Plans

MSC-PLN-QA-599

Quality Assurance Program Description

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Exclusion Reason:

CHANGE SUMMARY

Description of Change

Adding/clarifying roles into Sections 1.0 - 7.0
QUALITY ASSURANCE POLICY

The Mission Support Contract (MSC) with the U. S. Department of Energy (DOE), Richland Operations Office, specifies that the Mission Support Alliance (MSA) will comply with applicable Federal and State Regulations and the listed DOE Orders (Contract DE-AC06-09RL14728, Paragraph C3.5, Quality Assurance). For Quality Assurance, this requires compliance with Title 10, Code of Federal Regulations, Part 830, Nuclear Safety Management, Subpart A, Quality Assurance Requirements; DOE O 414.1D, Contractor Requirements Document, Quality Assurance; Richland Requirements Document (RRD) 008, Revision 3, Quality Assurance Program Requirements; and State and Federal Environmental Regulations.

The Quality Assurance Program Description (QAPD) identifies our commitment to these contractual requirements. It establishes requirements, assigns responsibilities, and describes the management systems established to assure the quality of MSA activities and products. The QAPD is the top-level document of the Mission Support Alliance and compliance is mandatory. Implementation of the QAPD is supported by procedures and instructions to ensure the quality of Mission Support Alliance processes, activities, and products.

The President and Project Manager of the Mission Support Alliance has responsibility for the quality of Mission Support Alliance activities and products. The Director of Quality Assurance has responsibility for developing and assuring the implementation of the QAPD. The Mission Support Alliance is accountable for managing its projects and performing Hanford work in accordance with the quality requirements established by the QAPD.

All employees are responsible for performing work in accordance with the requirements set forth in this QAPD. Those employees performing oversight and verification of QAPD compliance have the authority and responsibility to identify quality problems and recommend solutions.

MSA is committed to performing work in accordance with the requirements of this QAPD to ensure high quality products and services meeting the customer’s needs and to fulfill the expectations of our customers to achieve adequate protection of workers, the public, and the environment, taking into account the work to be performed and the associated hazards. It is incumbent upon each employee to be open and candid in bringing to management’s attention, without fear of retribution, any instance of inferior work or any behavior that would compromise the attainment of quality.

Bill K. Johnson  
President and Project Manager  
Mission Support Alliance, LLC

5-3-2017  
Date

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1.0 INTRODUCTION

The Quality Assurance Program Description (QAPD) defines the Mission Support Alliance (MSA) implementation of the Quality Assurance Program requirements specified by Title 10, Code of Federal Regulations, Part 830, Nuclear Safety Management (10 CFR 830), Subpart A, U.S. Department of Energy (DOE) Order DOE O 414.1D, Contractor Requirements Document (CRD), Quality Assurance; and Richland Requirements Document (RRD) 008, Revision 3, Quality Assurance Program Requirements. Compliance with 10 CFR 830 is a statutory requirement. Compliance with DOE O 414.1D CRD and RRD 008 is imposed on MSA through its contract with the DOE, Contract DE-AC06-09RL14728, Paragraph C.3.5, Quality Assurance. The Quality Assurance (QA) Program defined by this QAPD is also the management system utilized for assuring quality in the conduct of environmental programs that acquire, generate, compile, report, and use environmental data and technology. The MSA QA Program defined by this QAPD is to be applied on a graded basis to MSA activities.

2.0 MISSION SUPPORT ALLIANCE QUALITY ASSURANCE PROGRAM

The QAPD describes the MSA organization and functional responsibilities for QA, documents the MSA QA Program structure, and defines the quality management system necessary to implement the program.

In order to develop and implement an effective management system consistent with quality expectations of 10 CFR 830, Subpart A; DOE O 414.1D CRD and RRD 008, guidance from the latest revision of the documents listed below, as applicable, are considered during the development and implementation of this QAPD:

DOE G 414.1-2B, Admin Chg. 2, Quality Assurance Program Guide;

DOE G 414.1-1C, Management and Independent Assessment Guide;

2.1 Format and Contents of the Quality Assurance Program Description

10 CFR 830, Section 121, Quality Assurance Program (10 CFR 830.121), requires the use of a voluntary national consensus standard, where practicable and consistent with contractual and regulatory requirements in the development and implementation of the QAPD. Additionally, RRD 008, Rev. 3 requires adoption of ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications, 2008 Edition, with 2009 Addenda.

This QAPD describes the quality management processes that are the basis of the MSA QA Program. The 10 sections of the QAPD correspond with the 10 criteria of 10 CFR 830, Section 122, Quality Assurance Criteria (10 CFR 830.122), DOE O 414.1D CRD, and EM-QA-001, Office of Environmental Management (EM) Quality Assurance Program (QAP), as specified by RRD 008. Each section contains the following subsections:

a. REQUIREMENTS - The criteria of 10 CFR 830.122, 10 CFR 835, DOE O 414.1D CRD and EM-QA-001 implemented by the section.
b. IMPLEMENTATION - Criteria for achieving compliance with the requirements.
c. RESPONSIBILITIES - Responsibilities for implementing the criteria to achieve compliance to the requirements.

2.2 Quality Assurance Requirements

1. 10 CFR 830.121 requires that contractors conducting activities, including providing items and services that affect or may affect the safety of DOE radiological facilities, work in accordance with 10 CFR 830.122 and 10 CFR 835. The MSA QA Program requirements for activities within the scope of 10 CFR 830, along with the methodology for their application to MSA are documented in this QAPD.

2. 10 CFR 830.122 applies, in a graded approach, to all DOE reactor and nonreactor nuclear facilities. Nonreactor nuclear facilities are those facilities, activities, or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear hazard or a nuclear explosive hazard potentially exists to the workers, the public, or the environment. This does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscope, and X-ray machine. 10 CFR 830.122 includes those activities related to design, manufacture, and assembly of items for use with radioactive materials in such form or quantity that a nuclear hazard potentially exists even when no nuclear material is present. 10 CFR 830, Subpart A does not specify a minimum for such a hazard. (Reference Enforcement Guidance Supplement 99-01: Enforcement of 10 CFR Part 830.120 [Quality Assurance Rule] for Facilities below Hazard Category III).

3. Mission Support Alliance will implement the criteria contained in DOE O 414.1D, Quality Assurance, Attachment 1, Contractor Requirements Document (CRD), Attachment 3.

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Suspect/Counterfeit Item Prevention, and Attachment 4, Safety Software Quality Assurance Requirements for Nuclear Facilities, Para. 2.a, and will develop and maintain an implementation mechanism that identifies where the specific criteria are implemented including identification, documentation, and maintenance of safety software inventory.

Non-Safety Quality-related software for nuclear facility or EM mission critical application will be managed and controlled in accordance with the requirements of NQA-1-2008, with 2009 Addenda, Part I, Requirements for Quality Assurance Programs for Nuclear Facilities, and Part II, Quality Assurance Requirements for Nuclear Facility Applications, Subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,” as applicable in a graded approach.

4. DOE O 414.1D CRD and EM-QA-001 define the foundation for a comprehensive QA program to be applied to MSA activities not within the scope of 10 CFR 830.

5. MSA Organizations with service contracts for equipment and labor resources with other Hanford Prime Contractors (OHC) shall work in accordance with the QA program and Safety envelope requirements specified in the governing Inter-Hanford Contractor Work Orders (ICWO) and Statements of Work, as applicable when performing work activities outside of the MSA confines.

6. MSA is responsible for procurement of Safety Class and Safety Significant items and services in accordance with Other Prime Contractors Safety Basis/Hazards Analysis requirements as specified in procurement documents and or ICWO’s. MSA is only responsible for procurement, receiving inspection, and status tagging activities. MSA does not contractually have any Hazard Category 1, 2, or 3 facilities and is not responsible for USQ activities based on Non-conforming conditions.

2.3 Integrated Environment, Safety, and Health Management System

1. Effective implementation of the QA Program requirements involves management and provides tools to support the principles and functions of the Integrated Environment, Safety and Health Management System (ISMS). The fundamental quality expectation is that all work meet established requirements. The ISMS fundamental expectation is that all work be performed safely. In this regard, the quality management system described in this QAPD ensures compliance with the approved standards so the expectation for safe and environmentally protective work within controls is met.

2. Work must be accomplished safely while minimizing potential hazards to the public, site, facility workers, and the environment.

3. This QAPD describes management systems for accomplishment and assessment of the work scope in accordance with established requirements. This management system is compliant with and integrated with ISMS. The quality management system provides processes and

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tools for ensuring integrated quality and safety management expectations are accomplished safely and performance can be objectively assessed and measured.

4. The quality requirements and ISMS functions and principles are interrelated and share fundamental management system attributes. MSA ensures environmental, safety, health, and quality requirements are integrated into its work activities through the MSA ISMS and QA Program documents. MSA procedures and project/facility specific procedures implement each of the core functions of ISMS. See Table 1.
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## QA Program and ISMS Integration

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1.0 REQUIREMENTS

The QA Program shall be established and implemented by MSA to satisfy the requirements of 10 CFR 830.122 (a), "Criterion 1-Management/Program," DOE O 414.1D CRD, Attachment 2, Section 1, "Criterion 1-Management/Program" and EM-QA-001, Section 7.1, "Management/Program (Criterion 1),” Attachment D, “Graded Approach,” E, “Integrated Management System,” and Attachment G, “Software Quality Requirements.”

2.0 IMPLEMENTATION

MISSION SUPPORT ALLIANCE ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES

Figure 1 details the MSA organization. Detailed organizational charts are maintained and made available by the Human Resource Organization. MSC-PLN-PC-42374, Mission Support Contract Project Execution Plan is the official source for MSA roles and responsibilities.

2.1 General Responsibilities

1. The MSA President and Project Manager, Chief Operations Officer, and direct reports are responsible for ensuring:

   a. Mission accomplishment and performance in accordance with the Mission Support Contract with DOE, Richland Operations Office (RL), program/project-specific requirements, and the QAPD.

   b. Organizations plan and perform work in accordance with the MSA QA Program.

   c. Organizational charts, functional responsibilities, and levels of authority are defined and documented.

   d. Interfaces among MSA, DOE RL, regulators, oversight organization (e.g., DNFSB), contractors, suppliers, and Other Hanford Contractors (OHCs) are defined and documented, and communications between organizations, are effective.

2. The Management of all organizations are responsible and accountable for:

   a. Planning work to ensure it efficiently and effectively meets applicable technical and quality requirements and identifies associated hazards or potential hazards.

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b. Establishing processes to perform work in accordance with plans and effectively mitigating the risks due to identified hazards while meeting technical and quality requirements.

c. Verifying work is scheduled and correctly performed and unacceptable work is identified and corrected.

d. Establishing the means to measure performance and to provide feedback for improvement.

e. Passing down applicable requirements, including QA requirements to contractors and suppliers, and ensuring the work meets specified requirements.

f. Establishing and achieving quality objectives within their organizations’ activities and work products.

g. Performing work in accordance with this MSA QA Program document.

h. Ensuring implementation of the ISMS.

i. Demonstrating commitment and leadership to achieve quality through active involvement in the implementation of the QA Program.

j. Responding to analyses of performance data and ensuring identification of problem, root causes, and completion of corrective actions.

k. Ensuring procedures and instructions are available to their organizations for implementing this QAPD.

l. Ensuring personnel are trained, qualified, and proficient for the work they perform.

m. Providing individuals performing the work with proper information, tools, training, support, and encouragement to properly perform their assigned activities.

n. Considering resources as an integral part of the decision-making and planning processes.

3. Individuals are responsible for carrying out work in accordance with the policies, plans, procedures, and instructions issued by management. Individuals are expected to meet the quality requirements, self-check their own performance, and recommend improvements in the quality of work products and processes.

4. Individuals that procure or acquire items or services have the responsibility of imposing QA requirements on their subcontractors and suppliers through contract or purchase order.
documents applicable to the subcontractor's/supplier's scope of work and providing oversight of their activities.

2.2 Structure of the Mission Support Alliance Quality Assurance Program

The MSA QA Program is comprised of this QAPD, MSA documents, QAPP(s), QAPjP(s), implementing procedures, and work control documents, as applicable.

2.3 Development and Utilization of Quality Assurance Programs and Plans

QAPPs shall be developed to document implementation of this QAPD as it applies to Projects, Facilities and other activities. In addition, QAPPs are developed for specific programs, projects, or activities that involve QA requirements beyond this QAPD; for example, environmental. QAPjP’s are developed for sub-tier projects, facilities, environmental projects, and/or activities as necessary to ensure adequate controls for activities affecting quality. Development of QAPP(s) and QAPjP(s) shall be in accordance with approved processes and procedures.

Activities involving the collection, generation, acquisition, and use of environmental data identified in the Tri-Party Agreement (TPA) shall meet the requirements of the Environmental Protection Agency's quality assurance requirements. These additional requirements and others governed by Washington Administrative Codes (WAC) and Federal Environmental Regulations are incorporated in appropriate documentation meeting the requirements of established procedures. Compliance with codes and standards specified by the applicable WAC and Federal Environmental Regulations is mandatory. Likewise, activities such as those within the scope of the Hanford Analytical Services Quality Assurance Requirements Document (HASQARD) are controlled by QAPP’s.

Additionally, Department of Energy Consolidated Audit Program (DOECAP) and Department of Energy Laboratory Accreditation Program (DOELAP) are acceptable for use to ensure that commercial laboratories used to obtain analytical results for environmental samples meet applicable sample management and analytical services quality assurance requirements.

2.4 MSA Quality Assurance Procedures

Management processes that implement the QAPD and are common to multiple organizations or where there is a need to have consistent processes, are defined in MSA documents. MSA organizations implement applicable work controlling documents, augmented as needed through sub-tier procedures.
2.5 **MSA Quality Assurance Requirements Flowdown**

This QAPD defines QA requirements that shall be implemented by MSA organizations. Figure 2 depicts typical flow down of requirements to work control documents. Section 7.0, "Procurement," describes the requirements process for suppliers and subcontractors.

2.6 **Policy and Planning**

1. Senior management establishes written management policies for their areas of responsibility.

2. Management at all levels plan, schedule, organize, and provide the support necessary to implement the QA Program requirements to their activities and products.

2.7 **Organizational Responsibilities and Interfaces**

1. Organizations responsible for assuring that the QA Program has been properly implemented and for verifying activities affecting quality have been correctly performed shall have direct access to management at a level including the MSA Board of Directors where appropriate action can be effected. They have sufficient authority, access to work areas, and organizational freedom to:

   a. Identify quality problems.
   b. Initiate, recommend, or provide solutions to quality problems through designated channels.
   c. Verify implementation of solutions and ensure further processing, delivery, installation, or use of defective materials, equipment, or services is controlled until proper disposition of the nonconformance, deficiency, or unsatisfactory condition has occurred.

2. The individual(s) or organization(s) responsible for establishing and executing the MSA Quality Assurance Program requirements may delegate any or all the work to others, but shall retain the responsibility, which includes ensuring that the authority granted to managers or delegated professionals within the respective organization(s) is commensurate with the requirements of the position.

3. The organizational structure and the assignment of responsibility are such that quality is achieved and maintained by those who are assigned responsibility for performing the work. Quality achievement is verified by personnel not directly responsible for performing the work.

4. The internal and external interfaces between organizations shall be documented. When more than one organization is involved in the conduct of activities covered by the QA Program, the responsibility and authority of each organization is documented.
2.8 Assessments

Management regularly assesses the adequacy and effective implementation of the Quality Assurance program, as it relates to areas of ISMS. Each area of the quality program is subject to periodic independent assessment, based on a graded approach.

2.9 Graded Application of MSA Quality Assurance Program (10 CFR 830.7)

1. The requirements of this QAPD, QAPPs, QAPjPs, and the implementing procedures are applied to radiological facilities and activities, including environmental activities, on a graded basis. Other activities, not regulated by 10 CFR 830, comply with DOE O 414.1D CRD and EM-QA-001 criteria.

2. A graded approach permits a range of control over items and activities commensurate with the level of risk they present.

   a. Equipment Important to Safety (ITS), not identified as safety class or safety significant, which performs an important defense-in-depth function, is considered General Service. The graded approach associated with General Service items is discussed in paragraph 7 below.

3. The graded approach in nuclear and non-nuclear applications gives flexibility in the degree of rigor involved when implementing QA program requirements. This allows the requirements to be applied appropriately to items, activities, and services. Use of the graded approach involves consideration of the factors listed below, as applicable, when determining the QA requirements and the degree of rigor to be applied in their implementation to an activity or process.

   a. The relative importance to safety, safeguards, and security;
   b. The magnitude of any hazard or risk involved;
   c. The life cycle stage of a facility or activity;
   d. Impact/consequences on the programmatic mission of a facility;
   e. The particular characteristic of a facility or activity;
   f. The nuclear safety classification or hazard category of the item or activity;
   g. Adequacy of existing safety documentation;

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h. The relative importance of radiological and non-radiological hazards;

i. Complexity of products or services involved;

j. Performance history of a facility or activity; and

k. Any other relevant factors.

4. The graded approach for environmental activities that involve generating, acquiring, or using environmental data is based on the intended use of the data, the analytical protocol selected, and on parameters of accuracy, precision, comparability, completeness, and representativeness. These are part of the QA objectives defined in implementing documents.

5. The graded approach for software is used to determine the applicable software category, the level of control, the required life-cycle phase documentation, and verification activities. The rationale for the grading criteria is to provide for differing levels of review, testing activities, and documentation based on the safety significance of the software, regulatory requirements, function, and the risk of software failure. Safety software classification/grading criteria are:

Level A – Safety Software application that meet one or more of the following criteria:

- Software failure that could compromise a limiting condition for operation
- Software failure that could cause a reduction in the safety margin for safety structures, systems, and components (SSC) that is cited in DOE approved documented safety analysis
- Software failure that could cause a reduction in the safety margin for other systems such as toxic or chemical protection systems that are cited in either (A) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE G 450.4-1C, Integrated Safety Management System Guide
- Software failure that could result in non-conservative safety analysis, design, or misclassification of facilities or SSCs.

Level B – Safety Software applications that do not meet level A criteria, but meet one or more of the following criteria:

- Safety management databases used to aid in decision making whose failure could impact safety SSC operation
- Software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or public

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• Software failure that could compromise the defense-in-depth capability for a nuclear facility.

Level C – Software applications that do not meet Level B criteria, but meet one or more of the following criteria:

• Software failure that could cause a potential violation of regulatory permitting requirements
• Software failure that could affect environment, safety, health (ES&H) monitoring or alarming systems
• Software failure that could affect the safe operation of an SSC.

Software applications that meet safety software definitions include:

a. Software applications important to safety that may be included or associated with SSCs for less than hazard category 3 facilities. Safety software includes safety system software, safety and hazard analysis software and design software, and safety management and administrative control software.

b. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC, but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.

c. Safety management and administrative controls software that performs a hazard control function in support of nuclear facility or 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, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause.

6. The Design Authority, engineer, or qualified personnel for non-design-related activities (e.g., Scientist), with assistance from a QA representative, as appropriate, shall determine and document the extent, depth and rigor applied to the process/activity.

7. Items, services, and processes that do not have an engineered safety function are classified as General Service (GS). The graded approach for GS items and activities consists of:

a. Using the administrative processes established in MSA documents and project or facility specific procedures to manage, perform, and assess the work being performed (e.g., document control, work control, records and data management).
b. The Design Authority determines, on a case-by-case basis, a need to apply additional QA controls (e.g., supplier evaluation, receipt/source inspection, process inspection, testing, sample custody controls, etc.) to mitigate the risk associated with failure of an item (e.g., an item Important-to-Safety not identified as safety class or safety significant, which performs an important defense-in-depth function, or an item that performs a function to minimize impact to the environment, etc.) or performance of a task. When additional controls are necessary, drawings, specifications, plans, or other work instructions are prepared that identify the characteristics and functions to be verified, inspected, or tested and the necessary acceptance criteria to measure conformance.

8. Risks equate to the probability of failure and the consequence to health and safety of the public, worker, and/or the environment. These factors are considered part of the hazards and accident analysis process when determining the safety classification of the SSC.

9. Activities are controlled through appropriate planning, staffing, procedures, reviews, verification, and deficiency resolution.

10. The graded application process is not to be used to circumvent applicable QA, legal, or contractual requirements; rather, grading determines the scope and degree of rigor applied.

11. Methods and criteria for grading QA Program applications that effectively evaluate and integrate safety and non-safety related risks, considering applicable factors of this section, shall be developed and documented.

2.10 Computer Software Quality Assurance & Controls

The processes for software planning, design, analysis, testing, acquisition, installation, development, operations, maintenance, and retirement shall be developed and documented in accordance with DOE O 414.1D CRD, Quality Assurance and EM-QA-001, EM Quality Assurance Program. The basis shall be ASME NQA-1-2008, with 2009 Addenda, Quality Assurance Requirements for Nuclear Facility Applications, Requirements 3, 4, 7, 11, and Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Application, to promote consistency to requirements of this document, in a graded approach.

1. Software engineering elements shall define the control points and associated reviews. Reviews of software shall assure compliance with approved software design requirements. Two reviews are required and can be combined with or be part of the design verification process.

   a. One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing.
b. The second review shall provide assurance of satisfactory completion of the software
development cycle including acceptance testing.

2. When review alone is not adequate to determine that requirements are met, alternate
calculations shall be used or tests shall be developed and integrated into the activities of the
software development cycle.

3. Software verification and validation process shall:

   a. Ensure the software adequately and correctly performs the intended functions.

   b. Ensure the software does not function in a manner to which the system can be degraded.

   c. Be planned and performed for system configuration that may impact the software.

   d. Be documented.

4. Engineering method shall ensure that software life cycle activities are planned, performed,
documented, and traceable to the software utilized.

5. Method(s) for documenting, evaluating, correcting, and reporting of software problems shall
be established and approved.

6. Legacy software which may have been acquired or developed without a lifecycle approach,
yet has been performing satisfactorily in production shall be controlled, classified, and
documented in accordance with the Justification for Continued Use process.

3.0 RESPONSIBILITIES

All organizations are responsible for implementing this QAPD for MSA activities under their
purview through a combination of company, project-specific, and facility-specific documents.

Task-focused groups that oversee or manage specific work processes, such as welder
qualifications, are established as necessary to promote consistency in the application of the
specific work processes.
Figure 1
Mission Support Alliance Organization

NOTE: Employees may print off this document for reference purposes but are responsible to check MSA PS to ensure the most current version is used to prevent unintended use of obsolete versions.
Figure 2
Mission Support Alliance QA Program
Document Hierarchy
(Typical)
SECTION 2.0
Personnel Training and Qualifications

1.0 REQUIREMENTS

Training and qualification programs shall be established and implemented to satisfy the requirements of this section in accordance with 10 CFR 830.122 (b), "Criterion 2-Management/Personnel Training and Qualifications," DOE O 414.1D CRD, Attachment 2, Section 2, "Criterion 2-Management/Personnel Training and Qualifications," and EM-QA-001, Section 7.2 “Management/Personnel Training and Qualification, (Criterion 2).”

2.0 IMPLEMENTATION

2.1 Mission Support Alliance Training and Qualification Program

The training and qualification program shall provide for the development and maintenance of proficiency commensurate with the scope, complexity, and the nature of the activity.

2.2 Training and Indoctrination

1. Training and indoctrination needs for personnel shall be identified and documented, and resources provided.

2. Personnel performing or managing activities relative to quality shall receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitments; company procedures; and Quality Assurance Program requirements.

3. Personnel training shall be provided to achieve initial proficiency, maintain established proficiency, and adapt to changes in technology, methods, or job responsibilities.

4. Personnel shall be trained to perform assigned tasks in a manner that minimizes risk to themselves, coworkers, and the public; minimizes negative impacts to the environment; and minimizes risk of damage to the facility and equipment.

5. Training shall be conducted by competent instructors who are knowledgeable of the training subject matter.

6. The effectiveness of training shall be evaluated and the results used for continuous improvement of training systems and processes. The bases for evaluation include feedback from trainees and their management, assessment results, and trend analyses.

7. Training and qualification requirements for specific job functions shall be based on an analysis of the specific duties and tasks associated with the functions.

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8. Training and qualification requirements for job functions shall be periodically reviewed to ensure they continue to reflect the correct system, procedures, and policies applicable to each position.

2.3 Qualification and Certification

1. Based on the work to be performed, job function descriptions shall be developed that describe minimum requirements for education and experience and if required, physical condition and certification requirements.

2. Management shall verify training, qualifications, and proficiency of personnel prior to assigning them to perform work activities.

3. Qualification of personnel assigned to conduct inspection and/or activities for acceptance shall be documented.

4. Inspection and Test personnel shall be certified and re-qualified/recertified in accordance with procedures based on ASME NQA-1-2008, with 2009 Addenda Requirement 2 and Nonmandatory Appendix 2A-1 and/or other standards applicable to the work performed. The specific standards used shall be identified in implementing documents for qualification and certification.

5. Lead Assessors and QA Lead Auditors requiring certification shall be certified in accordance with approved procedures based on ASME NQA-1-2008, with 2009 Addenda Requirement 2.

2.4 Training and Qualification Records

Records shall be maintained to enable verification of personnel qualification and completion of required training. Processing, storing, and disposition of training and qualification records shall be in accordance with Section 4.0, "Documents and Records."

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Management

Management is responsible for the training, qualification, and proficiency of personnel in their organizations.
3.2 Projects

Project organizations are responsible for developing training and qualification programs specific to their project/facility, obtaining the required training services, and working with the MSA Training organization and QA to implement the requirements of this section.

3.3 MSA Training

The MSA Training organization is responsible for:

1. Establishing or supporting MSA training and qualification programs that comply with applicable requirements.

2. Establishing MSA training standards and procedures.

3. Interfacing with QA to ensure appropriate MSA QA Program orientation and training are provided.

3.4 Quality Assurance

1. Quality Assurance is responsible for:

   a. Developing MSA QA Program indoctrination materials for use by MSA QA and the Training organization.

   b. Developing and maintaining training and qualification programs for QC inspectors, Assessors, Lead Auditors/Assessors, and Quality Assurance Engineers.
SECTION 3.0
Quality Improvement

1.0 REQUIREMENTS

Quality improvement processes shall be established and implemented by MSA organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (c), "Criterion 3-Management/Quality Improvement," DOE O 414.1D CRD, Attachment 2, Section 3, "Criterion 3-Management/Quality Improvement," and EM-QA-001, Section 7.3, “Management/Quality Improvement (Criterion 3).”

2.0 IMPLEMENTATION

Quality improvement processes shall be established and implemented to detect and prevent quality problems. The quality improvement processes shall include, at a minimum, issue identification, evaluation, control, and tracking; corrective action management; and feedback and improvement. Collectively, these systems provide for continuous evaluation and improvement of processes. They also ensure implementation of ISMS functions; Feedback and Improvement activities.

2.1 Issues Identification

Personnel at all levels in the company shall be encouraged to identify potential deficiencies and opportunities for improvement. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected.

2.2 Corrective Action Management

1. MSA shall develop a corrective action management system for:

   a. Evaluating deficiencies, potential deficiencies, and opportunities for improvement for the purpose of establishing priorities and corrective actions.

   b. Determining causes of problems and implementing appropriate corrective and preventive actions.

   c. Verifying completion of actions.

   d. Tracking the status of actions from initial reporting to closure.

   e. Determining the effectiveness of corrective actions for significant quality issues utilizing management assessments, independent assessments, or surveillances.

   f. Determining extent of conditions on significant issues.


NOTE: Employees may print off this document for reference purposes but are responsible to check MSA PS to ensure the most current version is used to prevent unintended use of obsolete versions.
2. Deficiency identification, response, and action effectiveness reviews shall be documented and tracked. Typical documents include Assessment Reports, Occurrence Reports, Corrective Action Requests, and Deficiency Reports. "Deficiency" is an all-inclusive term meaning items, services and processes that do not meet the established requirements.

2.3 Price-Anderson Amendments Act Reportability

Deficiencies shall be reviewed for reportability to DOE in the Noncompliance Tracking System.

2.4 Nonconformance Control

1. Nonconforming items shall be controlled in accordance with documented and approved procedures to prevent their inadvertent installation or use. Responsibility for preventing the use, delivery, installation, or operation of nonconforming items shall be designated in procedures.

2. An NCR shall be used to notify the affected organization and to document the description, disposition, action, verification, and closure of identified nonconforming items.

3. Identification of nonconforming items shall be accomplished by legible marking, tagging, or other methods that do not affect the end use of the item.

4. Nonconforming items shall be segregated, when practical, by placing them in an identified and designated hold area until properly dispositioned. When segregation is not possible or practical, other appropriate means shall be used to avoid or eliminate the risk of inadvertent installation or use until dispositioned.

5. Personnel responsible for reviewing and dispositioning nonconformances shall have an adequate technical understanding of the items or activities involved, and shall have access to pertinent information relative to the nonconformance.

6. Items dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. Such dispositions shall be documented, including justification.

7. Repaired, reworked, or replaced items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria, unless the nonconforming item disposition has established alternate acceptance criteria.

8. The status of nonconforming items shall be tracked to closure.
9. Satisfactory completion of actions required by the nonconformance disposition shall be verified prior to closure. Required as-built records shall reflect any changes from the original condition.

2.5 Performance Data Analysis

1. Performance indicators shall be developed and used to identify trends relative to MSA performance.

2. In addition to trend analysis, data shall be analyzed to identify other potential opportunities for improvement.

3. The results of data analysis shall be reported to appropriate levels of management.

4. Appropriate actions shall be taken when adverse trends or improvement opportunities are identified.

5. When an adverse trend is identified, causal analysis shall be performed to determine appropriate actions.

2.6 Feedback and Improvement

1. A feedback and improvement system shall be developed and implemented to integrate and analyze performance data.

2. The results of analyses shall be reviewed by senior management and actions shall be initiated when appropriate.

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Management

Managers at all levels are responsible for:

1. Encouraging personnel to identify deficiencies and potential areas for improvement.

2. Controlling nonconforming conditions.

3. Correcting identified deficiencies.

4. Ensuring corrective actions are effective to prevent or reduce the probability for recurrence of identified deficiencies.

5. Acting upon identified quality improvement opportunities.

NOTE: Employees may print off this document for reference purposes but are responsible to check MSA PS to ensure the most current version is used to prevent unintended use of obsolete versions.
6. Using and supporting implementation of the MSA Corrective Action Management (CAM) process.
3.2 Projects

Project organizations are responsible for:

1. Conducting project/facility specific performance data analysis and taking actions to correct adverse trends.

2. Ensuring corrective action effectiveness reviews are performed, as required, utilizing management assessment, independent assessment, or surveillances.

3.3 Performance Assurance

Performance Assurance has the responsibility for developing and maintaining the MSA feedback and improvement process and reporting the results to MSA management, as follows:

a. Providing oversight activities to assure QA Program compliance.

b. Managing and maintaining the CA System.

c. Maintaining a system for tracking issues, deficiencies, performance data, and follow-up.

d. Reporting nuclear safety and worker safety and health reportable noncompliance's to DOE in the Noncompliance Tracking System (NTS).

e. Providing expertise as the Interpretive Authority for MSA PAAA issues.

f. Conducting performance data analysis to identify adverse trends that potentially meet Noncompliance Tracking System reporting criteria.

g. Evaluating deficiencies for potential nuclear safety and health and safety noncompliances.

h. Perform corrective action effectiveness review as required utilizing management assessments, independent assessments, or surveillances.
3.4 Functional Organizations

Functional organizations are responsible for:

1. Conducting project/facility specific performance data analysis and taking actions to correct adverse trends.

2. Ensure corrective action effectiveness reviews are performed as required utilizing management assessments, independent assessments, or surveillances.
SECTION 4.0
Documents and Records

1.0 REQUIREMENTS

Document and records control processes shall be established and implemented by MSA organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (d), "Criterion 4-Management/Documents and Records," pursuant to 10 CFR 830.6, "Recordkeeping," DOE O 414.1D CRD, Attachment 2, Section 4, "Criterion 4-Management/Documents and Records," and EM-QA-001, Section 7.4 – "Management/Documents and Records (Criterion 4)."

2.0 IMPLEMENTATION

Documents and records shall be accurate and complete and in a form that can be controlled, protected, and retained for the required/specified duration.

2.1 Documents

1. Documents that define processes, specify requirements, or establish design shall be identified, prepared, reviewed, approved, issued, used, and revised when necessary.

2. The process for distribution of controlled documents shall ensure the latest approved revisions are provided to personnel using these documents.

3. Controlled documents, including revisions, shall be reviewed for adequacy, completeness, and correctness before approval and release by authorized personnel.

4. Major changes are any changes that do not meet the criteria of minor changes. Major changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. The reviewing organization shall have access to pertinent data or information upon which to base its approval. Specifically designating other organizations is permitted in cases where organizational responsibilities and authorities have changed, or review/approval requests are no longer valid.

5. Minor changes to documents, such as editorial corrections, do not require the extent of review and approval required for major changes. Minor changes shall be specified.

6. Copies of superseded or canceled controlled documents shall be identified and maintained as records for their specified retention period.
2.2 Records

1. Records shall be specified, identified, prepared, reviewed, approved, authenticated, maintained, and the final disposition specified. These requirements and responsibilities shall be documented.

2. Records shall be legible and traceable to associated items and activities and shall reflect completed work and demonstrate compliance with applicable requirements.

3. Maintenance of records shall include provisions for correction, replacement, retention, protection, preservation, traceability, accountability, and retrievability.

4. MSA documents shall be classified as record material or non-record material and shall be managed in accordance with approved procedures. Records shall be dispositioned in accordance with the General Records Schedule published by the National Archives and Records Administration (NARA) or per DOE-unique schedules.

NOTE: The records management process for MSA records is based on the controls specified in NQA-1. However, all MSA records are subject to these requirements, not just QA records as specified by NQA-1. Consequently, there is no need to differentiate between QA records and other record types. Additionally, since MSA records are subject to the NARA records schedules, designating records as nonpermanent or lifetime is not necessary.

5. For projects with contracts specifying alternate QA Program criteria the records shall be classified, and retention periods shall be documented as required by the applicable QA Program requirements.

6. Records shall be stored and maintained in a manner that minimizes the risk of damage or destruction.

7. Computer hardware and software used to maintain, index, store, or access records shall be maintained and controlled to ensure accountability, reproducibility, and protection from loss.

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Management

1. Managers of MSA organizations are responsible for:
   a. Defining specific document and record control requirements for their organizations.
   b. Establishing processes for controlling documents and records.
c. Providing adequate and proper documentation and records of MSA work.

d. Identifying and controlling documents and records generated in the course of their activities.

2. QA is responsible for defining QA Program requirements for documents and records.

3.2 Information Management

Information Management is responsible for developing and maintaining the document control and records management processes. This includes performing as the Interpretive Authority and assuring compliance with applicable requirements.
1.0 REQUIREMENTS

Work processes shall be described and implemented by MSA organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (e), "Criterion 5-Performance/Work Processes," DOE O 414.1D CRD, Attachment 2, Section 5, "Criterion 5-Performance/Work Processes," and EM-QA-001, Section 7.5 – “Performance/Work Processes (Criterion 5).”

2.0 IMPLEMENTATION

2.1 Work Process Documents

1. Work processes shall be controlled by approved instructions, procedures, and design documents. Additional consideration shall be given to technical standards or other hazard controls adopted to meet regulatory or contractual requirements appropriate to the specific tasks to be performed. These additional considerations shall meet the minimum work process requirements established by NQA-1-2008 w/2009 Addenda.

2. Work process documents shall be developed, reviewed, and approved by personnel technically knowledgeable of the work.

3. To assure consistent and acceptable results, the level of detail contained in work process documents shall be appropriate relative to the:
   
   a. Complexity of the specific tasks.

   b. Work environment and worker proficiency.

4. Work process documents shall be readily accessible to the worker.

5. Proper work completion shall be documented and appropriate records maintained.

2.2 Special Processes

Those processes that are highly dependent on process control, operator skill, and the quality of the product, which cannot be readily determined by inspection or test, shall be controlled as special processes. These processes shall be performed by qualified personnel using approved procedures, drawings, checklists, travelers, or other appropriate means to specify requirements.
2.3 Identification and Control of Items

1. Methods of item identification and administrative control shall be used to prevent the use of incorrect or defective items and to maintain traceability for items as required by specifications, codes, and standards.

2. Status of inspection and test activities shall be maintained through indicators (e.g., tagging). Individuals with authority for application and removal of such indicators shall be identified.

3. Indicators shall be used to signify the operating status of systems and components, such as the tagging of valves and switches to prevent inadvertent operation.

4. Physical identification of items shall be used to the extent possible. Marking or labeling shall not be detrimental to the item.

5. Items requiring additional controls beyond standard commercial practices shall be identified from initial receipt and fabrication through installation for use.

6. Where physical identification is either impractical or insufficient, physical separation, procedural control, or other means shall be employed.

2.4 Handling, Shipping, and Storage

1. A process shall be implemented to ensure procured materials that require additional controls beyond standard commercial practices are segregated or marked to prevent co-mingling with materials that do not require additional controls.

2. Handling, storage, cleaning, packaging, shipping, and preservation of items shall be performed in a manner that prevents damage or loss and minimizes deterioration.

3. Methods used to control the packaging, shipping, receiving, storage, handling, cleaning, and preservation of items shall be documented.

4. Methods shall be established to protect sensitive or perishable items for precision instrumentation and limited shelf-life items, and items requiring special protective controls, such as temperature and humidity controls.

5. Required marking and labeling of items shall be maintained throughout packaging, shipping, handling, and storage.

6. Special handling tools and equipment shall be utilized, controlled, inspected, and tested periodically or prior to use to assure performance and ensure safe and adequate handling.
7. Operators of special handling and lifting equipment shall be experienced, trained, and evaluated as competent for the specified equipment.

2.5 Process Monitoring or Data Collection Instruments

Portable and installed instruments used for process monitoring or data collection shall be controlled, calibrated, and maintained as required by applicable regulations, DOE Orders, and site procedures.

2.6 Control of Computer Software

Computer software used in applications important to safety, health, environmental, and quality aspects of MSA activities, including design calculations and laboratory analysis, shall be subject to appropriate controls, including configuration management, throughout the software life cycle.

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Management

Managers are responsible for controlling their work processes by:

1. Establishing performance standards for their work processes, including defining criteria for acceptable work performance.

2. Placing qualified personnel in positions to accomplish work activities.

3. Identifying and/or developing procedures, instructions, or other appropriate means of control.

4. Ensuring personnel are trained in the requirements of the job, including retraining when the work process is changed.

5. Ensuring work is completed in accordance with the applicable established requirements.

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3.2 Mission Support Alliance Employees

Employees are responsible for ensuring the quality of work by:

1. Performing work in accordance with the identified work control documents and specified requirements.

2. Advising supervisors or managers when work cannot be performed safely and/or in accordance with the work control documents. Employees have the responsibility to notify management of conditions adverse to quality. Work stoppage for significant quality issues shall be accomplished through management processes.

3. Striving to perform work correctly the first time.

4. Identifying potential improvements in the work processes and recommending changes when work performance could be improved.
SECTION 6.0
Design

1.0 REQUIREMENTS

Design processes shall be established and implemented by MSA organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (f), "Criterion 6-Performance/Design," DOE O 414.1D CRD, Attachment 2, Section 6, "Criterion 6-Performance/Design," and EM-QA-001, Section 7.6, “Performance/Design (Criterion 6).”

2.0 IMPLEMENTATION

2.1 Design Input

1. Design inputs include such information as technological decisions, design bases, health and safety considerations, environmental conditions and regulations, expected life cycle, performance parameters, codes and standards requirements, reliability requirements, safety classification, and interfaces with existing structures/equipment. Information derived from experience, as set forth in reports or other documentation, shall be made available to the responsible design organization.

2. Design inputs shall be identified and documented, and the selection reviewed and approved by the responsible design organization.

3. Design input shall be specified and approved prior to use, and at a level of detail adequate to support design decisions and design activity, including verification and evaluation of design changes.

4. Changes from approved design inputs, including the reason for the changes, shall be identified, documented, approved by the responsible design organization, and controlled.

2.2 Design Process

1. The design shall be defined, controlled, and verified. Design documents shall support the facility design, construction, and operation. The design methods, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.

2. Design documents, including changes, shall be based upon sound engineering/scientific principles and shall incorporate appropriate requirements, standards, and design bases.

3. The design process shall translate design input into design output documents that are technically correct and meet the end user's requirements.

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4. Technical design interfaces shall be identified, documented, and controlled throughout the design process.

5. Administrative interfaces, which include authorities, responsibilities, and lines of communication between project team members, shall be defined in sufficient detail to identify and establish relationships of such team members as end users, stakeholders, responsible design organizations, designers, purchasing agents, suppliers, and testers/inspectors.

6. Transmittal of design information across organizational interfaces shall be documented and controlled.

7. Aspects of design that are important to safety, reliability, or environmental considerations shall be identified during the design process.

8. Design calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or other data so the calculations are retrievable.

9. Computer software used to originate or verify safety or other risk-significant design solutions during the design process shall be validated and the status of validation shall be identified and documented prior to use.

10. The organization accomplishing the design shall ensure design output documents meet design input requirements and are usable for their intended purpose. It shall verify any deviations from applicable standards or requirements have been approved and documented.

11. The final design shall be relatable to the design input in sufficient detail to permit design verification.

12. The design shall provide sufficient information so that spare parts, spare equipment, and special tools may be established in inventory, as appropriate, to maintain continuity of system/facility operations and reduce downtime through availability of equipment, parts, and components.

13. The final design shall specify acceptance and in-service inspections and test requirements and include or reference appropriate acceptance criteria.

2.3 Design Verification

1. Design verification shall be performed in a planned and controlled manner and shall provide assurance the final design is correct and satisfactory. Design verification methods may include, but are not limited to, one or more of the following: technical reviews, peer reviews,
alternate calculations, or qualification testing. The responsible design organization shall identify and document the particular design verification method(s) used.

2. Design verification shall be completed prior to releasing the design outputs and prior to relying on structures, systems, components, or computer programs to perform their function. However, if design outputs are used to support other work (e.g., procurement/acquisition, manufacture, construction, or experiment) before design verification is complete, then the unverified portion of the design outputs shall be identified and controlled. In those cases where design verification results in the need to revise the design output, the effect on previously performed work shall be determined, evaluated, and resolved prior to releasing the design output for use.

3. Design verification shall be performed by technically knowledgeable individuals or groups separate from those who performed the design.

4. The results of design verification shall be documented and the identification of the verifier indicated.

5. The extent of design verification shall be commensurate with the design's complexity and importance to safety, the environment, degree of standardization, state of the art, and similarity with previously approved designs.

2.4 Design Change Control

1. Design changes, including changes to design inputs, final design, field changes, and facility modifications, shall be controlled by measures equal to those applied to the original design.

2. Design change control measures shall include assurance the design analyses for the structure, system, or components are still valid.

3. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified, as necessary.

4. Changes shall be approved by the same affected group or organization that reviewed and approved the original design documents.

2.5 Design Documentation and Records

Design documentation and records, providing evidence that the design and design verification processes were performed in accordance with the requirements of this section, shall be generated, collected, stored, and maintained in accordance with documented procedures that satisfy the requirements of Section 4.0, "Documents and Records."

NOTE: Employees may print off this document for reference purposes but are responsible to check MSA PS to ensure the most current version is used to prevent unintended use of obsolete versions.
3.0 RESPONSIBILITIES

3.1 Engineering

Engineering is responsible for:

1. Providing oversight, direction, and control of design(s).

2. Providing technical direction to subcontractors, reviewing subcontractor designs for compliance to the technical direction, and assuring an adequate technical baseline.

3. Acquiring design services and software development services from sub-tier contractors, conveying the applicable requirements of this section, and reviewing/assessing the work for compliance.

4. Ensuring development, maintenance, and control of the integrated technical baseline.

5. Coordinating engineering and technology services requirements to support project needs and integrating engineering and technology project support activities. This includes ensuring the development and implementation of MSA design standards and processes.

6. Providing oversight of the engineering and design processes.

7. Ensuring development and implementation of the configuration management process.

3.2 Information Management

Information Management is responsible for supporting engineering design activities including providing expertise as the Interpretive Authority for Software QA, computer services, software development and overseeing compliance with those requirements.

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SECTION 7.0
Procurement

1.0 REQUIREMENTS

Contractors/Subcontractors conducting activities, including providing items and services that
affect or may affect the safety of DOE nuclear facilities, must conduct work in accordance with
QA criteria in 10 CFR 830.120 [10 CFR 830.121 (a)]. Procurement/acquisition processes shall
be established and implemented by Mission Support Alliance organizations to satisfy the
requirements of this section in accordance with 10 CFR 830.122 (g), "Criterion 7-
Performance/Procurement," DOE O 414.1D CRD, Attachment 2, Section 7,"Criterion 7-
Performance/Procurement," and EM-QA-001, Section 7.7, "Performance/Procurement," and
Attachment F, "Suspect/Counterfeit Items Prevention."

2.0 IMPLEMENTATION

2.1 Procurement/Acquisition Planning

1. Procurement/acquisition activities shall be planned and documented to ensure a systematic
approach to the procurement/acquisition process.

2. The extent of procurement/acquisition planning shall be commensurate with the importance
of the purchased item or service to the facility or process.

3. The Design Authority, engineer, or other technical individuals for non-design (e.g., scientist,
technical authority) shall determine the technical requirements for procurements/acquisition,
including on-line ordering E-Commerce.

4. Supply Chain/Procurement Management shall determine the applicability of federal
procurement regulations and U. S. Department of Energy Acquisition Regulations; and shall
ensure procurement/acquisition documents convey this information to the supplier.

2.2 Content of Procurement/Acquisition Documents

1. Procurement/acquisition documents for items or services requiring controls beyond standard
commercial practices shall include as applicable:
   a. Statement of the scope of work to be performed by the supplier.
   b. Intended use of the item or service.
   c. Risk designation (safety or other).
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d. Technical requirements and references to specific drawings, specifications, codes, standards, regulations, procedures, or instructions that describe the items or services to be provided.

e. Test and inspection requirements, and acceptance criteria.

f. QA requirements applicable to the scope of work and commensurate with the importance and/or complexity of the item or service.

g. Deficiency notification requirements.

h. Requirement to impose the appropriate technical and QA Program requirements, including inspection criteria, on sub-tier suppliers through procurement/acquisition documents.

i. Documentation required to be submitted by the supplier for information, review, or approval by the purchaser.

j. Right-of-access to supplier's facilities and records for inspection, assessments, or audits by the purchaser or designee authorized by the purchaser.

k. Provisions for establishing hold points (if needed) beyond which work cannot proceed without purchaser authorization.

l. Flowdown of 48 CFR 952.250-70, Nuclear Hazards Indemnity Agreement.

m. Flowdown of the Integration of Environment, Safety and Health into Work Planning and Execution requirements.

2. Procurement/acquisition documents shall be reviewed prior to award to ensure documents transmitted to supplier(s) meet the requirements of this section.

3. Changes to procurement/acquisition documents shall be subject to the same controls and approvals as the original documents in accordance with Section 4.0, "Documents and Records."

2.3 Supplier Evaluation and Selection

1. Prior to award the prospective suppliers shall be evaluated in accordance with the criteria set forth in the procurement/acquisition documents to verify their capability to meet performance and schedule requirements. The evaluation may include one or more of the following:

a. Supplier's history of providing identical or similar products.

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b. Supplier's current quality records.

c. Direct evaluation of the facility, personnel, and implementation of the supplier's QA program.

2. Once selected, suppliers of the following items or services (except services accepted in accordance with paragraph 2.6.2 and Commercial Grade Items, see paragraph 2.7 of this Section), at a minimum, shall be identified on the MSA ESL.

a. Safety Class or Safety Significant items and services (e.g., inspection, testing, architect engineer).

b. Environmental analytical services.

3. Contractors providing support services used for staff augmentation shall work to the MSA QA Program and implementing procedures and need not be evaluated for placement on the MSA ESL.

4. Methods for evaluating suppliers for inclusion on the MSA ESL shall include:

a. On-site evaluation of the suppliers' facilities, personnel, and QA program implementation, or

b. Evaluation of documented quantitative and qualitative information (e.g., supplier evaluation performed by a contractor at another DOE site).

5. As appropriate, OHCs and other DOE contractors with QA Programs approved by DOE that supply items or services shall be placed on the ESL as specified in this section. Suppliers of DOE directed services may be placed on the MSA ESL based on DOE contractual direction. Other DOE Contractors may be approved based on review of their DOE approved QA Programs and on the condition that they are providing the same service(s) or item(s) at their sites based on their DOE approved QA programs.

2.4 Supplier Performance Monitoring

Supplier performance shall be monitored during the life of the contract to ensure the supplier continues to satisfy the QA criteria of the procurement/acquisition documents and provide acceptable items and services. Supplier performance monitoring may include source verification, review of plans and progress reports, and review and disposition of nonconformances.

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2.5 Acceptance of Items and Services

1. Procured/acquired items and services shall meet established requirements and perform as specified.

2. Methods shall be established and documented for the acceptance of items or services furnished by a supplier.

3. Methods shall be established and documented for disposition of items or services that do not meet procurement/acquisition documentation requirements.

2.6 Acceptance Methods

1. General

   a. Methods used to accept items and services from a supplier shall be Certificate of Conformance, source verification, receiving inspection, or post-installation test at the facility site or a combination of these methods.

   b. Receiving inspection shall be performed, as a minimum, on safety class and safety significant items.

2. Acceptance of services shall be based on technical verification of data produced, assessment of activities, or review of objective evidence for conformance to requirements. Acceptance methods used shall be documented in accordance with Section 5.0, Work Processes.

2.7 Commercial Grade Items for Use in Nuclear Safety Applications

1. For an item to be procured as a CGI, the following criteria shall be met:

   a. The item is not subject to design or specification requirements unique to nuclear facilities.

   b. The item is used in applications other than nuclear facilities.

   c. The item is ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer’s published product description (e.g., a catalog or national standard, such as American Society for Testing and Materials [ASTM]).

2. Where the design uses CGI, meeting the following requirements is an acceptable alternative to using an MSA ESL supplier.

NOTE: Employees may print off this document for reference purposes but are responsible to check MSA FS to ensure the most current version is used to prevent unintended use of obsolete versions.
a. The CGI and its critical characteristics shall be identified in an approved design document. An alternate CGI may be applied, provided the Design Authority verifies the alternate CGI performs the intended function and meets design requirements applicable to the replaced item and its application.

b. Critical design characteristics and appropriateness of the item for use shall be verified (e.g., inspection, testing). The acceptance method shall be specified by the Design Authority and critical characteristics are verified through inspections or testing.

3. Commercial grade material and items purchased for other uses (e.g., spares and other warehoused items) may be upgraded and dedicated for use if the following conditions are met:

a. There is documented verification that the material or item to be used is the same as that specified by design in terms of critical characteristics and acceptance criteria.

b. There is traceability from the material or item to the CGI's vendor/manufacturer part/catalogue number such that its specifications can be confirmed as meeting design requirements.

c. Acceptance tests specified by the design are conducted and documented.

4. Use of the CGI process shall **not** alter the design identified risk designation (safety or other).

2.8 General Services

Certain GS items and services may be required to be acquired from suppliers on the ESL if through engineering evaluation it is determined they pose significant project risk or impact the safety function of an item or service classified as Safety Class or Safety Significant.

2.9 Procurement/Acquisition Document Control, including Supplier-generated Documents

1. Procurement/acquisition documents, including supplier-generated documents, shall be issued, handled, revised, reviewed, approved, and controlled in accordance with documented procedures that meet the requirements of Section 4.0, "Documents and Records."

2. The purchaser shall require that supplier-submitted documentation, including nonconformance notification, be traceable to the originating procurement/acquisition document (e.g., Material Request, Contract Requisition, Work Package) number.

2.10 Suspect/Counterfeit Items

Methods shall be established to prevent procurement of suspect counterfeit items to the extent commensurate with risk posed by the facility.

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2.11 Software Acquisition

Procurement documents for software and software services shall identify the requirement for the supplier to report software errors to MSA.

3.0 RESPONSIBILITIES

3.1 Management of all organizations are responsible for:

1. Defining the technical and QA requirements for MSA project/facility-related procurements/acquisitions and subcontracts.

2. Using MSA procurement/acquisition process procedures for initiating procurement/acquisition activity managed by MSA unless certain classes of procurement/acquisition are delegated to a subcontractor by MSA.

3. Conducting procurement/acquisition activities, including document review, in accordance with procedures that meet the requirements of this section.

4. Assigning a technical representative for procurement/acquisition activities.

5. Controlling procurement/acquisition documents and maintaining procurement/acquisition records in accordance with this section and Section 4.0, "Documents and Records."

3.2 Business Operations

Supply Chain Management is responsible for:

1. Awarding and administering applicable contracts between MSA and subcontractors. This includes ensuring the MSA QA requirements are included in contract documents for MSA services and products.

2. Providing the contractual interface with RL for MSA.

3. Providing all phases of the acquisition process, contract interpretation, and serving as the procurement/acquisition focal point for Projects and other MSA organizations.

4. Managing acquisition of software and software suppliers.

5. Serving as custodian of MSA procurement/acquisition policies and procedures.

6. Coordinating MSA procurement/acquisition planning.

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7. Ensuring deficiencies in procured/acquired items or services that are reported to MSA from subcontractors, including potential noncompliances to 10 CFR 830.122, are reviewed by the appropriate technical and QA organizations.

3.3 Quality Assurance

Quality Assurance is responsible for:

1. Managing the MSA supplier evaluation program, including the MSA ESL.

2. Performing source and receipt inspection. In some cases this function may be delegated to other technically qualified personnel.

3. Managing the MSA Suspect/Counterfeit Items Program.


5. Providing technical evaluation, review and approval of project/facility-related procurements/acquisitions and non-project-related on-line ordering, such as central commodities not procured for a unique project/facility.

3.4 Engineering

Engineering is responsible for providing a Technical Authority to perform technical evaluation, review and approval for non-project-related on-line ordering, such as central commodities not procured for a unique project/facility.
SECTION 8.0
Inspection and Acceptance Testing

1.0 REQUIREMENTS

Inspection and acceptance testing processes shall be established and implemented by MSA and its subcontractors to satisfy the requirements of this section in accordance with 10 CFR 830.122 (h), "Criterion 8-Performance/Inspection and Acceptance Testing," DOE O 414.1D CRD, Attachment 2, Section 8, "Criterion 8-Performance/Inspection and Acceptance Testing," and EM-QA-001, Section 7.8, "Performance/Inspection and Acceptance Testing (Criterion 8)."

2.0 IMPLEMENTATION

2.1 Inspection and Acceptance Test Planning

1. Procedures shall be prepared that govern inspection and acceptance testing associated with the application of the requirements of this section.

   a. Test procedures shall include or reference the test configuration and test objectives.

   b. Test procedures shall include provisions for assuring prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, and necessary monitoring is performed.

   c. Prerequisites shall include, as applicable, calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and items to be tested, suitable environmental conditions, and provisions for data acquisition.

2. The inspection requirements and acceptance test criteria for items, services, and processes shall be based upon specified requirements identified in the applicable design documents or other pertinent technical documents that provide approved requirements by the responsible design organization.

3. Tests shall be controlled, planned, performed, and documented. This includes prototype qualification tests, operational tests, post-maintenance tests, and acceptance tests.

4. Inspection points shall be identified in implementing documents. Hold points are mandatory inspection points and work shall not proceed until the hold point requirement has been met.

5. Characteristics to be inspected, methods of inspections, and the acceptance criteria shall be specified at inspection planning phase.

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6. Acceptance parameters and other inspection or acceptance test requirements shall be specified as part of the design documentation and work planning process and included in work control documents.

7. When temporary changes to the approved configuration of a facility are necessary for testing purposes, approval by the Design Authority is required and approval shall be obtained prior to the performance of the test.

2.2 Inspection and Acceptance Testing Process

1. Inspections and acceptance tests shall be performed by technically qualified personnel, other than those who performed or directly supervised the work, and who have the freedom of access and communication to conduct and report inspection and acceptance test results.

2. Inspections and acceptance tests shall be performed in accordance with approved documents. Sampling procedures, where used, shall be based upon valid statistical methods.

3. Inspections shall confirm that the work conforms to the design requirements and that work and documentation are complete.

2.3 Inspection and Acceptance Testing Results

Inspection and acceptance test results shall be documented and conformance with acceptance criteria evaluated to ensure requirements have been satisfied.

2.4 Inspection and Acceptance Testing Status

The status of inspection and acceptance test activities shall be identified on the items or in documents traceable to the items to ensure items that have not passed the required inspections and acceptance tests are controlled.

2.5 Control of Measuring and Test Equipment

1. Measuring and Test Equipment (M&TE) used for verifying conformance to requirements, monitoring processes, or collecting data shall be controlled, calibrated at specified intervals, and maintained to required accuracy limits.

2. M&TE shall be selected based on the type, range, accuracy, and tolerance needed to accomplish conformance to the specified requirements.

3. M&TE shall be calibrated at prescribed intervals or when the accuracy of the M&TE is suspect. Calibration shall be against certified equipment having known valid relationship to nationally recognized standards. If no recognized standard exists, the basis for calibration shall be documented.

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4. Control of M&TE shall be in accordance with established procedure(s) that specify methods and frequency of calibration and identification and control of M&TE found to be out-of-calibration or out-of-tolerance.

5. When M&TE is found to be out-of-tolerance, an evaluation shall be conducted and documented commensurate with the significance of the condition, including the validity of previous inspection or test results and the acceptability of items previously inspected or tested.

6. When M&TE is found to be out-of-calibration, it shall be removed from service and recalibrated prior to use.

7. M&TE shall be marked or otherwise identified to indicate calibration status and shall be handled and stored in a manner to maintain the accuracy of the equipment.

8. These calibration and control methods are not required for commercial equipment such as rulers, tape measures, levels, if such equipment provides the required accuracy.

9. M&TE records shall be maintained in accordance with Section 4.0, "Documents and Records."

2.6 Computer Program Testing

1. Verification tests, hardware integration tests, and in-use tests shall be conducted and appropriate controls applied. Acceptance testing shall be performed prior to approval of the computer program for use.

2. Computer program test procedures shall demonstrate adherence of the computer program to the specified documented requirements.

   a. Computer programs used for design activities; the computer program test procedures shall assure the computer program produces correct results.

   b. Computer programs used for operational controls; the computer program test procedures shall demonstrate performance over the range of the operation of the controlled function or process.

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

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Quality Assurance Program Description

Section 8.0, Inspection and Acceptance Testing

2.7 In-process Inspection

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

2. If in-process inspection of items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

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

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Organizations

Organizations that perform inspection and acceptance test activities are responsible for implementing the requirements of this section.

3.2 Projects

Projects are responsible for:

1. Implementing these requirements and ensuring that design and construction activities comply with the requirements of this section.

2. Ensuring design agencies identify inspection and acceptance test requirements, including acceptance criteria, in design documents.

3. Coordinating inspection and acceptance test activities to ensure design requirements are met.

4. Monitoring subcontractors to ensure the subcontractors meet the specified QA requirements.
SECTION 9.0
Management Assessment

1.0 REQUIREMENTS

Management assessment processes shall be established and implemented to satisfy the requirements of this section in accordance with 10 CFR 830.122 (i), "Criterion 9-Assessment/Management Assessment," DOE O 414.1D CRD, Attachment 2, Section 9, "Criterion 9-Assessment/Management Assessment," and EM-QA-001, Section 7.9, "Assessment/Management Assessment (Criterion 9)."

2.0 IMPLEMENTATION

2.1 Management Assessments

1. A written process shall be established and implemented describing the management assessment process. This process shall include assessment planning, conduct, results reporting, and tracking of issues to closure.

2. Management assessments shall be planned in a systematic manner on an annual basis by responsible managers to address areas under their responsibility and to focus on those areas presenting the greatest risk for failure or potential for improvement.

3. Performance data and results of independent assessments shall be periodically reviewed to identify areas for additional management assessment emphasis.

4. Managers at every level shall be involved in the assessment of their management programs, systems, and processes important to achieving objectives. Specific support activities (i.e., data collection) may be delegated to staff.

   a. Management assessments conducted by first line management shall focus on procedural adequacy, compliance, and effectiveness of the process being assessed.

   NOTE: First line management includes personnel assigned as subject matter experts (SME) in support of either the facility/project or a functional organization. This includes Design Authorities, Shift Managers, Fire Projection Engineers, Lock and Tag Administrators, Interpretive Authorities, persons designated as "Leads" and others.

   b. Management assessments conducted by facility/project/program managers shall focus on the effectiveness of their management systems.

5. Personnel performing assessments shall be trained in the assessment process and shall be knowledgeable of the program, system, or process being assessed.

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6. Problems identified by management assessments that hinder the organization in achieving its objectives shall be resolved in accordance with the process described in Section 3.0, “Quality Improvement.”

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Management

1. The Performance Assurance organization is responsible for administration and coordination of the MSA Management Assessment Program.

2. Directors of Projects and Functional Organizations are responsible for:

   a. Scheduling and planning management assessments.

   b. Acting on identified improvement opportunities, including correcting deficiencies, and resolving negative observations, weaknesses or problems identified by management assessments, and assuring actions taken are effective.

3. Managers at all levels are responsible for:

   a. Performing management assessments.

   b. Resolving quality problems, considering opportunities for improvement, and ensuring corrective actions are effective in accordance with Section 3.0, "Quality Improvement," and associated procedures.
SECTION 10.0
Independent Assessment

1.0 REQUIREMENTS

Independent assessment processes shall be established and implemented to satisfy the requirements of this section in accordance with 10 CFR 830.122 (j), "Criterion 10-Assessment/Independent Assessment," DOE O 414.1D CRD, Attachment 2, Section 10,"Criterion 10-Assessment/Independent Assessment," and EM-QA-001, Section 7.10, "Assessment/Independent Assessment (Criterion 10)."

2.0 IMPLEMENTATION

2.1 Focus of Independent Assessments

1. Independent assessments include programmatic and implementation assessments, and surveillances; supplemented by external assessments (DOE, Environmental Protection Agency, etc.).

2. Independent assessments shall be planned and conducted to measure the adequacy of work performed in complying with applicable requirements and determine the effectiveness of QA Program implementation. This includes Projects and Functional Groups.

3. Scheduled assessments shall be supplemented by additional assessments of specific subjects when necessary to provide adequate coverage or as a result of performance data reviews.

4. Independent assessments shall evaluate program requirements, the quality of MSA items and services, and promote improvement in MSA processes and activities.

5. The QA Program implementation for Projects and Functional Groups shall be regularly assessed, with resources focused on those activities that pose the greatest risks and that stand to benefit the most from improvement opportunities. The effectiveness of the QA program is also evaluated and reported by the QA organization through inspections, reviews, monitoring, and surveillance functions.

6. The effectiveness of corrective actions for previously identified issues shall be periodically evaluated as part of the independent assessment program.
2.2 Performance of Independent Assessments

1. Independent assessment personnel shall have sufficient authority and freedom to carry out their independent assessment responsibilities.

2. The organization or staff performing independent assessments shall have sufficient authority and freedom from the line organization to carry the assessment responsibilities and shall not have direct responsibility for the work they are assessing.

3. Schedules shall be developed based on status, complexity, risk, and importance of the activity and coordinated with ongoing activities to be assessed.

4. Assessments shall be planned to identify the assessment scope, requirements, team members, activities included in the assessments, pertinent documents, schedule for the assessment, and procedures or checklist. Assessments on the QAPD shall be performed on a triennial basis.

5. Personnel performing independent assessments shall be identified prior to performance of the assessment. Assessment teams shall consist of one or more members and shall not have direct responsibility for work in the areas they are assessing. An individual shall be designated to organize and direct the assessment activities. Assessment team members shall be technically qualified and knowledgeable in the areas they assess, and be qualified in accordance with established procedures relevant to the assessment type (e.g., assessments, surveillances, startup readiness reviews).

6. Assessment elements shall be evaluated against specified requirements. Evaluation shall include examination of objective evidence to the depth necessary to determine if the elements are being implemented effectively. Conditions requiring prompt corrective action shall be immediately reported to responsible management.

7. A report of the assessment results shall be issued to the affected organization(s). Reports identifying significant programmatic issues shall be reported to the Office of the President. The report shall include, as a minimum, the scope of the assessment, identification of the assessment team members, summary of results, and adverse conditions identified during the assessment. Follow-up actions shall be taken where indicated.

8. Tracking of deficiencies shall be in accordance with Section 3.0, "Quality Improvement."

9. Management of assessed organizations or activities shall investigate adverse findings, identify and schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organizations in writing of actions taken or planned.

10. Follow-up actions shall be taken in accordance with Section 3.0.
2.3 Records

Records shall be in accordance with Section 4.0, "Documents and Records," and include assessment plans, reports, documented responses, and corrective actions.

2.4 External Independent Assessment

Organizations external to MSA (e.g., DOE, EPA, etc.) also perform independent assessments of MSA activities. Results of external independent assessments are managed in accordance with Section 3.0.

3.0 RESPONSIBILITIES

3.1 Mission Support Alliance Management

Managers at all levels are responsible for:

1. Cooperating with independent assessment personnel in planning, preparing, and performing assessments.

2. Evaluating the assessment results to identify improvement actions and determine if similar problems exist elsewhere in the organization.

3. Promptly correcting deficiencies identified by independent assessments and ensuring corrective actions are effective in accordance with Section 3.0, "Quality Improvement," and associated procedures.

3.2 Quality Assurance

Quality Assurance organization is responsible for:

a. Establishing and performing processes for independent audit, assessment, and surveillances, including supplier evaluations.