

<b>QUALITY ASSURANCE PROGRAM</b>		Identifier: PRD-5071
		Revision*: 23
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Companywide	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>
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\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for the company *quality assurance* (QA) (see def.) program.

## 2. APPLICABILITY

This PRD applies to company organizations that prescribe, perform, or verify activities, including those having responsibility for planning and scheduling.

## 3. RESPONSIBILITIES

### 3.1 CH2M-WG Idaho, LLC President and Chief Executive Officer

The CH2M-WG Idaho, LLC (CWI) president and chief executive officer is responsible for the scoping, planning, implementation, and maintenance of the overall Quality Assurance Program (QAP). Details of the president and chief operating officer's responsibilities are provided in PRD-5070, "Organization."

### 3.2 Environment, Safety, Health, and Quality Vice President

The Environment, Safety, Health, and Quality, (ESH&Q) vice president is responsible for defining policy and management direction for the establishment and implementation of the company QAP. The vice president, ESH&Q, also is responsible for the Price-Anderson Amendments Act of 1998 compliance program including Idaho Cleanup Project inputs to the Department of Energy (DOE) Headquarters Noncompliance Tracking System.

Further details of the ESH&Q vice president responsibilities are provided in PRD-5070.

### 3.3 Quality Assurance Director

The Quality Assurance director is responsible for directing, developing, and maintaining the company QAP, and ensuring and verifying its implementation. Additional details of the QA director's responsibilities are provided in PRD-5070.

The QA director is responsible for:

- A. Managing technical aspects of the company's QAP
- B. Providing technical assistance and guidance to directors, managers, and staff in identifying QA requirements

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- C. Resolving with line management those conditions not in compliance with QAP requirements to ensure that the conditions are corrected in an appropriate and timely manner
- D. Providing technical direction of QA *training* (see def.)
- E. Preparing, implementing, and maintaining the company QAP requirements documents
- F. Implementing established quality policy and defining program direction in compliance with QAP requirements
- G. Developing, coordinating, and maintaining company QA *procedures* (see def.) that establish requirements and *processes* (see def.) for implementing the QAP
- H. Providing for *indoctrination* (see def.) and training of *audit* (see def.) personnel
- I. Establishing a *qualification* (see def.) and *certification* (see def.) program for *auditor/lead auditors* (see defs.)
- J. Supporting the company's goal of operational excellence and integrated safety management
- K. Managing the company's process for controlling nonconforming items.

### 3.4 Nuclear Safety/Training/Performance Director

The Nuclear Safety/Training/Performance director's responsibilities include, but are not limited to:

- A. Maintaining and directing activities for the compliance assurance, issues management, and performance measurement programs
- B. Ensuring preparation and execution of an annual independent audit schedule
- C. Reporting the results of independent audits to the area manager assessed
- D. Administering the Issues Communication and Resolution Environment (ICARE) for electronic tracking of *issues* (see def.) and corrective actions
- E. Managing the Lessons Learned program for identification, evaluation, and tracking of noteworthy practices and conditions requiring corrective or preventive actions
- F. Administering the Performance Reporting and Analysis program for establishing, analyzing, and reporting ESH&Q performance objectives, measures, and commitments

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- G. Managing the Integrated Assessment program including the integrated assessment schedule and database and point-of-contact for assessments/audits/evaluations by external agencies.

### **3.5 Environmental and Regulatory Services Director**

The Environmental and Regulatory Services Director's responsibilities include, but are not limited to:

- A. Developing and maintaining documents that establish and implement Environmental program requirements, activities, and processes
- B. Assisting company management in implementation of Environmental program processes.

### **3.6 Quality Assurance Systems and Operations Support**

The Quality Assurance Systems provide quality assurance/quality control (QA/QC) support in the areas of QAP and policy development and maintenance; QA training and certification maintenance, audit assessment planning; performance and development; *surveillance* (see def.) planning, scheduling, and evolution; QAP trending; QA ICARE coordination and software QA leadership; and CWI procurement quality activities including supplier evaluation, qualified suppliers list, and review of procurement documents.

In addition, Quality Assurance Systems has the responsibility for overall environmental QA and waste certification official activities associated with Nevada National Security Site shipments.

### **3.7 Quality Engineering**

Quality Engineering provides QA support to all of the operations and maintenance activities at the Idaho Nuclear Technology and Engineering Center (INTEC), in particular, liquid waste treatment projects, spent nuclear fuel projects, high-level waste (HLW), tank farm closure, and Nuclear Regulatory Commission (NRC) regulated projects.

Other Idaho National Laboratory (INL) Site areas that Quality Engineering provides operations QA support include the Integrated Waste Treatment Unit (IWTU), Radioactive Waste Management Complex (RWMC), Idaho Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Disposal Facility (ICDF), Test Area North (TAN), Power Burst Facility (PBF), the Reactor Technology Complex (RTC) (formerly Test Reactor Area [TRA]) cleanup work, as well as other miscellaneous overall environmental QA site work (i.e., packaging and transportation planning and performance).

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### 3.8 Quality Inspection

The Quality Inspection Department provides QC support for all CWI locations and organizations.

In addition, the Quality Inspection group provides inspection support for the Owner/User Inspector Program under the National Board (NBIC) Boiler and Pressure Vessel Code, maintenance, hoisting and rigging program, receipt inspection, oversight, and CWI *suspect/counterfeit items (S/CIs)* (see def.) program responsibility.

### 3.9 Line Organization Managers

*Line organization* (see def.) managers responsibilities include but are not limited to:

- A. Designating individuals or organizations responsible for implementing the requirements of the QAP requirements documents (e.g., *technical support organization* [see def.]) and defining the interfaces with *external organizations* (see def.)
- B. Identifying the responsibilities and authorities of those organizations and management
- C. Ensuring implementation of the QAP within their organizations
- D. Resolving quality deficiencies and implementing timely *corrective action* (see def.).

### 3.10 Cognizant Quality Engineer

The cognizant quality engineer is responsible for providing QA support, which includes, but is not limited to:

- A. Reviewing QA implementing procedures and selected program documents and operating procedures prepared within the performing organization for quality related activities
- B. Assisting the line organization in identifying and resolving quality issues
- C. Preparing internal implementing procedures
- D. Assisting the line organization in identifying and solving problems
- E. Reviewing and approving quality *procurement documents* (see def.)
- F. Reviewing *nonconformance* (see def.) documentation for satisfactory resolution
- G. Performing and documenting independent QA inspections and tests, where applicable

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- H. Evaluating selected QA *data* (see def.), and reporting results to appropriate levels of management
- I. Identifying and documenting necessary *witness* and *hold points* (see defs.) through inspection planning and/or procedure review
- J. Providing analytical support for production processes as related to the QA discipline
- K. Participating in the Unusual Occurrence Report process as requested
- L. Issuing *stop work orders* (see def.) when *conditions adverse to quality* (see def.) require immediate corrective action
- M. Assessing the supported organization's QAP and identifying management problems that hinder the organization from achieving its objectives.

### 3.11 Cognizant Quality Inspectors

Cognizant quality *inspectors* (see def.) are responsible for:

- A. Providing inspection and nondestructive examination (NDE) support to programs, projects, facilities, and support organizations
- B. Interfacing with quality engineers and others in the preparation of inspection plans and procedures
- C. Performing inspection, NDE, and test *verifications* (see def.) in accordance with approved written plans and procedures
- D. Documenting the results of inspections, examinations, and tests on *items* (see def.) that have been submitted for quality verification
- E. Initiating a nonconformance report on items that do not meet inspection, test, or examination criteria
- F. Stating nonconforming items to prevent their inadvertent use or installation
- G. Maintaining personal qualifications current in inspection and NDE disciplines.

### 3.12 Company Employees

Company employees are responsible for:

- A. Performing work in compliance with the QAP requirements applicable to their job assignments
- B. Reporting an unsafe or noncompliant condition or act and stopping work when appropriate until such condition or act is corrected.

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**4. REQUIREMENTS****4.1 Companywide Application**

The requirements identified in this subsection meet the requirements in “Quality Assurance Requirements for Nuclear Facility Application,” American Society of Mechanical Engineers (ASME/NQA-1-2008 with Addenda through NQA-1a-2009), and the other standards listed in FWD-7, “Foreword.” This PRD applies to the entire company as defined by FWD-7.

**4.1.1 Basic**

4.1.1.1 A documented QAP will be planned, implemented, and maintained in accordance with ASME NQA 1, Part 1, Subparts 2.7 and 2.14. The project will identify the activities and items to which they apply.

4.1.1.2 The QAP will develop and implement:

4.1.1.2.1 QA criteria as defined in 10 Code of Federal Regulations (CFR) 830.120 using a *graded approach* (see def.) and describing how the criteria and graded approach are applied. The graded approach is determined by MCP-540, “Assigning Quality Levels.”

4.1.1.2.2 Use voluntary national or international consensus standard with contractual or regulatory requirements and identify the standard used. Appropriate standards include:

- A. ASME NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications” (for nuclear-related activities)
- B. American National Standards Institute/ International Standards Organization/ Quality (ANSI/ISO/Q) 9001-2000, “Quality Management System – Requirements” (for non-nuclear activities)

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- C. ANSI/American Society for Quality (ASQ) Z 1.13, “Quality Guidelines for Research,” 1999 (for non-nuclear research activities).
- 4.1.1.2.3 Apply additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary address unique/specific work activities.
- 4.1.1.2.4 Integrate quality management system requirements, S/CIs Prevention Process, and the Corrective Action System with other quality or management system requirements in DOE directives and external requirements, including, as applicable.
- A. DOE G 450.4-1B, “Integrated Safety Management System Guide”
  - B. DOE/RW-0333P DOE *Office of Civilian Radioactive Waste Management* (see def.), *QA Requirements and Description* (see def.)
  - C. DOE/CBFO-94-1012, DOE Carlsbad Field Office, *QA Program Description*, (for the Waste Isolation Pilot Plant and related activities).
- NOTE:** *This integration requirement does not establish or imply a hierarchy of quality requirements or programs.*
- 4.1.1.3 The QAP will be established at the earliest time consistent with the schedule for accomplishing the activities.
- 4.1.1.4 Regardless of the performer of the work, the contractor is responsible for complying with the requirements of these PRDs. The contractor is responsible for flowing down the requirements of these PRDs, ASME NQA-1, or other appropriate standard to subcontractors at any tier to the extent necessary to ensure the contractor’s compliance with the requirements. In doing so, the contractor does not unnecessarily or imprudently flow down requirements to subcontracts. That is, the contractor ensures that it and its

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subcontractors comply with the requirements of these PRDs and only incur costs that would be incurred by a prudent person in the conduct of competitive business.

- 4.1.1.5 The project will include monitoring activities against *acceptance criteria* (see def.) in a manner sufficient to provide assurance that activities affecting quality are performed satisfactorily.
- 4.1.1.6 These QAP requirements documents implement QA criteria as defined in DOE O 414.1D and S/CIs prevention requirements that integrate quality or management system requirements defined in these QAP requirements documents with DOE directives and similar external requirements.
- 4.1.1.7 The QAP requirements document includes requirements to integrate multiple QAP QA drivers imposed by QA regulations (see 10 CFR 830), the NRC, and other federal agencies. The QAP requirements document includes supplemental activity-specific requirements but does not supersede or alter compliance with QA regulations. If this PRD conflicts with any nuclear safety regulation, the regulation prevails.
- 4.1.1.8 The project will provide control over *activities affecting quality* (see def.) to an extent consistent with their importance.
- 4.1.1.9 A graded approach based upon risk will be used in categorizing *structures, systems, and components* (SSCs) (see def.) and software for applying QA controls, as referenced in Subsection 4.1.2.
- 4.1.1.10 Organizations will establish implementing documents applicable to their scope of work that translate the QA requirements into work processes.
- 4.1.1.11 The organization will establish and implement processes to detect and correct quality problems.
- 4.1.1.12 When more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization will be clear, defined, and documented.

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- 4.1.1.13 The external interfaces between organizations and internal interfaces between organizational units, and changes thereto, will be documented.
- 4.1.1.14 The QA *guidance* (see def.) provided by the latest revision of DOE G 414.1-1B, and DOE EM-QA-001 must be considered in developing and implementing the QAP.
- 4.1.1.15 QAP changes made the previous year will be submitted annually to DOE for review and *approval* (see def.). In the submittal, the changes will be identified, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of DOE O 414.1D. Changes to an approved QAP may be made at any time. Editorial changes made to correct spelling, punctuation, grammar, etc., do not require explanation.
- 4.1.1.16 Quality program plans will be written when there is a need to deviate from the company's base QAP or to address unique customer requirements for a specific program or project.
- 4.1.1.17 QA project plans will be written to address how Environmental Protection Agency requirements are applied to company operations.

#### **4.1.2 Applying Controls**

QA controls (grading) will be applied to the degree commensurate necessary to ensure that the level of analysis, documentation, and actions used to comply with requirements are proportioned with:

- A. The relative importance to safety, safeguards and security; the magnitude of any hazard involved; the life-cycle stage of a facility or item; the programmatic mission of a facility; the peculiar characteristics of a facility or item; the relative importance to radiological and nonradiological hazards; and any other relevant factors.

#### **4.1.3 Planning Work**

- 4.1.3.1 Planning will be documented to ensure work is accomplished under suitably controlled conditions.

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4.1.3.2 Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.

4.1.3.3 The project will provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items, and for verification of that quality.

#### **4.1.4 Personnel Qualification**

**NOTE:** *Personnel training and qualification requirements are addressed in PRD-5072, "Personnel Training and Qualification."*

#### **4.1.5 Quality Assurance Program Information Management**

4.1.5.1 Relevant organization management will, on a continuing basis, be apprised of the status, adequacy, and compliance aspects of the QAP.

4.1.5.2 Appropriate management will receive, as a minimum, audit reports, surveillance reports, trending reports, and *management assessment* (see def.) reports.

### **4.2 Specific Requirements for DOE/RW-0333P, Quality Assurance Requirements and Descriptions, Applications**

**NOTE:** *NRC Licensed Independent Spent Fuel Storage Installations (ISFSIs) maintain compliance with Revision 10 of DOE/RW-0333P.*

This subsection contains additional requirements from the *Quality Assurance Requirements and Descriptions* (QARD) (see def.) (DOE/RW 0333P) that are specific to the spent nuclear fuel and HLW activities as defined in FWD-7, "Foreword."

#### **4.2.1 Quality Assurance Program Documents**

4.2.1.1 *Affected organizations* (see def.) will issue a policy statement signed by senior line management directing mandatory compliance with this QAP.

4.2.1.2 A QARD requirements matrix or other similar cross-reference shall be maintained consistent with scope of work that provides the relationship between the QARD and implementing documents.

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**4.2.2 Applicability and Related Activities**

The QARD shall be applied to:

- A. All SSCs important to safety (ITS).
- B. All SSCs that are waste acceptance impacting (WAI).
- C. Design and characterization of barriers important to waste isolation (ITWI).
- D. SSCs important to worker and public safety, or the environment.
- E. Activities related to SSCs and barriers described in A and B above, which include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; performance of the preclosure safety analysis, total system performance assessment (postclosure safety analysis), and qualification of their inputs; and performance confirmation.
- F. Activities related to SSCs and barriers described in A, B, and C above, 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).
- G. The controls applied to activities related to SSCs described in C above using a graded approach. These SSCs and related activities are not within the scope of 10 CFR 63.142. However, if duplicate or conflicting requirements exist between 10 CFR 63.142 and DOE O 414.1D, 10 CFR 63.142 shall govern.
- H. Activities related to DOE HLW waste forms (i.e., waste form development through qualification, waste form production, and waste form acceptance.
- I. Activities related to DOE spent nuclear fuel (i.e., spent nuclear fuel characterization, conditioning, treatment, and/or canisterization and acceptance.

**NOTE:** *Although items A through I above are QARD-related activities, only B, C, G, and H are activities by the Idaho Cleanup Project.*

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### **4.2.3 Classifying SSCs**

- 4.2.3.1 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 Q-List (e.g., it may be more appropriate for some EM waste custodians and their contractors to maintain an item and activities list.

### **4.2.4 Readiness Reviews**

- 4.2.4.1 The need for readiness reviews will be identified for major scheduled or planned work to ensure that the Office of Civilian Radioactive Waste Management (OCRWM) program objectives are met. Where needed, readiness reviews will be conducted for the planned scope of work to ensure that *objective evidence* (see def.) 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.

### **4.2.5 Peer Reviews**

- 4.2.5.1 Peer reviews shall be conducted in accordance with NUREG-1297, February 1988, Section III, “Definitions,” and Section IV, “Staff Position.”

### **4.2.6 Expert Elicitation**

- 4.2.6.1 Expert elicitation shall be conducted in accordance with NUREG-1563, November 1996, Section 3, “Branch Technical Position,” and Appendix A, “Glossary,” except Step 7.

### **4.2.7 Personnel Indoctrination, Training, Qualification, and Certification**

**NOTE:** *Personnel training and qualification requirements are addressed in PRD-5072.*

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**5. RECORDS**

All records generated by this document that are designated in implementing documents as *QA records* (see def.) will be controlled in accordance with PRD-5088, “Quality Assurance Records.”

**6. DEFINITIONS**

Refer to LST-199, “Quality Assurance Program Requirements Document Definitions,” for the definitions of the following terms:

*acceptance criteria*

*activities affecting quality*

*affected organization*

*approval*

*audit*

*auditor*

*certification*

*conditions adverse to quality*

*corrective action*

*data*

*external organization*

*graded approach*

*guidance*

*hold point*

*indoctrination*

*inspector*

*issues*

*item*

*lead auditor*

*line organization*

*management assessment*

*nonconformance*

*objective evidence*

*Office of Civilian Radioactive Waste Management*

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*procedure**process**procurement document**qualification (personnel)**quality assurance**quality assurance record**Quality Assurance Requirements and Description (QARD)**stop work order**structure, system, and component**surveillance**suspect/counterfeit item**technical support organization**training**verification**witness point***7. REFERENCES**

10 CFR 63.142, "Quality Assurance Criteria"

10 CFR 830, 2010, "Nuclear Safety Management," *Code of Federal Regulations*, Office of the Federal Register

ANSI/ASQ/Z 1.13, 1999, "Quality Guidelines for Research," American National Standards Institute

ANSI/ISO/Q 9001-2008, "Quality Management System—Requirements" (for non-nuclear activities), American National Standards Institute

ASME NQA-1-2008 with Addenda through NQA-1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," American Society of Mechanical Engineers

DOE/CBFO-94-1012, *QA Program Description* (for the Waste Isolation Pilot Plant and related activities), Department of Energy Carlsbad Field Office

DOE EM-QA-001 "DOE Environmental Management Quality Assurance Program"

DOE G 414.1-1B, 2001, "Management Assessment and Independent Assessment Guide," Department of Energy Guide DOE O 414.1D, "Quality Assurance," Attachment 2, Department of Energy

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DOE G 450.4-1B, Volumes 1 and 2, “Integrated Safety Management System Guide for Use with Safety Management System Policies (DOE P 450.4, 450.5, 450.6): The Functions, Responsibilities, and Authorities Manual; and DOE Acquisition Regulation”

DOE/RW-0333P, “*Quality Assurance Requirements and Description*,” Rev. 20, Department of Energy Civilian Radioactive Waste Management Program

FWD-7, “Foreword”

LST-199, “Quality Assurance Program Requirements Document Definitions”

MCP-540, “Assigning Quality Levels”

NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*, Section III, “Definitions,” Section IV, “Staff Position.”

NUREG-1563, *Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program*, Section 3, “Branch Technical Position,” and Appendix A, “Glossary”

PRD-5070, “Organization”

PRD-5072, “Personnel Training and Qualification”

PRD-5088, “Quality Assurance Records”