



U.S. Department of Energy
Oak Ridge Office of
Environmental Management

**Quality Assurance Implementation
Plan for the Outfall 200
Mercury Treatment Facility Balance of
Construction Activities for Critical Decision-2/3**

APPROVAL



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ACRONYMS

| | |
|--------------|--|
| AD | Administrative Document |
| CD | Critical Decision |
| DOE | U.S. Department of Energy |
| EM | Office of Environmental Management |
| EM-QA-001/R1 | EM Quality Assurance Program, Revision 1 |
| MTF | Mercury Treatment Facility |
| NQA-1 | Nuclear Quality Assurance-1-2008 |
| NQA-1a-2009 | Nuclear Quality Assurance-2008, <i>Quality Assurance Requirements for Nuclear Facility Applications</i> , including addenda through 2009 |
| O | Order |
| OF200 | Outfall 200 |
| OREM | Oak Ridge Office of Environmental Management |
| QA | Quality Assurance |
| QAP | Quality Assurance Program |
| QIP | Quality Assurance Implementation Plan |
| QIP/C | Quality Assurance Implementation Plan for balance of construction activities |
| UCOR | URS CH2M Oak Ridge LLC |
| Y-12 | Y-12 National Security Complex |

1.0 PURPOSE

This document identifies the quality requirements implemented by the U.S. Department of Energy (DOE) Oak Ridge Office of Environmental Management (OREM) to support the balance of construction of the Outfall 200 (OF200) Mercury Treatment Facility (MTF) under the OREM Quality Assurance (QA) Program (QAP). The quality requirements are implemented through plans, policies, procedures, desktop instructions, forms, and checklists from the OREM Administrative Document (AD) set and from OREM Construction Support Services contractor procedures. This document also identifies additional site-specific requirements and guidance related to OF200 MTF construction activities.

2.0 SCOPE AND METHOD OF ACCOMPLISHMENT

DOE Order (O) 413.3B, *Program and Project Management for Acquisition of Capital Assets*, requires the development of project-specific QAP for the OF200 MTF balance of construction activities for Critical Decision (CD)-2/3.

OREM adopts in its entirety the DOE Office of Environmental Management (EM) QAP, Revision 1 (EM-QA-001/R1), as the QAP for OF200 MTF balance of construction activities for CD-2/3. This approach ensures a QAP consistent with the Office of EM projects while allowing the OREM to grade the application of requirements based on importance to safety and applicability to the OF200 MTF balance of construction activities for CD-2/3.

EM-QA-001/R1 meets the requirements of DOE O 414.1D, *Quality Assurance*, and Title 10, Code of Federal Regulations, Part 830, Subpart A, *Quality Assurance Requirements*, utilizing the American Society of Mechanical Engineers Nuclear Quality Assurance (NQA-1)-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, including addenda through 2009 (NQA-1a-2009), as the consensus standard for implementation of the QAP. OREM demonstrates how these requirements are applied to the OF200 MTF project through this QA Implementation Plan (QIP/C) for balance of construction activities (QIP/C).

Consequently, this QIP/C is OREM's system to ensure applicable requirements of the QAP are implemented. The requirements and processes described in this QIP/C are applied in a graded approach commensurate with the type of work being performed and the importance of the work, while contributing to safe operations.

The quality requirements of the QAP apply to all processes and services identified as applicable in this QIP/C. OREM ensures applicable requirements are passed down to contractors and their vendors/subcontractors through the administration of contracts which ensure contractor functions are carried out in a manner that protects Federal and contractor personnel and the general public against environmental, safety and health hazards arising during the execution of the contract.

The OF200 MTF project has been assigned a Hazard Category – Radiological (less than Category 3) and non-nuclear hazard of “High.” Using the “graded approach,” the DOE QA

criteria are applied to this project's activities. The graded approach is the process by which the extent (level of rigor) of application of control is determined based on the importance of the activity or scope of work relative to public and worker safety, potential for environmental releases, working within facility performance boundaries, and achieving programmatic mission objectives. A graded approach is applied to meet customer expectations and utilize resources in a cost-effective manner. The construction contractor's QA strategy shall be tailored to risk using the graded approach.

The Federal Project Director's role in this project is to develop the overall project strategy, and this QIP/C provides the QA strategy for the construction project. The OREM construction contractor shall adopt NQA-1-2008 and NQA-1a-2009 to provide the necessary controls and the "how to" for implementing those controls. To achieve and demonstrate excellence in meeting this requirement, the OREM construction contractor shall develop and implement an OREM-approved QAP that addresses the contract scope of work in accordance with Title 10, Code of Federal Regulations, Part 830, Subpart A, DOE O 414.1D, and EM-QA-001/R1.

The construction contractor shall also develop an organizational-specific QIP describing how the applicable requirements of the QAP are met and implemented and/or passed down to lower-tier organizations. It is anticipated that as the project progresses, this QIP/C may be updated to reflect current requirements, and the performing contractors shall develop implementing QA documents as required.

The OREM construction contractor shall need a fully implemented quality control program that directly integrates the fulfillment of acceptance criteria contained within design specifications and other design criteria.

3.0 PROJECT BACKGROUND

The DOE Oak Ridge Reservation is located within and adjacent to the corporate limits of the City of Oak Ridge, Tennessee. The area proposed for construction of the OF200 MTF is located in the south-central portion of the Y-12 National Security Complex (Y-12).

Historical missions at Y-12 have resulted in the release of mercury to the environment and contamination has been identified in soil, sediment, surface water, groundwater, buildings, drains and sumps. Discharges from the West End Mercury Area at Y-12 are primary point source distribution contributors to mercury flux into the East Fork of Poplar Creek, which flows from the south-central portion of Y-12 and eventually through the City of Oak Ridge. Mercury is released via OF200 through direct erosion of contaminated soil, migration of dissolved mercury through storm drains and several outfalls, and shallow groundwater. Mercury contamination is a major environmental risk in the Oak Ridge Reservation. OREM intends to construct and operate the OF200 MTF, a water treatment system that will collect and treat the mercury-impacted surface water near OF200. Operation of the OF200 MTF will supplement other Comprehensive Environmental Response, Compensation, and Liability Act response actions to further reduce mercury concentrations in surface water and releases to the offsite environment.

URS | CH2M Oak Ridge LLC (UCOR), as an OREM Construction Support Services contractor for construction activities, is the OF200 MTF Design Authority and shall provide design reviews, special inspections, and Title III engineering support. CH2M HILL, Inc., through UCOR, is the Design Agent.

The MTF includes a Headworks area (weir intake structure, grit removal chambers, storage tank and pumping station) located adjacent to OF200. It also includes a Treatment Plant (equalization tank, chemical reaction tanks, inclined plate clarifiers, treatment building, chemical storage and utilities) located near the east end of the Y-12 site. The Headworks and Treatment Plant are connected via an above-grade pipeline extended along the south side of Upper East Fork Poplar Creek.

The OF200 MTF scope is organized to include the following major activities:

- Design and acquisition
- Site preparation
- Facility construction and construction support
- Construction acceptance testing
- Construction contract closeout

This QIP/C covers the OF200 MTF balance of construction scope that is detailed in the *Construction Execution and Management Plan, OF200 Mercury Treatment Facility at the Y-12 Nuclear Security Complex, Oak Ridge, Tennessee (UCOR-4972)*

4.0 APPLICABILITY

This Plan is applicable to all OREM employees and OREM direct support contractors involved in this project. Each level of line management has the responsibility to consider the impacts of their activities on the quality of goods and services provided by OREM.

5.0 REFERENCES

- DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*
- DOE O 227.1, *Independent Oversight Program*
- DOE Guide 414.1-2B, *Quality Assurance Program Guide*
- DOE O 414.1D, *Quality Assurance*
- DOE O 450.2, *Integrated Safety Management*
- EM-QA-001, Rev. 1, *EM Quality Assurance Program*
- ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications, including addenda through 2009 (NQA-1)*

- ANSI/ISO/ASQ Q 9001-2008, *American National Standard Quality Management Systems Requirements (ISO)*
- OREM-OM-PL-01, *Management System Descriptions*
- OREM-OM-PL-02, *Functions, Responsibilities, Authorities, and Accountabilities*
- OREM-OM-PL-03, *Integrated Safety Management System Description*
- OREM-OM-PL-05, *OREM Program Plan*
- *Integrated Support Center-Oak Ridge Renewal Plan and Service Agreement between the U.S. Department of Energy Oak Ridge Reservation Entities, March 2012*
- *Construction Execution and Management Plan, OF200 Mercury Treatment Facility at the Y-12 Nuclear Security Complex, Oak Ridge, Tennessee (UCOR-4972)*

6.0 RESPONSIBILITIES

6.1 OAK RIDGE OFFICE OF ENVIRONMENTAL MANAGEMENT MANAGER

The OREM Manager has the overall responsibility and accountability for the scope and implementation of the OREM QAP including the procedures, plans and processes identified in this QIP.

6.2 OAK RIDGE OFFICE OF ENVIRONMENTAL MANAGEMENT FEDERAL PROJECT DIRECTOR

The OREM Federal Project Director is responsible for the QAP for the project and for ensuring that all applicable QA requirements must be addressed.

7.0 SUPPORTING MANAGEMENT SYSTEMS, SUBJECT AREAS, AND PROCEDURES

Organizational functions and responsibilities are defined through the *Management System Description* (OREM-OM-PL-01), the *Functions, Responsibilities, Authorities and Accountabilities* (OREM-OM-PL-02), and the *Integrated Safety Management System Description* (OREM-OM-PL-03). The role of each organization in achieving quality is defined in ADs used to conduct day-to-day work. These ADs are also identified in the OREM QIP Matrix (Appendix A).

8.0 ORGANIZATION CHART

The OREM Manager publishes and updates an organizational chart showing the overall structure of the organization. The current organizational chart is located on the home page of the OREM SharePoint site: [https://teamsites.oro.doe.gov/sites/em/SitePages/EM Home.aspx](https://teamsites.oro.doe.gov/sites/em/SitePages/EM%20Home.aspx). The QA Function is a part of the OREM Quality and Mission Support Division.

9.0 INTEGRATION WITH THE OAK RIDGE OFFICE OF ENVIRONMENTAL MANAGEMENT INTEGRATED SAFETY MANAGEMENT SYSTEM

The DOE fundamental quality expectation is that all work meets established requirements. In this regard, the quality management system ensures compliance with the approved safety standards so the expectation for safe work within controls is met in accordance with DOE O 450.2, *Integrated Safety Management*, and as detailed in OREM-OM-PL-03, *Integrated Safety Management System Description*. Requirements are established which, if properly implemented, will provide adequate assurance that the workers, the public, and the environment are protected from adverse consequences.

10.0 MANAGEMENT EXPECTATIONS

Management Expectations and Implementation Requirements as identified in the EM QAP-001 are utilized during planning, development and assessment of OREM processes and procedures as identified in the OREM QIP Matrix (Appendix A).

11.0 GRADING APPLICATION

OREM implements the graded approach process by assignment of quality levels for OREM work activities as required by DOE O 414.1D and EM-QA-001/R1.

The grading process within the OREM QAP ensures that work activity controls are consistent with the importance of the work activity to nuclear safety and the achievement of other OREM mission objectives. The graded approach process requirements are developed commensurate with the following factors:

- a) Relative importance of an item or activity with respect to safety, safeguards, security, and regulatory compliance.
- b) Magnitude of a hazard, the risk involved the consequences of failure, and the probability of the occurrence of the postulated consequences that include natural phenomena hazards.
- c) Lifecycle stage of a facility, item, or activity.
- d) Performance history or standardization of a facility, item, or activity.
- e) Impact/consequences on the programmatic mission of a facility.
- f) 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).
- g) Nuclear safety classification or hazard category of the item or activity.
- h) Adequacy of existing safety documentation.
- i) Relative importance of radiological and non-radiological hazards.
- j) Complexity of products, items, or services involved.

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- k) The difficulty and impact on the results of performance assessments and engineering analyses.
- l) Importance of the data to be generated.
- m) Need to demonstrate compliance with specific regulatory design and QA requirements including special controls and oversight.

APPENDIX A.

**LEGEND DESCRIPTION AND OREM QUALITY ASSURANCE
IMPLEMENTATION PLAN MATRIX**

1
The following information is for your information only and should not be used for any other purpose.

Information is provided for your information only and should not be used for any other purpose.

DISCLAIMER

The information contained herein is for your information only and should not be used for any other purpose.

Legend Description

The following column headers define the content of the tables in Appendix A.

DOE O 414.1D:

Listing of the criteria requirements copied from Attachment 2 of the DOE Order.

Applies to OREM:

Identifies DOE O 414.1D criteria requirements that apply to OREM. "A" indicates that the criterion applies to OREM and "NA" indicates that the criteria is not applicable to OREM activities.

NQA-1 Requirements:

Listing of NQA-1 requirements that are applicable to DOE O 414.1D as detailed in EM-QA-001/R1.

Applies to 414.1D:

Provides additional information regarding the linkage between the DOE O 414.1D criteria requirement and NQA-1 requirements. This column will identify DOE O 414.1D criteria requirement (e.g., a, b, c, or NA). NA indicates that the NQA-1 requirement is not applicable to OREM or that the NQA-1 requirement is addressed under a separate DOE O 414.1D criteria requirement. If this is the case, the appropriate criteria requirement will be indicated in ().

EM-QA-001 Management Expectations and Implementing Requirements:

In addition, EM management expectations are included for each section of the QAP. These expectations are intended as a statement of conduct or performance that should be considered in implementation of the QAP requirements and, as such, are not strict requirements.

Key Processes:

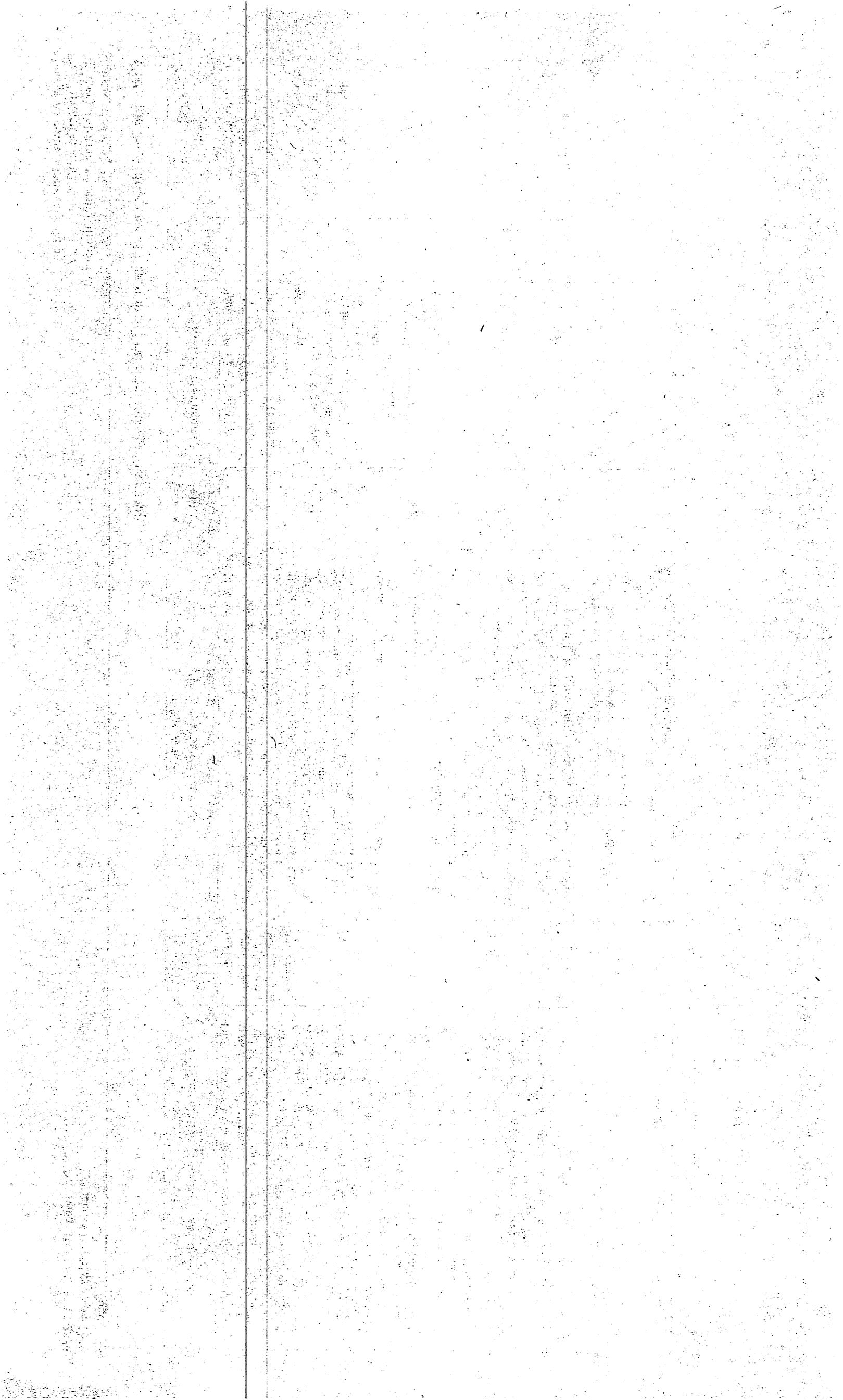
List of OREM applicable processes (or activities).

Implementation Procedures and Documents:

Listing of the OREM and/or OREM Construction Support Services ADs (e.g., policies, plans, implementing procedures, desktop instructions, and other documents as appropriate).

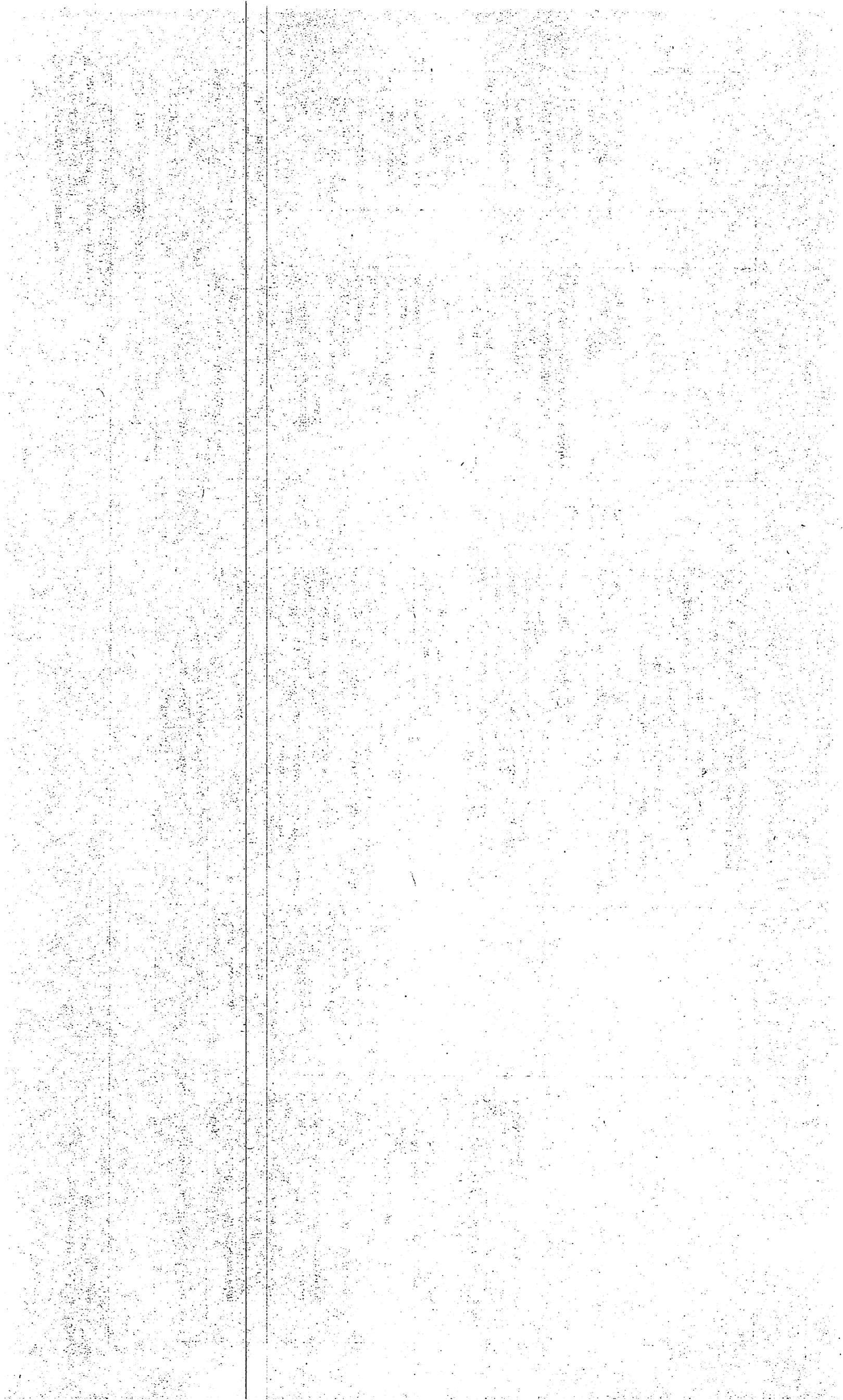
Criterion 2 – Management/Personnel Training and Qualification

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|---|-----------------|---|---|--|---|--|
| (a) Train and Qualify personnel to be capable of performing their assigned work. (b) Provide continuing training to personnel to maintain their job proficiency. | A A | Requirement 2 – Quality Assurance Program 100 Basic 200 Indoctrination and Training 201 Indoctrination 202 Training 300 Qualification Requirements 301 Nondestructive Examination 302 Inspection and Test 303 Lead Auditor 304 Auditors 305 Technical Specialists 400 Records of Qualification 500 Records Appendix 2A-1 Appendix 2A-3 | a,b a,b a,b N/A a,b | <u>Management Expectations:</u> <ul style="list-style-type: none"> Qualifications of specific job categories are based on requirements established by the organization's personnel management, DOE Directives, other requirement documents, or management. Specialized design, engineering, construction, and operational training include formal and informal training, education, and developmental and other learning assignments. Employee-specific training needs are documented and updated as required to ensure the maintenance of competence required by the position. Technical qualification records are maintained separately from other training records. <u>Implementation Requirements:</u> <ul style="list-style-type: none"> The method and process for ensuring personnel are trained, qualified and capable of performing assigned work are identified in training and qualification procedures as described in the applicable QIP. Requirements for qualification of QA and Software QA personnel are in accordance with the Technical Qualification Program. Specific initial and continuing training includes General Employee Training, Job-Specific Training, Assessment and Oversight Training, Lead Auditor Training, Technical Qualification Training (including inspection and test personnel, and Software QA per Appendix G, Software Quality Requirements), Suspect/Counterfeit Items (S/CI) per Appendix F, S/CI Prevention, and Professional Qualification/Certification Training, as applicable. Qualifications and competency levels are maintained through continuing education, training, etc., as required in the applicable standards. Plans, implementing procedures, and documents are referenced in the respective organizational QIPs. | Training Technical Qualification Professional Qualification | <ul style="list-style-type: none"> OREM-TQ-IP-01, <i>Facility Representative Training and Qualification Program</i> OREM-TQ-IP-02, <i>Nuclear Quality Assurance Auditor and Lead Auditor Qualification and Certification Program</i> OREM-TQ-IP-03, <i>Safety System Oversight Training and Qualification Program</i> OREM-TQ-IP-04, <i>Required Reading Program</i> OREM-TQ-IP-05, <i>Training Program</i> OREM-TQ-CL-01, <i>Training Checklist</i> OREM-TQ-STD-01, <i>U.S. Department of Energy Oak Ridge Office of Environmental Management Senior Technical Safety Manager Office/Facility Specific Qualification Standard</i> OREM-TQ-STD-02, <i>U.S. Department of Energy Oak Ridge Office of Environmental Management Office/Facility-Specific Qualification Standard</i> OREM-FO-IP-01, <i>Startup and Restart Program</i> OREM-FO-IP-03, <i>Facility Representative Program</i> OREM-OM-IP-07, <i>Reviewing and Approving Contractor Program Documents</i> OREM-OM-IP-09, <i>Oversight Program</i> OREM-ESH-IP-01, <i>Safety System Oversight Program</i> OREM-QA-D1-01, <i>Suspect/Counterfeit Items</i> OREM-QA-IP-06, <i>Software Quality Assurance</i> |



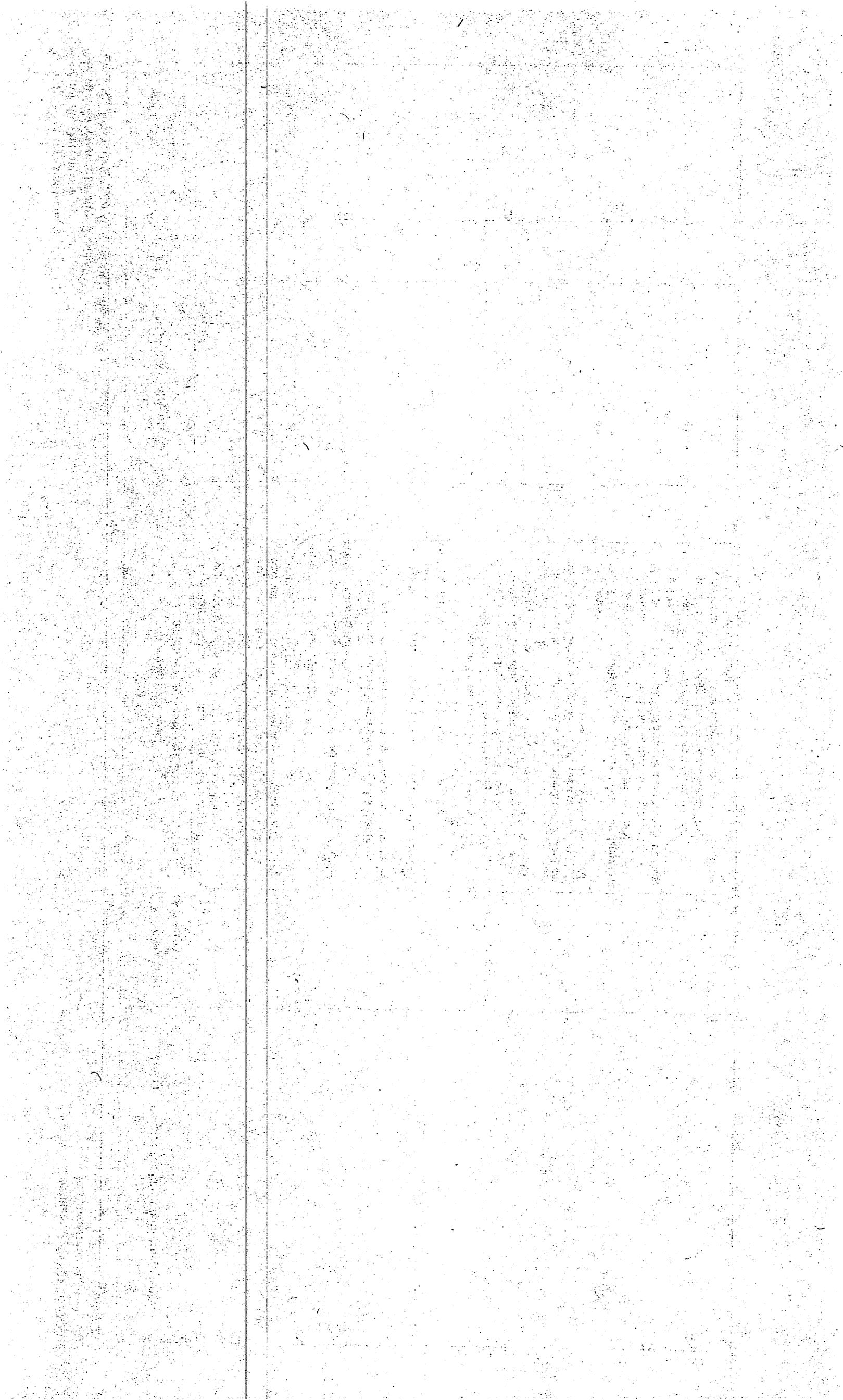
Criterion 3 – Management/Quality Improvements

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|---|-------------------------------------|---|---|--|--|--|
| <p>(a) Establish and implement processes to detect and prevent quality problems.</p> <p>(b) Identify, control, and correct items, services, and processes that do not meet established requirements.</p> <p>(c) Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.</p> <p>(d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.</p> | <p>A</p> <p>A</p> <p>A</p> <p>A</p> | <p>Requirement 2 – Quality Assurance Program 100 sic 200 Indoctrination and Training 201 Indoctrination 202 Training 300 Qualification Requirements 301 Nondestructive Examination 302 Inspection and Test 303 Lead Auditor 304 Auditors 305 Technical Specialists 400 Records of Qualification 500 Records</p> <p>Requirement 15 – Control of Nonconforming Items 100 Basic 200 Identification 300 Segregation 400 Disposition 401 Control 402 Responsibility and Authority 403 Personnel 404 Disposition Examination</p> <p>Requirement 16 – Corrective Action 100 Basic Appendix 2A-4 Appendix 16A1 Subpart 4.5</p> | <p>a,b,c,d</p> <p>NA (2)</p> <p>NA (2)</p> <p>NA (2) NA (2)</p> <p>NA NA NA NA</p> <p>a,b,c,d a,b,c,d a,b,c,d a,c</p> | <p><u>Management Expectations:</u></p> <ul style="list-style-type: none"> Management sets performance goals and standards. Management establishes metrics that monitor project/program performance to identify QA processes needing improvement. Corrective actions are developed and implemented for problems/findings related to item characteristics, products, process implementation, or services. A process to determine the significance of identified problems/findings is developed. In the case of significant conditions adverse to quality, causes or problems are identified and prevention of recurrence is included as a part of corrective actions planning. Management identifies the causes of problems and takes corrective actions to address the problems. Formal root cause analysis should be considered. An Extent of Condition determination is considered for significant conditions adverse to quality. In the case of significant conditions adverse to quality, proposed corrective actions are evaluated to ensure they will effectively address the underlying QA performance. Completed corrective actions are independently verified for implementation and the verification documented to indicate closure. <p><u>Implementation Requirements:</u></p> <ul style="list-style-type: none"> Operational awareness processes are critical to detect, communicate, and prevent quality problems and processes in an effective and timely manner. These processes include facility tours/walkthroughs, work observations, document reviews, meeting attendance and participation, and ongoing interactions with contractor workers, suppliers that provide continuing support, support staff, and management. Other processes include assessments/audits of facilities, operations, item inspection results, and programs; assessments/audits of CASs; evaluations of contractor performance; and self-assessment of DOE line management functions and performance. The corrective action programs | <ul style="list-style-type: none"> Assessment Corrective Action Preventive Action Management Review Integrated Assessment Planning Annual Effectiveness Review Annual Declaration Reporting Annual Performance Objectives, Measures and Commitments | <ul style="list-style-type: none"> ISMS/QA Annual Declarations OREM-OM-PL-05, <i>OREM Program Plan</i> OREM-FO-IP-02, <i>Corporate Operating Experience/Lessons Learned Program</i> OREM-FO-IP-03, <i>Facility Representative Program</i> OREM-OM-IP-01, <i>Walkthrough Program</i> OREM-OM-IP-02, <i>Integrated Assessment Program</i> OREM-OM-IP-03, <i>Directives Management Program</i> OREM-OM-IP-11, <i>Stop Work</i> OREM-OM-IP-06, <i>Formal and Informal Assessments</i> OREM-OM-IP-09, <i>Oversight Program</i> OREM-ESH-IP-01, <i>Safety System Oversight Program</i> OREM-QA-IP-01, <i>Quality Assurance Audits</i> OREM-QA-IP-03, <i>Graded Approach Program</i> OREM-QA-IP-04, <i>Issue Reporting and Resolution</i> OREM-REC-IP-01, <i>Enforcement Program</i> |

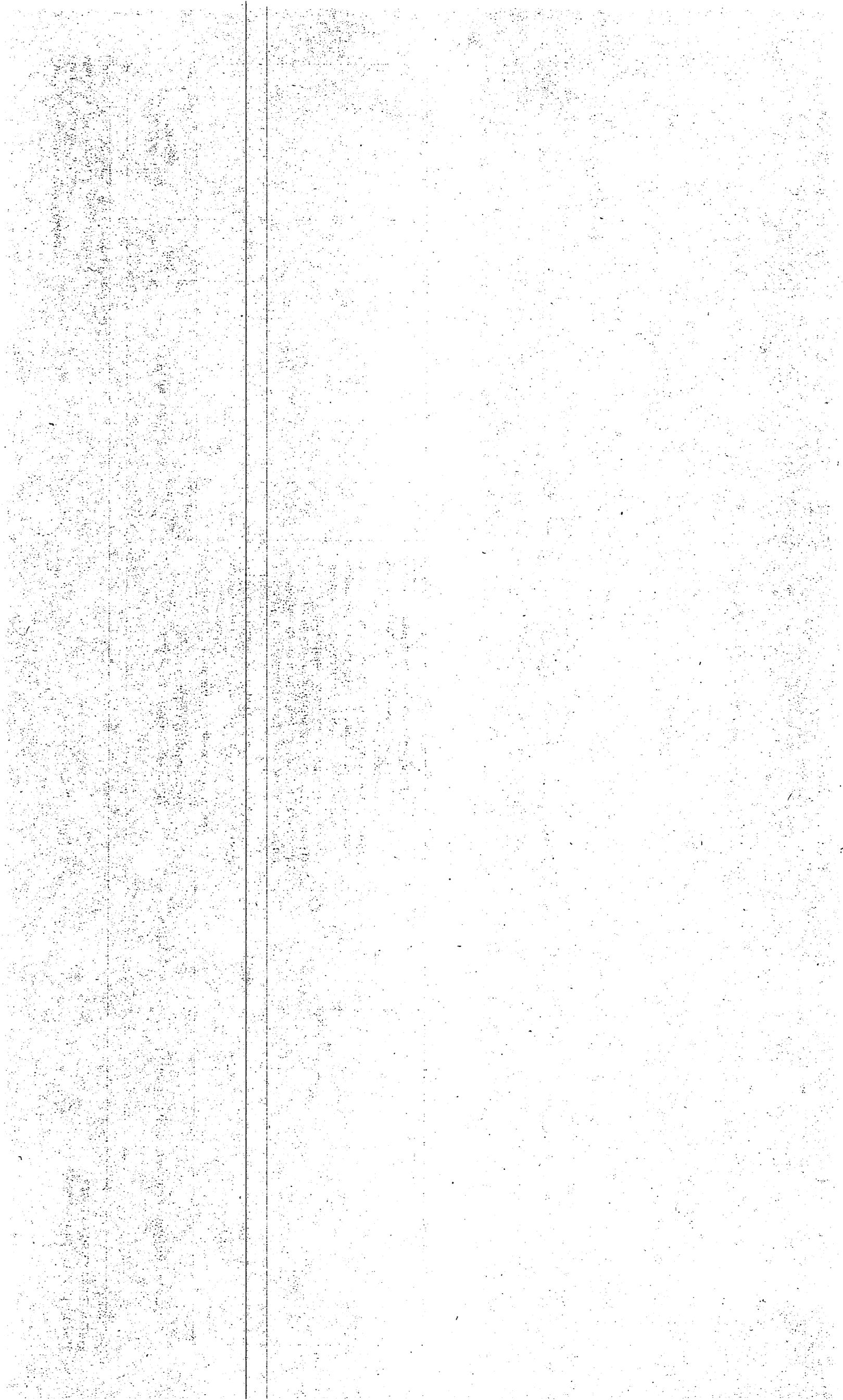


| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements serve to ensure issues are corrected and actions put in place to preclude recurrence. | Key Processes | Implementation Procedures and Documents |
|--------------------------|-----------------------|--------------------|-----------------------------------|---|---------------|---|
| | | | | | | |

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|--------------------|--------------------|--------------------------------------|---|---------------|---|
| | | Subpart 4.4 | b | <ul style="list-style-type: none"> • Documents that describe the methods of implementing the requirements of this QAP are identified by OREM and maintained current. • Maintenance of QA records falls within phase two of the Federal records lifecycle (Maintenance/Use) and consists of retention, classification, file arrangement, authentication, receipt control, and active records storage. <p><u>Implementation Requirements:</u></p> <p>The following shows how the NQA-1 requirements fit into the Federal records lifecycle:</p> <ul style="list-style-type: none"> • Creation/Receipt: Record identification includes identifying QA records within implementing procedures prior to the start-up of work. • Maintenance/Use: Retention is the length of time that records must be kept. • Federal records (including QA records) are required to be scheduled by content/subject within a specific record series. The record series are found in the NARA-approved DOE Records Disposition Schedules, which provide mandatory instructions for the disposition of Federal records. • Classification: An additional form of QA record identification for filing purposes. QA records are further classified as lifetime or non-permanent. • Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. Therefore, lifetime QA records are those associated with items. • Non-permanent records are those required to show evidence that an activity was performed in accordance with applicable requirements, but the records do not need to be retained for the life of the item. Therefore, non-permanent QA records are those associated with activities. • File Arrangement: Arrangement of records by subject (activity/item), chronology, etc., to ensure traceability. • Authentication: Record that is stamped, initialed, or signed and dated for authentication. | | |



| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|--------------------|--------------------|--------------------------------------|---|---------------|---|
| | | | | <ul style="list-style-type: none"> • Receipt Control: Form of validating receipt of records in a centralized location. • Active Record Storage: QA records are to be stored in two-hour fire proof cabinets, vault storage, or dual storage while in active status. • QA records are maintained in active storage that protects the records from loss or damage by employing filing equipment suitable for the level of protection defined in NQA-1 until the item is no longer being used or it is retired from service (lifetime) or until the records are no longer required to support the work activity (non-permanent). When the QA records become inactive, the responsible personnel transfer the QA records to inactive records storage that meets NARA requirements, the records are maintained for their retention period in accordance with the DOE Records Disposition Schedules. | | |



Criterion 5 – Performance/Work Processes

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--|--|--|-----------------------------|--|---|--|
| <p>(a) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.</p> <p>(b) Identify and control items to ensure their proper use.</p> <p>(c) Maintain items to prevent their damage, loss, or deterioration.</p> <p>(d) Calibrate and maintain equipment used for process monitoring or data collection.</p> | <p>A</p> <p>NA</p> <p>NA</p> <p>NA</p> | <p>Requirement 5 – Instructions, Procedures, and Drawings Basic 100</p> <p>Requirement 8 – Identification and Control of Items</p> <p>Requirement 9 – Control of Special Processes</p> <p>Requirement 12 – Control of Measuring and Test Equipment</p> <p>Requirement 13 – Handling, Storage, and Shipping</p> <p>Requirement 14 – Inspection, Test, and Operating Status</p> <p>Requirement NQA-1 Part 1 Introduction</p> | <p>a</p> <p>NA</p> | <p><u>Management Expectations:</u></p> <p>Specific expectations for Work Processes include:</p> <ul style="list-style-type: none"> Documents clearly establish the roles and responsibilities for employees. Employees identify and assist in making changes that improve project processes and documents. Safety- and quality-related software has the appropriate controls in place as required by the QA Order and NQA-1a-2009, even if it is off-the-shelf. (Also see Appendix G, <i>Software Quality Requirements</i>). <p><u>Implementation Requirements:</u></p> <ul style="list-style-type: none"> Plans, implementing procedures, and documents are referenced in the respective organizational QIPs. | <ul style="list-style-type: none"> QA ISMS Emergency Management Business Operations Oversight/ Assessment Programs | <ul style="list-style-type: none"> OREM-OM-PL-01, <i>Management System Description</i> OREM-OM-PL-02, <i>Functions, Responsibilities, Authorities, and Accountabilities</i> OREM-OM-PL-03, <i>Integrated Safety Management System Description</i> OREM-OM-PL-05, <i>OREM Program Plan</i> OREM-OM-PO-01, <i>Safety Conscious Work Environment and Safety Culture Sustainment Policy Statement</i> OREM-AD-IP-01, <i>Administrative Documents Development & Control</i> OREM-OM-IP-02, <i>Integrated Assessment Program</i> OREM-OM-IP-06, <i>Formal and Informal Assessments</i> OREM-OM-IP-09, <i>Oversight Program</i> <p>UCOR, as an OREM Construction Support Services contractor for construction activities will use the following procedures:</p> <p>2012 International Building Code, Chapter 17, Special Inspections and Tests</p> <p>PROC-PCMS-1120, <i>Construction Management</i></p> <p>PROC-PCMS-1121, <i>Constructability Review</i></p> <p>PROC-PCMS-1122, <i>Development of Technical Requirements for Construction Statements of Work</i></p> <p>PROC-PCMS-1123, <i>Construction Document Control Processes</i></p> <p>PROC-PCMS-1124, <i>Construction Management Processing</i></p> <p>PROC-PCMS-1125, <i>Construction Meetings</i></p> <p>PROC-PCMS-1126, <i>Construction Daily Activity & Manpower Reports</i></p> <p>PROC-PCMS-1127, <i>Constructability Delays</i></p> |

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|-----------------------|--------------------|--------------------------------------|---|---------------|---|
| | | | | | | <p>PROC-PCMS-1128, <i>Construction Subcontractor Backcharges</i> PROC-PCMS-1129, <i>Construction Acceptance Testing</i> PROC-PCMS-1130, <i>Construction Completion and Turnover</i> PROC-PCMS-1131, <i>Construction Contractor Closeout</i></p> <p>OREM only performs work activities under Criterion 5 (b-d) as part of information technology and institutional type software programs. OREM assigns implementation authority for these activities through contracts and/or technical directions. OREM monitors these practices to ensure proper implementation through oversight and assessment activities.</p> <p>See QIP/C Matrix Table section titled Software Quality Assurance (EM-QA-001, Appendix G) for OREM specific software requirements.</p> |

Criterion 6 – Performance/Design

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--|---|--|---|---|---------------|---|
| <p>(a) Design items and processes using sound engineering/scientific principles and appropriate standards.</p> <p>(b) Incorporate applicable requirements and design bases in design work and design changes.</p> <p>(c) Identify and control design interfaces.</p> <p>(d) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.</p> <p>(e) Verify or validate work before approval and implementation of the design.</p> | <p>NA</p> <p>NA</p> <p>NA</p> <p>NA</p> <p>NA</p> | <p>Requirement 3 – Design Control</p> <p>Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications</p> <p>Appendix 3A-1</p> <p>Subpart 4.1</p> | <p>NA</p> <p>NA</p> <p>NA</p> <p>NA</p> | <p>UCOR, the OREM Construction Support Services contractor for construction activities, shall comply with the applicable requirements of EM-QA-001/R1, 10 CFR 830 Subpart A. and DOE O 414.1D.</p> <p>For any design delegated to the OREM construction contractor, the OREM construction contractor shall:</p> <ul style="list-style-type: none"> • Design items and processes using sound engineering/scientific principles and appropriate standards. • Incorporate applicable requirements and design bases in design work and design changes. • Identify and control design interfaces. • Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. • Verify or validate work before approval of the design. <p>Software controls typically are placed over engineered items with programmatic capability. The OREM construction contractor shall have a program capable of controlling unverified software from entering the project. UCOR, as the Design Authority, shall oversee the preparation of changes to design and as-built documentation for design not delegated to the OREM construction contractor. UCOR shall also provide engineering, including computer software interface requirements (e.g., Supervisory Control and Data Acquisition programming) during construction, evaluate design changes, maintain and update design documents that consolidate functional and design requirements, and interface with OREM and the OREM construction contractor. UCOR shall follow its established engineering, construction and software QA procedures for these activities.</p> | | <p>This Criterion is not applicable to OREM work activities. OREM assigns authority for design through contracts and/or technical directions. OREM contractors are expected to have and implement a complete design control system as required by EM-QA-001. OREM monitors contractors to ensure proper implementation through oversight and assessment activities.</p> <p>UCOR, the OREM Construction Support Services contractor for construction activities, is the Design Authority responsible for special inspections and Title III engineering support and will use the following procedures:</p> <p>PPD-DE-1035, <i>Engineering Program Description</i> PROC-DE-0704, <i>Project Calculations</i> PROC-DE-0705, <i>Project Drawings</i> PROC-DE-1007, <i>Specifications</i> PROC-DE-1008, <i>Design Change Notice (DCN), Field Change Request (FCR), or Alternative Authorization for Design Changes</i> PROC-DE-1010, <i>Scopes of Work</i> PROC-DE-1016, <i>Design Criteria</i> PROC-DE-1018, <i>Evaluation and Approval Processes for Dedicating Commercial Grade Items for Use as Configured Items</i> PROC-DE-1022, <i>Control of Measuring and Test Equipment</i> PROC-DE-1027, <i>UCOR Structural Inspections</i> PROC-DE-1031, <i>Welding Procedures</i> PROC-DE-1032, <i>Preparation and Maintenance of UCOR Code of Record (COR) Documentation</i> PROC-DE-1033, <i>Development of UCOR Requirements Documentation</i> PROC-NS-1016, <i>Configuration Management Plans for Nuclear and Non-Nuclear Facilities</i></p> |

Criterion 9 – Assessment/Management Assessment

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|---|-----------------|---|---|---|--|--|
| (a) Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. | A | Requirement 2 – Quality Assurance Program 100 Basic 200 Indoctrination and Training 201 Indoctrination 202 Training 300 Qualification Requirements 301 Nondestructive Examination 302 Inspection and Test 303 Lead Auditor 304 Auditors 305 Technical Specialists 400 Records of Qualification 500 Records Requirement 18 – Audits 100 Basic 200 Scheduling 300 Preparation 301 Audit Plan 302 Personnel 303 Selection of Audit Team 400 Performance 500 Reporting 600 Response 700 Follow-up Action 800 Records Appendix 2A-1 Appendix 2A-3 Appendix 2A-4/Appendix 18A-1 Subpart 4.5 | a a NA a a a a a a a a NA a a a | <u>Management Expectations:</u> <ul style="list-style-type: none"> • Management assessments are performed by personnel knowledgeable in the subject area and trained in assessment techniques. • Managers within organizations assess their organization's performance with regards to such things as safety, quality, mission completion, and performance against technical and financial goals and objectives. • Management consolidates the ISMS and QA validation and declaration activities where possible. • Results of management assessments are documented. • Deficiencies identified (during management assessments) are tracked with corrective actions taken. • Management assessments use guidance provided in DOE Guide 414.1-1B <i>Management Assessment and Independent Assessment Guide</i>. • Areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis. • Management assessments include an introspective evaluation to determine if the Integrated Safety and Quality Management Systems effectively meet strategic goals. • Assessment results requiring corrective actions are tracked until corrective actions have been completed and verified. • Assessment procedures include requirements to document improvement actions. • Assessment procedures include requirements process lessons learned (as applicable). • Assessment procedures include requirements to provide a copy of the final assessment report so that follow-up actions resulting from the assessment can be entered into an issues tracking system for tracking and a record of the assessment can be established. <u>Implementation Requirements:</u> <ul style="list-style-type: none"> • Plans, implementing procedures and documents are referenced in the respective organizational QIPs. | <ul style="list-style-type: none"> • Management Assessments | <ul style="list-style-type: none"> • OREM-OM-PL-01, <i>Management System Description</i> • OREM-OM-PL-02, <i>Functions, Responsibilities, Authorities, and Accountabilities</i> • OREM-OM-PL-03, <i>Integrated Safety Management System Description</i> • OREM-FO-IP-02, <i>Corporate Operating Experience Program/Lessons Learned Program</i> • OREM-OM-IP-01, <i>Management Walkthrough Program</i> • OREM-OM-IP-02, <i>Integrated Assessment Program</i> • OREM-QA-IP-03, <i>Graded Approach Program</i> • OREM-QA-IP-04, <i>Issue Reporting and Resolution</i> • OREM-OM-IP-06, <i>Formal and Informal Assessments</i> • OREM-OM-IP-09, <i>Oversight Program</i> |

Criterion 10 – Assessment/Independent Assessment

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|---|----------------------------|--|---|---|--|---|
| <p>(a) Plan and conduct independent assessments to measure item and service quality, the adequacy of work performance, and to promote improvement.</p> <p>(b) Establish sufficient authority and freedom from line management for independent assessment teams.</p> <p>(c) Ensure the persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.</p> | <p>A</p> <p>A</p> <p>A</p> | <p>Requirement 1 – Organization 100 Basic 200 Structure and Responsibility 201 General 202 Delegation of Work 300 Interface Control Requirement 2 – Quality Assurance Program 100 Basic 200 Indoctrination and Training 201 Indoctrination 202 Training 300 Qualification Requirements 301 Nondestructive Examination 302 Inspection and Test 303 Lead Auditor 304 Auditors 305 Technical Specialists 400 Records of Qualification 500 Records Requirement 10 – Inspection Requirement 11 – Test Control Requirement 15 – Control of Nonconforming Items Requirement 16 – Corrective Action 100 Basic Requirement 18 – Audits 100 Basic 200 Scheduling 300 Preparation 301 Audit Plan 301 Personnel 303 Selection of Audit Team</p> | <p>b</p> <p>b</p> <p>b</p> <p>a</p> <p>c</p> <p>(301, 302 NA)</p> <p>c</p> <p>c</p> <p>NA</p> <p>NA</p> <p>NA</p> <p>a,b,c</p> <p>a,b,c</p> <p>a,b,c</p> <p>a,b,c</p> | <p><u>Management Expectations:</u></p> <ul style="list-style-type: none"> Organizations develop and implement a comprehensive plan and schedule to independently assess and conduct audits of reporting organizations against technical, programmatic, administrative, and quality program requirements. The Federal and contractor offices ensure their QAPs are assessed to verify compliance and effectiveness of the quality requirements implementation at a frequency such that all elements of the QAP are addressed at least triennially. Independent assessments are performed by personnel knowledgeable in the subject area and trained in assessment techniques. Results of independent assessments/audit are documented; deficiencies tracked; corrective action plans reviewed; and corrective actions verified with the verification documented to indicate closure. Independent assessments use guidance provided in DOE Guide 414.1-1B, <i>Management Assessment and Independent Assessment Guide</i>. The SRP Modules may be used in the development of Lines of Inquiry for Independent Assessments. The review modules can be found online at http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx. In the course of issue identification, proposed solutions, or alternative courses of action are brought forward with the objective of seeking to improve organizational excellence. Findings, observations, and recommendations are presented in assessment/audit reports that are transmitted formally to the audited organization. Deficiencies identified as significant are documented, a formal root cause analysis should be considered based on the complexity of the identified significant issue, extent of | <ul style="list-style-type: none"> Independent Assessment | <ul style="list-style-type: none"> OREM-FO-IP-02, <i>Corporate Operating Experience Program/Lessons Learned Program</i> OREM-OM-IP-02, <i>Integrated Assessment Program</i> OREM-QA-IP-01, <i>Quality Assurance Audit</i> OREM-QA-IP-03, <i>Graded Approach Program</i> OREM-QA-IP-04, <i>Issue Reporting and Resolution</i> |

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|-----------------------|----------------------|-----------------------------------|---|---------------|---|
| | | 400 Performance | a,b,c | conditions identified, and corrective/preventive actions implementation verified. <u>Implementation Requirements:</u> • Plans, implementing procedures, and documents are referenced in the respective organizational QIPs. | | |
| | | 500 Reporting | a,b,c | | | |
| | | 600 Response | a,b,c | | | |
| | | 700 Follow-up Action | a,b,c | | | |
| | | Appendix 2A-1 | c | | | |
| | | Appendix 2A-3 | c | | | |
| | | Appendix 2A-4 | a,b,c | | | |
| | | Appendix 10A-1 | NA | | | |
| | | Appendix 11A-1 | NA | | | |
| | | Appendix 16A-1 | a,b,c | | | |
| | | Appendix 18A-1 | a,b,c | | | |

Certified Type B and Fissile Packaging Quality Assurance Program (EM-QA-001, Appendix A)

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|-----------------------|--------------------|-----------------------------------|---|---------------|--|
| NA | NA | NA | a, b | NA | NA | The OF200 MTF construction project will not generate, store, treat, transport or dispose spent nuclear fuel or high-level waste. Therefore this criterion is inapplicable. |

Suspect/Counterfeit Items Prevention (EM-QA-001, Appendix F)

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|---|-----------------|--|-----------------------------|--|-----------------|---|
| <p>(a) Establish DOE and contractor QAPs to establish, document and implement effective controls and processes that will: (1) ensure items and services meet specified requirements; (2) prevent entry of S/CIs into the DOE supply chain; and (3) ensure detection, control, reporting, and disposition of S/CIs.</p> <p>(b) QAPs shall address and provide for implementation of the requirements in DOE O 414.1D, Attachment 3, and Paragraph 2.</p> | A | Note: NQA-1 does not address the requirements for the prevention and control of S/CI | a.b | <p><u>Management Expectations:</u></p> <ul style="list-style-type: none"> Guidance provided in DOE Guide 414.1-2B, Quality Assurance Program Guide and IAEA-TECDOC1169, <i>Managing Suspect and Counterfeit Items for the Nuclear Industry</i> is reviewed and utilized during the preparation process. The latest information on S/CI awareness is used, which can be located at the DOE website: http://www.hss.energy.gov/csa/csp/sci/ (click on S/CI Awareness Training Manual). <p><u>Implementation Requirements:</u></p> <ul style="list-style-type: none"> EM assigns implementation authority for S/CI prevention through contracts and/or technical direction. EM monitors S/CI prevention practices through oversight activities. Plans, implementing procedures and documents are referenced in the respective organizational QIPs. | SC/I Prevention | <ul style="list-style-type: none"> OREM-QA-DI-01, <i>Suspect Counterfeit Items</i> <p>Federal employees do not perform inspection functions. OREM assigns implementation authority for inspection through contracts and/or technical direction. OREM monitors inspection practices through assessment and oversight activities. OREM employees and direct support contractors receive S/CI training as part of the ISC support training program.</p> |

Software Quality Assurance (EM-QA-001, Appendix G)

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--|-----------------|---|-----------------------------|---|---|--|
| <p>(a) Safety software must be acquired, developed, and implemented using American Society of Mechanical Engineers (ASME) NQA-1-2008 with the NQA-1a-2009 addenda (or later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2008. DOE approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority.</p> | A | <p>Part II, Subpart 2.7 – <i>Quality Assurance Requirements for Computer Software for Nuclear Facility Applications</i></p> <p>Part II Subpart 2.14 – <i>Quality Assurance Requirements for Commercial Grade Items and Services</i></p> | NA | <p><u>Management Expectations:</u></p> <ul style="list-style-type: none"> • DOE EM Manager - Provide adequate resources and qualified staff to develop and effectively implement an approved QAP/QIP governing the work under their purview including as applicable software development/use in accordance with requirements defined in the DOE HQ EM QAP. Ensure that programs provide for proper identification and grading of safety software. • Implement QA criteria as defined in Attachment 2 (DOE O 14.1D), as well as the requirements in Attachment 3 for all facilities, and the requirements in Attachment 4 for nuclear facilities, and describe how the criteria/requirements are met, using the documented graded approach. Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach. • Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2008. DOE approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority. • Safety Software QA processes use guidance provided in DOE Guide 414.1-4, <i>Safety Software Guide</i>. • Computer safety software used to develop or execute the model meets the applicable criteria of NQA-1a-2009 Part I, Subpart 2.7, Subpart 2.14 and DOE O 414.1D Attachment 4. • EM model development and operation considers and utilizes the following consensus standards as appropriate: <ul style="list-style-type: none"> – ANSI/ANS-10.2-2009, <i>Portability of Scientific and Engineering Software</i> – ANSI/ANS 10.4-2008, <i>Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry</i> – ANSI/ANS-10.5-2011, <i>Accommodating User Needs in Scientific and Engineering Computer Software Development</i> | <ul style="list-style-type: none"> • Software QA | <ul style="list-style-type: none"> • OREM-QA-IP-06, <i>Software Quality Assurance</i> • OREM does not use or maintain safety software as defined in DOE O 414.1D |

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|-----------------------|--------------------|--------------------------------------|--|------------------|---|
| | | | | <ul style="list-style-type: none"> • ASME V&V 20-2009, Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer Software Validation Requirements (safety and non-safety software). • Software validation activities are planned, documented, and performed for software, software changes, or system configurations that are determined to impact the software. • The validation test plans, test cases, and test results are documented, reviewed, and approved prior to use of the software. • Software Verification Requirements (safety and non-safety) . • Software verification is performed at the end of the requirements, design, and testing lifecycle phases to ensure that the products of a given lifecycle phase are traceable and fulfill the requirements still applicable from the previous phase and/or previous phases. <ul style="list-style-type: none"> – Software verification is performed at the end of the requirements, design, and testing lifecycle phases to ensure that the products of a given lifecycle phase are traceable and fulfill the requirements still applicable from the previous phase and/or previous phases. – Software verification evaluates the technical adequacy, ensures correctness of the software, and verifies that software is traceable to the software design requirements. • Tests and test results from reviews and verifications are included in the acceptance test documentation. Tests conducted as reviews or verifications do not substitute for performing comprehensive, end-of development acceptance tests. • Software verification includes review of the test results. Software verification is completed prior to approval of the computer program for use. Verification reviews identify the reviewer(s) and each reviewer's specific responsibilities during the review. • Documentation of review comments and their disposition is retained as part of the records package. Software verification and validation activities are performed by individuals not associated with the development of the software. In those instances where this level of independence may not be achieved, an individual associated with the development of the software performs these activities with management approval and documented justification. • As part of the configuration change control, software verifications are performed for the changes, as necessary, to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained. | | |

Model Development, Use, and Validation (EM-QA-001, Appendix H)

| DOE O 414.1D Criteria | Applies to OREM | NQA-1 Requirements | Applies to 414.1D Criterion | EM-QA-001 Management Expectations and Implementation Requirements | Key Processes | Implementation Procedures and Documents |
|--------------------------|-----------------------|--------------------|-----------------------------------|---|---------------|--|
| NA | NA | NA | NA | NA | NA | OREM is not involved in the development, use or validation of computer models. |