by the originating organization.
- I. Documents shall be approved for release by authorities designated in accordance with approved procedures.
- J. Implementing documents shall be controlled in a manner that ensures they are current and are readily available to the users.
- K. Only designated individuals or organizations, in accordance with approved procedures, shall issue documents.

6.3.1 Document Distribution and Use

The distribution and use of both controlled documents and forms that document or prescribe work (including changes and editorial corrections to documents), shall be controlled to meet the following requirements:

- A. Controls shall be established for the identification of controlled documents.
- B. Controls shall be established for the specified distribution of controlled documents for use at the appropriate location.
- C. Controls shall be established for the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents.
- D. Controls shall be established for the review of controlled documents for adequacy, completeness, and approval prior to distribution.
- E. A method shall be established to ensure the correct documents are being used.

6.3.2 Document Changes

- A. Changes to documents, other than those defined below as editorial changes, shall be reviewed and approved as required by Section 6.3 and by the same organization(s) that

performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures.

B. Document changes shall be:

1. Reviewed by the organizations or technical disciplines affected.
2. Clearly indicated in the changed document.

C. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document. The organization responsible for preparing the document shall identify and approve editorial changes. The following items are considered editorial or minor changes:

1. Correcting a grammatical or spelling error (the meaning has not changed).
2. Renumbering sections or attachments.
3. Updating organizational titles.

Note: A change in an organizational title accompanied by a change in responsibilities is not considered an editorial change.

4. Changing to non-quality-affecting schedules.
5. Revising or reformatting forms provided the original intent of the form has not been altered.
6. Adding, removing, or changing attachments marked "Example," "Sample," or exhibits that are clearly intended to be representative only.
7. Clarifying changes that do not affect the purpose of the document.

6.4 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described above.

- A. Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained.
- B. Document history shall be reviewed each time additional changes to the document are proposed.

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7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 DESCRIPTION

The control of purchased items and services process includes:

- A. Selecting qualified suppliers or contractors
- B. Evaluating items and services to ensure they meet contract requirements
- C. Performing surveillance to ensure approved suppliers continue to provide acceptable items and services.

ORP does not procure items that affect the quality of ORP work but does procure services that are quality affecting. If ORP requires the purchase of an item affecting the quality of ORP work, this QAPD must be revised to address purchases of such items. Purchases of computer equipment and software do not require a special procedure to address QA requirements, because TRS-QSH-IP-05, *Software Quality Assurance*, provides for verifying the quality of data produced by ORP computer equipment.

FAR 15.3, “Source Selection”; *Department of Energy Acquisition Regulation*; and this QAPD establish requirements for evaluating and selecting prospective suppliers. The supplier’s QA program and technical capabilities are evaluated to ensure the supplier can comply with the procurement document requirements.

Processes to ensure ORP contractors provide acceptable services are established and implemented through *Waste Treatment & Immobilization Plant Contract, Contract Management Plan* (DOE 2009); *Tank Operations Contract, Contract Management Plan* (ORP 2008); and this QAPD. Deliverable requirements are specified in the contract, response times are established, and the level of ORP involvement is defined (e.g., concurrence, comment, or approval). The ORP Contract Management Plan specifies ORP organization deliverable review responsibilities (both lead and support roles). For small technical support services, deliverable requirements are specified in the contract and tailored to the particular acquisition.

Contractor performance relative to DOE-awarded contracts is evaluated by affected ORP organizations through oversight processes. Oversight includes processes such as independent assessments, technical reviews, and financial reviews. The RL Finance Division and the ORP project organizations perform contractor financial reviews and internal assessments that focus on verifying work is being performed at a cost that provides reasonable value to the government, and contract terms and conditions are satisfactorily accomplished in accordance with DOE O 224.2A, *Auditing of Programs and Operations*. They also perform assessment resolution and followup activities in accordance with DOE O 224.3, *Audit Resolution and Follow-Up Program*.

7.2 CONTROL OF PURCHASED SERVICES REQUIREMENTS

ORP shall ensure procured services meet established technical and QA requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of documented criteria. ORP shall verify that approved suppliers continue to provide acceptable services.

7.2.1 Procurement Planning Requirements

ORP procurement activities shall be planned as early as possible, but no later than at the start of those procurement activities that are required to be controlled. Procurement activities shall be planned and documented to ensure a systematic approach to the procurement process. The following shall be considered:

- What is to be accomplished?
- Who is to accomplish it?
- How it is to be accomplished?
- When it is to be accomplished?

Planning shall be accomplished as early as practicable, but no later than at the start of those procurement activities that are required to be controlled to ensure interface compatibility and a uniform approach to the procurement process.

A. Procurement planning shall:

1. Identify procurement methods and organizational responsibilities, including those for the QAD.
2. Identify and document the sequence of actions and milestones needed to effectively complete the procurement.
3. Ensure procedures that address the procurement activities are prepared and approved before their required implementation date.
4. Be performed relative to the level of importance, complexity, and quantity of the item or service being procured, as well as the supplier's previous quality performance.
5. Include participation of representatives from technical organizations and individuals that are trained and qualified in QA practices and concepts.
6. Provide for the integration of the following activities:
 - a. Procurement document preparation, review, and change control.
 - b. Selection of procurement sources.
 - c. Proposal or bid evaluation and award.
 - d. Purchaser evaluation of supplier performance.
 - e. Purchaser verifications (surveillance, inspection, or audit), including notification for hold and witness points.
 - f. Control of nonconformances.
 - g. Corrective action.
 - h. Acceptance of services.
 - i. QA records.

7.2.2 Supplier Evaluation and Selection

A. Supplier selection shall be based on evaluation of the supplier's ability to provide services in accordance with procurement document requirements. Before the award of a contract or

purchase order, the supplier's ability to provide the services in accordance with the requirements shall be evaluated.

- B. Organizations responsible for supplier source selection shall be identified and shall include the QAD.
- C. Measures for selecting procurement sources shall include one or more of the following elements:
 - 1. An evaluation of the supplier's history for providing an identical or similar service, of providing a product that performs satisfactorily in actual use, and that is representative of the supplier's current capability, including:
 - a. Experience of users of identical or similar services of the prospective supplier.
 - b. Purchaser's records that have been accumulated in connection with previous procurement actions and product operating experience.
 - 2. If there has been no recent experience with the supplier or if the supplier is new, the prospective supplier shall submit information on a similar item or service for evidence of the supplier's current capabilities. Quality performance is highly dependent on the supplier's personnel capabilities, the physical conditions of the manufacturing facility and equipment, and management attitude toward quality. Historical data shall be representative of the supplier's current capability.
 - 3. An objective evaluation of the supplier's current QA documentation, supported by any documented qualitative and quantitative information. This may include review and evaluation of the supplier's QA program, manual, and procedures, as appropriate.
 - 4. An evaluation of the supplier's technical and QA capability, based on an evaluation of the supplier's facilities, personnel, and quality program implementation.
- D. The results of procurement source selection shall be documented.

7.2.3 Proposal/Bid Evaluation

- A. The proposal or bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified personnel, including the QA organization, and shall include, at a minimum, the following:
 - 1. Technical considerations.
 - 2. QA program requirements.
 - 3. Supplier personnel skills.
 - 4. Supplier production capabilities.
 - 5. Supplier past performance.
 - 6. Alternatives proposed by the supplier.
 - 7. Exceptions taken by the supplier.
- B. Before the contract is awarded or before starting quality-affecting work, the purchaser shall correct or resolve deficiencies identified during the proposal or bid evaluation.

- C. Supplier QA provisions shall be accepted by the QAD before the supplier is authorized to start work.

7.2.4 Supplier Performance Evaluation

ORP shall establish measures to interface with the supplier and to verify supplier performance, as deemed necessary. The extent of verification activities, including planning, shall be a function of the relative importance, complexity, quantity of the services, relative risk of future work, and the supplier's past quality performance. These verification activities shall be performed as early as possible within the procurement process and documented by ORP. Special verification activities are performed as needed to respond to circumstances that cannot be foreseen (e.g., events/incidents, employee concerns, degrading performance, adverse trends). The measures shall include:

- A. Establishing an understanding between ORP and supplier of the requirements and specifications identified in the procurement documents.
- B. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.
- C. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements.
- D. Identifying and processing necessary change information.
- E. Establishing the method to be used to document information exchanges between ORP and the supplier.
- F. Establishing the extent of assessment and audit activities.

Activities such as assessments, audits, or surveillances that are performed to verify conformance to procurement requirements, as well as nonconformances, dispositions, waivers, and corrective actions shall be documented.

7.2.5 Control of Supplier-Generated Documents

- A. Supplier-generated documents shall be controlled, processed, and accepted in accordance with established methods.
- B. Measures shall be implemented to ensure the submittal and evaluation of supplier-generated documents is controlled. Any changes are accomplished in accordance with procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of QA, technical, inspection, and test documentation or data compared against the acceptance criteria.

7.2.6 Control of Changes

Changes to procurement documents shall be subject to the same level of controls used for their development, except for editorial, price, delivery, or other minor changes that do not affect technical or quality requirements.

7.2.7 Procured Services Acceptance

- A. The extent of the verification activities performed by ORP for procured service(s) acceptance considers the relative importance, complexity, and quantity of the service(s) procured and the supplier's quality performance.

- B. For procurement of services only (e.g., third-party management and operating contractors; design and construction contractors; and inspection, engineering, testing, and consulting services), ORP shall accept the service by any or all of the following methods before use:
 - 1. Services comply with purchaser procurement document requirements.
 - 2. Evaluation of the supplier certificate of conformance (items and related services).
 - 3. Performance of one or a combination of source verification, receipt inspection, or post-installation test (items and related services).
 - 4. Technical verification of data produced (services only).
 - 5. Surveillance and/or audit of the activity (services only).
 - 6. Review of objective evidence (e.g., certifications, certificate of conformance, test reports) for conformance to procurement document requirements (services only).

7.3 CONTROL OF SUPPLIER NONCONFORMANCES

ORP and the supplier shall establish and document the process for the disposition of items or services that do not meet procurement document requirements in accordance with the following:

- A. The supplier shall submit a report of nonconformance to ORP that includes supplier-recommended disposition (e.g., “use as is” or “repair”) and provide technical justification for such disposition.
- B. Reports of nonconformances to procurement document requirements, or documents approved by ORP, shall be submitted to ORP for approval. Examples of conditions requiring a report of nonconformance include:
 - 1. Failure to meet technical and material requirements.
 - 2. Failure to meet a requirement in supplier documents that have been approved by the purchaser.
 - 3. Nonconformance cannot be corrected by continuation of the original process or by rework.
 - 4. Product does not conform to the original requirement even though the product can be restored to a condition such that its capability to function is unimpaired.
- C. ORP shall evaluate and approve (if adequate) the supplier-recommended disposition and verify implementation of the approved disposition.
- D. ORP shall maintain records of supplier’s submitted nonconformances.

7.4 RECORDS

Records shall be established and maintained to indicate the performance of the following:

- A. Supplier evaluation and selection.
- B. Acceptance of items and services.
- C. Supplier nonconformances to procurement document requirements, including their evaluation and disposition.

7.5 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described previously.

7.5.1 Control of Purchased Material, Equipment, and Services

7.5.1.1 Supplier Performance Evaluation

- A. Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional assessments. This evaluation shall be documented and based on:
 - 1. Review of supplier-furnished documents and records (i.e., certificates of conformance, the American Society of Mechanical Engineers [ASME] Certificate of Authorization, ASME Quality System Certificate, nonconformance notices, corrective actions).
 - 2. Results of previous source verifications, assessments, and management assessments, including results of assessments from other sources (e.g., other customers, ASME, U.S. Nuclear Regulatory Commission).
 - 3. Operating experience of identical or similar products furnished by the same supplier to other purchasers.
- B. Qualified personnel assigned to check, inspect, assess, or witness supplier activities shall accomplish verification activities.
- C. Verifications shall be conducted as early as practical and shall not relieve the supplier of their responsibility for the verification of quality achievement.
- D. Verifications shall include the use of assessments to evaluate the supplier's performance, and evaluation of ORP's documentation to aid in the determination of the effectiveness of the supplier's QA program. This documentation shall include, as appropriate, source surveillances, assessments, nonconformances, dispositions, waivers, and corrective actions as they relate to the scope of procurements.

7.5.1.2 Acceptance of Items or Services

- A. Suppliers shall verify that furnished services comply with ORP's procurement document requirements before offering the items or services for acceptance.
- B. When required by code, regulation, or procurement document requirement, documentary evidence that services conform to procurement documents shall be available at the purchaser's facility before the service is used.
- C. Methods for accepting supplier-furnished services shall ensure services comply with ORP's procurement requirements, and include one or more of the following, as appropriate to the services being procured:
 - 1. Evaluating the supplier's certificate of conformance (items and related services).
 - 2. Performing source verification (items and related services).
- D. ORP shall accept services prior to installation or use.

7.5.1.3 Source Verification

ORP may accept services by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.

- A. Source verification is planned and performed with QAD participation in accordance with written procedures to ensure conformance to procurement requirements. Procedures applicable to the method of procurement provide for:
 - 1. Specification of the characteristics or processes to be witnessed and verified; as well as the methods of surveillance to be used and the extent of documentation required.
 - 2. Assessments or surveillance to verify the effectiveness of the supplier's QA program and quality control activities and to ensure the supplier complies with QA and technical requirements.
- B. Source verification shall be implemented to monitor, witness, or observe activities consistent with the supplier's planned inspections, examinations (tests), and shipments of items at predetermined points; and shall be performed at intervals consistent with the importance and complexity of the item.

Documented evidence of acceptance of source-verified services shall be furnished to the receiving destination of the product, to ORP, and to the supplier.

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8.0 CORRECTIVE ACTION

8.1 DESCRIPTION

The ORP Corrective Action Program addresses problems and issues identified with ORP work activities.

ORP personnel are required to identify conditions not meeting established requirements, as well as issues, and recommend improvements to products and processes. When a deficiency is identified within ORP, the condition is documented on an issue report in the ORP IMS and evaluated. When issues are identified through external assessments performed by ORP, issues are documented and controlled within the assessment and audit programs.

ORP management has established and implemented processes to detect and prevent quality problems and to ensure quality improvement. ORP identifies issues on issue reports as a result of issues discovered during any of the following:

- Management and independent assessments
- Audits
- Surveillances
- Inspections
- Assessments by external organizations
- Anomalous behavior of some measured quantity against a predefined metric
- Benchmarking
- Failure to achieve performance goals
- Failure to accomplish improvement plans
- Result of an event.

Identification of issues can also result from unfulfilled expectations of customers served by the organization. In most cases, issues result from deviations or inconsistencies with a requirement, or failures to meet customer or management expectations. Contractor quality problems detected during ORP external assessments are documented and controlled within the ORP assessment and audit programs.

The ORP corrective action process requires identified quality problems to be analyzed, causal factors identified, effective corrective actions identified and implemented, and actions to prevent recurrence identified and implemented, on a graded approach. Corrective actions identify, control, and correct items, services, and processes that do not meet established requirements; are directed towards preventing recurrence; and address the identified cause(s) according to the importance of the problem and the work affected.

Actions associated with the resolution of issues are input directly into the ORP IMS. ORP uses the ORP IMS to track each identified action through closure. ORP managers evaluate quality problems, identify causal factors, and establish and implement corrective actions. ORP performs verification to ensure proper implementation of approved corrective action.

8.1.1 Quality Trending

To perform trend analysis, historical data are accumulated and available. Historical data from periods of acceptable performance or industry benchmarks establishes the reference or performance baseline for determining the acceptability of current trends. The comparison between the latest set of data points and the historical reference can be done in a variety of ways. A more formal statistical data reduction may be performed when there are enough data points and, in the opinion of the analyst, the simple chart comparison gives ambiguous results. ORP TRS personnel are responsible for conducting quality trending that establishes metrics for monitoring performance so that processes needing improvement can be identified.

8.2 CORRECTIVE ACTION REQUIREMENTS

8.2.1 Quality Problems

Quality problems and items, services, and processes that do not meet established requirements shall be identified, documented, reported, controlled, and corrected. Quality problems may be identified by ORP or by an external source.

8.2.2 Problem Identification

All personnel shall be responsible for identifying quality problems and shall be encouraged by management to suggest improvements. ORP fosters a “no-fault” attitude for quality problems, and prioritizes and focuses resources on preventive actions and on those quality problems that have the greatest potential for:

- A. Posing adverse risks to the environment and human health
- B. Adversely impacting the quality, safety, and reliability of operations
- C. Affecting the ability to meet quality requirements.

8.2.3 Quality Improvement

Quality improvement is an ORP management process carried out to improve items, services, products, or processes through review of item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement. All aspects of work that affect quality and the management system are subject to continuous improvement through assessment and feedback processes. Quality improvement integrates the following basic elements into the ORP QA Program corrective action process:

- A. Identification and documentation
- B. Classification
- C. Causal analysis
- D. Corrections
- E. Followup.

8.2.4 Identifying Conditions Adverse to Quality

A CAQ occurs when a requirement has not been met. This includes failures, malfunctions, deficiencies, defective items, and nonconformances.

8.2.4.1 Conditions Adverse to Quality

- A. CAQs shall be documented and reported to the appropriate levels of management responsible for the condition.

- B. Responsible management shall determine the extent and impact of the adverse condition and, at a minimum, complete remedial action as soon as practical.

8.2.4.2 Documenting and Tracking Conditions Adverse to Quality

- A. CAQs within ORP, and CAQs found during the external ORP assessment and audit process, are documented on an issue report in the ORP IMS. The ORP IMS supports the cognizant manager's ability to monitor the corrective action status. Managers are responsible for implementing this aspect of the quality improvement process in their areas of responsibility.
- B. CAQs, including SCAQs, shall be investigated, documented (including the extent of the condition, the impact on completed and/or related items and activities, action to preclude recurrence, and the causal factors), and reported to the manager responsible for the condition as well as their senior management. The QAD Director shall evaluate SCAQs for consideration of suspending work.

Note: ORP utilizes a graded approach in characterizing the significance of CAQs. These are documented as Priority Level 1, 2, and 3 issues. Where Priority Level 1 issues equate to SCAQs, and Priority Level 2 and 3 issues equate to CAQs. A Priority Level 3 issue is a minor issue identifying noncompliance with a procedure or requirement in a process, program, system, or management structure. A minor issue is an isolated occurrence (one or two instances) with no impact on worker health and safety, the public, the environment, facility operations, or regulatory compliance, and requires only remedial action. However, if left uncorrected, the condition could deteriorate into a condition meeting the criteria for Priority Level 1 or 2 issues, whereas Priority Level 2 issues require corrective action plans (CAP) that include the elements described in Section 8.2.4.3.

8.2.4.3 Corrective Action Planning

The action(s) necessary to correct issues shall be determined and implemented. CAPs or other corrective actions as required by procedure or directed by the ORP Manager are required for all Priority Level 1 and 2 issues.

- A. The analysis to determine the action(s) to be taken to prevent recurrence of Priority Level 2 issues may include studies, simulations, investigations, experimentation, trending, and interviewing personnel. The analysis shall be documented in a CAP and include:
 1. Remedial action: Actions necessary to resolve the initial problem.
 2. Identification of preventive action to be taken.
 3. A determination of the generic implications.
 4. A determination that action taken will preclude recurrence.
 5. A determination of the apparent cause.
- B. For Priority Level 1 issues the analysis shall be documented in a CAP and include:
 1. Remedial action: Actions necessary to resolve the initial problem.
 2. Identification of preventive action to be taken.
 3. A determination of the generic implications.
 4. A determination that action taken will preclude recurrence.

5. A determination of the root cause.
6. Schedule: Milestones for completion of the CAP, including expected completion dates for each step and identification of responsible individuals.

8.2.4.4 Corrective Action Followup

As required by procedure or as directed by the ORP Manager, the implementation of corrective actions for Priority Level 1 and 2 issues shall be verified. Additionally, Priority Level 1 issues shall be assessed to determine effectiveness. Corrective action status shall be monitored. Corrective actions shall be verified as complete only when the actions to correct the Priority Level 1 and 2 issues, including, where appropriate, the actions to prevent recurrence, are complete and documented. When completion of corrective action cannot be verified due to a delay for an extended period of time, notification of the delay shall be made to management of the affected organizations.

After verification of completion of corrective actions, followup reviews, surveillance, or audits shall be performed for Priority Level 1 and selected Priority Level 2 issues to determine whether actions taken have been and continue to be effective. When corrective actions have not been effective, further analysis shall be performed to identify and correct the cause. In addition, the problem shall receive escalated management attention.

8.2.4.5 Trending

The need for quality improvement is identified through quality analysis and trending. To provide reliable trending information, the following activities shall be performed:

- A. Quality performance data shall be identified, collected, and routinely analyzed to identify opportunities to improve items, services, activities, and processes. This analysis shall consider information from external sources and not be limited to one type of work or to one organization.
- B. The analyses shall be performed semiannually to provide for prompt identification of trends adverse to quality. Reports of issues, including those identified during QA audits or assessments, shall be evaluated to identify adverse quality trends and causes, with results reported to the organization responsible for the corrective actions.
- C. Trending information shall be reported to responsible management and to the applicable organization. Lessons learned reports for use in program improvement shall be issued as required by the Lessons Learned Program. Adverse trends shall be documented in an issue report.

8.2.4.6 Corrective Action Management Program Headquarters Managed Issues

TRS-ISS-IP-02, *Issue Reporting and Resolution*, describes the process for resolving issues arising from:

- A. Findings identified by the Office of Health, Safety, and Security (DOE O 227.1, *Independent Oversight Program*)
- B. Judgments of need identified by Type A and Type B accident investigations (DOE O 225.1B, *Accident Investigations*)

- C. Other sources as directed by the Secretary or Deputy Secretary, including cross-cutting safety issues.

These issues shall be documented as issues and the identification, resolution, tracking, and closure of these issues shall be performed in accordance with TRS-ISS-IP-02.

8.3 SUSPECT AND COUNTERFEIT ITEMS

ORP has developed and implemented an S/CI prevention process as part of ORP's QA Program. The QA Program (and procedures, desk instructions, plans, and/or guides) meets the requirements of DOE O 414.1D, Attachment 3, and establishes, documents, and implements effective controls and processes that ensures items and services meet specified requirements; prevents entry of S/CIs into the DOE supply chain; and ensures detection, control, reporting, and disposition of S/CIs.

The ORP S/CI Program addresses the following attributes of an effective S/CI program:

- A. An oversight and prevention process commensurate with the facility/activity hazards and mission impact.
- B. Identity of the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.
- C. A training program that provides for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).
- D. A process to prevent introduction of S/CIs into DOE work by:
 - 1. Engineering involvement:
 - a. In the development of procurement specifications.
 - b. During inspection and testing.
 - c. When maintaining, replacing, or modifying equipment.
 - 2. Identifying and placing technical and QA requirements in procurement specifications.
 - 3. Accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices.
 - 4. Inspecting inventory and storage areas to identify, control, and disposition S/CIs.
- E. Includes processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards. Also, address the use of supporting engineering evaluations for acceptance of installed S/CIs, as well as marking to prevent future reuse.
- F. Provides for the conduct of engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the environment, the public, and workers, along with a cost/benefit impact, and a schedule for replacement (if required).
- G. Performance of evaluations to determine whether S/CIs installed in nonsafety applications pose potential safety hazards or may remain in place.

- H. Reporting to the DOE Inspector General in accordance with paragraph L (below) and DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*.
- I. Collection, maintenance, dissemination, and use of the most accurate, up-to-date information on S/CIs and suppliers. Sources are identified on the DOE S/CI Web site (<http://www.hss.energy.gov/csa/csp/sci/>).
- J. Conduct of a trend analyses for use in improving the S/CI prevention process.
- K. Review of existing lessons learned reports and submittal of new lessons learned reports for use in improving the S/CI prevention process as required by DOE O 210.2A, *DOE Corporate Operating Experience Program*.
- L. Requirement to contact the DOE Inspector General, before destroying or disposing of S/CIs and corresponding documentation, to allow the Inspector General to determine whether the items and documentation need to be retained for criminal investigation or litigation.
- M. Requirement to report S/CIs in accordance with DOE O 232.2, *Occurrence Reporting and Processing of Operations Information*.

8.4 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described in above. No additional requirements are identified.

9.0 RECORDS

9.1 DESCRIPTION

Managers are responsible for and must ensure records are maintained in accordance with approved procedures, desk instructions, plans, and/or guides. ORP procedures identify which documents are to be retained as records.

Quality records are specified as prepared, reviewed, and approved in accordance with approved procedures, and stored and maintained in a manner that preserves their integrity and allows retrieval.

ORP identifies documents designated to become records and assigns retention schedules in accordance with the schedules published by the DOE Chief Information Officer (CIO). The CIO schedules address National Archives and Records Administration, ASME NQA-1, and QARD requirements.

ORP maintains and disposes of records in accordance with National Archives and Records Administration-approved records disposition schedules, as posted on the DOE Office of the Chief Information Officer Records Management Web pages (<http://energy.gov/cio/office-chief-information-officer/services/guidance/records-management>).

When documents become records, ORP turns them over to the Mission Support Contractor (MSC) for indexing, storing, retaining, safeguarding, retrieving, and disposing. They remain accessible to ORP through Integrated Document Management System. ORP conducts oversight activities to ensure the requirements of this chapter are satisfied.

9.2 RECORD REQUIREMENTS

The records system shall provide for the following requirements:

- A. A “record” is an authenticated document (i.e., stamped, initialed, or signed and dated) that provides documented evidence that items or activities meet specified quality requirements.
- B. Records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Records shall be controlled in accordance with the following requirements and with the requirements of DOE O 243.1B, *Records Management Program*.

9.2.1 Records System

- A. A records system shall be established as prescribed by laws, regulations, directives, and processes, and shall reflect adequate and proper documentation of ORP’s organizations, missions, functions, policies, and decisions by ORP organizations at the earliest practical time, consistent with the schedule for accomplishing work activities. The records system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation and include the maintenance of up-to-date inventories, file plans, or electronic information systems that provide for the identification, location, and retrieval of all categories of records created and received in the course of official business.
- B. As part of ORP indoctrination and training, ORP will provide mandatory records management training, including the management of electronic and vital records, for all Federal personnel, as appropriate for their responsibilities. Such training will include records

management training for all new employees (within 30 days of appointment) and an annual refresher course.

- C. ORP will preserve records beyond their approved retention periods when they have been placed under a destruction moratorium for purposes of audits, litigation, *Freedom of Information Act* appeals, and similar obligations. Only the Departmental Records Officer, in coordination with the DOE/National Nuclear Security Administration Office of General Counsel or Office of Chief Counsel, shall lift this destruction moratorium.

9.2.2 Generating Records

The records system shall provide for the generation of records according to the following requirements:

- A. Prior to conducting a work activity, the responsible ORP organization(s) shall identify, in the applicable specifications, procurement documents, and procedures, those documents that shall become records and the organization responsible for submitting the records to the records system.
- B. Records shall be legible, accurate, traceable to associated items and activities, and completed appropriately for the work accomplished.
- C. Records to be generated, supplied, or maintained shall be specified in documents such as design specifications, procurement documents, plans, instructions, and procedures.
- D. Individuals handling documents intended to become records shall provide the records reasonable protection from damage or loss until the records are submitted to the records system (this includes documents generated during field operations). Documents shall be considered valid QA records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated. Statements of authenticity, handwritten signatures, electronic signatures, or any other means that ensures traceability to a specific individual or organization shall be used as acceptable methods for authentication. When initials are used, a system shall be implemented that ensures traceability to the authenticating individual or organization. If the nature of the record (e.g., magnetic or optical media) precludes stamping or signing of copies, or original records are unable to be authenticated due to contamination or loss of the original, then other means of authentication by authorized personnel are required. This authentication represents a certification as to the content of the record by those individuals with knowledge of the related facts, whether by direct personal knowledge or through the direct reports of others, and provides traceability to a specific individual or organization providing the authentication. For non-QA records, authentication may also be accomplished through supplemental attachments, logs, acceptance sheets, electronic system logons, execution of established business processes that reflect normal routine disciplined processes or workflows, and corroboration or affirmation from supporting documents or related records. The authentication of QA and non-QA records shall not be confused with any subsequent reviews of the content.
- E. If authentication is accomplished through initials or codes assigned to individuals, then a system shall be established to ensure traceability to the authenticating individual or organization.
- F. Once authenticated, records shall be submitted to the records system as prescribed by approved procedures. Upon completion of a project or other discrete task or activity,

responsible management shall verify the contents of the applicable records package are stored in the records system.

- G. Records may be originals or reproducible copies unless otherwise required, provided a method for authentication of reproducible copies is established.

9.2.3 Indexing Records

The records system shall provide for the indexing of records according to the following requirements:

- A. The MSC has the responsibility of indexing and maintaining records, in accordance with their procedures.
- B. The indexing system shall include, at a minimum, summary information for the record, the associated item or activity, title or description, originating individual or organization, record retention period, the location of the record within the records system, identification of the item or related activity to which the record pertains, and the media used for retention. These and other features of the records system shall facilitate the disposition of scheduled records and ensure the retrievability within planned retrieval times based upon the record type or content of any records entered. For nonpermanent records, the period of retention shall be defined.

9.2.4 Classifying Records

The records system shall provide for the classification of records according to the following requirements:

- A. Records shall be classified as QA or non-QA records. QA records shall be further classified as either “lifetime” or “nonpermanent.”
- B. QA records falling into one or more of the following categories shall be classified as lifetime records:
 - 1. QA records of significant value in demonstrating capability of safe operation of facilities or in determining the cause of an accident or a malfunction of an item in a facility.
 - 2. QA records of significant value in maintaining, reworking, repairing, replacing, or modifying SSCs.
 - 3. QA records of computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual tests and data analyses.
 - 4. QA records relating to site characterization samples and data.
 - 5. QA records that provide baseline data for in-service inspection.
 - 6. QA records documenting regulatory compliance.
- C. Lifetime QA records are required to be retained and preserved in an acceptable condition for the operating life of the item or SSC while it is installed in the facility or stored for future use.
- D. QA records that provide objective evidence that the QA program has been properly implemented or provide evidence that an activity was performed in accordance with the

applicable requirements, but that do not meet the above criteria for lifetime records shall be classified as nonpermanent QA records. The retention period for nonpermanent QA records shall be established in writing.

Note: Record retention periods are specified in the records retention schedules published by the DOE CIO.

- E. Nonpermanent QA records are those required to show evidence that an activity was performed in accordance with applicable requirements, but need not be retained for the life of the item, because they do not meet the criteria for lifetime QA records.

9.2.5 Receiving Records

Each organization responsible for the receipt of records shall designate the person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of controls for the receipt of records for permanent and temporary storage. Receipt controls shall provide a method for identifying the record received, receipt and inspection of incoming records, and submittal of records to storage. The MSC receives ORP records in accordance with their procedures. ORP conducts oversight activities to ensure requirements are satisfied. At a minimum, the receipt control system shall include:

- A. Provisions to permit a current and accurate assessment of the status of records.
- B. Method for identifying the records required to be included in the records system.
- C. Method for identifying the records that have been received.
- D. Procedures for the receipt and inspection of incoming records, including verification the records received are in agreement with the transmittal document and the records are legible.
- E. Provisions to control and protect the records from damage or loss during the receiving processes.
- F. Method for submitting completed records to the storage facility without unnecessary delay.

9.2.6 Storage, Preservation, Safekeeping, and Disposition of Records

The MSC stores and maintains ORP records in accordance with its procedures. ORP conducts oversight activities to ensure the records system provides for the storage, safekeeping, and disposition of records according to the following requirements.

- A. Records shall be stored and preserved in predetermined locations in facilities, containers, or combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction in accordance with approved procedures, desk instructions, plans, and/or guides that provide:
 1. Description of the storage facility, containers, or the combination thereof.
 2. Description of the filing and indexing systems used to ensure records are retrievable.
 3. Description of the controls for verifying the records received are in agreement with the transmittal document, are the records designated for the activity, and the records are legible.

4. Description of the controls governing records access, retrieval, and removal, including limiting access to authorized personnel to the records processing, storage, and retrieval areas.
 5. Method for maintaining control of and accountability for records removed from the storage facility, the filing of supplemental information, and the disposal of superseded records.
 6. Prohibition of activities in the storage area that would be detrimental to the records.
- B. The records storage arrangements shall provide adequate protection of records, including special processed records (e.g., radiographs, photographs, negatives, microfilm, magnetic media, optical media) to preclude damage, loss, destruction, or degradation of electronic record media from:
1. Natural disasters such as winds, floods, or fires.
 2. Environmental conditions such as high and low temperatures and humidity, including excessive light, stacking, or electromagnet fields, as appropriate for the type of record being stored.
 3. Infestation of insects, mold, or rodents.
 4. Dust or airborne particles.
- C. Records that require special processing and control, such as software and related documentation, electronic record media, information on high-density media, and optical media, shall remain retrievable after the hardware, software, or technology changes. The hardware and software required to maintain and access these records shall be controlled to ensure the records are useable.
- D. Records that are duplicated or transferred to the same electronic media or to a different electronic media for the purposes of maintenance or storage shall require that the duplication or transfer is authorized and that the record content, legibility, and retrievability are maintained.
- E. A single storage facility is defined as a facility, vault, room, or container that has, at a minimum, a 2-hour fire rating.
- F. When a single facility, container, or combination thereof is not capable of providing the protection required above, a dual facility, container, or combination thereof shall be provided for records storage.
- G. When a single storage facility or container is used to store records, the storage facility, file room, vault, or record protection containers shall meet the applicable requirements of NFPA 232, "Standard for the Protection of Records." When file rooms are used, a forced air circulation system may be used, provided the system is dampered in accordance with the room rating.
- H. The design and construction details for single storage facilities, vault room, or container shall be reviewed by a person who is competent in the technical field of fire protection and fire extinguishing (or has a certification or rating from an accredited organization) to determine the adequacy of protection of contents. If the facility is located within a building or structure,

the environment and construction of that building can provide a portion or all of these criteria.

- I. If storage at dual facilities for each record is provided, the facilities, containers, or combination thereof shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard based upon the type of hazard, such as earthquakes, fires, or tornadoes, and their probability of occurrence. Each facility is not required to satisfy the requirements of items E through H above, but shall meet all other records storage requirements prescribed in this QAPD.
- J. When temporary storage of records (e.g., for processing, review, or use) is required by an organization's procedures, the storage facility or container shall include a 1-hour fire rating unless dual storage requirements are followed. The procedures shall specify the storage methods and storage duration (i.e., the maximum allowable time limit for temporary storage).
- K. Access to storage facilities shall be controlled. A list designating personnel who are permitted access to the records shall be maintained and posted. Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against theft and vandalism.
- L. Preservation and safekeeping of records shall include consideration of the following criteria when establishing the program:
 - 1. Placement of records in binders, folders, or envelopes for storage in steel file cabinets or on shelving.
 - 2. Manufacturer's recommendations on storage.
 - 3. Measures for replacement, restoration, or substitution of lost or damaged records.
 - 4. Inspections of records to detect deterioration.

9.2.6.1 Records Disposition

The MSC conducts ORP records disposition activities in accordance with its procedures. ORP conducts oversight activities to ensure the requirements in this section are satisfied.

- A. The records system shall provide for records disposition according to the following requirements:
 - 1. The retention periods for records shall be documented and the records retained for the established retention periods.
 - 2. The records system shall ensure records are retrievable through their life cycle.
 - 3. Lifetime QA records are required to be maintained for the life of the project.
 - 4. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.
- B. Records shall not be destroyed until the following conditions are met:
 - 1. Appropriately assigned National Archives and Records Administration-authorized disposition specifies destruction.
 - 2. Regulatory requirements are satisfied.

3. Operational status permits the disposal of such records.
4. Related contractual requirements have been satisfied.

9.2.7 Correcting Information in Records

The records system shall provide for the correction of records according to the following requirements:

- A. Shall be documented and include the initials or signature of the authorized person making the correction and the date the correction was made.
- B. Shall be reviewed and approved by a responsible individual from the originating or authorized organization.
- C. Shall be made using a single line through and shall not obliterate the prior entry. Records shall not be corrected with correction fluids or tapes.

9.3 ELECTRONIC RECORDS

- A. ORP shall develop and implement procedures and processes for electronic records that:
 1. Prevent unauthorized addition, modification, or deletion.
 2. Protect the records against power interruptions.
 3. Provide a secure audit trail to enable addition, modification, or deletion of records and retrieval activities.
 4. Prevent deletion of a record identifier once it is defined.
 5. Prevent deletion of indexes, categories, labeling, or other records identification.
 6. Retain records in an accessible and usable format until the authorized disposition date.
 7. Provide adequate recovery and rebuild procedures so that records may be restored following a system or storage media malfunction.
 8. Maintain the integrity of redacted records and assure that redacted material is not accessible by unauthorized persons.
- B. Electronic records include electronic data, email, and records resulting from the conversion from one media type to another.
- C. Electronic data designated to be records shall be traceable to the associated items or activities by developing a naming scheme for both the electronic data itself and for the media (e.g., file folders, compact discs) that is used to store the electronic data.

Electronic databases may be used to create and/or maintain electronic records, including electronic data. Controls shall be in place to ensure that the database record content, context, and structure are maintained. The database record content may contain, but is not limited to, electronic data, an image in a not easily alterable format (e.g., tif, pdf), or an electronic address of the location where the image is stored. The database context is considered to be information about the internal structure of the database tables. The database structure is information about the table relationships.

- D. Electronic records are maintained in accordance with 36 CFR Subchapter B, "Records Management," by building electronic recordkeeping functionality into the native electronic

information system or by capturing the electronic information system's records in an electronic records management application. The use of any records management system that meets the functional requirements of DOD 5015.2-STD, *Electronic Records Management Software Applications Design Criteria Standard*, satisfies this requirement.

- E. Email used as a quality record shall utilize the controls provided in this section, and meet the following:
1. Email records shall be managed along with their metadata (including name of the sender and all addressees, date the message was sent and/or time of receipt) and attachments by means of an electronic information system that has electronic records keeping functionality, or an electronic records management application. The records may not be deleted from the email system until the records management application or electronic information system electronic recordkeeping functionality has been implemented, the records' authorized retention period has elapsed, or the records have been copied to paper or microform or some other suitable media. Transitory records (i.e., records that may be destroyed in 180 days or less) may be managed in their native email system.
 2. Email must be traceable to the subject of the record, the originator, and the date of origination.
 3. The information contained in the email is acceptable as a record, provided that the email system prevents unauthorized alterations or changes.
 4. Corrections to email must be processed in the same manner as the original.
- F. Conversion of a record from one media type to another shall include verification to ensure content, context, and structure are maintained, as follows:
1. The conversion process includes conversion from various media forms, including hardcopy, photographic, optical, and magnetic.
 2. The conversion process may involve scanning the original hardcopy record to create an image in a not easily altered format (e.g., tif, pdf).
 3. Verification shall include reviews of the page, paragraph, and individual record configuration to ensure the converted information adequately represents the original document. This also applies to the situation where an electronic record is the original.
 4. When the conversion involves an electronic migration, a statistically valid sample set shall be selected for verification purposes. Any recognized sampling standard that provides requirements for inspection and acceptance sample size may be used as a basis for the development of a sample set verification plan. To prevent data corruption or loss during the conversion process, any changes to the database context or structure shall be approved.

9.3.1 Authentication of Electronic Records

- A. Provisions for the authentication of electronic records shall provide for the use of automated systems for the identification and signature recognition of the personnel performing the record authentication, as follows:
1. An electronic signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to represent the individual's handwritten signature.
 2. If electronic codes or user account information (e.g., username and password) is used for identification, controls shall be established to ensure traceability to the authenticating individual or organization.
 3. Consideration shall be given to periodically requiring that new user passwords be established.
 4. Methods for authenticating electronic records shall be reliable and generally equivalent to paper records with handwritten signatures.
 5. Electronic signatures that are not based on biometrics shall employ at least two distinct verification components such as user identification and password.
 6. Electronic signatures based upon biometrics shall be controlled to ensure they cannot be used by anyone other than the legitimate owners.
 7. The integrity of the records in the new system or media shall be verified.
 8. A "not easily alterable" format shall be used to ensure the content, context, and structure is maintained consistent with the original record copy.
 9. If use of a "not easily alterable" format is not practical, controls shall exist to provide an equivalent level of control.
 10. When a record is converted to electronic media, the authentication of that record does not need to be performed again.

9.3.2 Indexing of Electronic Records

Electronic records shall be indexed by ORP to provide for timely retrieval of the records as follows:

1. ORP shall develop and document external and/or internal indexing methods for the index system(s).
2. External indexing includes labeling records stored on external offline media.
3. External labeling shall be developed and attached to the media used.
4. Internal indexing of electronic records shall enable the user to identify and access a specific record by using a table of contents, directory, key word, or other index strategy.
5. The index may be automatically created by the system or the originator may generate it.
6. When the originator creates the index, provisions are established to ensure all indices are identified using a common naming convention.

9.3.3 Storage of Electronic Records

- A. Storage of electronic records requires both media and compatible processing systems. The media containing the electronic records and the compatible processing systems access shall translate the records into an appropriate retrievable, legible format and meet the following:
1. The types of media used for electronic record storage shall be identified in the records management program. The selection of the storage media shall consider the manufacturers' recommended shelf life and take into account that the degradation of electronic media starts immediately after manufacture.
 2. Electronic records shall be migrated onto new media before the manufacturer's recommended useful life is exceeded.
 3. Two sets of electronic records shall be maintained to ensure timely recovery in the event they are damaged or lost. These sets may be established in processing systems installed on separate servers, standalone computer platforms, or in a removable media format (e.g., optical disk, floppy disk).
- B. The level of user access and the security of the compatible processing systems may also impact the required controls for the storage of electronic records. Controls for remote access, local access, and secure processing systems shall be established to prevent the alteration, damage, or loss of electronic records. Remote access systems are systems that store records on a network server, which are accessible to multiple users through a network or Internet hub. Local access systems are systems that store records on a local area network server that is accessible only to local users. Secure processing systems are standalone processing systems that are not accessible through a local area network or Internet hub.
- C. Storage procedures for remote and local access systems shall include security measures such as user passwords, network firewalls, file encryption, and virus protection. Appropriate environmental controls shall be established for each type of electronic media to prevent damage to electronic media from environmental conditions such as light, heat, humidity, or electromagnetic fields. Recommendations from the media manufacturer shall be considered in establishing environmental controls.
- D. Storage procedures shall consider the control of the record media, and only release copies of the electronic records to requestors. All electronic processing systems shall also have power isolation devices to minimize the risk of damage from voltage surges, spikes, and other power line disturbances. If temporary storage for electronic records is used, two sets of in-process records shall be maintained because the electronic media may be exposed to computer viruses and inadvertent alteration.

9.3.4 Disposal of Electronic Records

Electronic records designated for disposal shall be erased or overwritten because using the delete function may not actually delete the record, but only make it irretrievable for one using the standard access methods. Physical destruction of the storage media or device may be used as an acceptable alternative. Storage media previously used for electronic records containing sensitive or proprietary information shall not be reused.

9.3.5 Maintenance of Electronic Records

- A. Lifetime electronic records shall be reviewed periodically for legibility through the ORP audit process. This review shall also confirm the accessibility and retrievability of the record, thus providing assurance that compatible software and hardware systems are available. Media intended for storage of electronic records shall be tested prior to use to ensure it is free of errors, defects, and corruption.
- B. Electronic records shall be protected against technological obsolescence by:
 - 1. Planning and budgeting for migration to a new system before the current system is retired and ensuring the migration strategy addresses inactive electronic records stored offline.
 - 2. Retaining functionality and integrity of electronic records during upgrades of hardware and software to retain a usable format, ensure compatibility with current hardware and software, and preserve links between records and corresponding metadata.
 - 3. Decommissioning and migration of systems shall not be completed until records disposition has been completed. See DOE O 150.1, *Continuity Programs*.

9.4 RECORDS PROCESSES INTERNAL EVALUATIONS

ORP conducts internal evaluations of records management practices and programs, including assessing the economy of the operation, at least every 3 years in accordance with Chapter 10.0.

9.5 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described above.

9.5.1 Quality Assurance Records

9.5.1.1 Creating Valid Quality Assurance Records

Handwritten signatures shall not be required if the document is clearly identified as a statement of the reporting individual or organization.

- A. Lifetime QA records shall be retained and maintained until permanent closure. Lifetime QA records include those directly related to waste form or other items that will be supplied to Office of Civilian Radioactive Waste Management (e.g., the standard canister). These records shall be transferred to the DOE office responsible for high level waste repository.
- B. QA records shall be classified as lifetime as follows:
 - 1. Documents that provide evidence of the quality of items on the waste affecting items list items/activities list.
 - 2. Documents that provide evidence of the quality of activities related to items on an items/activities list.
 - 3. Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials.
 - 4. Documents that provide evidence of the quality of the production process for the HLW form and acceptance of the HLW form product.

5. Personnel training and qualification documents for individuals executing QA program requirements.

9.5.1.2 Storing and Preserving Quality Assurance Records

The MSC stores and preserves ORP records in accordance with its procedures. ORP conducts oversight activities to ensure the following requirements are satisfied:

- A. QA records shall be stored and preserved in predetermined storage facilities that meet the requirements of applicable standards, codes, and regulatory agencies in accordance with an approved implementing document that provides:
 1. A description of the storage facility.
 2. A description of the filing system to be used.
 3. A method for verifying that the QA records received are in agreement with the transmittal document and that the records are legible.
 4. A description of controls governing QA record access, retrieval, and removal.
 5. A method for filing supplemental information.
 6. A method for disposition of superseded QA records.
- B. Storage methods shall be developed to preclude deterioration of QA records in accordance with the following:
 1. Approved filing methods shall require QA records to be firmly attached in binders or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the QA record medium being stored.
 2. The storage arrangement shall provide adequate protection of special processed QA records (i.e., radiographs, photographs, negatives, microform, and electronic and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored.

9.5.1.3 Correcting Information in Quality Assurance Records

If the organization responsible for generating the record is no longer available, a new responsible organization shall be identified and documented as such.

9.5.1.4 Retention of Quality Assurance Records

The MSC conducts ORP records disposition activities in accordance with its procedures. Retention periods are specified in the retention schedules published by the DOE CIO. These schedules satisfy QARD requirements. ORP conducts oversight activities to ensure the following requirements are satisfied:

- A. Lifetime QA records shall be retained and maintained until permanent closure. Lifetime QA records are those that meet one or more of the following criteria:
 1. Those that would be of significant value in demonstrating capability for safe operation.
 2. Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.

3. Those that would be of significant value in determining the cause of an accident or malfunction of an item.
 4. Those that provide required baseline data for in-service inspection.
- B. Nonpermanent QA records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not meet the criteria for lifetime QA records.
1. Nonpermanent QA records shall be retained until the issuance of a license to receive and possess SNF/HLW. At a minimum, nonpermanent QA records shall be retained for 10 years or the life of the item if less than 10 years.
 2. For programmatic nonpermanent QA records, the retention period shall be considered to begin on completion of the activity.
 3. For product nonpermanent QA records, the retention period shall be considered to commence upon completion of delivery.
- C. Records retained by suppliers shall be retained in accordance with procurement document requirements. Records shall be made available upon request, as required by the QARD.

9.5.1.5 Turnover of Quality Assurance Records

- A. Suppliers shall submit those QA records being temporarily stored by the supplier that are subject to records turnover requirements. The timing of the submittal shall be as records packages become complete, as items are released for shipment, or as prescribed by the purchaser.
- B. The records management organization shall inventory the submittal, acknowledge receipt, and process the QA records.
- C. The responsible line organizations shall identify those QA records in temporary storage to be submitted for long-term storage to the records management system in accordance with QARD Subsections 17.2.10 or 17.2.11.

9.5.1.6 Temporary Storage Facility

The MSC stores and preserves ORP records in accordance with MSC's procedures. ORP conducts oversight activities to ensure the following requirements are satisfied:

- A. Temporary storage shall provide for the storage of QA records during processing, review, or use until turnover under the QARD for disposition according to the following requirements:
1. ASME NQA-1a-1983, Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records."
 - a. This supplement addresses the requirements and recommendations for the storage of records that are determined to be QA records, but it does not include a provision for the temporary storage of QA records. The following requirements shall apply to the temporary storage of QA records:
 - QA records shall be temporarily stored in a container or facility with a 1-hour fire rating or dual storage shall be provided.

- Single storage containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection.
 - The period of time allowed for records to be in temporary storage will be specified in appropriate procedures.
- b. QARD, Subsection 4.4.2—An alternate facility will not be used.
 - c. QARD, Section 5—The records retrieval system is not configured in such a manner as to provide retrieval times based on the type of record. The retrieval times for all record types are the same regardless of record type.
 - d. QARD, Section 6—Specifies certain conditions and events prior to which supplier's nonpermanent records shall not be disposed of. In addition to these requirements, the requirements specified in QARD, Subsection 17.2.8B shall be implemented.

9.5.1.7 Long-Term Single Storage Facility

A. Single storage facilities for the storage of QA records shall meet the following design and construction requirements:

1. Reinforced concrete, concrete block, masonry, or equivalent construction.
2. Drainage control for the floor and roof. If a floor drain is provided, a check valve or equivalent shall be included.
3. Minimum 2-hour fire-rated structure, doors, frames, and hardware.
4. Sealant applied over walls as a moisture or condensation barrier.
5. Surface sealant on the floor providing a hard-wearing surface to minimize concrete dusting.
6. Foundation sealant and provisions for drainage.
7. Forced air circulation with a filter system.
8. A fire protection system.
9. Penetrations limited to fire protection, communication, lighting, and temperature and humidity controls.
10. Seal or damper penetrations to meet 2-hour fire protection rating.

9.5.1.8 Control of the Electronic Management of Information

The MSC maintains ORP electronic records and supporting systems in accordance with its procedures. ORP conducts oversight activities to ensure the following requirements are satisfied:

A. Controls shall be established to ensure:

1. Information is suitably protected from damage and destruction during its prescribed lifetime and is readily retrievable.
2. A description is prepared of how information will be stored with respect to media, conditions, location, retention time, security, and access.

3. Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).
4. The completeness and accuracy of the information input and any subsequent changes to the information are maintained.
5. The security and integrity of the information is maintained.
6. Transfers of information are error free or (where applicable) within a defined permissible error rate, to ensure no information is lost in transfer and the input is recoverable from the output. Examples of information transfers include copying raw information from a notebook to a computerized form, copying from computer tape to disk, and writing to a compact disk.

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10.0 INDEPENDENT ASME NQA-1 AUDITS AND SURVEILLANCES

10.1 DESCRIPTION

ORP QAD plans and conducts ASME NQA-1-based independent audits and surveillances to measure item and service quality, to measure the adequacy of work performance, and to promote improvement within ORP and its contractors.

ORP audits are conducted in accordance with ASME NQA-1-2008 with addenda through 2009.

10.2 AUDITS

- A. Audits evaluate the performance of work processes with regard to requirements, compliance, and expectation for safely performing the work and achieving the goals of the organization. The audit is performed to verify compliance with QA program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. The focus of audits shall be on the items and services produced and their associated processes. The purpose is to improve the product/service performance and process effectiveness. An independent audit is one performed by individuals within the organization or company who work independently of the work or process being evaluated, or by individuals from an external organization or company. Thus, management receives an objective view of the audited activity.
- B. Assessments performed by ORP organizations other than the ORP QAD are led by qualified lead assessors and performed in accordance with Chapter 11.0.
- C. Auditors and lead auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits and to ensure they meet auditor qualification requirements of Chapter 3.0, Section 3.5.3.
- D. Independent audits (both external and internal) performed by the ORP QAD are led by qualified ASME NQA-1 lead auditors and performed by auditors certified in accordance with the requirements of Chapter 3.0, Section 3.5.3.
- E. ORP may elect to use individuals that are knowledgeable in the area being audited but not qualified as auditors in accordance with the requirements of this QAPD to perform audits through the use of a limited certification process. Limited certifications will be documented and maintained as described in procedures or desk instructions.

10.2.1 Audit Team Selection and Scheduling

ORP management selects qualified teams of personnel to conduct cross-cutting audits of selected functional areas within ORP and ORP contractors to determine whether opportunities for improvement exist. Individuals who are independent from performing or supervising the work being assessed, and who are technically qualified and knowledgeable in the areas to be assessed, conduct the independent audits. These individuals shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

The ORP Manager has overall responsibility for ensuring effective audits are conducted by ORP. The QAD assists the ORP Manager in this responsibility. The audit team leader is responsible for planning and executing an audit.

- A. Audits shall be scheduled by ORP management in accordance with the following:
1. Internal audits of organizations and facility activities, conducted prior to placing the facility in operation, shall be performed at least once each year or at least once during the life of the activity, whichever is shorter for each functional area and shall address all applicable QA program elements.
 2. Internal audits of activities, conducted after placing the facility in operation, shall be performed within a period of 2 years of all applicable QA program elements for each functional area (e.g., engineering, procurement, operations, and maintenance).
 3. Internal audit frequencies of well-established activities, conducted after placing the facility in operation, may be extended 1 year at a time beyond the above 2-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation shall include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency interval shall not exceed a maximum of 3 years.
 4. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval shall be rescinded and an audit scheduled as soon as practicable.
- B. AMs recommend to the ORP Manager potential areas or activities that could benefit from these types of audits. The ORP Manager ensures that audits are scheduled and tracked. AMs schedule any AM-specific independent audits.

10.2.2 Documentation of Results

- A. The results of each internal audit are presented to management and ORP corrective actions are processed in accordance with the requirements of Chapter 8.0.
- B. The results of each audit of ORP contractors are presented to ORP management and the management of the organization assessed and the results and findings are processed in accordance with the requirements of the procedures that governed that activity.
- C. Audit reports and records of corrective action are processed in accordance with the requirements of Chapter 9.0.

10.3 AUDIT REQUIREMENTS

This section establishes the ORP requirements for planning, scheduling, and conducting audits. Planned and scheduled audits shall be performed by ORP to:

- A. Determine that an effective QA program has been developed, documented, and implemented
- B. Verify by examination and evaluation of objective evidence whether QA program elements, items, processes, work areas, or records, conform to specified requirements
- C. Assess the effectiveness of controls and verification activities
- D. Report deficiencies to all levels of management for implementation of corrective action
- E. Verify that corrective action has been planned, initiated, and completed.

10.4 SCHEDULING AUDITS

The audit system shall provide for the scheduling of audits according to the following requirements:

- A. Audits shall be scheduled to begin as early in the life of a project or activity as practicable, and continue at intervals consistent with the schedule for accomplishing the work and commensurate with assigned control level.
- B. Regularly scheduled audits may be supplemented by either additional audits or surveillances. Supplemental audits or surveillances shall be scheduled based on the following considerations:
 - 1. When significant changes are made in the functional areas of the QA program, such as significant reorganization or procedure revisions.
 - 2. When it is suspected that the quality of an item or activity is in jeopardy due to deficiencies in the QA program.
 - 3. When a systematic, independent audit of program effectiveness is considered necessary.
 - 4. When it is necessary to verify implementation of required corrective action.

10.4.1 Planning and Preparation

The organization performing the audit shall develop and document a plan for each audit that includes the following:

- A. The plan shall include the scope, requirements, purpose, audit personnel, activities to be assessed, organizations to be notified, applicable documents to be requested and reviewed, scheduled, and written procedures or checklists to be used.
- B. Audit planning shall include a review of past audit results to determine the nature of problems that have occurred. When recurring problems are found, the audit team shall review corrective actions that have been taken and attempt to determine whether the corrective actions were effective in preventing recurrence.
- C. Audit preparation and team familiarization shall include review of pertinent background information, procedures, technical documents, and type of service or product to be evaluated, including performance criteria or metrics and industry experience related to performance and effectiveness of the product. Checklists are prepared as guidance that may be expanded or condensed during the audit performance, so that audit team members are familiar with the work being audited.
- D. Audit preparation shall include evaluations of the applicable procedures and instructions for compliance with requirements.
- E. The scope shall include related corrective actions taken since the previous audit.

10.4.2 Audit Team Selection

The audit system shall provide for the selection of an audit team according to the following requirements:

- A. Audit team members shall be identified prior to the start of the audit activity. Team members shall be selected on the basis of technical qualifications and knowledge of the item or process

being assessed and shall be independent from the items or processes being assessed. Audit team members shall have sufficient authority and organizational freedom to carry out their assigned responsibilities. In the case of internal independent audits, personnel having direct responsibility for performing the activities being assessed shall not be involved in the selection of the audit team.

- B. An audit team leader shall be appointed to provide indoctrination and supervision of the team, to organize and direct the audit, and to coordinate the preparation and issuance of the audit report.
- C. Before starting the audit, the audit team leader shall ensure the assigned personnel collectively have experience and training commensurate with the scope, complexity, or special nature of the work to be audited.
- D. Technical specialists, with appropriate technical expertise or experience in the work being assessed, shall be used when assessing the adequacy of technical processes.

10.4.3 Performing Audits

Audits shall be performed according to the following requirements:

- A. Audits shall be performed using the written procedures or checklists related to the activity being assessed and include a preaudit conference and a postaudit conference with management of the audited organization.
- B. Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if those elements are being implemented effectively.
- C. Audit results shall be documented by audit personnel, reported to, and reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.
- D. For internal audits, CAQs shall be documented and corrected according to the requirements of Section 8.2.4.

10.4.4 Reporting Audit Results

Audit results shall be reported according to the following requirements:

- A. The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization and any affected organizations.
- B. The audit report shall include the following, as appropriate:
 - 1. Description of the audit scope.
 - 2. Identification of the auditors.
 - 3. Identification of persons contacted during the audit.
 - 4. Summary of audit results, including a statement of the QA program adequacy, implementation, and effectiveness, as appropriate to the scope.
 - 5. Description of each reported CAQ in sufficient detail to enable corrective action to be taken by the audited organization.

10.5 AUDIT RESPONSE AND FOLLOWUP

Management of the audited organization will investigate the CAQ, determine and schedule corrective actions, including measures to preclude recurrence, and notify the auditing organization, in writing, of the actions planned or taken. The adequacy and timeliness of audit responses shall be evaluated by the auditing organization, and followup action shall be taken to verify corrective action is accomplished as scheduled. If the audited organization disagrees with one or more of the audit CAQs, the audit response shall identify them and provide sufficient supporting information to permit resolution by ORP management.

10.6 AUDIT RECORDS

The following documents, when developed in fulfillment of the audit requirements of this QAPD, shall be controlled as QA records in accordance with Chapter 9.0:

- A. Audit plan
- B. Audit reports
- C. Audit responses
- D. Documentation of corrective action completion and followup.

10.7 ASME NQA-1 BASED INDEPENDENT SURVEILLANCES

Surveillances are highly focused reviews or observations of a narrowly defined area, such as a field observation to verify existence or closure of an issue or issues, including procedure compliance.

- A. A program of surveillance of processes or activities shall be planned, scheduled, performed, documented, and reported to appropriate management personnel. The surveillance process consists of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements.
- B. Surveillance team members shall consider what processes, activities, or conditions are important and which emphasis areas should be addressed, including regulatory impact, safety and reliability significance, experience and previous history, followup of previous concerns, and related industry experience.
- C. Surveillances use observation or monitoring techniques to provide confidence that ongoing processes and activities are adequately and effectively performed. Surveillances effectively complement audits to provide timely data on performance and to identify quality issues before they have a significant impact on safety and reliability. Surveillances shall accomplish the following:
 - 1. Monitor work in progress
 - 2. Document compliance or noncompliance with established requirements and procedures
 - 3. Identify actual and potential CAQs
 - 4. Provide notification to responsible managers of the status and performance of work under surveillance

5. Result in timely corrective action commitments from cognizant and responsible managers for identified CAQs
6. Verify timely implementation of corrective actions.

10.8 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described above.

10.8.1 Audits

10.8.1.1 Audit Scheduling

Audits shall be performed in areas where the requirements of the QARD or supplier's QA program description document are applicable. The following areas shall also be considered when scheduling audits:

- A. Preparation, review, approval, and control of early procurements
- B. Indoctrination and training programs
- C. Interface control between the ORP/contractor and suppliers
- D. Corrective action, calibration, and nonconformance control systems
- E. Documented Safety Analysis and Preliminary Documented Safety Analysis commitments
- F. Development and control of computer software supporting a safety or waste isolation function
- G. Purchase of ASME code items
- H. Audits of ASME code suppliers.

10.8.1.2 Scheduling Internal Audits

Internal audits of applicable QARD elements to verify ORP QA Program-compliance and effectiveness shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter.

10.8.1.3 Scheduling External Audits

- A. External audits (audits of ORP contractors and suppliers) shall be coordinated with responsible supplier management and scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.
- B. External audits shall be scheduled to begin as early in the life of the work as practical, to continue at intervals consistent with the schedule for accomplishing the work, and at a frequency commensurate with the status and importance of the work.

- C. External supplier audits for compliance and effectiveness shall be performed triennially or at least once during the life of the work, whichever is shorter. Audits of principal contractors, for compliance and effectiveness, shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter. Regularly scheduled external audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate audit of compliance or effectiveness (performance based):
 - 1. The audit period (triennial or annual) shall begin when the audit is performed.
 - 2. The purchaser shall perform annual external audits on suppliers or other external organizations when the supplier or external organization does not maintain a purchaser accepted audit program.
 - 3. The initial audit shall be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program that has the required scope for purchases placed during the audit period (triennial or annual).
 - 4. When a major change in the contract scope, work methodology, or organization occurs, an audit of the modified requirements shall be performed. This audit shall start a new audit period (triennial or annual).
- D. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.
- E. External audits may not be required for procured items that are relatively simple and standard in design, manufacturing, testing, and adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery. Rationale for not performing audits for these items shall be documented.
- F. Preaward surveys, if applicable, may serve as the first triennial audit, provided:
 - 1. The supplier is implementing the same QA program for other contracts that is proposed for the purchaser's contract.
 - 2. The preaward survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.

10.8.1.4 Audit Schedule

The audit schedule shall be developed annually, reviewed periodically, and revised as necessary to ensure that coverage is maintained current.

General clarification of audit scheduling is as follows:

- A. In no case will the frequency be less than once every 3 years for a site performing work under an accepted QARD-compliant QA program.

10.8.1.5 Audit Planning

The scope of each internal audit shall be based on evaluation of the impact of significant changes in personnel, organization, or the QA program.

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11.0 ASSESSMENTS

11.1 DESCRIPTION

ORP plans and conducts assessments and independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement within ORP and its contractors.

ORP assessments are conducted in accordance with DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*.

The term “assessment” as used in this section of this QAPD is an all-inclusive term that pertains to assessments and independent assessments.

11.2 ASSESSMENTS

- A. Assessments evaluate the performance of work processes with regard to requirements, compliance, and expectations for safely performing the work and achieving the goals of the organization. The focus of assessments is on the items and services produced and their associated processes. The purpose is to improve the product/service performance and process effectiveness. An independent assessment is one performed by an individual without direct responsibilities in the areas being assessed. Thus, management receives an objective view of the assessed activity.
- B. Assessments are led by qualified assessors certified per the requirements within Chapter 3.0, Section 3.5.2.
- C. Assessors have, or will be given, appropriate training or orientation to develop their competence for performing assessments and to ensure they meet assessor qualification requirements.
- D. ORP may elect to use individuals to perform assessments that are knowledgeable in the area being assessed but not qualified as assessors in accordance with the requirements of this QAPD. A limited certification process is used and will be documented and maintained as described in procedures or desk instructions.

11.2.1 Assessment Team Selection and Scheduling

- A. ORP management selects qualified assessors or teams of assessment personnel to conduct cross-cutting assessments or assessments involving selected functional areas within ORP and its contractors to determine whether opportunities for improvement exist. Assessors not responsible for the work being assessed, and who are technically qualified and knowledgeable in the areas to be assessed, perform independent assessments. Assessors will have experience or training commensurate with the scope, complexity, or special nature of the activities to be assessed. The ORP Manager has overall responsibility for ensuring effective assessments are conducted by ORP. The AMTRS, through the Safety and Health Division, assists the ORP Manager in this responsibility. The assessor is responsible for planning and executing an assessment.

- B. AMs recommend to the ORP Manager potential areas or activities that could benefit from these types of assessments. The ORP Manager ensures Level 1 and 2 assessments are scheduled and tracked in the Integrated Assessment Schedule.

11.2.2 Documentation of Results

- A. The results of each internal Level 1 and 2 assessments are presented to management, and any necessary ORP corrective actions are processed in accordance with the requirements of Chapter 8.0.
- B. The results of each Level 1 and 2 assessments of ORP contractors are presented to ORP management and the management of the contractor organization assessed. Findings are processed in accordance with the requirements of the procedures that governed that activity.
- C. Level 1 and 2 assessment results, both reports and records of corrective action(s), are processed in accordance with the requirements of Chapter 9.0.

11.3 ASSESSMENT REQUIREMENTS

This section establishes the ORP requirements for planning, scheduling, and conducting assessments. Planned and scheduled assessments shall be performed by ORP to:

- A. Determine that an effective environmental, safety, health, and quality program (e.g., functional areas) has been developed, documented, and implemented.
- B. Verify by examination and evaluation of objective evidence whether functional areas, items, processes, work areas, or records, conform to specified requirements.
- C. Assess the effectiveness of controls and verification activities.
- D. Report deficiencies to appropriate levels of management for evaluation and implementation of corrective action.
- E. Verify corrective actions are planned, initiated, and completed.

11.3.1 Scheduling Assessments

The assessment system shall provide for assessment scheduling according to the following requirements:

- A. Level 1 and 2 assessments shall be scheduled to periodically evaluate functional areas, target areas of weakness, and evaluate targeted first of a kind activities for conformance with requirements.
- B. Regularly scheduled assessments may be supplemented by additional assessments as needed. Supplemental reactive assessments shall be scheduled based on the following considerations:
 - 1. When significant changes are made to functional areas, such as significant reorganization or procedure revisions.
 - 2. When it is suspected that the quality of an item or activity is in jeopardy.
 - 3. When a systematic, independent assessment of program effectiveness is considered necessary in response to events or issues that indicate the potential for programmatic inconsistencies.
 - 4. When it is necessary to verify implementation of required corrective actions.

5. When evidence has been found that items, processes, work areas, or records, do not conform to specified requirements.

11.3.2 Planning and Preparation

A. There are three levels of assessments:

1. Level 1 – Formal assessment, evaluation, check, or oversight activity performed by ORP organizations to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. A Level 1 assessment is usually a team effort, led by an assessor, to evaluate a program, process, equipment, or activity over a period of 1–2 weeks.
2. Level 2 – Assessment of ongoing program, functional area, or activity to verify that it complies with standards and requirements, is conducted safely, and conforms to procedures and best practices. A Level 2 assessment is narrower in scope than a Level 1 assessment, uses fewer team members, and can be led by an assessor to provide a “snapshot” of program implementation.
3. Level 3 – Operational awareness of facilities, ongoing operations, and programs performed on a daily basis to monitor work.

B. The organization performing the Level 1 assessment shall develop and document a plan that includes the following:

1. The plan will include the scope, requirements, purpose, assessment personnel, activities to be assessed, organizations to be notified, applicable documents to be requested and reviewed, schedule, and written procedures, checklists, or other documents to be used.
2. Assessment planning will typically include a review of past related assessment results to determine the nature of problems that have occurred in the area being assessed. When recurring problems are found, the assessment team will review corrective actions that have been taken and attempt to determine whether the corrective actions were effective in preventing recurrence.
3. Assessment preparation and team familiarization will typically include review of pertinent background information, procedures, technical documents, and type of service or product to be evaluated so that assessment team members are familiar with the work being assessed. This may include performance criteria or metrics, industry experience with performance and effectiveness of the product, and the use of checklists prepared as guidance that may be expanded or condensed during the assessment performance.
4. Assessment preparation may include evaluations of applicable procedures and instructions to determine compliance with requirements.
5. Scope typically includes related corrective actions taken since the previous assessment.

11.3.3 Assessment Team Selection

The Level 1 and 2 assessment system shall provide for the selection of an assessment team according to the following requirements:

- #### **A. Assessment team members typically are identified prior to the start of the assessment activity. Team members are selected on the basis of technical qualifications and knowledge**

of the item or process being assessed and are independent from the item or process being assessed. Assessment team members have sufficient authority and organizational freedom to carry out their assigned responsibilities. In the case of internal independent assessments, personnel having direct responsibility for performing the activities being assessed shall not be involved in the selection of the assessment team.

- B. For Level 1 assessments, an assessment team leader shall be appointed to provide indoctrination and supervision of the team, to organize and direct the assessment, and to coordinate the preparation and issuance of the assessment report.
- C. Before starting a Level 1 assessment, the assessment team leader shall ensure the assigned personnel collectively have experience and training commensurate with the scope, complexity, or special nature of the work to be assessed.
- D. Technical specialists, with appropriate technical expertise or experience in the work being assessed, are used when assessing the adequacy of technical processes.

11.3.4 Performing Assessments

- A. Assessments are typically performed according to the following requirements:
 - 1. Level 1 assessments are performed using criteria (e.g., criteria review approach documents) or a plan and typically evaluate the written procedures or checklists related to the activity being assessed and include a preassessment conference and a postassessment conference with the management of the assessed organization.
 - 2. Elements that have been selected for assessment shall be evaluated against specified requirements. Objective evidence is examined to the depth necessary to determine if those elements are being implemented effectively.
 - 3. Assessment results are documented by assessment personnel, reported to, and reviewed by management having responsibility for the area assessed. Conditions requiring prompt corrective action are reported immediately to management of the assessed organization.
 - 4. For internal assessments, CAQs shall be documented and corrected according to the requirements of Section 8.2.4. External assessment findings shall be documented and Priority Level 1 and 2 findings tracked to closure.

11.3.5 Reporting Assessment Results

Assessment results shall be reported according to the following requirements:

- A. Level 1 and 2 assessment reports shall be prepared, signed by the assessment team leader and their ORP director, and issued to the management of the assessed organization and any affected organizations in accordance with the ORP assessment procedures. Level 1 and 2 assessment reports include the following, as appropriate:
 - 1. Description of the assessment scope.
 - 2. Identification of the assessors.
 - 3. Summary of assessment results, including (for QA assessments) a statement of the program adequacy, implementation, and effectiveness, as appropriate to the scope.
 - 4. Description of each reported finding in sufficient detail to enable corrective action to be defined and taken by the assessed organization.

11.4 ASSESSMENT RESPONSE AND FOLLOWUP

As required by procedures, management of the assessed organization will investigate any identified findings and determine and schedule corrective actions. For Priority Level 1 and 2 findings, the assessed organization will include measures to preclude recurrence and notify the assessing organization of the actions planned or taken. The adequacy and timeliness of assessment responses shall be evaluated by the assessing organization, and followup action shall be taken to verify Priority Level 1 and 2 corrective actions are accomplished as scheduled. If the assessed organization disagrees with one or more of the findings, the assessment response will identify them and provide sufficient supporting information to permit resolution by ORP management.

11.5 ASSESSMENT RECORDS

The following documents, when developed in fulfillment of the Level 1 and 2 assessment requirements of this QAPD, shall be controlled as QA records in accordance with Chapter 9.0:

- A. Assessment plan, if applicable
- B. Assessment reports
- C. Level 1 and 2 assessment responses
- D. Documentation of Priority Level 1 and 2 finding corrective action completion and followup.

11.6 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS

This section provides IHLW requirements that are in addition to those described in above.

No additional requirements are identified.

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12.0 SOFTWARE CONTROL

12.1 DESCRIPTION

The TRS organization is responsible for oversight of ORP computer software QA. The AMTRS identifies at least one individual to serve as the ORP computer software QA technical lead. This individual is responsible for coordinating and performing activities involving oversight of contractor safety software, as well as for providing a point of contact for DOE Headquarters elements interested in ORP software QA. ORP qualifies the software technical lead using DOE-STD-1172-2011.

12.2 SOFTWARE QUALITY ASSURANCE

12.2.1 Application Software Quality Assurance

- A. Software used in applications that could affect the quality of ORP work but does not provide input into the design of WTP or the Federal repository waste acceptance criteria under the QARD must be approved and controlled, as follows:
 1. Site standard applications obtained from the Software Distribution application or preloaded by Lockheed Martin Services, Inc. (LMSI) on computers are already approved and require no further documentation, testing, or controls. Each ORP organization must maintain an inventory of all software that:
 - a. Could affect the quality of ORP work.
 - b. Was not obtained from LMSI Software Distribution.
 - c. Was not preloaded on a Hanford Site computer by LMSI.
- B. These requirements apply to spreadsheets and other user-configurable files developed using Microsoft^{®1} Office[®] applications and other programs if the user configurable files manipulate data and the output could affect the quality of an ORP organization's work.
- C. Software obtained from sources other than LMSI that could affect the quality of ORP work must be approved in accordance with Hanford Site computer security procedures before installing them on ORP computers. The software must also be verified to be appropriate to the work for which it was obtained, and its use approved by management. Tests must be performed and documented to verify the software produces correct output. The organization using the software will test the software to demonstrate that it produces correct results using an approved test procedure. The tests will be repeated if a new release of the software is installed.
- D. Spreadsheets and other user-configurable files will be named and listed in the organization's quality-affecting software inventory. Someone other than the person who developed the software will test the software to show that it produces correct results. When testing is complete, spreadsheet cells will be locked down and password protected. A version number will be assigned and listed in the organization's software inventory. If the application is

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changed, a new version number will be assigned and the software inventory updated. Testing of affected cells will be documented.

- E. Simple and easily understood computer programs (i.e., computer programs whose results can be easily confirmed through hand calculations) that are used in the design of plant SSCs may be excluded from the controls of this chapter if designs using these computer programs are individually verified. Design verification documentation should include design inputs, the computer program-generated results, and computer-generated evidence of the programmed algorithms or equations (e.g., computer program listings, spreadsheet cell contents). However, frequent use of the software may justify the application of this chapter in order to simplify future use of the software.

12.2.2 Quality-Affecting Software Quality Assurance

ORP performs work associated with the Federal repository program under the requirements contained within the QARD. As such, some of ORP's work, specifically the work associated with glass formulation, will affect and is a deliverable under the Waste Acceptance System Requirements Document. ORP's glass formulation activities pertaining to the Federal repository do not have input to or impact the waste acceptance criteria, and therefore are not considered safety software but are quality affecting. ORP software activities are limited to acquisition of otherwise acquired software, operation, maintenance, and retirement of software. As such, ORP imposes the following requirements on software that pertains to glass formulation or any other software that may be used by ORP that affects an ORP activity in a quality-affecting manner.

- A. ORP will apply the QA requirements for commercial grade items and services to the acquisition of software that has not been previously approved under a program consistent with this QAPD for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software). The acquired software shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following:
1. Identification of the capabilities and limitations for intended use as critical characteristics.
 2. Utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations.
 3. Instructions for use (e.g., user manual) within the limits of the dedicated capabilities.
- B. The dedication process shall be documented and the performance of the actions necessary to accept the software shall be reviewed and approved. The resulting documentation and associated computer program(s) shall establish the current baseline. Subsequent revisions of accepted software received from organizations not required to follow this QAPD shall be dedicated in accordance with this section.

12.2.3 Operation of Quality-Affecting Software

After ORP has dedicated the software, and the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions, which include:

1. Application documentation (e.g., application log)
2. Access control specifications
3. Computer system vulnerability protections

4. Problem reporting and corrective action
5. In-use tests
6. The configuration change control process.

12.2.4 Maintenance of Quality-Affecting Software

ORP controls changes to dedicated quality-affecting software that are initiated by the software developer. ORP does not initiate changes to quality-affecting software that has been approved through dedication. Any changes by the developer in response to any of the following will be controlled and evaluated to determine if a new dedication process is required:

1. Enhancement requests from the user community
2. Revisions to software based on software design requirements
3. Changes to the operating environment and changes to computer system vulnerability protections
4. Reports of software problems that must be corrected.

12.2.5 Retirement of Quality-Affecting Software

During retirement, support for the software product is terminated and the routine use of the software shall be prevented.

12.3 SOFTWARE TEST CONTROL

ORP must implement a software test control program that meets the requirements in the following sections in addition to implementing a commercial grade dedication (CGD) program for the acquisition of software for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software) that has not been previously approved under a program consistent with this QAPD.

12.3.1 Test Requirements

- A. Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.
- B. Test requirements and acceptance criteria shall be based on specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.
- C. If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required before the test is performed.

- D. Test requirements and acceptance criteria for computer programs shall be provided by the organization responsible for the use of the computer program and shall include the following, as applicable:
1. Software design verification testing shall demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage.
 2. Computer program acceptance testing shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.
 3. In-use computer program testing shall demonstrate required performance over the range of operation of the controlled function or process.

12.3.2 Computer Program Test Procedures

- A. Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures shall provide for assuring the computer program produces correct results. For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods, such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.
- B. In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.
- C. Test procedures or plans shall specify the following, as applicable:
1. Required tests and test sequence.
 2. Required ranges of input parameters.
 3. Identification of the stages at which testing is required.
 4. Criteria for establishing test cases.
 5. Requirements for testing logic branches.
 6. Requirements for hardware integration.
 7. Anticipated output values.
 8. Acceptance criteria.
 9. Reports, records, standard formatting, and conventions.

12.3.3 Test Results

Test results shall be documented, maintained, and evaluated by ORP to ensure test requirements have been satisfied.

12.3.4 Computer Program Test Records

A. Computer program test records shall be maintained in accordance with the requirements of Chapter 9.0 and shall consist of the following information, as a minimum:

1. Name of computer program tested, including system software used
2. Name of computer hardware used
3. Test equipment and calibrations used, where applicable
4. Date of test
5. Name of tester or data recorder
6. Simulation models used, where applicable
7. Test problems
8. Results and applicability
9. Action taken in connection with any deviations noted
10. Name of person evaluating test results
11. Acceptability.

12.4 COMMERCIAL GRADE DEDICATION OF QUALITY-AFFECTING SOFTWARE

ORP will implement a CGD program for the acquisition of software that has not been previously approved under a program consistent with this QAPD for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf or otherwise acquired software). In accordance with the definition for “item” found in Appendix B, software is defined as an “item.”

12.4.1 Utilization of Commercial Grade Dedication

- A. When using a commercial grade item or service, ORP will establish and implement controls to provide reasonable assurance the item or service will perform its intended function. These controls shall include the following:
1. Determination that the item or service performs a quality-affecting function.
 2. Confirmation that the item or service meets the applicable commercial grade item definitions.
 3. Identification and documentation of the critical characteristics, including acceptance criteria.
 4. Selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.

- B. Only items or services that perform a quality-affecting function and meet the commercial grade definitions shall be considered for CGD. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item or service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication. Items or services that successfully complete the dedication process are subsequently subject to the controls of this QAPD.

12.4.2 Commercial Grade Dedication Technical Evaluation

- A. ORP performs technical evaluation(s) of quality-affecting software that will be commercial grade dedicated to:
1. Determine the quality-affecting function(s) of the item or service.
 2. Identify performance requirements, the component/part functional classification, and applicable service conditions.
 3. Confirm that the item or service meets the commercial grade definition criteria.
 4. Identify the critical characteristics, including acceptance criteria.
 5. Identify the dedication method(s) for verification of the acceptance criteria.
 6. Determine if a replacement item is a like-for-like or equivalent item.
- B. CGD requirements are only applicable to commercial grade items or services that perform a quality-affecting function. Applicable design output documents, supplier technical information, and other relevant industry technical and operating experience information, shall be utilized to prepare the technical evaluation. Components that perform a quality-affecting function can contain items that do not perform a quality-affecting function. Replacement items shall be evaluated to determine their individual quality-affecting function in relation to the item or service. The credible failure modes of an item in its operating environment, and the effects of these failure modes on the quality-affecting function, shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the quality-affecting function of item. If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific quality-affecting function. In this case, consideration of failure modes is not required and the item's design parameters and allowables become the critical characteristics and acceptance criteria. If the design criteria or quality-affecting function of the original item have changed, the replacement item must meet the new design criteria and quality-affecting function. Like-for-like and equivalent items are not a design change subject to this QAPD.
- C. If ORP can demonstrate the replacement item is identical, then the quality-affecting function, design requirements, and critical characteristics need not be redetermined. However, verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.
- D. When a difference(s) exists from the original item, an equivalency evaluation is required to determine if any changes in design, development process, or function could prevent the

replacement item from being interchangeable under the design condition of the original items and prevent it from performing its required quality-affecting function.

- E. The equivalency evaluation shall be documented and include the following:
1. Identification of the change(s) in design, development process, or function of the replacement item that is different from the original item.
 2. Evaluation of the change(s).
 3. Confirmation that the change(s) does not adversely affect the current design or quality-affecting functions of the item.
 4. If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with this QAPD.
 5. Equivalency evaluations can determine the acceptability of the difference in the item to perform its quality-affecting function and identify critical characteristics for acceptance for the replacement item. Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

12.4.3 Critical Characteristics

ORP shall determine the critical characteristics of the item that is being dedicated in accordance with the following requirements:

- A. Critical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. Critical characteristics of an item for acceptance shall include the identification number, version number, physical characteristics, and performance characteristics, as appropriate.
- B. The critical characteristic acceptance criteria shall include ranges, when appropriate.
- C. An item's part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the developer's product description and published data.
- D. The dedication process shall not rely on the identification number alone as the only critical characteristic to be verified. Commercial grade items or services can have numerous characteristics that are related to the composition, identification, or performance of the item or service. However, for acceptance, not all of these characteristics need to be verified to provide reasonable assurance that the item or service will perform its intended safety function.
- E. The developer's published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and development of the item. The developer can employ standard tests or inspections as part of the development process and utilize a quality program to make sure appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria.

- F. In cases where the critical characteristics and acceptance criteria cannot be determined from the developer's documentation or other documentation, ORP may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria.
- G. Critical characteristics selected for acceptance shall include either criteria related to the design basis conditions (or design limits) of the item, or criteria addressing the most severe location criteria/design basis conditions (or design limits) of the item, unless controls are in place to prevent usage in undesignated locations.
- H. Commercial grade items designated for installation or installed in seismically or environmentally qualified equipment, or in locations that require such qualification, shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.

12.4.4 Methods of Accepting Commercial Grade Items and Services

- A. To provide reasonable assurance a commercial grade item or service will perform its intended safety function, ORP verifies the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods:
 - 1. Method 1: Special Test(s), Inspection(s), and/or Analyses.
 - 2. Method 2: Commercial Grade Survey of the Supplier.
 - 3. Method 3: Source Verification.
 - 4. Method 4: Acceptable Supplier Item or Service Performance Record.
- B. Before classifying the item or service as acceptable to perform its safety function, ORP determines the following have been successfully performed, as applicable:
 - 1. Damage was not sustained during shipment.
 - 2. The item or service has satisfied the specified acceptance criteria for the identified critical characteristics.
 - 3. Specified documentation was received and is acceptable.

The dedication methods listed previously provide a means to assure the commercial grade item or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method is planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, ORP may select another or combination of dedication methods to verify the critical characteristic. The four methods are explained on the following pages.

- C. Method 1: Special Test(s), Inspection(s), and/or Analyses:
 - 1. Special test(s), inspection(s), or analyses, either individually or in combination, shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. The special test(s), inspection(s), and/or analyses may include post-installation testing; and may be performed using a sampling plan, when appropriate.

2. Special inspections may include receipt inspection activities to verify adequate criteria associated with procurement activities. The receipt inspection activities may be included in the dedication plan.
 3. Sampling plans used to select items for special test(s), inspection(s) and/or analyses shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item.
 4. When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the commercial grade item or service shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities.
 5. When critical characteristics acceptance criteria are based on certificates of conformance, the criteria of this QAPD shall be met.
 6. Services can result in a deliverable product that can be evaluated upon receipt, or result in an activity that can be evaluated during or at the conclusion of its performance.
- D. Method 2: Commercial Grade Survey of the Supplier:
1. A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier's commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following:
 - a. Identification of the item(s), product line, or service included within the scope of the survey.
 - b. Identification of the critical characteristics to be controlled by the supplier.
 - c. Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics.
 - d. Identification of the survey methods or verification activities performed, including results obtained.
 - e. Documentation of the adequacy of the supplier's processes and controls.
 2. A commercial grade survey shall not be employed as a method for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls. After a supplier's processes and controls have been determined to be adequate, ORP shall invoke or reference the verified processes and controls, including revision level as a part of the purchase order or control requirements for the commercial grade item or service and require the supplier to provide a certificate of conformance attesting to the implementation of the identified processes and controls.
 3. When critical characteristics acceptance criteria are based on certificates of conformance, the criteria contained in Chapter 7.0 shall be met.

4. Surveys shall not be employed as a method for accepting items from distributors, unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the developer. A survey of the distributor may not be necessary if:
 - a. The distributor acts only as a broker and does not warehouse or repackage the items.
 - b. In cases where traceability can be established by other means such as verification of the developer's markings or shipping records.
5. Surveys performed by organizations other than ORP may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier's processes and controls, and acceptance criteria are evaluated by ORP to be acceptable and consistent with ORP's dedication requirements.
6. The scope of the survey shall be determined by ORP based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the commercial grade item or service being procured. When several items or services are purchased from a supplier, a survey of representative groups of commercial grade items or services can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier.
7. If the scope of the survey cannot verify a designated critical characteristic due to lack of controls by the supplier's subsupplier(s), ORP shall extend the survey to the subsupplier(s) or select another dedication method(s) to verify the critical characteristic.
8. Organizations performing surveys shall develop criteria for the personnel qualifications and for the processes used to perform surveys. The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s).
9. ORP shall establish a survey frequency to ensure process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.

E. Method 3: Source Verification:

1. Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verification(s) shall include activities such as witnessing the development processes, performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics.

2. When performing source verification, ORP shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence the supplier's activities for the identified characteristics were observed and evaluated for acceptance. Source verification is only applicable to the actual item(s) or service(s) that is verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan, with the documented evidence of the source verification furnished to the dedicating entity, and shall include or address the following:
 - a. Identification of the item(s) or service(s) included within the scope of the source verification.
 - b. Identification of the critical characteristics, including acceptance criteria, being controlled by the supplier.
 - c. Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics.
 - d. Identification of the activities witnessed during the source verification and the results obtained.
 - e. Identification of mandatory hold points during development and/or testing processes to verify those critical characteristics that cannot be verified by evaluation of the completed item.
 - f. Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria.

F. Method 4: Acceptable Supplier Item or Service Performance Record

1. A documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a commercial grade item or service against the supplier's performance record for identical or similar services. This method allows ORP to have reasonable assurance of the item's or service's performance, based on historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data.
2. Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the commercial grade item or service.
 - a. An acceptable supplier item or service performance record shall include the following:
 - Identification of the supplier item or service being evaluated.
 - Identification of previously established critical characteristics specific to the supplier item or service.
 - Identification of data examined to evaluate the supplier item or service.

- Identification of the basis for determining that performance data substantiates acceptability of the supplier item or service.
 - Documentation of the adequacy and acceptance of the supplier/item/service performance record.
- b. An acceptable item or service performance record shall not be employed alone as a method of acceptance unless:
- The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application (i.e., single sources of information are not adequate to demonstrate satisfactory performance).
 - The manufacturer's/supplier's measures for the control of applicable design, process, and change control have been accepted by ORP, as verified by survey.
3. Continued application of an acceptable supplier/item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

12.4.5 Supplier Deficiency Correction

The supplier shall correct deficiencies with the supplier's processes and controls identified by the acceptance method(s) if it affects the acceptance criteria for critical characteristic(s) utilized for CGD. Corrective actions shall be evaluated for acceptability by ORP. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.

12.4.6 Commercial Grade Services

- A. Commercial grade services include services such as training, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, or maintenance that do not physically alter an item's critical characteristics, are also commercial grade services. Critical characteristics for the dedication of commercial grade services include personnel qualification, activity controls, independent certifications, and documents.
- B. ORP shall review Chapter 7.0 to determine if this requirement is applicable before considering the dedication of a service. As an alternative to CGD, services may be performed under the dedicating entities or other organization's quality program and procedures that meet the requirements of this QAPD.
- C. Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered commercial grade services.

12.4.7 Documentation

- A. Documentation of the commercial grade item or service dedication process shall be traceable to the item, group of items, or services, and shall contain the following types of documents, depending on the applicable dedication method:
1. Dedication plans or procedures, including the essential elements of the dedication process
 2. Commercial grade item or service procurement documents
 3. Technical evaluations
 4. Critical characteristic identification and acceptance criteria.
 5. Test reports or results, inspection reports, and analysis reports
 6. Commercial grade survey reports
 7. Source verification reports
 8. Historical performance information
 9. A dedication report containing sufficient data to accept the item or service.

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13.0 GRADED APPLICATION OF THE NUCLEAR QUALITY ASSURANCE STANDARD FOR RESEARCH AND DEVELOPMENT

13.1 RESEARCH AND DEVELOPMENT AND CONVENTIONAL ASME NQA-1 APPLICATIONS

This section of the QAPD establishes ORP requirements for performing nuclear research and development (R&D) activities or procuring such activities that directly impact ORP work (e.g., direct contracts with universities). Application of the requirements contained within this section extends the scope of this QAPD to basic research, applied research, and development work. The basic products of R&D are knowledge and technology supported by data, which generally can be validated and replicated. A graded approach based on importance and significance of activities is the key to the successful application of this section.

13.2 QUALITY AND NATURE OF RESEARCH AND DEVELOPMENT WORK

The term “research and development” includes two types of activities. The first type is scientific (i.e., work that results in the advancement of knowledge or development of technology); the second type of activity is secondary in nature and supports R&D science (e.g., procurement, maintenance, facility operation). Practices to ensure quality of research include peer review and publication of results in refereed journals. Laboratory notebooks are generally used and maintained as records for the documentation of R&D events to ensure their reproducibility. Alternate means of data recording and storage (e.g., electronic media) may be used for large volumes of data.

13.3 RESEARCH AND DEVELOPMENT IN THE TECHNOLOGY LIFE CYCLE

The technology life cycle is depicted in Figure 13-1, which shows the progression of technology development, commercialization, and retirement in process phases of basic and applied R&D, engineering, production, and operation until process completion. The life cycle is characterized by flexible and informal QA activities in basic research, which becomes more structured and formalized through the applied R&D stages.

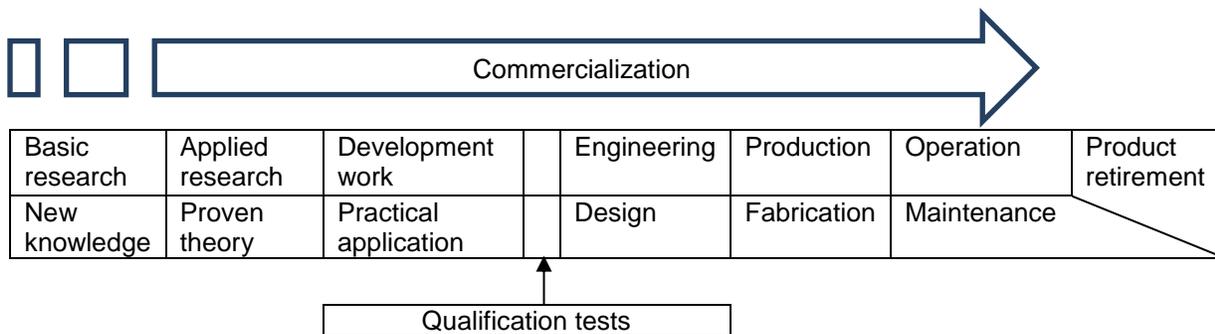


Figure 13-1. Technology Life Cycle.

13.3.1 Basic Research

Basic research is conducted to acquire and disseminate new knowledge of a theoretical or experimental nature. It does not always lend itself well to a prior establishment of predetermined results. The timetable for completion of basic research tasks in preparation for their definitive measurement generally cannot be predicted to a high degree of accuracy. By its very nature, the

basic research phase of R&D is subject to the highest level of uncertainty, clouding the issue of predetermined results. The results of testing a basic research hypothesis will always be useful, by definition, because they could not be predicted with certainty. Most basic research is predicated on previous work and guided by hypothesis testing, with the hypothesis providing the framework of bounded uncertainty for the activity.

QA principles do apply to basic research work. Even in basic research, work is broken down into a series of tasks, with anticipated results and anticipated milestones. A series of assumptions is either confirmed or not. When assumptions are not confirmed, work is redirected through a planning activity.

Basic research is subject to the same success criteria that governs applied R&D work:

- A. A hypothesis is defined and tested in a planned way with a statement of qualification conditions.
- B. Variability and uncertainty conditions are identified and accounted for in stating expectations of experimental results.
- C. Methodology and results are documented to describe all elements of inquiry, regardless of the results.
- D. Results are validated through a peer review process.
- E. Results can be reproduced by qualified personnel in the same field of research as that being investigated.

13.3.2 Applied Research

Applied research is a process initiated with the intent of solving a specific problem or meeting a practical need. Successful results may be applied to a future development activity. Proof of a principle usually occurs in the applied research stage, and with its more explicit objectives, warrants a set of milestones. This leads to the need for a records system that can protect patent rights by ensuring an orderly procedure for maintaining the necessary documentation. Good data and documentation are needed to ensure reproducibility of results, an essential element of good work practice, whether it is basic science, applied science, or development work.

13.3.3 Developmental Work

Development activity entails the application of proven theory and experimental results and their extension to its end use (e.g., use in a design environment). Because the developmental objective may be to accomplish goals that have not been achieved previously, a degree of uncertainty exists as to the ultimate success of the effort. A plan that governs a developmental activity leads to a more structured management of the process. Developmental tests define performance boundaries. Qualification tests confirm predicted performance. Tests with or without acceptance criteria are prescribed with requirements commensurate with the complexity and scale of the effort, and with the associated risk to the public and workers, to the environment, and to the success of the project.

13.3.4 Research and Development Support Activities

Support activities are those that are conventional and secondary in nature to the advancement of knowledge or development of technology, but allow the primary purpose of the work to be

accomplished in a credible manner. An example of a support activity is the calibration of a measurement instrument.

13.3.5 Research and Development Process Interfaces and Continuity

The process interfaces between basic, applied research, and development phases afford an opportunity for technology life-cycle quality problems, analogous to the design interface challenges of a manufacturing operation. By ensuring a consistent application of QA principles to R&D activities, the transition from development to engineering can be accomplished smoothly, and design quality problems can be minimized. Traditionally, research activities are performed as discrete tasks rather than integrated efforts. For basic research, where uncertainty is a significant operational factor, the lack of a life-cycle approach is understandable. However, the development stage of the technology cycle can be treated from an integrated process perspective, anticipating the needs of the engineering phase of the cycle.

13.4 RESEARCH AND DEVELOPMENT QUALITY ASSURANCE THROUGH PEER REVIEW

The peer review activity can be quantitative or qualitative in nature, depending on the work being evaluated. Peer review is a primary QA mechanism for basic research. Basic research peer review may require intuition on the part of the reviewers to appreciate the creative and innovative characteristics being explored. Applied research peer reviews may rely on quantitative analyses to assess the accuracy of the original results. Developmental peer review may resemble an independent design review in its verification of proof of principle.

A strong planning function is essential for the success of any peer review activity. When used, the scope and content of the peer review activity shall be well defined to ensure that an authoritative, independent, and fair evaluation is accomplished, and to assemble the proper mix of expertise to cover the subject matter. Peer review methodologies and results shall be documented to verify that success factors for R&D are achieved (i.e., a qualified practitioner in the field being investigated can achieve replication of results). The critical aspects of the R&D work shall be examined during the peer review to verify the validity of the results. Those as knowledgeable as those doing the R&D shall examine the basic premise (or hypothesis) of the work. A peer shall accomplish a verification of the literature search conducted originally to support the R&D review activity: someone who has extensive discipline knowledge to assess the underlying assumptions and logic associated with the activity. Documentation of the R&D work shall be critiqued to ensure reproducibility of results.

13.5 GRADED APPROACH

Graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life-cycle state of the facility or work, or programmatic mission.

Broken into a basic format for application, the following evaluations of importance or significance shall be made for each contemplated activity:

- A. Relative significance of accomplishing the proposed R&D work to the prospective customer, the proposing organization, and stakeholders (i.e., the value of the work).

- B. Relative priority for accomplishing the work to the prospective customer, the organization, and the stakeholders (i.e., the ranking of the activity relative to similar activities).
- C. Potential consequences to customers, the organization, and stakeholders resulting from doing (or not doing) the work.
- D. Technological impact of producing invalid data or loss of essential data due to avoidable events.
- E. Probability of occurrence of postulated consequences.

The aggregated results of these evaluations indicate the relative need to impose controls on activities.

Categorization of R&D activity shall be performed based on the determination of significance and priority. This categorization defines the level of importance of the project, and shall be used in the determination of the set of evaluation criteria that needs to be applied to the R&D activity. The evaluation criteria shall define the set of control systems needed to ensure success. The need to meet success criteria is the fundamental consideration in grading the application of control systems. It is not just associated with environment, safety, and health concerns. The graded approach addresses the relative importance to any success factor, including safety, the environment, public health, programmatic mission, and profitability. It provides the quantitative and qualitative expression of possible loss, which considers both the probability of an event occurrence causing harm or loss, and the consequences of the event. The leader of a research project (i.e., the one responsible for the quality of the research) is responsible for overall quality and for satisfying client expectations. This will include R&D and support work processes that directly affect the quality of the research. Balancing the application of process controls with need (i.e., do the right thing to achieve performance objectives) provides an efficient work process. R&D and support work processes shall be documented to provide staff with the basis for exercising good judgment in foreseeable circumstances, and providing them with the means to do so.

13.5.1 Basic Research

In basic research, grading shall be accomplished at the discretion of the researcher. The graded approach or risk assignment is normally not documented or formalized.

13.5.2 Applied Research

During applied research, grading shall be defined at the project or program level. Grading shall be largely contingent upon the complexity of the research and the ability to duplicate the research if data were lost. The application of quality criteria may be minimal.

13.5.3 Development Work and Research and Development Support Activities

Grading in this phase is formalized. Work processes, and supporting activities, shall be graded with regard to safety considerations, cost, schedule, and programmatic mission (e.g., importance of data accuracy). The graded approach, methods of implementation, and documentation shall be formally defined in procedures.

13.6 QUALITY ASSURANCE RESEARCH AND DEVELOPMENT APPLICATIONS

QA requirements shall be applied to R&D activities based on the operational characteristics of the work process, as well as all of the success factors for a high-quality-end product in terms of

risk management. QA will apply in varying degrees to the broad spectrum of R&D that involves the use of nuclear materials, both in nuclear and nonnuclear facilities; the degree of application shall be approved by ORP.

Risk is an all-encompassing concern that includes public safety, environmental impact, project cost, and perceived usefulness of data. Risk determinations are made before and during the project design phase, and are reevaluated during the life of the project when design changes occur or research results indicate the need to do so. To ensure effective risk management, a set of risk evaluation criteria shall be established during project design, and carried forward and updated as needed during the life of the project. Risk is a concern that extends beyond environment, safety, and health factors. It shall be considered in all aspects of work, including business objectives.

A graded approach to project risk management shall be followed. Risk evaluation criteria will be reflected throughout the stages of the technology project life cycle. The elements of a graded approach shall be integrated into the work process, appropriate to the work function, and with sufficient rigor to meet operating needs. Aspects of hazard identification and risk management shall be reflected in work process activities to ensure risks associated with doing business (i.e., project work) are handled effectively. Expression of risk considerations shall be contained in policies and procedures that give guidance and direction for R&D activities.

13.7 RESEARCH AND DEVELOPMENT QUALITY ASSURANCE GLOSSARY OF TERMS

Applied Research – A process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Basic Research – A process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

Development – Systematic use of the knowledge or understanding gained from research, directed toward the creation of useful materials, devices, systems, or methods, including prototypes and processes.

Graded Approach – The process by which the extent (level of rigor) of application of controls and verification efforts is determined on the basis of the importance and significance of activities, and associated consequences of the activities.

Peer Review – A critical review of R&D work that is performed by one or more individuals who collectively have scientific expertise at least the equivalent of those who performed the work.

Referee Process – A peer review performed by an individual(s) independent of the organization doing research and/or development, prior to publication of the results of that R&D in a technical journal.

Risk – A quantitative or qualitative measure of the likelihood and unfavorable consequence of an action. Consequences may be related to public or employee safety, the environment, programmatic impact, cost, schedule, or public perception.

Support Activities – Secondary actions associated with R&D work that are conventional in nature and allow the primary purpose of work to be accomplished.

13.8 APPLICATION OF ASME NQA-1 TO RESEARCH AND DEVELOPMENT ACTIVITIES

Appendix C depicts the applicability of ASME NQA-1 to R&D activities. The following sections describe how to apply the ASME NQA-1 requirements using a graded approach to R&D activities.

13.8.1 Requirement 1: Organization

- A. **General:** The organization responsible for R&D work shall be defined and its roles, responsibilities, and authorities that support achievement of R&D work objectives shall be described. Interface responsibilities shall be defined between R&D and support functional elements.
- B. **Basic Research:** An authoritative relationship shall be defined for basic research. It shall identify those involved in collaboration and peer review activities to document the credibility of the research process.
- C. **Applied Research:** The relationship of those performing specific tasks in applied research shall be defined to ensure task objectives are met individually and collectively.
- D. **Development and Support:** Roles, responsibilities, and authorities shall be defined for development and support activities. They shall address those doing the work and those who perform independent verification that work objectives have been met. Interface responsibilities with design and engineering functions shall be defined, as appropriate, to ensure that developmental results are useable.

13.8.2 Requirement 2: Quality Assurance Program

- A. **General:** A graded approach based on importance and significance of activities is key to the successful application of these requirements to R&D activities. The R&D QA Program shall be based on the proven processes that govern the performance of successful scientific research. Only qualified individuals shall engage in selective investigation activities. Independent competent peers shall carefully review investigative activities and the documented results will be verifiable and able to withstand scrutiny by reviewers, potential users, and the entire research community.
- B. **Basic Research:** Basic research is that phase of the R&D process that is subject to the greatest uncertainties; therefore, it does not lend itself to predetermination of results. Accomplishing the tasks necessary to perform proposed measurements often means breaking new ground in instrumentation or in computational techniques. The timetable for completion of these tasks in preparation for the ultimate measurements generally cannot be predicted because of the obstacles or uncertainties that are frequently encountered. Notebooks of investigators and other collected data assume great importance as evidence of what was done and the methods that were employed. Often, the methods are innovative and cannot be identified with standard procedures; therefore, laboratory notebooks become an important component of the research documentation. The ultimate judgment of the quality of a basic research effort shall be rendered through peer reviews. Prior awareness of these procedures prompts researchers to ensure research quality.
- C. **Applied Research:** The goal of applied research is to solve a specific problem or to meet a practical need. In general, applied research is more amenable to the predetermination of

results than is basic research. Applied research shall be accompanied by more documentation than basic research; research plans, testing, recordkeeping, and periodic reports commensurate with the scope of a given project shall be developed and maintained. The peer review process can augment the application of these elements; this, too, will depend on the magnitude and complexity of the project.

- D. ***Development and Support:*** Development activity entails the application of a proven theory and its extension to a practical situation. The plan that governs a developmental activity leads to a more structured management of the entire process. For example, progress is measured against a predetermined set of results that appear to be appropriate at the outset. However, there are sufficient technical uncertainties in a development project to warrant some flexibility. This is frequently taken into account in the formality associated with the preparation and revision of design and process documentation, and by including in the milestones a plan for evaluating performance at various key junctures during the project. Tests shall be prescribed with requirements commensurate with the complexity and scale of the work, and with the associated risk to the public, workers, and environment and with the future success of the project.

13.8.3 Requirement 3: Design Control

- A. ***General:*** ASME NQA-1-2008 with the ASME NQA-1a-2009 addenda, Requirement 3, “Design Control,” applies to engineering design definition, verification, and change control in all phases of R&D using a graded approach. Design control does not apply to design of experiments or experimental plans for basic and applied research; ORP currently is not performing any R&D activity that will require application of design requirements. If contracted work requires design work that will be conducted in accordance with ASME NQA-1, Requirement 3, this will be specified in the procurement documentation.
- B. ***Basic Research:*** Design control does not apply to research for expanding fundamental knowledge.
- C. ***Applied Research:*** As the applied research matures, design control, commensurate with that activity (using a graded approach), shall be used to support subsequent development work.
- D. ***Development and Support:*** For development and support activities, the level of design control shall be applied to support the input needs of the design process. In some cases, considerable importance is placed on R&D results to demonstrate the acceptability of innovative design.

13.8.4 Requirement 4: Procurement Document Control

- A. ***General:*** This element is applicable to R&D activities. The application approach shall be to anticipate the needs of the next phase of the R&D life cycle.
- B. ***Basic Research:*** The graded application of this requirement to basic research shall be consistent with the maturity of the research. For example, if final results of the work are expected in the next stage of the work, and if the pedigree of materials being used could influence the usefulness of the results of the work during applied research, procurement document specifications shall be controlled appropriately.

- C. **Applied Research:** As the applied research matures toward an expected completion point, procurement document control shall be applied to support the anticipated needs of future development work.
- D. **Development and Support:** For development and support activities, the level of procurement document control shall be applied to support a commercial design basis (i.e., engineering design system criteria).

13.8.5 Requirement 5: Instructions, Procedures, and Drawings

- A. **General:** Activities shall be planned to the extent possible. R&D work does not always lend itself to preplanned instructions and procedures. However, sufficient documentation shall be developed to ensure replication of the work. The researcher/developer shall document work methods and results in a complete and accurate manner.
- B. **Basic Research:** Basic research shall be documented in proposals, conceptual drawings, sketches, and notebooks. The level of documentation shall be sufficient to successfully withstand a peer review. Protocols on generation and safeguarding of data and process development from basic research shall be developed and documented.
- C. **Applied Research:** The work proposal for applied research shall describe the methods for reaching the objectives of the applied research. As work progresses, the researcher shall document the work in instructions, procedures, and drawings. These instructions, procedures, and drawings will serve as guidance for subsequent development work.
- D. **Development and Support:** Activities shall be performed in accordance with documented instructions, procedures, or drawings.

13.8.6 Requirement 6: Document Control

This element is applicable to R&D activities. As a minimum, laboratory notebooks shall be subject to document control procedures. In addition, the process for development of intellectual property documentation shall be subject to document control.

13.8.7 Requirement 7: Control of Purchased Materials, Items, and Services

This element is applicable to R&D activities. The degree of application shall support the desired results of the work, within the specified performance boundaries. The need to ensure conformance with specified requirements depends on the objectives of the work. If the quality of work results depends on the pedigree of materials, items, or services, the work shall be planned to include this requirement.

13.8.8 Requirement 8: Identification of Control Items

This element is applicable to R&D activities. The degree of application shall support the desired results of the work, within the specified performance boundaries. If the quality of work results depends on the pedigree of materials or items (e.g., analytical chemistry), this requirement applies.

13.8.9 Requirement 9: Control of Processes

- A. **General:** The control of processes varies considerably as one advances from basic research through development.

- B. **Basic Research:** In basic research, control of processes is left to the researcher to define. Process control shall be recorded in a laboratory notebook.
- C. **Applied Research:** During applied research, process control shall be defined as the process is better understood. Process control is minimal and is largely contingent upon the complexity of the research and the ability to duplicate the research if data were lost. Process control instructions shall be defined in laboratory notebooks or in operating logs.
- D. **Development and Support:** Process control during this phase is formalized. Formalization occurs at the project or program level. Work processes and supporting activities shall be defined, and work and operating procedures shall be developed and implemented with respect to safety considerations, quality, cost, schedule, and programmatic mission. Methods of implementation and training requirements shall be formally defined.

13.8.10 Requirement 10: Inspection

- A. **General:** Basic and applied research activities are not amenable to inspection. Consideration may be given to performing inspection-like activities on basic and applied research to establish process or product control limits.
- B. **Basic Research:** This requirement does not apply to basic research because it requires work to be inspected to predetermined acceptance criteria.
- C. **Applied Research:** This requirement does not apply to applied research because it requires work to be inspected to predetermined acceptance criteria.
- D. **Development and Support:** The researcher/developer shall anticipate the need and plan for inspection criteria for advanced development work to interface with design process needs.

13.8.11 Requirement 11: Test Control

- A. **General:** Test control does not apply uniformly to basic and applied research. Where applicable, test methods and characteristics shall be documented and the approaches and procedures recorded. Test control does not apply to basic and applied research activities in which hypotheses are being evaluated. It does apply to support activities associated with the conduct of research.
- B. **Basic Research:** Test methods are not well defined and are usually determined by the researcher as work progresses.
- C. **Applied Research:** Test control can be specified to the degree that scientific knowledge is understood. These test procedures will serve as guidance for subsequent development work.
- D. **Development and Support:** Characteristics to be tested and test methods shall be specified. The test results shall be documented and their conformance to acceptance criteria evaluated. Tests required shall be planned, executed, documented, and evaluated.

13.8.12 Requirement 12: Control of Measuring and Test Equipment

- A. **General:** The researcher shall specify the requirements of accuracy, precision, and repeatability of measuring and test equipment (M&TE). These requirements have different implications for basic, applied, and development work.
- B. **Basic Research:** In basic research, calibration might not be necessary during the initial (or scope-setting) stages of an activity.

- C. **Applied Research:** Depending on the need for accuracy, precision, and repeatability of M&TE used in research, industry standard M&TE practices shall be followed. Where standard M&TE procedures are not used, effects of the instrument's performance on the uncertainty of the accuracy of the measurements and tests shall be considered in the research.
- D. **Development and Support:** During the process development stage and for all R&D support activities, M&TE shall be controlled per industry standard practices. The degree of control shall be dependent upon the application of the measurement.

13.8.13 Requirement 13: Handling, Storage, and Shipping

This element is applicable to R&D activities. Good laboratory practices shall be defined as instructions used for conducting the activity.

13.8.14 Requirement 14: Inspection, Test, and Operating Status

- A. **General:** This criterion has limited applicability for R&D activities.
- B. **Basic Research:** Inspection, test, and operational status of equipment or systems that support research are controlled at the discretion of the researcher.
- C. **Applied Research:** The status of items and processes that have inspection and test requirements specified by the researcher shall be identified by indicators such as tags, markings, or other suitable means.
- D. **Development and Support:** Tags, markings, inspection and test records, or other suitable means shall identify the status of items and processes for which inspections and tests are specified. The authority for application and removal of inspection and test identification shall be specified.

13.8.15 Requirement 15: Control of Nonconforming Items

This requirement should apply only to R&D support activities. The results of R&D activities are not expected to meet predetermined requirements; therefore, obtaining unexpected results does not constitute a nonconforming condition. The point at which a nonconformance can be identified is the point at which development work has transitioned into design or production of engineered items.

13.8.16 Requirement 16: Corrective Action

- A. **General:** CAQs can be identified for R&D activities, depending on the certainty of operating assumptions and expected results. Documenting, reporting, and tracking of CAQs are done at the discretion of the researcher.
- B. **Basic Research:** The use or formality of corrective action identification and tracking systems shall be defined by the researcher(s), depending on the need to transmit information to peers.
- C. **Applied Research:** The formality of corrective action identification and tracking systems to be used shall be defined by the researcher(s), depending on the need to transmit information to peers.
- D. **Development and Support:** Responsibility shall be defined for the identification, cause, and corrective action for SCAQs; these shall be documented and reported to appropriate levels of

management. Followup actions shall be taken to verify implementation and effectiveness of corrective action.

13.8.17 Requirement 17: Quality Assurance Records

This element is applicable to R&D activities. In many cases, the notebook or journal of the researcher is the QA record. Controls are needed for these documents (e.g., maintain copies of critical pages or access-controlled filing when not in use) to preserve process repeatability and the QA record. Electronic media may be used to record data and shall be subject to appropriate administrative controls for data handling and storage.

13.8.18 Requirement 18: Audits

- A. **General:** Planned requirements are not always defined for R&D work; therefore, audits shall be conducted in a graded manner. R&D audit activities include normally accepted audit practices, peer reviews, or both.
- B. **Basic Research:** For basic research, the objectives of the audit process shall be achieved as a part of peer review activities if the peer review process is sufficiently comprehensive.
- C. **Applied Research:** As knowledge gained by basic research matures through applied research, audits shall be used in conjunction with peer reviews to support subsequent development work.
- D. **Development and Support:** Responsibility shall be defined for audits and the results of these audits shall be documented and reported to appropriate levels of management. Followup actions shall be taken to verify implementation and effectiveness of corrective action.

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14.0 QUALIFICATION OF EXISTING DATA

14.1 DESCRIPTION

This section contains requirements unique to the qualification of existing data and information that support the ORP mission, but were collected in accordance with a program that is not compliant with ASME NQA-1, this QAPD, or data published in scientific publications. The data qualification process includes data qualification planning, a controlled process for evaluating and establishing data quality, and documentation of the results of this process. Existing data is defined as data determined to be necessary for activities specified in this QAPD, but developed prior to the implementation or outside of this QAPD; or data published in scientific publications. Existing data does not include information that is accepted by the scientific and engineering community as an established fact (e.g., engineering handbooks, density tables, gravitational laws). The qualification process shall be conducted in accordance with approved procedures that provide for documentation of the decision process, the factors used in arriving at the choice of the qualification method, and the decision that the data are qualified for their intended use.

14.2 QUALIFICATION OF EXISTING DATA

- A. Existing data that are used as direct input to analysis or performance modeling addressing safety, shall be qualified at appropriate times, and must be qualified before relying on the item for which the data were used as design input for functional performance. It must also be qualified prior to relying on the data to resolve safety issues. The identification of data sets to be recommended for qualification shall be based on its end use and a consideration of the potential impact on risk, safety, or mission.
- B. Existing data developed from activities that are used as direct input to analysis or performance modeling that address safety shall be qualified. External source data, that are not identified as established fact and are used as direct input to analyses or performance modeling, shall be qualified. One or a combination of the following methods shall be used in performing qualification activities.

14.2.1 Data Qualification Process

The qualification process shall be planned. Planning shall include:

- A. Reasons for qualifying the data.
- B. Selected qualification method(s).
- C. Rationale for selecting the method(s).
- D. Evaluation criteria planned for use in qualifying the data set, including specific information such as size of sample to be tested, statistical method to be used, and identification of computer codes to be used.
- E. Description of the required technical disciplines and subject matter experts knowledgeable of enough background information pertaining to the data.

- F. Identification of individuals performing the data qualification effort and their requisite qualifications.
- G. Schedule for completing the work.

14.2.2 Data Qualification Preparation

Before initiating the qualification of existing data activity, background information on the subject data set shall be collected, including proprietary records concerning any available procedures or documentation of data acquisition or development methodology, and prior reviews of data.

14.2.3 Data Qualification Attributes

During the qualification of existing data the following attributes shall be considered:

- A. Qualifications of personnel or organizations generating the data.
- B. Technical adequacy of equipment and procedures used to collect and analyze the data.
- C. Extent to which the data demonstrate the properties and ranges of interest (e.g., physical, chemical, geological, mechanical).
- D. Environmental conditions under which the data were obtained (if germane to the quality of the data).
- E. Quality and reliability of the measurement control program under which the data were generated.
- F. Extent to which conditions under which the data were generated may generally meet the requirements and guidance of ASME NQA-1.
- G. Prior range of uses of the data and associated verification processes.
- H. Prior peer or other professional reviews of the data and their results.
- I. Extent and reliability of the documentation associated with the data.
- J. Extent and quality of corroborating data or confirmatory test results.
- K. Degree to which independent audits of the process that generated the data were conducted.
- L. Extent to which conditions generating the data may partially meet requirements of this QAPD.
- M. Extent and quality of corroborating data or confirmatory testing results.

14.2.4 Qualification Methods

Existing data shall be qualified using one or a combination of the following methods:

- A. QA Program equivalency
- B. Data corroboration
- C. Confirmatory testing
- D. Peer review.

14.2.4.1 Quality Assurance Program Equivalency Method

The QA Program equivalency method may be used to determine if the acquisition, development, or processing of data have been performed in accordance with sound technical, administrative practices, or procedures that can be demonstrated to generally meet the applicable requirements and guidance of this QAPD. The employed practices or procedures must demonstrate industry-acceptable scientific, engineering, or administrative practices or processes with appropriate compliance documentation as defined in data qualification planning.

Examples of conditions for which the QA Program equivalency method may be useful include the following:

- A. Data acquisition, collection, or development records, including equipment calibration documentation and personnel qualification records are available.
- B. Documentation of the technical or administrative practices or procedures used to process the data is available.

This method shall include a review to determine the technical correctness of the data in accordance with established review criteria.

14.2.4.2 Data Corroboration Method

The data corroboration method may be used in order to determine if subject matter data comparisons can be shown to substantiate or confirm parameter values. This method may include comparisons of the data to both other sources of qualified data, as well as to sources of other existing data, as defined in data qualification planning. Examples of conditions for which the data corroboration method may be useful include the following:

- A. A sufficient quantity of corroborating data is available to permit valid statistical comparison with the unqualified data set(s).
- B. Inferences drawn to corroborate the existing data can be clearly identified, justified, and documented.

This method shall include a review to determine the technical correctness of the data in accordance with established review criteria.

14.2.4.3 Confirmatory Testing Method

The confirmatory testing method may be used when tests can be designed and performed to establish the quality of existing or indeterminate data. Confirmatory testing also may be used when previous test results are not verifiable as a result of questionable testing methodology or a lack of applicable documentation. Confirmatory test results shall demonstrate direct correlation to previous test results, if feasible. However, data extrapolation is acceptable within the limits defined in data qualification planning. Examples of conditions for which the confirmatory testing method may be useful include the following:

- A. Similar test conditions are prescribed
- B. Test result correlation or extrapolations are applicable.

This method shall include a review to determine the technical correctness of the data in accordance with established review criteria.

14.2.4.4 Peer Review Method

The peer review method is used to independently evaluate data to determine if the employed methodology is acceptable, confidence is warranted in the data acquisition or developmental results, or the data have been used in a similar range of applications. Use of the peer review method for this purpose shall include:

- A. An evaluation of the data acquisition and development approach, including test plans, to determine the acceptability of the uncertainties associated with the employed data acquisition or development methodology, the adequacy and appropriateness of the interpretations derived from the data, and the extent to which the uncertainties affect the interpretations, conclusions, and overall validity of the data.
- B. If the evaluation indicates the uncertainties are unacceptable or the data interpretations are inappropriate, this result shall be fully documented. A report documenting the peer review activity shall be prepared as defined during data qualification planning and provide for the inclusion of any dissenting conclusions and comments by individual peer reviewers.

14.2.5 **Documentation of Results**

The results of the data qualification task shall be documented in a report that shall include:

- A. Scope of the task
- B. Data set(s) for qualification
- C. Expertise of the individuals performing the data qualification effort
- D. Method(s) of qualification and rationale for the selected option(s)
- E. Rationale for abandoning any of the qualification methods
- F. Evaluation criteria
- G. Qualification criteria
- H. Data generated by the evaluation
- I. Results of the evaluation
- J. Recommendation for/against changing the qualification status of the data.

Management shall evaluate the recommendation and disposition of the data appropriately. For example, if the data set(s) is determined to be “qualified,” update the data qualification status from “existing” to “qualified.” If the data set(s) is determined to be “not qualified;” a decision shall be made and documented regarding the need to collect more data.

14.3 **QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION REQUIREMENTS**

This section provides IHLW requirements that are in addition to those described above.

14.3.1 **Planning**

- A. Planning shall be coordinated with organizations providing input to or using the results of the data.
- B. Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

14.3.2 **Data Identification**

- A. Data shall be identified in a manner that facilitates traceability to associated documentation.

- B. Data shall be identified in a manner that facilitates traceability to its qualification status.
- C. Identification and traceability shall be maintained throughout the lifetime of the data.

14.3.3 Data Review, Adequacy, and Usage

- A. Data reduction shall be described to permit independent reproducibility by another qualified individual.
- B. Data from scientific investigation activities that are used as direct input to site characterization, and scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified from origin, except as allowed in Paragraph 14.3.3.B.2. External source data that are not identified as established fact and are used as direct input to scientific analysis or performance modeling must be qualified for its intended use.
 - 1. Data shall be reviewed by qualified individuals other than those who collected or reduced the data to ensure technical correctness.
 - 2. Unqualified data may be used in scientific investigation provided traceability to its status as unqualified data is maintained. Unqualified data that are used as direct input to scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified in accordance with Section 14.3.3.C at appropriate times during the scientific investigations and before:
 - a. Relying on the item for which the data were used as design input to perform its function.
 - b. Relying on the data to resolve safety or waste isolation issues.
- C. Unqualified data developed from scientific investigation activities that are used as direct input to site characterization, scientific analysis, or performance modeling that address safety and waste isolation issues shall be qualified. External source data that are not identified as established fact and are used as direct input to scientific analyses or performance modeling shall be qualified. One or a combination of the following methods shall be used in performing qualification activities:
 - 1. Determination that the controls under which the data were generated are similar in scope and implementation to the QARD.
 - 2. Evaluation of corroborating data-rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.
 - 3. Confirmatory testing.
 - 4. Peer review shall be conducted in accordance with NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories* (February 1988).
 - 5. Technical assessment to independently evaluate data, which includes one or a combination of the following:
 - a. Determination that the employed methodology is acceptable.
 - b. Determination that confidence in the data acquisition or developmental results is warranted.
 - c. Confirmation that the data have been used in similar applications.

- D. Methods in Sections 14.3.3.C.1, 14.3.3.C.2, and 14.3.3.C.3 shall include a review to determine the technical correctness of the data in accordance with established review criteria.
- E. The qualification basis shall be documented. Documentation shall include:
 - 1. Factors used in arriving at the choice of the qualification method(s).
 - 2. Decision as to the qualification of the data.
- F. When data is acquired as nonimportant to safety/nonimportant to waste isolation data and is subsequently identified as necessary to support an activity in which the QARD applies, that data may be used provided:
 - 1. Prior review and approval by the responsible Office of Civilian Radioactive Waste Management line organization director and the Office of Civilian Radioactive Waste Director, is obtained.
 - 2. Planning for data use is performed in accordance with Section 14.3.1.
 - 3. Data to be used is identified, controlled, and qualified as described in Sections 14.3.2 and 14.3.3.

14.3.4 Technical Report Review

Technical reports shall be reviewed in accordance with the requirements of Section 6.3.

15.0 REFERENCES

- 10 CFR 21, "Reporting of Defects and Noncompliance," *Code of Federal Regulations*, as amended.
- 10 CFR 63.142, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada," "Quality assurance criteria," *Code of Federal Regulations*, as amended.
- 10 CFR 830, "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.
- 10 CFR 835, "Occupational Radiation Protection," *Code of Federal Regulations*, as amended.
- 36 CFR Subchapter B, "Records Management," *Code of Federal Regulations*, as amended.
- 48 CFR 970-5223-1, "Integration of Environment, Safety, and Health into Work Planning and Execution," *Code of Federal Regulations*, as amended.
- ASME NQA-1-1983 Supplement 17S-1, *Supplementary Requirements for Quality Assurance Records*, American Society of Mechanical Engineers, New York, New York.
- ASME NQA-1-2008, 2008, *Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.
- ASME NQA-1a-2009, 2009, *Addenda A to ASME NQA-1-2008: Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.
- Comprehensive Environmental Response, Compensation, and Liability Act of 1980*, 42 USC 9601, et seq., United States Code.
- Contract No. DE-AC27-01RV14136, *Design, Construction, and Commissioning of the Hanford Tank Waste Treatment and Immobilization Plant*, Section J, Attachment E (a), "List of Applicable Directives," U.S. Department of Energy, Washington, D.C., as amended.
- Contract No. DE-AC27-08RV14800, *Washington River Protection Solutions LLC*, U.S. Department of Energy, Office of River Protection, Richland, Washington, as amended.
- Contract No. DE-AC27-10RV15051, *Laboratory Analytical Services and Testing Contract*, Advanced Technologies and Laboratories International, Inc., U.S. Department of Energy, Office of River Protection, Richland, Washington, as amended.
- DEAR 909, "Contractor Qualifications," *Department of Energy Acquisition Regulation*, as amended.
- DOD 5015.2-STD, 2007, *Electronic Records Management Software Applications Design Criteria Standard*, U.S. Department of Defense, Washington, D.C., April 25.
- DOE 2009, *Waste Treatment & Immobilization Plant Contract, Contract Management Plan*, Rev. 6, U.S. Department of Energy, Office of River Protection, Richland, Washington.
- DOE M 140.1-1B, 2001, *Interface with the Defense Nuclear Facilities Safety Board*, U.S. Department of Energy, Washington, D.C., March 30.

- DOE O 150.1, 2008, *Continuity Programs*, U.S. Department of Energy, Washington, D.C., March 8.
- DOE O 151.1C, 2005, *Comprehensive Emergency Management System*, U.S. Department of Energy, Washington, D.C., November 2.
- DOE O 210.2A, 2011, *DOE Corporate Operating Experience Program*, U.S. Department of Energy, Washington, D.C., April 8.
- DOE O 221.1A, 2008, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*, U.S. Department of Energy, Washington, D.C., April 18.
- DOE O 224.2A, 2007, *Auditing of Programs and Operations*, U.S. Department of Energy, Washington, D.C., November 8.
- DOE O 224.3, 2005, *Audit Resolution and Follow-Up Program*, U.S. Department of Energy, Washington, D.C., January 23.
- DOE O 225.1B, 2011, *Accident Investigations*, U.S. Department of Energy, Washington, D.C., March 3.
- DOE O 226.1B, 2011, *Implementation of Department of Energy Oversight Policy*, U.S. Department of Energy, Washington, D.C., April 24.
- DOE O 227.1, 2011, *Independent Oversight Program*, U.S. Department of Energy, Washington, D.C., August 29.
- DOE O 232.2, 2011, *Occurrence Reporting and Processing of Operations Information*, U.S. Department of Energy, Washington, D.C., August 29.
- DOE O 243.1B, 2013, *Records Management Program*, U.S. Department of Energy, Washington, D.C., March 10.
- DOE O 413.1B, 2008, *Internal Control Program*, U.S. Department of Energy, Washington, D.C., October 27.
- DOE O 414.1D, 2011, *Quality Assurance*, U.S. Department of Energy, Washington, D.C., April 24.
- DOE O 420.1C, 2012, *Facility Safety*, U.S. Department of Energy, Washington, D.C., December 3.
- DOE O 426.1, 2009, *Federal Technical Capability*, Chg. 1, U.S. Department of Energy, Washington, D.C., November 18.
- DOE P 226.1B, 2011, *Department of Energy Oversight Policy*, U.S. Department of Energy, Washington, D.C., April 25.
- DOE P 450.4A, 2011, *Integrated Safety Management Policy*, U.S. Department of Energy, Washington, D.C., April 24.
- DOE P 470.1A, 2010, *Safeguards and Security Program*, U.S. Department of Energy, Washington, D.C., December 28.
- DOE/RW-0333P, 2008, *Quality Assurance Requirements and Description*, Rev. 20, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Washington, D.C., January 31.

- DOE/RW-0351P, 2008, *Waste Acceptance System Requirements Document*, Rev. 05, U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Washington, D.C., March.
- DOE-STD-1150-2002, 2002, *Quality Assurance Functional Area Qualification Standard*, DOE Defense Nuclear Facilities Technical Personnel, U.S. Department of Energy, Washington, D.C., April.
- DOE-STD-1172-2011, 2011, *Safety Software Quality Assurance Functional Area Qualification Standard*, DOE Defense Nuclear Facilities Technical Personnel, U.S. Department of Energy, Washington, D.C., March.
- Ecology, EPA, and DOE, 1989, *Hanford Federal Facility Agreement and Consent Order*, Washington State Department of Ecology, U.S. Environmental Protection Agency, and U.S. Department of Energy, Olympia, Washington, as amended.
- EM-QA-001, 2012, *EM Quality Assurance Program*, Rev. 1, U.S. Department of Energy, Washington, D.C., June 11.
- FAR 1, "Federal Acquisition Regulations System," *Federal Acquisition Regulation*, as amended.
- FAR 11, "Describing Agency Needs," *Federal Acquisition Regulation*, as amended.
- FAR 15.3, "Source Selection," *Federal Acquisition Regulation*, as amended.
- FAR 46, "Quality Assurance," *Federal Acquisition Regulation*, as amended.
- Freedom of Information Act*, 5 USC 552, et seq., United States Code.
- IAEA-TECDOC-1169, 2000, *Managing suspect and counterfeit items in the nuclear industry*, International Atomic Energy Agency, Vienna, Austria, August.
- IEEE Std 1012-2004, 2004, *IEEE Standard for System Verification and Validation*, Institute of electrical and Electronics Engineers.
- IEEE Std 1012-2012, 2012, *IEEE Standard for System and Software Verification and Validation*, Institute of electrical and Electronics Engineers, May 25.
- MGT-PM-PL-02, 2013, *Safety Management Functions, Responsibilities, and Authorities (FRA) for the U.S. Department of Energy Office of River Protection*, Rev. 6, U.S. Department of Energy, Office of River Protection, Richland, Washington.
- MGT-PM-PL-03, 2012, *Integrated Safety Management System Description*, Rev. 4, U.S. Department of Energy, Office of River Protection, Richland, Washington.
- MGT-PM-PL-04, 2012, *Quality Assurance Program Description*, Rev. 2, U.S. Department of Energy, Office of River Protection, Richland, Washington.
- National Environmental Policy Act of 1969*, 42 USC 4321, et seq., United States Code.
- NFPA 232, 2012, *Standard for the Protection of Records*, National Fire Protection Association, Quincy, Massachusetts.
- NUREG-1297, 1988, *Peer Review for High-Level Nuclear Waste Repositories*, Generic Technical Position, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C., February.

RIS 2000-18, 2000, *Guidance on Managing Quality Assurance Records in Electronic Media*, U.S. Nuclear Regulatory Commission, Washington, D.C., October 23.

ORP 2006, *U.S. Department of Energy, Office of River Protection Correspondence Manual*, U.S. Department of Energy, Office of River Protection, Richland, Washington, December.

ORP 2008, *Tank Operations Contract, Contract Management Plan*, Rev. 0, U.S. Department of Energy, Office of River Protection, Richland, Washington.

Price-Anderson Amendments Act of 1988, as amended, 42 USC 2010, et seq., United States Code.

Resource Conservation and Recovery Act of 1976, 42 USC 6901, et seq., United States Code.

Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, Pub. L. 105-261, October 17, 1998.

TRS-ISS-IP-02, 2013, *Issue Reporting and Resolution*, Rev. 2, U.S. Department of Energy, Office of River Protection, Richland, Washington, July 3.

TRS-QSH-IP-05, 2014, *Software Quality Assurance*, Rev. 3, U.S. Department of Energy, Office of River Protection, Richland, Washington.

APPENDIX A
U.S. DEPARTMENT OF ENERGY, OFFICE OF RIVER PROTECTION QUALITY
ASSURANCE IMPLEMENTATION PLAN

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Table A-1. U.S. Department of Energy, Office of River Protection Quality Assurance Implementation Plan.

ASME NQA-1-2008 with the ASME NQA-1a-2009 Addenda Criteria		DOE O 414.1D Criteria		ORP QAPD Chapters MGT-PM-PL-04	ORP Procedures, Desk Instructions, Plans, and Documents
Requirements	Title	Criterion	Title	Number and Title	Number and Title
1	Organization	1	Program	QAPD Chapter 2.0, "Organization"	<ul style="list-style-type: none"> • MGT-PM-PL-02, <i>Safety Management Functions, Responsibilities, and Authorities (FRA) for the U.S. Department of Energy Office of River Protection</i> • MGT-PM-PL-03, <i>Integrated Safety Management System Description</i> • MGT-PM-PL-13, <i>ORP Management Mission and Functions Statement</i> • MGT-PM-IP-01, <i>ORP Management System Work Process Control</i> • TRS-QSH-IP-01, <i>Reviewing and Accepting Contractor Program Documents</i>

Table A-1. U.S. Department of Energy, Office of River Protection Quality Assurance Implementation Plan.

ASME NQA-1-2008 with the ASME NQA-1a-2009 Addenda Criteria		DOE O 414.1D Criteria		ORP QAPD Chapters MGT-PM-PL-04	ORP Procedures, Desk Instructions, Plans, and Documents
Requirements	Title	Criterion	Title	Number and Title	Number and Title
2	Quality Assurance Program	2	Personnel Training and Qualification	QAPD Chapter 3.0, "Quality Assurance Program"	<ul style="list-style-type: none"> • MGT-QT-PL-01, <i>Technical Qualifications Program Plan</i> • MGT-QT-IP-01, <i>ORP Federal Employee Training Program</i> • MGT-QT-IP-02, <i>ORP Mentoring and Coaching Procedure</i> • MGT-QT-IP-03, <i>ORP Safety System Oversight Engineer Qualification Process</i> • MGT-PM-IP-03, <i>Facility Representative Qualification</i> • TRS-OA-DI-02, <i>QA Lead Auditor and Auditor Qualification Program</i> • TRS-QSH-IP-10, <i>ORP Graded Approach</i> • MGT-ENG-IP-03, <i>Graded Application of Quality Assurance Requirements for Nuclear Related Research and Development</i> • TRS-OA-IP-07, <i>Management (Self) Assessment</i> • TRS-OA-IP-01, <i>Integrated Assessment Process</i>
		9	Management Assessment		
3	Design Control	6	Design	Not applicable to ORP	—

Table A-1. U.S. Department of Energy, Office of River Protection Quality Assurance Implementation Plan.

ASME NQA-1-2008 with the ASME NQA-1a-2009 Addenda Criteria		DOE O 414.1D Criteria		ORP QAPD Chapters MGT-PM-PL-04	ORP Procedures, Desk Instructions, Plans, and Documents
Requirements	Title	Criterion	Title	Number and Title	Number and Title
4	Procurement Document Control	7	Procurement	QAPD Chapter 4.0, "Procurement Document Control"	<ul style="list-style-type: none"> • CPM-AAM-IP-08, <i>Acquisition Planning</i> • CPM-AAM-IP-10, <i>Contract Management</i> • CPM-AAM-IP-14, <i>Processing Change Orders and Requests for Equitable Adjustments</i> • CPM-AAM-IP-19, <i>Requirements Packages for inter-entity Work Orders and Modifications Thereto</i> • CPM-AAM-DI-06, <i>Contract Close</i>
5	Instructions, Procedures and Drawings	5	Work Processes	QAPD Chapter 5.0, "Instructions, Procedures, and Drawings"	<ul style="list-style-type: none"> • MGT-PM-IP-01, <i>ORP Management System Work Process Control</i> • TRS-QSH-IP-01, <i>Reviewing and Approving Contractor Program Documents</i> • TRS-QSH-IP-10, <i>ORP Graded Approach</i> • MGT-PM-IP-17, <i>Professional Proposal Evaluation Process</i> • TRS-OA-GU-01, <i>Guide for Trending Data</i> • MGT-PCA-IP-03, <i>Writer's Manual</i>

Table A-1. U.S. Department of Energy, Office of River Protection Quality Assurance Implementation Plan.

ASME NQA-1-2008 with the ASME NQA-1a-2009 Addenda Criteria		DOE O 414.1D Criteria		ORP QAPD Chapters MGT-PM-PL-04	ORP Procedures, Desk Instructions, Plans, and Documents
Requirements	Title	Criterion	Title	Number and Title	Number and Title
6	Document Control	4	Documents and Records	QAPD Chapter 6.0, "Document Control"	<ul style="list-style-type: none"> • MGT-PM-IP-01, <i>ORP Management System Work Process Control</i> • TRS-QSH-IP-08, <i>Records Management</i> • MGT-PCA-IP-01, <i>Web Page Maintenance and Control</i> • TRS-QSH-IP-01, <i>Reviewing and Accepting Contractor Program Documents</i> • TRS-QSH-IP-12, <i>Change Management</i>
7	Control of Purchased Items and Services	7	Procurement	QAPD Chapter 7.0, "Control of Purchased Items and Services"	<ul style="list-style-type: none"> • CPM-AAM-IP-08, <i>Acquisition Planning</i> • CPM-AAM-IP-09, <i>Solicitation and Award</i> • CPM-AAM-IP-18, <i>Government Property (Federal Employees)</i>
8	Identification and Control of Items	5	Work Processes	Not applicable to ORP	—
9	Control of Special Processes	5	Work Processes	Not applicable to ORP	—
10	Inspection	8	Inspection and Acceptance Testing	Not applicable to ORP	—
11	Test Control	8	Inspection and Acceptance Testing	Not applicable to ORP	—
12	Control of Measuring and Test Equipment	8	Inspection and Acceptance Testing	Not applicable to ORP	—

Table A-1. U.S. Department of Energy, Office of River Protection Quality Assurance Implementation Plan.

ASME NQA-1-2008 with the ASME NQA-1a-2009 Addenda Criteria		DOE O 414.1D Criteria		ORP QAPD Chapters MGT-PM-PL-04	ORP Procedures, Desk Instructions, Plans, and Documents
Requirements	Title	Criterion	Title	Number and Title	Number and Title
13	Handling, Storage, and Shipping	5	Work Processes	Not applicable to ORP	—
14	Inspection, Test, and Operating Status	8	Inspection and Acceptance Testing	Not applicable to ORP	—
15	Control of Nonconforming Items	3	Quality Improvement	Not applicable to ORP	—
16	Corrective Action	3	Quality Improvement	QAPD Chapter 8.0, "Corrective Action"	<ul style="list-style-type: none"> • TRS-ISS-IP-02, <i>Issue Reporting and Resolution</i> • TRS-QSH-DI-05, <i>Suspect and Counterfeit Items</i> • TRS-QSH-IP-03, <i>Quality Assurance and Safety Stop Work</i> • TRS-QSH-IP-11, <i>Operating Experience and Lessons Learned Program</i> • TRS-OA-GU-01, <i>Guide for Trending Data</i>
		Attachment 3	Suspect Counterfeit Items		
17	Quality Assurance Records	4	Documents and Records	QAPD Chapter 9.0, "Records"	<ul style="list-style-type: none"> • TRS-QSH-IP-08, <i>Records Management</i>
18	Audits	10	Independent Assessment	QAPD Chapter 10.0, "Independent Audits and Surveillances"	<ul style="list-style-type: none"> • TRS-OA-IP-05, <i>Quality Assurance Audits</i> • TRS-OA-IP-08, <i>Quality Assurance Independent Surveillances</i> • TRS-OA-DI-06, <i>Quality Assurance Supplier Audits</i>
N/A	—	10	Independent Assessment	QAPD Chapter 11.0, "Assessments"	<ul style="list-style-type: none"> • TRS-OA-IP-01, <i>Integrated Assessment Process</i>

Table A-1. U.S. Department of Energy, Office of River Protection Quality Assurance Implementation Plan.

ASME NQA-1-2008 with the ASME NQA-1a-2009 Addenda Criteria		DOE O 414.1D Criteria		ORP QAPD Chapters MGT-PM-PL-04	ORP Procedures, Desk Instructions, Plans, and Documents
Requirements	Title	Criterion	Title	Number and Title	Number and Title
Subpart 2.7	Software	Attachment 4	Safety Software	QAPD Chapter 12.0, "Software Control"	<ul style="list-style-type: none"> • TRS-QSH-IP-05, <i>Software Quality Assurance</i>
Subpart 2.14	Quality Assurance Requirements for Commercial Grade Items And Services	—	—	QAPD Chapter 12.0 Software Control	<ul style="list-style-type: none"> • To be included in TRS-QSH-IP-05, <i>Software Quality Assurance</i>
Subpart 4.2	Guidance on Graded Application of Quality Assurance for Nuclear-Related Research and Development	—	—	QAPD Chapter 13.0, "Graded Application of Quality Assurance for Nuclear-Related Research and Development"	<ul style="list-style-type: none"> • MGT-ENG-IP-03, <i>Graded Application of Quality Assurance Requirements for Nuclear Related Research and Development</i>
Nonmandatory Appendix 3.1	Qualification of Existing Data	—	—	QAPD Chapter 14.0, "Qualification of Existing Data"	<ul style="list-style-type: none"> • This procedure is in draft and in Concurrence Cycle.

ORP = U.S. Department of Energy, Office of River Protection.
 QAPD = Quality Assurance Program Description.

APPENDIX B
GLOSSARY OF TERMS

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^GLOSSARY OF TERMS

Acceptance Criteria – Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Acceptance Testing – Also known as software validation: the process of exercising or evaluating a system or system component by manual or automated means to ensure it satisfies the specified requirements and to identify any differences between expected and actual results in the operating environment.

Adverse Trend – A series of occurrences in which the frequency, combined with the significance of the occurrences, warrants further evaluation or corrective action.

Administrative Controls – The provisions relating to organization and management, procedures, recordkeeping, audits, assessments, and reporting necessary to ensure safe operation of a facility.

Assessment – A review, evaluation, inspection, test, check, surveillance or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively (as defined in DOE O 414.1D, *Quality Assurance*).

For the purposes of implementation at the U.S. Department of Energy (DOE), Office of River Protection (ORP), assessments are considered a review, evaluation, check, or any oversight activity performed by ORP organizations to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. Oversight activities are performed under the requirements of DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*. Within ORP, an assessment should not be confused with audit or surveillances performed by the ORP Quality Assurance Division, or a test or inspection activity conducted in accordance with this Quality Assurance Program Description (QAPD).

Audit – A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Audit, External – An audit of those portions of another organization's quality assurance (QA) program not under the direct control or within the organizational structure of the auditing organization.

Audit, Internal – An audit of those portions of an organization's QA program retained under its direct control and within its organizational structure.

Basic Component – A structure, system, component, or part thereof, that affects its safety function, which was designed and manufactured in accordance with the requirements of ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*, or commercial grade items that have successfully completed the dedication process.

Baseline – A specification or product that has been formally reviewed and agreed upon, and that thereafter serves as the basis for use and further development. This baseline can only be changed using an approved change control process.

Causal Analysis – A review of an activity to determine the root cause or apparent cause, to identify less-than-adequate contributing systematic factors, and to prevent or decrease the probability of further concerns.

Certificate of Conformance – A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Commercial Grade Dedication (CGD) – An acceptance process performed in accordance with this QAPD to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of ASME NQA-1. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery. This process may be supplemented, as necessary, by one or more of the following:

- Commercial grade surveys
- Product inspections
- Witness at manufacturer facility hold points
- Analysis of historical records for acceptable performance.

In all cases, the dedication process must be conducted in accordance with the applicable provisions of this QAPD.

Commercial Grade Item (related the dedication of commercial grade items - CGD) – A structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of ASME NQA-1 and this QAPD.

Commercial Grade Service (related the dedication of commercial grade items - CGD) – A service that was not provided in accordance with the requirements of ASME NQA-1 or this QAPD, and that affects the safety function of a basic component.

Certification – The act of determining, verifying, and attesting in writing to the qualification of personnel, processes, procedures, or items in accordance with specified requirements.

Computer Program – A combination of computer instructions and data definitions that enable computer hardware to perform computational or control functions.

Condition Adverse to Quality – An all-inclusive term used in reference to any of the following:

- Failures
- Malfunctions
- Deficiencies
- Defective items
- Nonconformances.

Configuration – The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

Configuration Item (Software) – A collection of computer hardware or software elements treated as a unit for the purpose of configuration control.

Configuration Management – The process that controls the activities and interfaces among design, construction, procurement, training, licensing, operations, and maintenance, to ensure the configuration of the facility is established, approved, and maintained.

Configuration Management (Software) – The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests.

Control Point – A point in the software life cycle at which specified agreements or controls (typically a test or review) are applied to the software configuration items being developed (e.g., an approved baseline or release of a specified document or computer program).

Corrective Actions – Measures taken to rectify conditions adverse to quality, and, where necessary, to preclude repetition or recurrence.

Critical Characteristics – Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

Dedicating Entity – The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or by the facility.

Document – Any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a QA record until it satisfies the definition of a QA record as defined in this QAPD.

Document Control – The act of ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

Electronic Document – A document stored in a form (magnetic or optical) that is accessible only by a computer.

Electronic Information System – An information system that contains and provides access to computerized Federal records and other information.

Equivalency Evaluation – A technical evaluation performed to confirm a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions.

Electronic Mail (Email) System – A computer application used to create, receive, and transmit messages and other documents. Excluded from this definition are file transfer utilities (software that transmits files between users but does not retain any transmission data), data systems used to collect and process data that have been organized into data files or data bases on either personal computers or mainframe computers, and word processing documents not transmitted on an email system.

Electronic Record – Any information recorded in a form that only a computer (e.g., desktop, laptop, tablet, smartphone) can process and that satisfies the definition of a Federal record under the *Federal Records Act*. The term includes both the record content and the associated metadata that the agency determines is required to meet agency business needs.

Equivalent Replacement Item – A replacement item not physically identical to the original. A replacement item requires an equivalency evaluation to ensure its intended functions, including its safety function, will be maintained.

Error – A condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements.

Existing Data – Data determined to be necessary for activities governed by this QAPD and ASME NQA-1, but developed before or outside of this QAPD and ASME NQA-1, or data published in scientific publications. Existing data does not include information that is accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables, gravitational laws).

Graded Approach – The process of ensuring the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

- Relative importance of an item or activity with respect to safety, safeguards, security, and regulatory compliance
- Magnitude of a hazard, the risk involved, the consequences of failure, the probability of the occurrence of the postulated consequences (including natural phenomena hazards)
- Life-cycle stage of a facility, item, or activity
- Performance history or standardization of a facility, item, or activity
- Impacts/consequences on the programmatic mission of a facility
- Particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, difficulty to perform services, necessity for special controls or processes, or oversight of processes and performance)
- Nuclear safety classification or hazard category of the item or activity
- Adequacy of existing safety documentation
- Relative importance of radiological and nonradiological hazards
- Complexity of products, items, or services involved
- Difficulty and impact of the results of performance assessments and engineering analyses
- Importance of the data to be generated
- Need to demonstrate compliance with specific regulatory design and QA requirements, including special controls and oversight
- Any other relevant factor (10 CFR 830.3, “Definitions”).

Guidance – A suggested practice that is not mandatory in programs intended to comply with this QAPD. The word “should” denotes guidance; the word “shall” denotes a requirement.

Hazard Controls – Measures to eliminate, limit, or mitigate hazards to workers, the public, and the environment, including:

- Physical, design, structural, and engineering features
- Safety structures, systems, and components

- Safety management programs
- Technical safety requirements
- Other controls necessary to provide adequate protection from hazards (10 CFR 830.3).

Identical Item – An item that exhibits the same technical and physical characteristics (physically identical).

Independence – Used in reference to the use of individuals within the organization or company, but independent from the work or process being evaluated, or individuals from an external organization or company for the performance of any quality-affecting activity.

Independent Assessment – An assessment process, with close management involvement, performed by appropriately qualified and knowledgeable independent personnel who have sufficient authority and independence from the organization being assessed. The intent of this assessment is to achieve continuous improvement by measuring item and service quality and the effectiveness of system performance. Individuals who are independent from performing or supervising the work being assessed and who are technically qualified and knowledgeable in the areas to be assessed conduct independent assessments. Personnel from other sites, DOE Office of Environmental Management, and subcontractors can also participate in independent assessments.

Inspection – Examination or measurement to verify whether an item or activity conforms to specified requirements.

Issue – Term used in this QAPD to refer to events, findings, conditions adverse to quality (failures, malfunctions, deficiencies, defective items, and nonconformances), and opportunities for improvement, that is any situation that may warrant management attention.

Item – An all-inclusive term used in place of any of the following:

- Appurtenance
- Assembly
- Component
- Equipment
- Material
- Module
- Part
- Product
- Software
- Structure
- Subassembly
- Subsystem
- System
- Support system
- Unit.

Lessons Learned – A “good work practice” or innovative approach that is identified and shared or an adverse work practice or experience that is shared to avoid recurrence.

Like-for-Like Replacement – The replacement of an item with an item that is identical.

Management Assessment – A periodic introspective self-analysis conducted by management, to evaluate management systems, processes, and programs with the goal of ensuring the organization’s work is properly focused on achieving desired results.

Managers – Positions within the ORP organizational structure at the level of supervisor, assistant manager, division director, office director, or above. For the purposes of this QAPD, managers have supervisory responsibilities.

Metadata – Preserved contextual information describing the history, tracking, and/or management of an electronic document.

Nonconformance – A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Nonrecord Materials – Federally owned informational materials that do not meet the statutory definition of “records” (44 USC 3301, “Definition of Records”) or that have been excluded from coverage by the definition. Excluded are extra copies of documents kept only for reference, stocks of publications and processed documents, and library or museum materials intended solely for reference or exhibit.

Nuclear Facility – A reactor or a nonreactor nuclear facility where an activity is conducted for, or on behalf of DOE, including any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by 10 CFR 830.3.

Objective Evidence – Any documented statement of fact, other information, or record, quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests, that can be verified.

Operating Environment – A collection of software, firmware, and hardware elements that provide for the execution of computer programs.

Procedure – A document that specifies or describes how an activity or process is to be performed.

Process – A series of actions that achieves an end result.

Procurement Document – Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Quality Assurance Record – A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms.

Qualification of Existing Data – Qualification of existing data process is used to qualify data of indeterminate quality. The data qualification process includes data qualification planning, a controlled process for evaluating and establishing data quality, and documentation of the results of this process.

Qualification (Personnel) – The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, which qualify an individual to perform a required function.

Quality – The condition achieved when an item, service, or process meets or exceeds the user’s requirements and expectations.

Quality-Affecting – An activity or product that produces an effect or change in a condition achieved when an item, service, or process meets or exceeds the user’s requirements and expectations or all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service and that quality is achieved.

Quality Assurance (QA) – All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service and that quality is achieved.

Quality Assurance Program – The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Records – All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal law, or in connection with the transaction of public business, that is preserved or is appropriate for preservation by that agency, or its legitimate successor, as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government, or because of the informational value of the data in them.

Recordkeeping System – Manual or automated mechanism in which records are collected, organized, and categorized to facilitate their preservation, retrieval, use, and disposition.

Root Cause – The most basic reason an event, failure, or inappropriate action occurred that, if corrected, will prevent recurrence.

Safety – An all-inclusive term to encompass protection of the public, workers, and the environment (used synonymously with environment, safety, and health).

Safety Function – The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

Safety Software –

1. **Safety System Software**. Software for a nuclear facility that performs a safety function as part of a system, structure, and component and is cited in either a DOE-approved documented safety analysis; or an approved hazard analysis in accordance with DOE P 450.4A, *Integrated Safety Management Policy*, and 48 CFR 970-5223-1, “Integration of Environment, Safety, and Health into Work Planning and Execution.”
2. **Safety and Hazard Analysis Software and Design Software**. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a system, structure, and component, but helps to ensure the proper accident or hazards analysis of nuclear facilities or of a system, structure, and component that performs a safety function.
3. **Safety Management and Administrative Controls Software**. Software that performs a hazard control function in support of nuclear facility, radiological safety management programs, or technical safety requirements, or other software that performs a control

function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, and the environment as addressed in 10 CFR 830, “Nuclear Safety Management”; 10 CFR 835, “Occupational Radiation Protection”; *Department of Energy Acquisition Regulation* Integrated Safety Management System clause; and 48 CFR 970-5223-1.

Service – The performance of work or activities such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental remediation, environmental restoration, waste management, laboratory sample analysis, safety software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, installation, or the like.

Significant Condition Adverse to Quality – A condition adverse to quality, which, if uncorrected, could have a serious effect on safety, operability, or credibility of ORP work. This definition extends to conditions that, if uncorrected, could lead to a significant impact on the environment or noncompliances with environmental regulations.

Software – Computer programs and associated documentation and data pertaining to the operation of a computer system.

Software Design Verification – The process used to determine if the end product of a software design activity fulfills the software design requirements.

Software Engineering –

1. Application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software (i.e., the application of engineering to software)
2. Study of approaches defined in number 1.

Software Life Cycle – The period of time that begins when a software product is conceived and ends when the software is no longer available for use. The life cycle typically includes a concept phase, requirements phase, design phase, implementation phase, test phase, installation and checkout phase, operation and maintenance phase, and, sometimes, retirement phase. These phases may overlap or be performed iteratively, depending on the software development approach used.

Supplier – Any individual or organization that furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following:

- Vendor
- Seller
- Contractor
- Subcontractor
- Fabricator
- Consultant
- Any of their sub-tier levels.

Surveillance – Surveillances are performed by ORP QAD and are evaluations of an ongoing program, functional area, or activity to verify it complies with standards and requirements, is conducted safely, and conforms to procedures and best practices or act of monitoring or

observing to verify whether an item or activity conforms to specified requirements. Surveillances are typically narrower in scope and use fewer team members compared with other types of assessments.

Suspect/Counterfeit Items – An item that is suspect when inspection or testing indicates it may not conform to established government or industry-accepted specifications or national consensus standards, or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the vendor, supplier, distributor, or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority, or whose material, performance, or characteristics the vendor, supplier, distributor, or manufacturer has misrepresented. Items that do not conform to established requirements are not normally considered suspect/counterfeit items if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

- Defects resulting from inadequate design or production quality control
- Damage during shipping, handling, or storage
- Improper installation
- Deterioration during service
- Degradation during removal
- Failure resulting from aging or misapplication
- Other controllable causes (IAEA-TECDOC-1169, *Managing suspect and counterfeit items in the nuclear industry*).

Testing – A process for verifying or determining the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Testing (Software) – A three-part process comprised of (1) operating a system (i.e., software and hardware) or system component under specified conditions, (2) observing and recording the results, and (3) making an evaluation of some aspect of the system (i.e., software and hardware) or system component in order to verify it satisfies specified requirements and to identify errors.

Test Case – A set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

Test Plan (Procedure) – A document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, tasks to be performed, and responsibilities for the testing activities.

Training – A systematic process provided to personnel so they achieve proficiency, maintain proficiency, and adapt to changes in technology, methods, processes, or responsibilities as necessary to perform assigned tasks. Training includes formal and informal training, education, and developmental and other learning assignments. Training also includes the application of acquired knowledge, skills, and experience to workplace responsibilities. Methods of training include, among others, reading assignments, observation and performance of activities, lessons

learned, on-the-job training, feedback from coworkers and managers, briefings, and formal training classes.

Trend – Collection of data gathered and analyzed over a period of time with a prevailing course of direction, tendency, or inclination.

Validation – The process of either evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements; or providing evidence the software, and its associated products, satisfies system requirements allocated to software at the end of each life-cycle activity, solves the right problem (e.g., correctly models physical laws, implements business rules, uses the proper system assumptions), and satisfies the intended use and user needs (IEEE Std 1012-2012, *IEEE Standard for System and Software Verification and Validation*).

Verification – The process of evaluating a system or component to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase; or providing objective evidence the software and its associated products conforms to requirements (e.g., for correctness, completeness, consistency, accuracy) for all life-cycle activities during each life-cycle process (acquisition, supply, development, operation, and maintenance); satisfies standards, practices, and conventions during life-cycle processes; and successfully completes each life-cycle activity and satisfies all the criteria for initiating succeeding life-cycle activities (e.g., building the software correctly) (IEEE Std 1012-2004, *IEEE Standard for Software Verification and Validation*).

Work – A defined task or activity such as oversight; assessments; surveillances; audits; document reviews; program reviews; research and development; project administration; safeguards and security; data collection and analysis; manufacturing; operations; environmental remediation; maintenance and repair; software (including safety software) development, validation, testing, and use; inspection; safeguards and security; and data collection and analysis. All activities or tasks necessary to accomplish the ORP mission and meet regulatory requirements.

APPENDIX C
APPLICABILITY OF ASME NQA-1 TO RESEARCH AND DEVELOPMENT
ACTIVITIES

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APPENDIX C
APPLICABILITY OF ASME NQA-1 TO RESEARCH AND DEVELOPMENT
ACTIVITIES

ASME NQA-1 Part 1 Requirements	R&D Activities			R&D Support Activities
	Basic	Applied	Development Activities	
Organization	Note (1)	Note (1)	Note (1)	Note (1)
Quality Assurance Program	Note (1)	Note (1)	Note (1)	Note (1)
Design Control	Note (2)	Note (3)	Note (1)	Note (1)
Procurement Document Control	Note (1)	Note (1)	Note (1)	Note (1)
Instructions, Procedures, and Drawings	Note (3)	Note (3)	Note (3)	Note (1)
Document Control	Note (1)	Note (1)	Note (1)	Note (1)
Control of Purchased Materials, Items, and Services	Note (1)	Note (1)	Note (1)	Note (1)
Identification of Control Items	Note (1)	Note (1)	Note (1)	Note (1)
Control of Processes	Note (3)	Note (3)	Note (1)	Note (1)
Inspection	Note (2)	Note (2)	Note (3)	Note (1)
Test Control	Note (2)	Note (3)	Note (1)	Note (1)
Control of Measuring and Test Equipment	Note (3)	Note (3)	Note (1)	Note (1)
Handling, Storage, and Shipping	Note (1)	Note (1)	Note (1)	Note (1)
Inspection, Test, and Operating Status	Note (3)	Note (3)	Note (1)	Note (1)
Control of Nonconforming Items	Note (2)	Note (2)	Note (2)	Note (1)
Corrective Action	Note (3)	Note (3)	Note (1)	Note (1)
Quality Assurance Records	Note (1)	Note (1)	Note (1)	Note (1)
Audits	Note (3)	Note (3)	Note (1)	Note (1)

ASME NQA-1-2008, 2008, *Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.

ASME NQA-1a-2009, 2009, *Addenda A to Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.

Notes:

- (1) = Applicable.
- (2) = No applicability for research and development activity.
- (3) = Graded applicability with explanation.
- R&D = research and development.

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