

NNSA POLICY LETTER

NAP 414.1

Approved: 1-10-17
Certification Due: 1-10-20

QUALITY MANAGEMENT SYSTEM



NATIONAL NUCLEAR SECURITY ADMINISTRATION Office of Management and Budget

CONTROLLED DOCUMENT
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Quality Management

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QUALITY MANAGEMENT SYSTEM

1. PURPOSE. Establish, implement, maintain, assess, and improve the Quality Management System (QMS) for NNSA federal operations in accordance with [DOE Order \(O\) 414.1*](#), *Quality Assurance* and, by citation, the American version of International Organization for Standardization (ISO) Standard Requirements Document ISO 9001-*, *Quality Management Systems – Requirements* (ASQ/ANSI/ISO 9001:2015).

* Unless otherwise specified, reference is made to the current version of these documents.

2. CANCELLATION. NAP 26A, *Quality Management System*, dated 6-1-16.

3. APPLICABILITY.

- a. Federal. This policy applies to all NNSA organizations.
- b. Contractors. This policy does not apply to contractors.
- c. Equivalency. In accordance with the responsibilities and authorities assigned by Executive Order 12344, codified at 50 United States Code sections 2406 and 2511, and to ensure consistency through the joint Navy/DOE Naval Nuclear Propulsion Program, the Deputy Administrator for Naval Reactors (Director) will implement and oversee requirements and practices pertaining to this Directive for activities under the Director's cognizance, as deemed appropriate.

4. SUMMARY OF CHANGES.

- a. Modified contact information (refer to section 10).
- b. Changed “Office of Quality Management (OQM)” to “Quality Management.”
- c. Added Management System Description (MSD) (refer to Appendix 4).
- d. Added Acronyms (refer to Appendix 5).
- e. Added References (refer to Appendix 6).
- f. Added Document Repositories (refer to Appendix 7).
- g. Added DOE O 414.1-MSD Traceability Matrix (refer to Appendix 8).
- h. Added MSD-ISO 9001:2015 Traceability Matrix (refer to Appendix 9).
- i. Added ISO 9001:2015-ISO 9001:2008 Traceability Matrix (refer to Appendix 10).

5. BACKGROUND. Both DOE O 414.1 and ANSI/ISO/ASQ Q9001 stipulate that quality systems be developed. The QMS referenced in this directive pertains to an Enterprise Management System for NNSA and is a process-based management system that controls the quality of customer products and mission requirements. This NAP was developed using DOE O 414.1, *Quality Assurance*, as a baseline and tailored to meet the mission requirements of NNSA. The selection and use of ANSI/ISO/ASQ Q9001 to establish the QMS is authorized by DOE O 414.1, paragraph 4.A.(2)(C):

“(c) Use appropriate national or international consensus standards in whole or in part, consistent with regulatory requirements and Secretarial Officer direction. When standards do not fully address these requirements, the gaps must be addressed in the QAP.

Examples of currently acceptable standards include:

- 1 ASME NQA-1-2008 with the NQA-1a-2009 addenda, Quality Assurance Requirements for Nuclear Facility Applications;
- 2 ANSI/ISO/ASQ Q9001-2008, Quality Management System-Requirements; and, [sic]
- 3 ANSI/ASQ Z 1.13-1999, Quality Guidelines for Research.”

6. REQUIREMENTS.

- a. The QMS is codified in the MSD (see Appendix 4) which serves as the description of the Quality Assurance Program (QAP), stipulated in DOE O 414.1.
- b. The NNSA QMS must be in full compliance with federal requirements and responsibilities of DOE O 414.1, and select and applicable ISO 9001 principles for quality management systems as identified in Appendix 4.
- c. The QMS must be in compliance with the current version of the NNSA *Enterprise Strategic Vision*.
- d. The MSD and associated work processes must be documented and available to all employees.
- e. Work processes, such as process descriptions outlined in Appendix 4 and those developed pursuant to paragraph 7.b.1, must be identified, controlled, and measured to assure that the quality of products and services fulfills customer requirements.
- f. Management System Assessments (MSAs) of the NNSA QMS must be performed periodically in accordance with the ISO 9001 requirements for the conduct of internal audits. Periodic management reviews will be conducted to assess the status of the QMS and to address improvements to processes, products, and services. (Appendix 2)

- g. Subject area-specific quality systems, developed in whole or in part to comply with DOE O 414.1, *Quality Assurance*, or specific technical programs or subject areas within NNSA, will be considered subordinate to the overarching business process focus of the QMS codified in the MSD. Quality systems must be verified as to their function and compliance with the pertinent standards around which they are organized.

7. RESPONSIBILITIES.

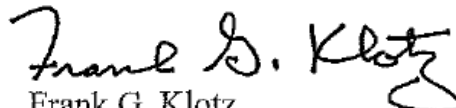
- a. Administrator and Principal Deputy Administrator:
 - (1) Establish QMS policy.
 - (2) Communicate management's commitment to the QMS.
 - (3) Ensure availability of sufficient resources to support the implementation and ongoing management of the QMS.
 - (4) Conduct periodic management reviews to identify progress of the QMS and implement any necessary changes to ensure its continuing improvement.
- b. Deputy Administrators, Associate Administrators, and Field Office Managers:
 - (1) Establish a process for implementing the NNSA QMS in their respective offices and functions that aligns with the NNSA QMS as established in the MSD.
 - (2) Establish organizational quality objectives.
 - (3) Develop, approve, and update office procedures and work processes in accordance with the NNSA QMS requirements stated in the MSD.
 - (4) Evaluate the implementation, efficiency, and effectiveness of the NNSA QMS for their respective offices and functions, using appropriate data analysis techniques.
 - (5) Appoint a representative to serve on the NNSA Management System Board (MSB). (See Appendix 3)
- c. NA-MB-1.2, Quality Management:
 - (1) The Quality Management Director serves as the QMS Executive Management Representative.
 - (2) The Quality Management Director serves as the chair of the NNSA Management System Board.

- (3) Ensures that the processes needed for the corporate QMS are established, approved, implemented, and maintained.
 - (4) Establishes an MSA internal audit process to ensure continuing improvement, as required by DOE O 414.1 and the ISO 9001 standard.
 - (5) Defines the criteria, scope, frequency, and methodology for the MSAs.
 - (6) Reports to top management on the performance of the QMS and any need for improvement.
 - (7) Ensures the promotion of awareness of customer requirements throughout the organization.
 - (8) Acts as liaison with external bodies and customers on matters relating to the organization's QMS.
 - (9) Designates an MSA manager who:
 - (a) Conducts MSAs in accordance with the ISO 9001 standard.
 - (b) Verifies through the MSAs that the QMS and subordinate organization management systems are implemented and effectively maintained.
 - (c) Schedules MSAs, taking into consideration the status and importance of the processes and areas to be assessed as well as the results of previous assessments.
 - (d) Establishes a documented procedure that defines the responsibilities and requirements for planning and conducting MSAs and reporting results.
 - (e) Supports the Office of the Administrator in conducting management reviews of the QMS.
 - (f) Maintains records of the MSA schedules and results.
- d. NNSA Management System Board:
- (1) Includes representatives from all Headquarters organizations and field offices.
 - (2) Shares information relating to issues or changes that have a direct impact on management system implementation or improvement.
 - (3) Ensures appropriate integration and alignment of NNSA Headquarters and field offices with the management system policies and requirements.

- (4) Advises Quality Management on policy matters pertaining to NNSA's Management System.
- (5) Prepares options to present to the Management Council on management system issues the Board cannot resolve.

- 8. REFERENCES. Refer to Appendix 6.
- 9. ACRONYMS. Refer to APPENDIX 5.
- 10. CONTACT. Quality Management, (202) 586-1925.

BY ORDER OF THE ADMINISTRATOR:


Frank G. Klotz
Administrator

Appendixes:

- 1. ISO Best Practices
- 2. Internal Audits
- 3. Management System Board (MSB) Charter
- 4. Management System Description (MSD)
- 5. Acronyms
- 6. References
- 7. Document Repositories
- 8. DOE O 414.1-MSD Traceability Matrix
- 9. MSD-ISO 9001:2015 Traceability Matrix
- 10. ISO 9001:2015-ISO 9001:2008 Traceability Matrix

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APPENDIX 1. ISO BEST PRACTICES

The ISO best practices can be summarized in four areas: Plan, Do, Check, Act.

Plan: Establish objectives, goals, and processes. The goal of quality management is to build a structure that supports organizational success. Quality management requires conformance with agency guidelines, regulations, and statutory requirements; organizational conformance with established work processes; and responsiveness to customer needs and feedback. Quality management creates a benchmark so that management can accurately measure the impact and performance of its collective work processes.

Do: Formalize procedures and implement those procedures. Create and document procedures, together with workflow training, establish a foundation upon which to build and manage continuous improvement. Best practices also include clarity in assigned responsibilities, effective records management, and a management system that captures organizational work procedures in an information system readily accessible to all. Benefits of quality management practices include the reduction of obstacles facing the workforce, documentation that facilitates a fair distribution of workload, and the overall improvement of the work environment.

Check: Monitor and measure. Management review conducted periodically by an organization's managers and staff helps ensure work is aligned with mission goals and carried out according to plan. Management review also serves to break down the stove-piped decision-making in an organization. Audits by an independent team of reviewers are an additional way to determine if an organization is following established processes.

Act: Pursue continuous improvement. Improvement occurs first during the development of work processes and workflow mapping, when efficiencies are recognized and working relationships clarified. Later, improvement stems from checks on conformance with established work processes and customer feedback.



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APPENDIX 2. INTERNAL AUDITS

MANAGEMENT SYSTEM ASSESSMENTS.

The NNSA Management System Assessment (MSA) is an activity sponsored by Quality Management. The assessments are conducted to fulfill Quality Management's responsibilities and cited requirements under [DOE O 414.1D, *Quality Assurance*](#), NAP 414.1, *Quality Management System*, and ISO 9001:2015, *Quality Management System*. MSAs are conducted by trained and certified ISO auditors and involve onsite management system reviews at the NNSA Headquarters (HQ) facilities in Washington, DC, Germantown, MD, Albuquerque, NM, and the field offices.

MSAs are a check, at a point in time, of an organization's management system to verify whether it is properly implemented, maintained, and whether mission-related processes are being planned, documented, executed, and subjected to periodic management review. The MSA objective is to strengthen accountability by ensuring that procedures are established and followed. MSAs also enhance risk management, resource stewardship, and governance across all NNSA federal organizations. These MSAs will be conducted in accordance with an assessment plan and schedule that is developed by the NNSA Management Systems Board (MSB). The plan will be approved by the NNSA Management Council.

MANAGEMENT SYSTEMS ASSESSMENT PROCEDURES.

Every MSA is unique and the order in which steps are performed may vary or overlap. However, the MSA typically includes the following steps:

- a. **Engagement Memo** – Prior to the beginning of an MSA, appropriate organizational points of contact are notified of the pending assessment and appraised of the MSA objectives. Certain preliminary information may be requested at this time, such as organization charts, internal office procedures manuals, etc.
- b. **Planning** – During this phase of the MSA, background information on the area to be assessed is obtained from a number of sources in order to learn as much as possible about the subject area or organization. Applicable policies and procedures are reviewed, as well as pertinent statutes and regulations. The results of any prior audits of the area will also be considered. Employees may be interviewed and MSA questionnaires may be distributed. At length, planning culminates with an MSA scope and schedule, which is developed in coordination with the subject organization's staff. Every reasonable attempt will be made by Quality Management's assessors to minimize disruption of staff duties and normal operations.
- c. **Entrance Conference** – This is a meeting between the managers of the area or organization being assessed and MSA personnel. The scope of the MSA will be reviewed again at this meeting and any scheduling changes or MSA-related concerns addressed. Managers will have an opportunity to share any management system concerns, and if there is a particular area or activity that a manager would like to have reviewed, Quality Management will include it in the assessment plan.

- d. **Fieldwork** – This phase may include interviewing employees, flow-charting processes, and testing transactions. Some of the work will be performed in the area under assessment, and some of the work will be performed in Quality Management's office. Appropriate managers (designated by the organization being assessed) will be kept informed of any findings as the MSA progresses.
- e. **Draft Report** – Once fieldwork is completed, a draft of the MSA report will be prepared. The report will describe organizational procedures performed, findings and observations, as well as any recommendations or opportunities for improvement (OFIs). The draft will be provided to the manager in charge of the area under assessment and anyone else deemed appropriate by the manager. The subject organization will be asked to provide written responses to Quality Management's recommendations and will, in turn, be included in the final report.
- f. **Exit Conference** – This is a meeting between management and the MSA audit personnel to discuss the results of the assessment and go over the draft report. If management discovers any factual errors or believes that Quality Management has misinterpreted anything, staff should inform Quality Management during the exit conference so that Quality Management may make corrections before the report is seen by anyone else. On occasion, there may be items that Quality Management does not feel are appropriate to include in the written report but should be brought to the attention of management. Quality Management will discuss any such items during the exit conference or include a specific issues summary in a separate management letter.

APPENDIX 3. MANAGEMENT SYSTEM BOARD (MSB) CHARTER

1. PURPOSE.

- a. To comply with [DOE O 414.1, *Quality Assurance*](#), and improve the effectiveness, efficiency, consistency, and accountability in executing its vital roles and responsibilities, the National Nuclear Security Administration (NNSA) is implementing a management system in accordance with select and applicable principles of ISO 9001, *Quality Management Systems – Requirements*.
- b. The Management System Board (MSB) is a successor organization to the ISO 9001 QMS Steering Committee (ISO-SC). The Steering Committee was chartered in 2012 to lead change and provide QMS technical expertise in developing and implementing an ISO 9001 QMS for the NNSA. As stated in its Charter, the ISO-SC is not responsible for preparing, developing, or implementing procedures. The Steering Committee Charter is dissolved upon the approval of the MSB Charter.
- c. The MSB Charter establishes the NNSA MSB and defines its authorities, applicability and scope, functions, membership, meetings, duration, and any applicable records to be retained.

2. APPLICABILITY AND SCOPE.

This charter applies to NNSA Headquarters' (HQ) program offices and field offices as it relates to management system policy implementation.

3. AUTHORITY.

[DOE O 414.1](#); NAP-414.1, *Quality Management System*; and [NNSA BOP-100.1, *Senior Leadership Councils*](#).

4. GOVERNING COUNCIL AFFILIATION.

The MSB reports to the NNSA Management Council.

5. FUNCTIONS.

- a. The MSB shares information relating to issues or changes that have a direct impact on management system implementation or improvement. MSB meetings promote the sharing of best practices as well as risk reduction or mitigation activities concerning management systems throughout NNSA.
- b. The MSB advises Quality Management on policy matters pertaining to NNSA's management system.
- c. The MSB ensures appropriate integration and alignment of NNSA Headquarters and field offices with the management system policies and requirements.

- d. The MSB prepares options to present to the Management Council for management system issues that Board members cannot resolve.
- e. MSB members act as management system liaisons for their respective offices.

6. MEMBERSHIP.

- a. The Board is chaired by the Director, Quality Management.
- b. Each HQ program office and field office appoints a member to the MSB, as determined appropriate by the HQ and field elements.

7. MEETINGS.

The MSB shall meet quarterly or at the direction of the Chair.

8. DURATION.

This charter shall continue until the Management Council cancels or amends it.

9. ASSESSMENT.

The performance and effectiveness of the MSB shall be assessed by its members on an annual basis and include the following considerations:

- Meetings conducted as defined in Section 7;
- Agendas provided in advance of the meeting;
- Meeting notes containing action items released within three weeks of meeting adjournment;
- Completion of action items ensured prior to next meeting – or as agreed and documented in meeting notes.

10. RECORDS.

Quality Management shall maintain this charter and all other records associated with the MSB.

11. OFFICE OF PRIMARY INTEREST.

Quality Management.

APPENDIX 4. MANAGEMENT SYSTEM DESCRIPTION (MSD)

1. INTRODUCTION

The National Nuclear Security Administration's (NNSA) Management System Description (MSD) provides a high-level description of NNSA federal business operations. The MSD was developed in accordance with select and applicable clauses (see Appendix 9) from the American version of the International Organization for Standardization's (ISO) 9001, *Quality Management Systems – Requirements* (ASQ/ANSI/ISO 9001:2015). The MSD and its supporting documentation and procedures serve the organization by providing for subordinate organizations an MSD of NNSA's responsibilities, the associated authorities it operates with, and its management approaches designed to deliver the NNSA mission.

2. PURPOSE

NNSA has engaged in multiple reform efforts to improve quality and customer satisfaction. These reforms were designed to address shortfalls in program and support functions management. One of the reforms included the development and completion of an MSD.

The MSD – which satisfies the Quality Assurance Program (QAP) and Quality Management System (QMS) requirements of [Department of Energy \(DOE\) O 414.1, *Quality Assurance*](#) while reflecting select and applicable principles of ISO 9001 – describes NNSA's integrated management system, business operations, organizational structure, and key crosscutting policies and procedures.

3. SCOPE

The MSD describes the management, technical activities, and business practices conducted by NNSA federal employees and contracted personnel – in NNSA HQ and field offices – to ensure the following:

- Implementation of the functions, responsibilities, and authorities depicted by mission and function statements;
- Execution of NNSA responsibilities to support customers as well as other interested parties; and
- Identification of the systems and mechanisms by which NNSA may ensure the quality of products, services, and processes.

Note: Individual program or field organizations may develop and institute additional operational guides, plans, or their own management systems that are subordinate to this corporate MSD. Organizations with established management systems should ensure their guides, plans, MSDs, etc., align – and are modified, as necessary – with this corporate MSD.

The following, however, have been determined to be out-of-scope:

- Validation of Processes for Production and Service Provision
- Identification and Traceability
- Customer Property
- Preservation of Product

Note: For more details, refer to paragraph 9.5.

4. ORGANIZATION

(DOE O 414.1D Criterion 1)

4.1. NNSA HEADQUARTERS (HQ)

NNSA manages its mission from its HQ in Washington, DC; Germantown, MD; and Albuquerque, NM. NNSA HQ is responsible for planning, managing, and overseeing the entire nuclear security enterprise. All program management and many functional management responsibilities reside in HQ.

Note: For details, refer to the mission and function statements as described in an NNSA policy.

4.2. NNSA FIELD OFFICES

Federal field offices at each NNSA site provide tailored contract management, oversight, and collaboration with Management and Operating (M&O) partners. In accordance with program direction, field offices led by a field office manager (FOM) are responsible for onsite federal oversight and administration of the M&O and other direct contracts.

4.3. MANAGEMENT AND OPERATING (M&O) PARTNERS

Unlike government agencies outside the DOE, NNSA has a unique arrangement of being a self-regulator. All of NNSA's laboratories, production plants, and sites are government-owned/contractor-operated (GOCO) and run by non-governmental organizations under an M&O contract (or similar contract). M&O partners are tasked with producing mission deliverables and meeting performance expectations as authorized by NNSA officials.

Note: For more details, refer to [DOE Order 226.1, Implementation of Department of Energy Oversight Policy](#), and [NNSA SD 226.1B, NNSA Site Governance](#).

4.4. OFFICES

The offices (listed below) function synergistically to carry out the NNSA mission from HQ (Forrestal and Germantown), the Albuquerque Complex (AC), and field office

locations. The NNSA structure is illustrated in the organizational chart provided below (Figure 1).

Note: For more details, refer to the mission and function statements as described in an NNSA policy.

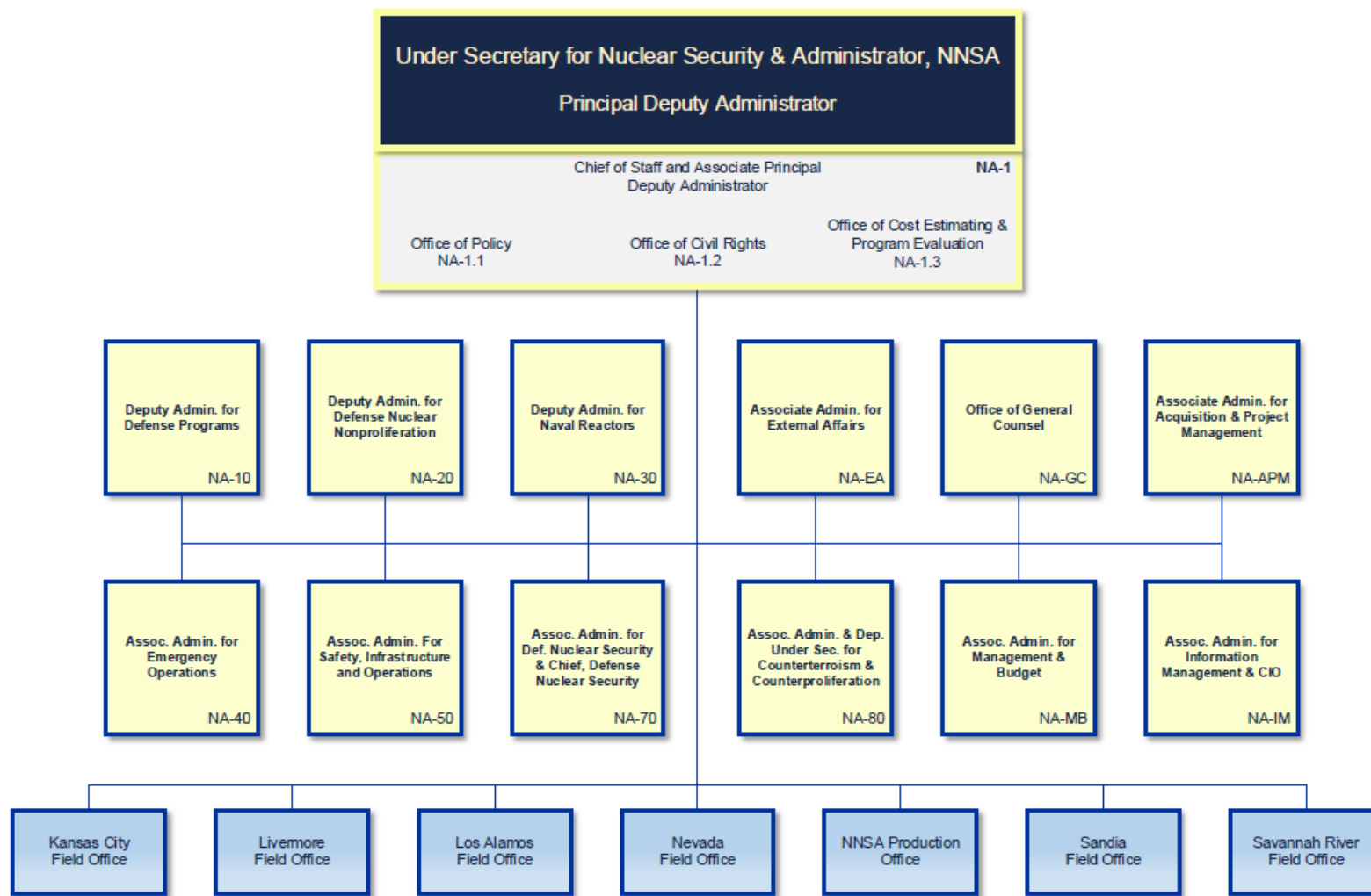


Figure 1 – NNSA Organizational Chart

5. INTEGRATED MANAGEMENT SYSTEM

(ISO 9001:2015 clause 9.3.1 and DOE O 414.1D Criterion 9)

NNSA operates as an integrated management system. The effective integration of the individual NNSA program office, field office, and mission support management systems allows continuous improvement, resulting in efficiency and effective achievement of NNSA's mission. For NNSA, policies and procedures provide a disciplined and consistent management approach to the accomplishment of work within the requirements established through laws, executive orders, regulations, DOE directives, and best management practices. NNSA's integrated management system fulfills the various requirements of other management systems such as the:

- Integrated Safety Management System,
- Integrated Safeguards and Security Management System,
- QAP, and
- QMS.

NNSA also expects that the implementation of quality procedures such as periodic management review and internal audits will result in continuous improvement and enhanced risk management.

5.1. MANAGEMENT OF NNSA

Following the decisions and guidance of the Administrator and the councils and boards, contract managers, program managers, and functional managers work in an integrated fashion to ensure the fulfillment of NNSA's mission. Managers are responsible for achieving assigned program objectives in a manner that is safe; environmentally sound; secure; legally, ethically, and fiscally responsible; and compliant with requirements that fall within the realm of their control. Primary responsibility rests with the lowest level manager responsible for directing the resources needed to meet a specific requirement or objective.

5.2. GOVERNANCE

NNSA's governance model is a system of strategic management, policy, and programmatic controls exercised for the stewardship of the organization and execution of mission. In NNSA, governance is implemented collaboratively by federal and contractor organizations in pursuit of shared mission objectives. The NNSA governance system is defined by documented organizational roles, responsibilities, and work processes. The governance system is implemented through a hierarchical and disciplined structure of councils, boards, and committees. Each group possesses distinct but interrelated responsibility and decision making authority and has a membership that includes appropriate representation of federal and contractor organizations. The governance system is informed by a matrixed quality management framework designed to reduce and eventually eliminate nonconformance to program specifications, standards, and customer

expectations, yet support and preserve the degree of independence needed for the contractor to function in a self-regulatory manner.

Note: For more details, refer to [NNSA BOP-100.1](#).

6. QUALITY MANAGEMENT SYSTEM (QMS)

6.1. GENERAL REQUIREMENTS

(ISO 9001:2015 clause 4.4.1)

NNSA has developed, documented, implemented, and maintained its Quality Management System (QMS) to ensure it aligns with select and applicable principles of ISO 9001. With this alignment, the NNSA QMS is based upon an approach that:

- Identifies the processes needed for the management system;
- Determines the sequence and interaction of processes;
- Establishes the criteria and methods required to ensure effective operation and management of processes;
- Ensures the availability of resources and information necessary to support processes; and
- Monitors, measures, and analyzes processes to achieve planned results and continual improvement.

6.2. DOCUMENTATION REQUIREMENTS

The level and type of documentation established for NNSA is reviewed periodically to ensure it remains appropriate for the following:

- Activities performed,
- Methods used,
- Complexity of processes and their interactions, and
- Skills and capabilities required by personnel.

Corporate NNSA procedures are provided in one of five ways:

1. MSD,
2. Existing DOE directives,
3. BOPs,

4. Procedures contained in NAPs and SDs, or
5. Standard Operating Procedures (SOPs).

6.2.1. NNSA POLICIES

NNSA policies are categorized as follows:

- **NAPs** – establish enterprise-wide policies, requirements, and responsibilities unique to NNSA; apply to all Federal NNSA Elements and to contractor elements when appropriate.
- **SDs** – augment policies, requirements, and responsibilities established in a DOE directive; apply to all Federal NNSA Elements and to contractor elements when appropriate.
- **BOPs** – establish business procedures that apply to more than one Federal NNSA Element.
- **Interim Policy Memoranda (IPMs)** – establish temporary enterprise-wide policy; apply to all Federal NNSA Elements and to contractor elements when appropriate.
- **SOPs** – establish business procedures that apply to a single Federal NNSA Element.

Note: For more details, refer to [NNSA SD 251.1, NNSA Policies, Supplemental Directives, and Business Operating Procedures](#).

6.2.2. QUALITY MANUAL

The MSD establishes NNSA quality management policy and serves as the quality manual for the organization. The manual includes the scope and description of the QMS and references documented procedures and external documents.

Note: The MSD is a controlled document subject to select and applicable principles of ISO 9001 and [DOE O 414.1](#).

6.2.3. CONTROL OF DOCUMENTS

(ISO 9001:2015 clauses 7.5.3.1, 7.5.3.2, and 8.1)

Procedures are established and maintained at NNSA to control documents within the scope of the NNSA management system. This includes the processes for preparing, reviewing, approving, releasing, distributing, changing, revising, tracking, maintaining, and canceling documents, quality manuals and plans, procedures, forms, and instructions.

Each NNSA organization is responsible for the establishment, maintenance, and control of organization-unique documents to include distribution of documents of external origin.

Documents are reviewed and approved for adequacy and accuracy prior to being issued and work being performed. Approval may rely upon concurrence from technical authorities and employee representatives performing the tasks, as appropriate. Each organization maintains the documents, such as procedures, instructions, and forms, or identifies the repository of the documents. Documents can be in multiple types of media.

Note: Electronic media are recommended, when available.

The documents must be controlled, using – at a minimum – the document’s title or subject, approval date, and document number. A master list identifying the current revision status of documents is established and readily available to preclude the use of invalid or obsolete documents. This control must ensure:

- Document issues and errors are readily available to essential NNSA management system personnel and functions.
- Invalid or obsolete documents are removed from points of issue or use, destroyed, or otherwise ensured against unintended use.
- Previous or obsolete versions of documents are identified as such.

Changes, revisions, and cancellations to documents will be reviewed and approved by the same NNSA organization that performed the original review and approval, unless designated otherwise.

Note: For details regarding the control of NNSA policies, refer to [NNSA SD 251.1](#).

6.2.4. CONTROL OF RECORDS

Per [NNSA SD 243.1, *Records Management Program*](#), Appendix 8, Section 19, *records* are defined as:

All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an Agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that Agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data in them.

Records management is critical to the NNSA mission as it provides evidence (i.e., records) of activities, organizations, functions, policies, decisions, procedures, and operations. The system also maintains and ensures the creation, maintenance, and proper disposition of records. Records management best practices ensure the protection of the legal and financial rights of the government and individuals, preserve historical legacy information, and facilitate the effective retrieval of essential and archived information.

Note: For more details, refer to [NNSA SD 243.1](#).

7. LEADERSHIP AND MANAGEMENT

7.1. LEADERSHIP AND COMMITMENT

(ISO 9001:2015 clause 5.1.1)

By issuing this document and in support of its commitment to quality and customer satisfaction, NNSA:

- Establishes, implements, assesses, and reports on the integrated management system to provide accountability and improve the effectiveness of the organization.
- Ensures compliance with applicable laws, regulations, and requirements such as the *Federal Managers' Financial Integrity Act* (FMFIA), the Office of Management and Budget (OMB) Circular A-123, *Management's Responsibility for Internal Control*, and NNSA directives.
- Maintains a QMS that ensures that management:
 - Creates and communicates to employees NNSA's organizational structure, strategic objectives, and cultural environment.
 - Establishes processes for setting goals and objectives that support and align with the organization's mission and customer needs.
 - Implements performance measures to track achievement of goals and objectives.
 - Provides trained and qualified personnel and supplies necessary resources.
 - Documents and implements policies, processes, and standards to identify and manage risks.
 - Promotes continual improvement, use of processes, and practice of risk-based thinking.

7.2. CUSTOMER FOCUS

(ISO 9001:2015 clause 5.1.2)

NNSA's main customers are the Secretary of Energy/DOE and Secretary of Defense/Department of Defense (DOD). NNSA management ensures customer needs and expectations are determined, converted into deliverable requirements, and fulfilled with the intention of meeting or exceeding expectations.

7.2.1. QUALITY POLICY

The NNSA Quality Policy is:

To ensure NNSA products and services meet or exceed customers' requirements and expectations, and to achieve quality work based upon the following principles:

- Products add value and are appropriate to the purpose of NNSA,
- Work is conducted through an integrated and effective management system;
- Management support for planning, organization, resources, direction, and control is essential to quality assurance;
- Performance and quality improvement require thorough, rigorous assessments and effective corrective actions;
- Personnel are responsible for achieving and maintaining quality; and
- Risks and adverse mission impacts associated with work processes are minimized while maximizing reliability and performance of work products.

7.2.2. NEEDS AND EXPECTATIONS OF CUSTOMERS

The needs of NNSA customers are defined by the programmatic and regulatory requirements for which NNSA provides advisory services, policy development and implementation, and oversight functions. Specific needs of NNSA customers are determined through verbal and written communications, as well as periodic visits to relevant sites, facilities, and offices to better understand individual processes and product or service requirements. Once requirements are identified and documented, work – at a subordinate level – is then executed to fulfill requirements. To continually improve, NNSA also monitors, measures, and analyzes customer satisfaction. Customer feedback, satisfaction, needs and expectations, issues, and their impact on the NNSA management system are reviewed periodically.

7.2.3. NEEDS AND EXPECTATIONS OF OTHER INTERESTED PARTIES

NNSA management ensures that the needs and expectations of its customers and other interested parties are determined and incorporated, as appropriate, into planning, processes, procedures, and product or service requirements. Needs and expectations may impact NNSA's ability to deliver on products and services and can often include legal and regulatory requirements. Other interested parties may include:

- Government organizations (e.g., White House; OMB; Members of Congress and various congressional committees; State, Local, and Tribal Governments; foreign governments),
- Regulatory or oversight organizations (e.g., Defense Nuclear Facilities Safety Board (DNFSB), Government Accountability Office (GAO), and Inspector General (IG)),
- Non-governmental organizations (e.g., corporations, watchdog groups, unions, and professional or industry associations), and
- NNSA employees.

7.3. PLANNING

7.3.1. QUALITY OBJECTIVES

(ISO 9001:2015 clauses 6.2.1 and 6.2.2 and NAP 26A requirement 6.c.)

NNSA management establishes quality objectives at relevant functions and levels within the organization. The objectives are derived from the NNSA Quality Policy consistent with the [*NNSA Enterprise Strategic Vision*](#). The quality objectives are documented and reviewed by NNSA management as part of the management review process. The quality objectives are measurable and consistent with the quality policy, and provide appropriate focus on continual improvement and customer satisfaction.

7.3.2. PROCESSES AND PROCEDURES

(ISO 9001:2015 clauses 6.1.1 and 6.1.2 and DOE O 414.1D Criterion 1)

Listed below (in Table 1) are core processes and procedures used by NNSA program and field offices to perform various functions, activities, and operations that align with NNSA missions and goals.

Table 1 – NNSA Processes and Procedures

TITLE	DESCRIPTION	REFERENCE
Corporate Performance Evaluation Process (CPEP)	Uniform and integrated process, which is facilitated via a Performance Evaluation Plan (PEP), for evaluating the performance of M&O contractors.	NAP 540.3 Corporate Performance Evaluation Process for M&O Contractors
Independent Cost Estimate (ICE)	Requires Independent Cost Estimates (ICEs) for projects and programs exceeding predetermined expected cost thresholds with participation from organizations external to the program office and – when appropriate – an Independent Cost Review (ICR) by the Office of Cost Estimating and Program Evaluation (CEPE).	NAP-28, Responsibilities for Independent Cost Estimates
Planning, Programming, Budgeting, and Evaluation (PPBE)	The NNSA PPBE process – similar to PPBE processes used by other federal government agencies – is a continuous cycle that consists of four major activities: • Planning, • Programming, • Budgeting, and • Evaluation.	NAP 130.1, Planning, Programming, Budgeting, and Evaluation (PPBE) Process
Program and Project Management	NNSA has established program and project management oversight processes to ensure the experience, diverse perspectives, and thoughtful programmatic and technical judgment at all levels are accessible, available, and applied to program and project activities.	BOP 413.7, Project Management for the Acquisition of Capital Assets

TITLE	DESCRIPTION	REFERENCE
Risk Management	Encourages continuous improvement in agency decision-making, operations, and performance by providing: • Increased likelihood of successfully delivering on goals and objectives, • Decreased unanticipated outcomes, • Improved ability to assess risks associated with changes, • Enhanced ability to communicate to customers and others regarding NNSA's risk management activities, and • Improved risk mitigation, particularly regarding impact of realized negative events.	<u>DOE G 413.3-7, Risk Management Guide</u>

7.4. RESPONSIBILITY, AUTHORITY, AND COMMUNICATION

7.4.1. RESPONSIBILITY AND AUTHORITY

(ISO 9001:2015 clause 5.3)

The basis for NNSA responsibilities and authorities is provided in the mission and function statements maintained by the Office of the Associate Administrator for Management and Budget (NA-MB). Functions, responsibilities, and authorities are flowed down for implementation through the NNSA management system and various NNSA NAPs, SDs, BOPs, or SOPs.

Note: For more details, refer to the mission and function statements as described in an NNSA policy.

7.4.2. COMMUNICATION

(ISO 9001:2015 clauses 5.2.2 and 7.4)

NNSA management ensures that communication is maintained throughout the organization regarding the processes of the NNSA management system and their effectiveness. NNSA has established the following in regards to its communication practices:

- What to communicate, including:
 - Progress regarding activities and products;
 - Audit/assessment results;
 - Organizational updates; and
 - Missions and initiatives (e.g., [*NNSA Strategic Vision*](#), memorandums, etc.).
- When to communicate, including:
 - Daily,
 - Bi-Weekly,
 - Monthly,
 - Quarterly, and
 - Yearly.
- Who communicates *and* with whom to communicate, including:
 - Administrators,
 - Managers,
 - Chief Operating Officers, and
 - Directors.
- How to communicate, including:
 - Reports (e.g., status reports, audit reports, meeting minutes, etc.);
 - Meetings (e.g., Management Council, NNSA Council, Operations Board., town hall, all hands, various working groups and committees, etc.); and

- Electronic distribution/media (e.g., NNSACASTs, [PowerPedia](#), NNSA Connects, [OneHR](#), [Enterprise Portal \(SharePoint\) online communication and collaboration sites](#), newsletters, procedures, and training).

8. RESOURCES

8.1. PROVISIONING OF RESOURCES

(ISO 9001:2015 clause 7.1.1 and DOE O 414.1D Criteria 1 and 7)

NNSA is responsible for providing sufficient resources, including trained and qualified personnel for performing management work and for verification activities. More specifically, resources are provided to implement, maintain, and improve the effective operations of NNSA management system processes, and to enhance customer satisfaction by meeting or exceeding requirements. Resources are assessed and reviewed on a periodic basis consistent with a management review process and management's strategic planning activities.

8.2. HUMAN RESOURCES

8.2.1. ASSIGNMENT OF PERSONNEL

(ISO 9001:2015 clause 7.1.2)

The following criteria are reviewed to determine if personnel are qualified and competent resources:

- Education,
- Training,
- Observed skills, and
- Experience.

Assignees to NNSA are expected to provide and support services based on the alignment of their:

- Knowledge,
- Skills,
- Ability to meet the needs and requirements of the task,
- Experience with the customer,
- Current workload, and

- Availability.

8.2.2. COMPETENCE, AWARENESS, AND LEARNING

(ISO 9001:2015 clause 7.1.2, 7.2, and 7.3 and DOE O 414.1D Criterion 2)

NNSA management provides for the training of personnel performing activities affecting quality of services. Training is provided either on- or off-the-job, internally, or externally, as appropriate.

NNSA offers a wide array of sponsored programs, products, and services to its federal workforce. The expanse of learning activities underscores NNSA's commitment to being a learning organization: actively promoting learning opportunities to enable performance of NNSA's dynamic missions. NNSA's learning program is fully funded to ensure that organizations can leverage resources and that centrally funded programs and courses are available to the workforce.

Note: For more details, visit the [OneLeadership "NNSA Sponsored Learning Activities" webpage](#).

A dynamic website and continuous communications promote awareness of upcoming and long-range opportunities so that employees and supervisors can consider, plan, and attend events to increase current job competence and long-range professional development.

Note: For more details, visit the [OneLearning Initiative \(OLI\) website](#) or [OneHR & OneLearning message repository](#).

Personnel are required to complete an Individual Development Plan (IDP), which is updated periodically and approved by their supervisor. The IDP is used to identify and plan for training and developmental activities that reflect career goals and performance plans of the employee. IDP approval rates are sent semi-monthly to organizational leaders to promote the importance of employee development. IDPs are aggregated to form the basis for an Annual Training Assessment (ATA), which tracks NNSA-wide learning and development needs for employees, groups, and organizations. By integrating it with IDPs, the ATA forms the basis for fiscal year (FY) allocations. NNSA also tracks training-related cancellations and denials to discern reasons for training not supported or attended.

NNSA emphasizes competencies as a means for talent development. For example, a foundational competency model applicable to the entire NNSA federal workforce will be deployed during FY2017. Functionally oriented technical competency models and attendant career paths are being developed, with initial implementation planned for FY2017.

Note: For details, refer to [NNSA SD 360.1, Federal Employee Training](#).

For select technical personnel, qualification processes are conducted in accordance with [DOE O 426.1 \(Change 1\), *Federal Technical Capability*](#). Each person assigned to an NNSA technical position identified by the Federal Technical Capability Program must meet at least one appropriate qualification. Staff personnel are expected to qualify within the prescribed qualification period. NNSA technical personnel are responsible for ensuring their technical qualifications remain current, including arranging for and meeting requalification requirements. Where a formal requalification requirement does not exist, maintenance of qualification is accomplished through successful participation in continuing education as assigned by supervisors and certified by a Qualifying Official, and verified by the NNSA Federal Technical Capability (FTC) Panel Agent.

Documented procedures are maintained to identify training requirements and ensure appropriate training of personnel performing NNSA work. Training and qualification records are created and maintained by the DOE's National Training Center using the e-TQP electronic records system.

9. OPERATIONS

(DOE O 414.1D Criteria 5 and 6)

9.1. PLANNING OF PRODUCT AND SERVICE REALIZATION

(ISO 9001:2015 clause 8.1 and DOE O 414.1D Criteria 5 and 6)

Planning is required before new services, products, or processes are implemented. During the planning phase, management or assigned personnel identify requirements for the following:

- Product or services;
- Affected processes, procedures, and resources;
- Monitoring, measurement, or review requirements;
- Product or service expectations or acceptance criteria;
- Deliverable requirements; and
- Schedule, as applicable.

9.2. DETERMINATION OF REQUIREMENTS RELATED TO PRODUCTS AND SERVICES

(ISO 9001:2015 clause 8.2.2 and DOE O 414.1D Criteria 5 and 6)

The product of NNSA is safe and secure execution of its mission objectives. The requirements of NNSA products and services are defined by the programmatic and regulatory requirements for which NNSA provides advisory services, policy development and implementation, and oversight functions. Requirements are incorporated into DOE and NNSA directives and customer-specific processes and procedures, which NNSA follows, as necessary, for the creation and delivery of products and services. Other requirements not detailed in directives, or unique to a given product/service or customer, are ascertained through communication with the customer and research or knowledge of industry standards or other relevant resources.

9.3. REVIEW OF REQUIREMENTS RELATED TO PRODUCTS AND SERVICES

(ISO 9001:2015 clause 8.2.3 and DOE O 414.1D Criteria 5 and 6)

Relevant requirements are identified and discussed with customers, as appropriate. Work is performed when NNSA and the customer organization have reached agreement in principle.

9.4. CUSTOMER COMMUNICATION

(ISO 9001:2015 clause 8.2.1 and DOE O 414.1D Criteria 5 and 6)

NNSA appoints various staff members to serve as leads or points of contact (POCs) for functional areas or NNSA customer organizations. POCs are responsible for interfacing with key POCs from customer organizations to establish and maintain awareness of needs and opportunities for providing assistance or improving support. The NNSA leads and POCs serve as the primary focal point for communication between NNSA and the customer's staff. NNSA staff providing support to a customer interface with the customer regarding an assigned task or project to ensure customer needs, requirements, and expectations are met.

9.5. CONTROL OF PRODUCTION AND SERVICE PROVISIONING

(ISO 9001:2015 clause 8.5.1 and DOE O 414.1D Criteria 5 and 6)

NNSA develops and implements SOPs for use in the creation and delivery of products and services. SOPs are the responsibility of individual NNSA offices and are controlled and maintained using best practices consistent with those processes stated in Section 6.2.3. The need for SOPs increases with regulatory requirements driving the product or service – or the associated level of prescription. Therefore, SOPs are associated with processes and products or services under NNSA policy development and implementation or oversight roles.

The following do not apply to the control of NNSA production and service provisioning:

- **Validation of Processes for Production and Service Provision** – NNSA products/services can be verified, monitored, and measured subsequent to realization.
- **Identification and Traceability** – NNSA products or services are discrete, unique products, and it would not be appropriate nor add value by applying identification and traceability. Process controls are in place to ensure products remain discrete and unique.
- **Customer Property** – No customer property is maintained by NNSA in the course of its business operations.
- **Preservation of Product** – NNSA products and services are not subject to deterioration or loss of conformity.
- **Control of Monitoring and Measuring Equipment** – No monitoring or measuring devices are used in product and service realization.

10. MONITORING, MEASUREMENT, ANALYSIS, AND EVALUATION

(ISO 9001:2015 clause 9.1.1 and DOE O 414.1D Criteria 8 and 10)

NNSA defines, plans, and implements appropriate methods to monitor, measure, analyze, and improve its processes to ensure product or service conformance and to continually improve the overall effectiveness of the NNSA management system.

10.1. MONITORING AND MEASUREMENT

(DOE O 414.1D Criteria 3, 8, and 10)

10.1.1. CUSTOMER SATISFACTION

(ISO 9001:2015 clause 9.1.2)

Specific needs of NNSA customers are determined through verbal and written communications, as well as periodic visits to relevant sites, facilities, and offices to better understand individual processes, thus ensuring the accuracy and quality of products and services and overall satisfaction of the customer. NNSA monitors, measures, and analyzes customer satisfaction through various means.

10.12 INTERNAL AUDIT

(ISO 9001:2015 clauses 9.2.1 and 9.2.2 and DOE O 414.1D Criteria 3, 8, and 10)

NNSA conducts periodic internal audits or schedules equivalent audits by other NNSA offices or external contractors. The purpose of the internal audit is to determine whether the NNSA management system is being effectively implemented and maintained.

Internal audits are planned and scheduled based on the status and importance of the activity to be audited. Audits are performed by trained personnel who are independent of the activity being audited. Because NNSA auditor resources may not always be available, the internal audit function may be performed by other qualified parties to assure independence.

The results of the internal audits are documented in a report, which is provided to management for action. Management personnel responsible for the audited activity are responsible for defining and implementing corrective action.

Follow-up activities verify and record the implementation of the corrective action, report the verification results, and close out the audit. Subsequent audits verify the effectiveness of the corrective actions taken. Results of internal audits and the corrective action are submitted for management review. NNSA implements its internal audit program in accordance with Quality Management's (NA-MB-1.2) Management System Assessment Guide.

10.13 MONITORING AND MEASUREMENT PROCESSES

(ISO 9001:2015 clause 8.5.1 and DOE O 414.1D Criteria 3, 8, and 10)

NNSA applies methods for monitoring and, whenever applicable, measurement of management system processes (see Appendix 2). Methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken to ensure conformity of the product or service.

10.14 MONITORING AND MEASUREMENT OF PRODUCTS/SERVICES

(ISO 9001:2015 clause 8.5.1 and DOE O 414.1D Criteria 3, 8, and 10)

The primary deliverables for NNSA are documents (e.g., technical evaluations, reports, memoranda, etc.). At HQ and AC, personnel work with internal and external customers to understand the requirements for each deliverable and task to satisfy needs. Deliverables undergo an iterative concurrence process that typically includes subject matter experts (SMEs), supervisors, customers, or other affected parties, as appropriate, to ensure requirements are met. Comments are resolved and incorporated into deliverables, which are finalized and issued.

102. CONTROL OF NON-CONFORMING PRODUCTS/SERVICES

(ISO 9001:2015 clauses 10.2.1 and 10.2.2 and DOE O 414.1D Criteria 3, 8, and 10)

NNSA minimizes the potential for nonconforming products by interfacing with customers to determine and understand requirements, needs, and expectations prior to work initiation. NNSA ensures products and services that do not meet requirements are identified, controlled whenever possible to prevent unintended use or delivery to the customer, and corrected.

103. DATA ANALYSIS

(DOE O 414.1D Criteria 3, 8, and 10)

NNSA collects and analyzes appropriate data to determine the suitability and effectiveness of the NNSA management system and to identify improvements. Data is derived from multiple sources including process metrics, internal audits, external audits, customer surveys, employee feedback, etc. Data are periodically analyzed during NNSA management staff meetings or management review meetings to provide information on customer satisfaction, conformance to requirements, performance of processes, quality of products and services, and trends, and to derive and implement corrective action.

104. EVALUATION AND CONTINUAL IMPROVEMENT

(ISO 9001:2015 clause 10.3 and DOE O 414.1D Criteria 3, 8, and 10)

NNSA management conducts evaluations and facilitates continual improvement, which is achieved through the use and execution of the quality policy, objectives, audit results, analysis of data, corrective and preventive action, and management reviews.

105. CORRECTIVE ACTION

(ISO 9001:2015 clauses 10.2.1 and 10.2.2 and DOE O 414.1D Criteria 3, 8, and 10)

The need for corrective action can be identified via the following:

- Internal or external audit;
- Customer or employee identification of unacceptable products, services, procedures, or process results; or
- Receipt or acceptance inspection of vendor-provided products or services against procurement specifications.

NNSA management takes action to correct or mitigate an identified issue and restore a product, service, procedure, or process to an acceptable level of compliance. Corrective actions are commensurate with the magnitude of the issue. Corrective action includes:

- Review of issues (including customer complaints);
- Identification of root cause;
- Evaluation of the need for corrective action;
- Determination and implementation of corrective action, if required;
- Tracking, verifying, and closeout of corrective action taken; and
- Follow-up effectiveness reviews.

Note: For more details, refer to [DOE O 226.1](#) and [DOE O 232.2, *Occurrence Reporting and Processing of Operations Information*](#).

APPENDIX 5. ACRONYMS

ACRONYM	DEFINITION
AC	Albuquerque Complex
BOP	Business Operating Procedure
CEPE	Cost Estimating and Program Evaluation
DNFSB	Defense Nuclear Facilities Security Board
DOD	Department of Defense
DOE	Department of Energy
FOM	Field Office Manager
FRA	Functions, Responsibilities, and Authorities
GAO	Government Accountability Office
GOCO	Government-Owned/Contractor-Operated
HQ	Headquarters
ICE	Independent Cost Estimate
ICR	Independent Cost Review
IDP	Individual Development Plan
IG	Inspector General
IPM	Interim Policy Memoranda
ISO	International Organization of Standardization
ISO-SC	ISO 9001 Quality Management System Steering Committee
M&O	Management and Operating
MSB	Management System Board

ACRONYM	DEFINITION
MSD	Management System Description
NA-MB	Office of the Associate Administrator for Management and Budget
NAP	NNSA Policy
NNSA	National Nuclear Security Administration
OFI	Opportunity for Improvement
OMB	Office of Management and Budget
PEP	Performance Evaluation Plan
POC	Point of Contact
PPBE	Planning, Programming, Budgeting, and Evaluation
SD	Supplemental Directive
SME	Subject Matter Expert
SOP	Standard Operating Procedure

APPENDIX 6. REFERENCES

ID	TITLE
ASME NQA-1-2008 (with the NQA-1a-2009 addenda)	Quality Assurance Requirements for Nuclear Facility Applications
ANSI/ASQ Z1.13-1999	Quality Guidelines for Research
BOP 100.1	Senior Leadership Councils
BOP 413.7	Project Management for the Acquisition of Capital Assets
DOE G 413.3-7A	Risk Management Guide
DOE O 226.1A	Implementation of Department of Energy Oversight Policy
DOE O 226.1B	Implementation of Department of Energy Oversight Policy
DOE O 232.2 (Admin Change 1)	Occurrence Reporting and Processing of Operations Information
DOE O 414.1D	Quality Assurance
DOE O 426.1 (Change 1)	Federal Technical Capability
ISO 31000:2009(en)	Risk Management — Principles and Guidelines
ISO 9001:2008	Quality Management Systems – Requirements
ISO 9001:2015	Quality Management Systems – Requirements
N/A	NNSA Office of Quality Management, Management System Assessment Guide
N/A	U.S. Department of Energy National Nuclear Security Administration <i>Enterprise Strategic Vision</i> , August 2015

ID	TITLE
NAP-28	Responsibilities for Independent Cost Estimates
NAP 540.3	Corporate Performance Evaluation Process for M&O Contractors
NNSA SD 226.1B	NNSA Site Governance
NNSA SD 243.1	Records Management Program
NNSA SD 251.1 (Admin Change 1)	Policy Letters: NNSA Policies, Supplemental Directives, and Business Operating Procedures
NNSA SD 360.1	Federal Employee Training
NNSA SD 450.2	Functions, Responsibilities, and Authorities (FRA) Document for Safety Management

APPENDIX 7. DOCUMENT REPOSITORIES

TYPE	REPOSITORY
BOP	https://nnsaportal.energy.gov/intranet/NA-MB/Active%20Policies/Forms/Active%20by%20Type.aspx
DOE Guide/ Order	https://www.directives.doe.gov/ <i>Note: After accessing the site above, click "Directives."</i>
NAP	http://www.nnsa.energy.gov/aboutus/ouoperations/managementandbudget/policysystem/nnsapolicies
SD	http://www.nnsa.energy.gov/aboutus/ouoperations/managementandbudget/supplementaldirectives

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APPENDIX 8. DOE O 414.1-MSD TRACEABILITY MATRIX

NOTE: The applicable requirements from [DOE O 414.1](#) are identified in this appendix to demonstrate a crosswalk between [DOE O 414.1](#) and the MSD. It contains no additional requirements.

DOE O 414.1 (ATTACHMENT 2)	MSD
Criterion 1 — Management/Program. a. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. b. Establish management processes, including planning, scheduling, and providing resources for the work.	Appendix 4, paragraph 4, Organization
	Appendix 4, paragraph 7.3.2, Processes and Procedures
	Appendix 4, paragraph 8.1, Provisioning of Resources
Criterion 2 — Management/Personnel Training and Qualification. a. Train and qualify personnel to be capable of performing their assigned work. b. Provide continuing training to personnel to maintain their job proficiency.	Appendix 4, paragraph 8.2.2, Competence, Awareness, and Learning

DOE O 414.1 (ATTACHMENT 2)	MSD
Criterion 3 — Management/Quality Improvement. a. Establish and implement processes to detect and prevent quality problems. b. Identify, control, and correct items, services, and processes that do not meet established requirements. c. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. d. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.	Appendix 4, paragraph 10.1, Monitoring and Measurement
	Appendix 4, paragraph 10.1.2, Internal Audit
	Appendix 4, paragraph 10.1.3, Monitoring and Measurement Processes
	Appendix 4, paragraph 10.1.4, Monitoring and Measurement of Products/Services
	Appendix 4, paragraph 10.2, Control of Non-Conforming Products/Services
	Appendix 4, paragraph 10.3, Data Analysis
	Appendix 4, paragraph 10.4, Evaluation and Continual Improvement
	Appendix 4, paragraph 10.5, Corrective Action
Criterion 4 — Management/Documents and Records. a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. b. Specify, prepare, review, approve, and maintain records.	Appendix 4, paragraph 6.2, Documentation Requirements

DOE O 414.1 (ATTACHMENT 2)	MSD
Criterion 5 — Performance/Work Processes. 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. b. Identify and control items to ensure proper use. c. Maintain items to prevent damage, loss, or deterioration. d. Calibrate and maintain equipment used for process monitoring or data collection.	Appendix 4, paragraph 9, Operations
	Appendix 4, paragraph 9.1, Planning of Product and Service Realization
	Appendix 4, paragraph 9.2, Determination of Requirements Related to Products and Services
	Appendix 4, paragraph 9.3, Review of Requirements Related to Products and Services
	Appendix 4, paragraph 9.4, Customer Communication
	Appendix 4, paragraph 9.5, Control of Production and Service Provisioning

DOE O 414.1 (ATTACHMENT 2)	MSD
Criterion 6 — Performance/Design. a. Design items and processes using sound engineering/scientific principles and appropriate standards. b. Incorporate applicable requirements and design bases in design work and design changes. c. Identify and control design interfaces. d. Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. e. Verify or validate work before approval and implementation of the design.	Appendix 4, paragraph 9, Operations
	Appendix 4, paragraph 9.1, Planning of Product and Service Realization
	Appendix 4, paragraph 9.2, Determination of Requirements Related to Products and Services
	Appendix 4, paragraph 9.3, Review of Requirements Related to Products and Services
	Appendix 4, paragraph 9.4, Customer Communication
	Appendix 4, paragraph 9.5, Control of Production and Service Provisioning
Criterion 7 — Performance/Procurement. a. Procure items and services that meet established requirements and perform as specified. b. Evaluate and select prospective suppliers on the basis of specified criteria. c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	Appendix 4, paragraph 8.1, Provisioning of Resources

DOE O 414.1 (ATTACHMENT 2)	MSD
Criterion 8 — Performance/Inspection and Acceptance Testing. a. Inspect and test specified items, services, and processes using established acceptance and performance criteria. b. Calibrate and maintain equipment used for inspections and tests.	Appendix 4, paragraph 10, Monitoring, Measurement, Analysis, and Evaluation
	Appendix 4, paragraph 10.1, Monitoring and Measurement
	Appendix 4, paragraph 10.1.2, Internal Audit
	Appendix 4, paragraph 10.1.3, Monitoring and Measurement Processes
	Appendix 4, paragraph 10.1.4, Monitoring and Measurement of Products/Services
	Appendix 4, paragraph 10.2, Control of Non-Conforming Products/Services
	Appendix 4, paragraph 10.3, Data Analysis
	Appendix 4, paragraph 10.4, Evaluation and Continual Improvement
	Appendix 4, paragraph 10.5, Corrective Action
Criterion 9 — Assessment/Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	Appendix 4, paragraph 5, Integrated Management System

DOE O 414.1 (ATTACHMENT 2)	MSD
Criterion 10 — Assessment/Independent Assessment. a. Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. b. Establish sufficient authority and freedom from line management for independent assessment teams. c. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	Appendix 4, paragraph 10, Monitoring, Measurement, Analysis, and Evaluation
	Appendix 4, paragraph 10.1, Monitoring and Measurement
	Appendix 4, paragraph 10.1.2, Internal Audit
	Appendix 4, paragraph 10.1.3, Monitoring and Measurement Processes
	Appendix 4, paragraph 10.1.4, Monitoring and Measurement of Products/Services
	Appendix 4, paragraph 10.2, Control of Non-Conforming Products/Services
	Appendix 4, paragraph 10.3, Data Analysis
	Appendix 4, paragraph 10.4, Evaluation and Continual Improvement
	Appendix 4, paragraph 10.5, Corrective Action

APPENDIX 9. MSD-ISO 9001:2015 TRACEABILITY MATRIX

NOTE: The select/applicable principles from ISO 9001:2015 are identified in this appendix to demonstrate a crosswalk between ISO 9001:2015 and the MSD. It contains no additional requirements/principles.

MSD	ISO 9001:2015
Appendix 4, paragraph 5, Integrated Management System	9.3.1 General (Subparagraph of <i>Management review</i>)
Appendix 4, paragraph 6.1, General Requirements	4.4.1 (Subparagraph of <i>Quality management system and its processes</i>)
Appendix 4, paragraph 6.2, Documentation Requirements	4.4.2 To the extent necessary, the organization shall: (Subparagraph of <i>Quality management system and its processes</i>)
	7.5.1 General (Subparagraph of <i>Documented information</i>)
	7.5.2 Creating and updating (Subparagraph of <i>Documented information</i>)
Appendix 4, paragraph 6.2.3, Control of Documents	7.5.3.1 (Subparagraph of <i>Control of documented information</i>)
	7.5.3.2 (Subparagraph of <i>Control of documented information</i>)
	8.1 Operational planning and control
Appendix 4, paragraph 7.1, Leadership and Commitment	5.1.1 General (Subparagraph of <i>Leadership and commitment</i>)

MSD	ISO 9001:2015
Appendix 4, paragraph 7.2, Customer Focus	5.1.2 Customer Focus
Appendix 4, paragraph 7.2.1, Quality Policy	5.2.1 Establishing the quality policy
Appendix 4, paragraph 7.3.1, Quality Objectives	6.2.1 (Subparagraph of <i>Quality objectives and planning to achieve them</i>)
	6.2.2 (Subparagraph of <i>Quality objectives and planning to achieve them</i>)
Appendix 4, paragraph 7.3.2, Processes and Procedures	6.1.1 (Subparagraph of Actions to address risks and opportunities)
	6.1.2 The organization shall plan: (Subparagraph of <i>Actions to address risks and opportunities</i>)
Appendix 4, paragraph 7.4.1, Responsibility and Authority	5.3 Organizational roles, responsibilities, and authorities
Appendix 4, paragraph 7.4.2, Communication	7.4 Communication
	5.2.2 Communicating the quality policy
Appendix 4, paragraph 8.1, Provisioning of Resources	7.1.1 General (Subparagraph of <i>Resources</i>)
Appendix 4, paragraph 8.2.1, Assignment of Personnel	7.1.2 People

MSD	ISO 9001:2015
Appendix 4, paragraph 8.2.2, Competence, Awareness, and Learning	7.1.2 People
	7.2 Competence
	7.3 Awareness
Appendix 4, paragraph 9.1, Planning of Product and Service Realization	8.1 Operational planning and control
Appendix 4, paragraph 9.2, Determination of Requirements Related to Products and Services	8.2.2 Determining the requirements for products and services
Appendix 4, paragraph 9.3, Review of Requirements Related to Products and Services	8.2.3 Review of requirements for products and services
Appendix 4, paragraph 9.4, Customer Communication	8.2.1 Customer communication
Appendix 4, paragraph 9.5, Control of Production and Service Provisioning	8.5.1 Control of production and service provision
Appendix 4, paragraph 10, Monitoring, Measurement, Analysis, and Evaluation	9.1.1 General (Subparagraph of <i>Monitoring, measurement, analysis and evaluation</i>)
Appendix 4, paragraph 10.1.1, Customer Satisfaction	9.1.2 Customer satisfaction
Appendix 4, paragraph 10.1.2, Internal Audit	9.2.1 (Subparagraph of <i>Internal audit</i>)
	9.2.2 (Subparagraph of <i>Internal audit</i>)
Appendix 4, paragraph 10.1.3, Monitoring and Measurement Processes	8.5.1 Control of production and service provision

MSD	ISO 9001:2015
Appendix 4, paragraph 10.1.4, Monitoring and Measurement of Products/Services	8.5.1 Control of production and service provision
Appendix 4, paragraph 10.2, Control of Non-Conforming Products/Services	10.2.1 (Subparagraph of <i>Nonconformity and correction action</i>)
	10.2.2 (Subparagraph of <i>Nonconformity and correction action</i>)
Appendix 4, paragraph 10.4, Evaluation and Continual Improvement	10.3 Continual improvement
Appendix 4, paragraph 10.5, Corrective Action	10.2.1 (Subparagraph of <i>Nonconformity and correction action</i>)
	10.2.2 (Subparagraph of <i>Nonconformity and correction action</i>)

APPENDIX 10. ISO 9001:2015-ISO 9001:2008 TRACEABILITY MATRIX

NOTE: *The following matrix was developed and distributed by ISO.*

ISO 9001:2015	ISO 9001:2008
1. Scope	1 Scope 1.1 General
4. Context of the organization	4 Quality management system
4.1 Understanding the organization and its context	4 Quality management system 5.6 Management review
4.2 Understanding the needs and expectations of interested parties	4 Quality management system 5.6 Management review
4.3 Determining the scope of the quality management system	1.2 Application 4.2.2 Quality manual
4.4 Quality management system and its processes	4 Quality management system 4.1 General requirements
5 Leadership	5 Management responsibility
5.1 Leadership and commitment	5.1 Management commitment
5.1.1 General	5.1 Management commitment
5.1.2 Customer focus	5.2 Customer focus
5.2 Policy	5.3 Quality policy
5.2.1 Establishing the Quality Policy	5.3 Quality policy
5.2.2 Communicating the Quality Policy	5.3 Quality policy
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and authority 5.5.2 Management representative 5.4.2 Quality management system planning

ISO 9001:2015	ISO 9001:2008
6 Planning	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 8.5.3 Preventive action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2 Quality management system planning
7 Support	6 Resource management
7.1 Resources	6 Resource management
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.1 Provision of resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4 Work environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.5.1 General	7.6 Control of monitoring and measuring equipment
7.1.5.2 Measurement traceability	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	No equivalent clause
7.2 Competence	6.2.1 General 6.2.2 Competence, training and awareness
7.3 Awareness	6.2.2 Competence, training and awareness
7.4 Communication	5.5.3 Internal communication

ISO 9001:2015	ISO 9001:2008
7.5 Documented information	4.2 Documentation requirements
7.5.1 General	4.2.1 General
7.5.2 Creating and updating	4.2.3 Control of documents 4.2.4 Control of records
7.5.3 Control of documented Information	4.2.3 Control of documents 4.2.4 Control of records
8 Operation	7 Product realization
8.1 Operational planning and control	7.1 Planning of product realization
8.2 Requirements for products and services	7.2 Customer-related processes
8.2.1 Customer communication	7.2.3 Customer communication
8.2.2 Determination of requirements for products and services	7.2.1 Determination of requirements related to the product
8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to the product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to the product
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	7.3.1 Design and development planning
8.3.2 Design and development planning	7.3.1 Design and development planning
8.3.3 Design and development inputs	7.3.2 Design and development inputs
8.3.4 Design and development controls	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation

ISO 9001:2015	ISO 9001:2008
8.3.5 Design and development outputs	7.3.3 Design and development outputs
8.3.6 Design and development changes	7.3.7 Control of design and development changes
8.4 Control of externally provided processes, products and services	7.4.1 Purchasing process
8.4.1 General	4.1 General requirements 7.4.1 Purchasing process
8.4.2 Type and extent of control	7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information 7.4.3 Verification of purchased product
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision
8.5.2 Identification and traceability	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
8.5.4 Preservation	7.5.5 Preservation of product
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision
8.5.6 Control of changes	7.3.7 Control of Design and Development Changes
8.6 Release of products and services	7.4.3 Verification of purchased product 8.2.4 Monitoring and measurement of product
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product

ISO 9001:2015	ISO 9001:2008
9 Performance evaluation	8 Measurement, analysis and improvement
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement
9.1.1 General	8.1 General 8.2.3 Monitoring and Measurement Processes
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal audit	8.2.2 Internal audit
9.3 Management review	5.6 Management review
9.3.1 General	5.6.1 General
9.3.2 Management review input	5.6.2 Review input
9.3.3 Management review output	5.6.3 Review output
10 Improvement	8.5 Improvement
10.1 General	8.5.1 Continual improvement
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual Improvement	8.5.1 Continual improvement 8.5.3 Preventive action