

**NNSA POLICY LETTER**

**NAP-26A**

Approved: 6-1-16

# **QUALITY MANAGEMENT SYSTEM**

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## **NATIONAL NUCLEAR SECURITY ADMINISTRATION Office of Management and Budget**

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**OFFICE OF PRIMARY INTEREST (OPI):  
Office of Quality Management**

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## QUALITY MANAGEMENT SYSTEM

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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 version of these documents currently in force.

2. CANCELLATION. NAP-26, *Quality Management System*, dated 12-11-13.

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 USC 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. Assigned the NNSA Quality Management System Executive Management Representative responsibilities of the Associate Principal Deputy Administrator to the Director, Office of Quality Management (OQM).

- b. Relocated the Office of Quality Management from the former Office of Infrastructure and Operations (NA-00) to the Office of Management and Budget (NA-MB).

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 the 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 is 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 414.1, Paragraph 4.a.(2);

“(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,
- 3 ANSI/ASQ Z 1.13-1999, *Quality Guidelines for Research*.

## 6. REQUIREMENTS

- a. The QMS will be codified in a management system description (MSD) document and will serve 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 ISO 9001 requirements for quality management systems. (Appendix 2)
- c. The QMS will be in compliance with the current version of the NNSA Enterprise Strategic Vision, August 2015.
- d. The MSD and associated work processes must be documented and available to all employees.
- e. Work processes, such as process descriptions, 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 improvement to processes, products, and services. (Appendix 2)
- g. Subject area specific quality systems, developed wholly or in part to comply with DOE O 414.1, *Quality Assurance*, and/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 and 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) Establishes QMS policy.
  - 2) Communicates management's commitment to the QMS.
  - 3) Ensures availability of sufficient resources to support the implementation and ongoing management of the QMS.
  - 4) Conducts 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) Establishes a process for implementing the NNSA QMS in their respective offices and functions that align with the NNSA QMS as established in the MSD.
  - 2) Establishes organizational quality objectives.
  - 3) Develops, approves, and updates office procedures and work processes in accordance with the NNSA QMS requirements stated in the MSD.
  - 4) Evaluates the implementation, efficiency, and effectiveness of the NNSA QMS for their respective offices and functions, using appropriate data analysis techniques.
  - 5) Appoints a representative to serve on the NNSA Management System Board (MSB). (See Appendix 3.)
  
- c. Office of Quality Management (OQM):
  - 1) The OQM Director serves as the QMS Executive Management Representative.
  - 2) The OQM 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 a Management System Assessment (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 a Management System Assessment 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 which 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 the Office of 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.

- a. 15 U.S.C. 272 note, Section 12(d) of Public Law 104-113, Utilization of Consensus Technical Standards by Federal Agencies.
- b. DOE Order 414.1D, *Quality Assurance*, Section 4, April 25, 2011.
- c. ANSI/ISO/ASQ Q9001:2015, *Quality Management Systems – Requirements*, September 15, 2015.

9. CONTACT. Office of Quality Management, (202) 586-6187.

BY ORDER OF THE ADMINISTRATOR:

  
Frank G. Klotz  
Administrator

Appendixes

1. ISO Best Practices
2. Internal Audits
3. Management System Board Charter

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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 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. Creating and documenting procedures, together with workflow training, establishes 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. Internal audits by an external team of reviewers are an additional way to determine if an organization is following established process.

**Act:** Pursue continuous improvement. Improvement occurs first during the development of work processes and work flow mapping, when efficiencies are recognized and working relationships clarified. Later on, 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 the Office of Quality Management (OQM). The assessments are conducted to fulfill OQM's responsibilities and requirements under DOE Order 414.1D, *Quality Assurance*, NAP 26A, *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, and the NNSA 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 subject to periodic management review. The MSA objective is to strengthen accountability by ensuring that procedures are established, 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. The plan will be approved by the NNSA Management Council. MSAs will be conducted to provide maximum benefit to the NNSA.

### Management Systems Assessment Procedures

Every Management System Assessment is unique and the order that steps are performed may vary or overlap. However, the MSA will typically include 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 also will be considered. Employees may be interviewed and MSA questionnaires may be distributed. At length, planning culminates with an MSA scope plan and schedule, which is developed in coordination with the subject organization's staff. Every reasonable attempt will be made by the OQM 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 again will be reviewed 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, OQM 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 our office. Appropriate managers (designated by the organization being assessed) are 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 OQM recommendations that 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 to go over the draft report. If management discovers any factual errors or believes that OQM has misinterpreted anything, staff should inform OQM during the exit conference so that OQM may make corrections before the report is seen by anyone else. On occasion, there may be items that OQM does not feel are appropriate to include in the written report but should be brought to the attention of management. OQM will discuss any such items during the exit conference and/or include a specific issues summary in a separate management letter.

### **APPENDIX 3: Management System Board Charter**

1. Purpose

- a. To comply with DOE O 414.1D, *Quality Management Systems*, 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 compliance with the ISO 9001-2008 International Standard for Quality Management Systems.
- b. The Management System Board (MSB) is a successor organization to the ISO 9001 Quality Management System (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 or developing implementing procedures. The Steering Committee Charter is dissolved upon the approval of the MSB Charter.
- c. The MSB Charter establishes the NNSA Management System Board and defines its authorities, applicability/scope, functions, membership, meetings, duration, and any applicable records to be retained.

2. Applicability/Scope

This charter applies to NNSA Headquarters' Program Offices and NNSA Field Offices as it relates to management system policy implementation.

3. Authority

DOE O 414.1D, *Quality Management Systems*; NAP-26, *Quality Management System*; and BOP-00.01, *NNSA Management Council*.

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 and/or mitigation activities concerning management systems throughout NNSA.
- b. The MSB advises the Office of Management Systems 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 to their respective offices.

6. Membership

- a. The Board is chaired by the Director, Office of Management Systems.
- b. Each Headquarters' Program Office and Field Office and will appoint a member to the MSB.

7. Meetings

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

8. Duration

This charter shall continue indefinitely or 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 including 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.

10. Records

The Office of Management Systems shall maintain this charter and all other records associated with the MSB.

11. Office of Primary Interest: Office of Management Systems.