



Department of Energy
National Nuclear Security Administration
Washington, DC 20585



December 6, 2005

The Honorable A. J. Eggenberger
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW, Suite 700
Washington, D.C. 20004-2901

Dear Mr. Chairman:

I am forwarding to you the enclosed Office of Defense Programs Quality Assurance Program (QAP) that demonstrates satisfactory completion of Commitment 10A in the Department's 2004-1 Implementation Plan. Also enclosed is the Office of Defense Programs QAP Implementation Plan that provides the path forward and scheduling information on achieving full implementation. We will provide the path forward and schedule for revision and implementation of the National Nuclear Security Administration Site Office QAPs by January 31, 2006.

If you have any questions, please contact Rabi Singh at (301) 903-5864.

Sincerely,

Thomas P. D'Agostino
Acting Deputy Administrator
for Defense Programs

Enclosures

cc w/enclosures:
M. Whitaker, DR-1





National Nuclear Security Administration
Office of Defense Programs

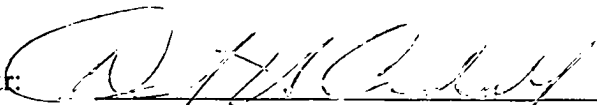
Quality Assurance
Program

(Rev. 0)

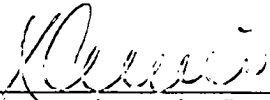
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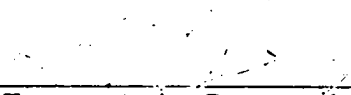
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Date: 10/24/05

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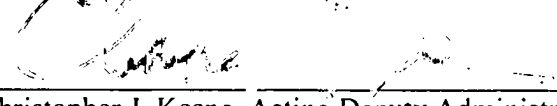
Date: 10/14/05

Concur: 
Antonio F. Tavares, Acting Deputy Administrator for
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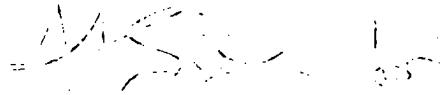
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Concur: 
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Date: 9-14-05

NA-10 QAP Change Log			
Revision No.	Date	Change Description	Pages Modified
Rev.0	11/05	Initial publication of NA-10 QAP.	All

Foreword

It is the policy of NA-10 to provide reliable products and services in a safe, secure, and cost effective manner. NA-10 is committed to meeting and exceeding customer' requirements and expectations by focusing on problem prevention, reducing variability, and providing continuous improvement in products, facilities and services. This policy affirms NA-10 management's commitment to quality using an integrated management system to establish and implement a quality program across all levels of NA-10 work planning and execution. The NA-10 Quality Assurance Program (QAP) identifies and communicates quality requirements and defines management expectations for the achievement of excellence and the prevention of inferior products and services. Senior management is committed to establishing and reviewing quality objectives at relevant functions and levels within the organization.

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1. Introduction

The mission of the National Nuclear Security Administration (NNSA) Office of Defense Programs (NA-10) is to achieve national security objectives established by the President for nuclear weapons. These objectives ensure that nuclear weapons continue to serve their essential deterrence role by maintaining and enhancing the safety, security, and reliability of the nuclear weapons stockpile.

NA-10's customers include the NNSA Administrator and the Department of Defense (DoD). Stakeholders include the Site Offices, M&O Contractors, Congress, specific elements of the executive branch such as OMB, IG and the DNFSB, and the public.

The core functions of NA-10 are:

- Stockpile Stewardship Program Management
- Secure Transportation of nuclear weapons and special nuclear material (SNM)
- Customer and stakeholder issues management necessary to meet customer requirements

NA-10 is composed of the following offices

- NA-11, Office of Research, Development and Simulation
- NA-12, Office of Military Application and Stockpile Operations
- NA-13, Office of Program Integration
- NA-15, Office of Secure Transportation
- NA-16, Office of Inertial Fusion and the National Ignition Facility

These organizations are described further in Section 5, Roles and Responsibilities, and in Appendix A, Organizational Structure.

The QAP defines the quality management system and its application for NA-10 federal employees that are common to all Program activities. Appendices provide additional information for application of the NA-10 QAP.

2. Purpose

The purpose of the NA-10 QAP is to describe the framework established to meet the quality assurance requirements of:

- 10 CFR 830, *Nuclear Safety Management*,
- DOE O 414.1C, *Quality Assurance*, and
- DOE/NNSA, *Weapon Quality Policy (QC-1)*.

Consensus standards, including ISO 9001:2000 *Quality Management Systems – Requirements*, were used to develop the NA-10 QAP. The NA-10 QAP describes how quality requirements are addressed in Section 7, Quality Assurance Criteria. The NA-10 QAP is designed to be consistent with the NNSA Functions, Responsibilities, and Authorities Manual (FRAM) and to provide for both the achievement and verification of quality within Defense Programs.

The purpose of the NA-10 QAP Implementation Plan (QAPIP) is to define the commitments and schedule to fully comply with the quality assurance (QA) requirements adopted by NA-10. The NA-10 QAP integrates these commitments within the description of how requirements are addressed in Section 7, Quality Assurance Criteria.

NA-10 has established the following quality objectives to guide the NA-10 QAP:

1. Quality is assured and maintained through clearly identified standards and requirements in a single, integrated, and effective quality assurance program (i.e. management system).
2. Management provides support and balances priorities in planning, organization, resources, direction and control.
3. Performance and quality improvement is achieved through problem prevention, assessment and corrective action, and management review.
4. All employees, including management, are responsible for achieving and maintaining quality with clear roles and responsibilities for quality.
5. Programmatic, environmental, safety, health and other risks and impacts that could affect the achievement of national security or quality objectives are minimized through work processes while reliability of work performance and products are maximized.

The NA-10 quality objectives are fully consistent with and supportive of Department of Energy (DOE) QA principles and Integrated Safety Management (ISM) functions and principles. This NA-10 QAP description details the methodologies employed to achieve excellence while conducting work processes safely, securely and in accordance with established procedures. It also describes the mechanism in place to seek continuous improvements by identifying and correcting deficiencies and preventing their recurrence.

3. Scope

This NA-10 QAP is limited to those functions and activities performed by NA-10 federal employees that are (1) of sufficient risk and (2) needed to meet national security objectives and/or quality objectives. The NA-10 functions and activities subject to the QAP include but not limited to:

- Management of the Stockpile Stewardship Program in:
 - The manufacturing, maintenance, refurbishment, surveillance, and dismantlement and disposal of the nuclear weapons stockpile;
 - Nuclear weapon related research, design, development, simulation, and modeling;
 - Non-nuclear testing of nuclear weapons;
 - Assessment and certification of stockpile safety and reliability; and
 - Review and evaluation of ongoing programs within the weapons laboratories and weapons production plants that are being carried out in support of Stockpile Stewardship.
- Manage and coordinate the Transportation Safeguards System (TSS), including the 24-Hour Transportation Emergency Control Center,
- Perform the safe and secure movement of nuclear weapons and all government-owned special nuclear material,

- Assure the appropriate integration of Nuclear Weapons Complex activities to enhance its efficiency and effectiveness in fulfilling its Stockpile Stewardship mission (DOE O 452.3, Management of the Department of Energy Nuclear Weapons Complex).
- Assure the materials (products), capabilities, and technologies to support the production of certified components necessary to meet requirements are provided by NNSA in an environmentally sound and cost-effective manner.
- Assure the satisfactory resolution of customer, stakeholder, and internal issues in order to meet customer requirements.

4. Requirements

The line organization is responsible for meeting customer (i.e., NNSA/DOE and DoD) quality requirements, and all NA-10 employees are responsible for the quality of their work. NA-10 expects all employees to complete their work in a quality manner and foster an attitude and environment that is supportive of quality principles.

The line organization is responsible for implementing the QAP in all work activities, commensurate with a graded approach. NA-10 implements the QAP by applying and integrating DOE, NNSA, and NA-10 management systems. A Requirements Crosswalk between DOE Order 414.1C and QC-1 is given in Appendix C.

NA-10 organizations use a graded approach to apply the quality controls and perform verification for work commensurate with the risk to safety, security, environment, cost, schedule, and success of their mission. Organizations identify risk and choose an appropriate risk handling strategy. See Appendix B, "NA-10 Risk Management Process". (NOTE: The current information in Appendix B will be replaced by the NA-10 Risk Management Process once it is developed. See the NA-10 QAPIP for schedule.)

The QAP applies to all NA-10 organizations, but all requirements are not necessarily applicable to every NA-10 activity. Exclusions will be documented in Section 8, "Exclusions." Unless requirements are excluded per Section 8, NA-10 organizations apply the requirements in a graded risk-based manner.

5. Roles and Responsibilities

Deputy Administrator for Defense Programs (NA-10)

- Provides leadership for quality management system implementation and quality problem resolution,
- Ensures NA-10 compliance with Federal, DOE, NNSA and customer quality requirements,
- As the Landlord Program Secretarial Officer, ensures that site offices and M&O contractors are applying and in compliance with appropriate Federal, DOE, NNSA, and customer quality requirements,
- Approves and issues DOE/NNSA Weapon Quality Policy (QC-1) and revisions,
- Reviews and approves QAPs, Weapon QAPs, associated implementation plans, and their revisions unless authority has been delegated to another organization,
- Approves any deviation from the QAP and QAPIP for any NA-10 Sub-organization,

- Acts as the final resolution authority, including exemption authority, for QC-1 requirements where QC-1 requirements conflict with other requirements,
- Provides QA goals and expectations for the NA-10 management to execute, conducts assessments to determine achievement, monitors QA metrics, and the results of NA-10 organization's management and independent assessments to determine the effectiveness of the quality assurance program implementation and monitor/track trends for process improvements and resolutions,
- Holds line management accountable for the performance of management assessments and continuous improvement to attain mission success,
- Provides direction to Contracting Officers where application or flow down of QC-1 and other related NNSA quality requirements apply, and
- Provides direction and expectations to Site Office Managers regarding safety system and safety software quality assurance. Monitors Site Office oversight of contractor safety system and safety software quality assurance activities.

Defense Programs' Assistant Deputy Administrators (ADAs) (NA-11/12/13/15/16)

- Implement the NA-10 QAP and QAPIP,
- Report management assessment results, continuous improvement initiatives, and metrics associated with the QAP annually to NA-10 and upon request,
- Execute delegated QAP and QAPIP responsibilities,
- As designated by NA-10, NA-12 establishes and maintains the DOE/NNSA Weapon Quality Program Policy (QC-1),
- As designated by NA-10, NA-12 provides independent oversight of Weapon Quality Program implementation within NA-10 and NNSA Site Offices,
- As designated by NA-10, NA-13 serves as the NA-10 Lead for the QAP and related management system, and
- As designated by NA-10, NA-15 performs QA activities for OST in accordance with the NA-15 Quality Assurance Program Plan as it flows down from the NA-10 QAP.

All NA-10 personnel

- Follow the NA-10 Quality Principles,
- Achieve quality improvements in work processes and products as tasks are performed,
- Report problems in quality through the chain of command for evaluation and initiation of corrective action, and
- Implement the NA-10 QAP.

6. Approval and Change Control

The NNSA Deputy Administrator for Defense Programs (NA-10) approves the NA-10 QAP and necessary implementation plans following joint submission of the QAP from each Assistant Deputy Administrator within NA-10. For NA-10 organizations that choose to develop a supplemental QAP due to unique operations relative to the rest of the organization, the Deputy Administrator will approve their QAP upon submission from the affected Assistant Deputy Administrator and appropriate review. The NA-10 QAP, any supplemental QAPs and necessary implementation plans are controlled documents. The NA-10 QAP and necessary implementation

plans will be evaluated at least annually, under the lead of NA-13, and updated as appropriate. Organizations with supplemental QAPs will implement annual evaluations under their own leadership.

As the Landlord Program Secretarial Officer, the Deputy Administrator for Defense Programs approves all Site Office QAPs upon submission from the respective Site Office Manager and appropriate reviews.

7. Quality Assurance Criteria

The NA-10 QAP describes the NA-10 framework in meeting the quality assurance requirements contained in 10 CFR 830, DOE Order 414.1C, and the requirements of QC-1. The NA-10 QAP is organized in this section by the ten criteria in 10 CFR 830 and DOE O 414.1C. For NA-10 headquarters, QC-1 requirements are met for weapon and weapon related work activities as described in this section. Reference the Requirements Crosswalk, Appendix C, for further detail.

Secure transportation facilities and activities are controlled by the *NA-15 Quality Assurance Program Plan* (developed and maintained by the Assistant Deputy Administrator for Secure Transportation). The NA-15 QAPP is approved by the Deputy Administrator for Defense Programs (NA-10).

ISO 9001:2000 was compared against the ten criteria in 10 CFR 830.120 and DOE O 414.1A. This comparison (prepared by the Kansas City Site Office with assistance from Honeywell FM&T in June 2002) reported all of the ten DOE Quality Assurance Criteria are covered in the ISO standard. Four areas were identified where the ISO standard would need supplemental DOE/NNSA requirements. These relate to two items where ISO allows for “where practical or appropriate” but DOE criteria states the requirement is a “must,” and two DOE requirements for independent verification of design and hazard controls. This comparison provides adequate assurance that a sound and credible quality system as defined by ISO 9001/2000 closely parallels the requirements defined by DOE.

7.1 QA Program

This section describes the quality assurance program in terms of the NA-10 organizational structure, functional responsibilities, levels of authority, interfaces, and the establishment of management processes.

DOE O 414.1C Requirements

- Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
- Establishing management processes, including planning, scheduling, and providing resources for work.

The NNSA Deputy Administrator for Defense Programs (NA-10) and each NA-10 Assistant Deputy Administrator and their Office Directors have responsibility for the development, implementation, assessment, and continuing improvement of the NA-10

QAP. NA-13 is assigned as the NA-10 lead for QAP activities, including the coordination for QAPIP accomplishment of commitments.

The NA-10 lead for QAP activities has responsibility for interfacing with other NNSA and DOE organizations to interpret quality assurance requirements contained in 10 CFR 830, DOE Order 414.1C, and QC-1, for selecting additional requirements from consensus quality standards, to define the necessary and sufficient set for the NA-10 QAP, and for planning, documenting, directing, and administering the NA-10 QAP.

The NNSA Deputy Administrator for Defense Programs (NA-10), each Assistant Deputy Administrator within NA-10 and their Office Directors are responsible for the planning, scheduling and resource loading of activities under their control with support from their staff.

The NA-10 QAPIP expresses several commitments in Section 4.1, *Quality Assurance Program*, which will assist the establishment and implementation of the NA-10 QAP.

7.2 Personnel Training & Qualifications

This section describes NA-10 mechanisms to ensure its employees are adequately trained and qualified, as appropriate to perform the activities for which they are responsible.

DOE O 414.1C Requirements

- Train and qualify personnel to be capable of performing assigned work.
- Provide continuing training to personnel to maintain job proficiency.

For NA-10 position descriptions, consideration is given to such items as: education, experience, physical requirements of the work, specialized skills, and training and certification. Managers, along with their employees, determine the minimum training and/or qualification requirements for personnel filling such positions, based on the activities to be performed.

Managers periodically evaluate training and qualification needs for employees and document such needs in each employee's Individual Development Plan (IDP) on an annual basis. The evaluation should consider factors such as:

- Changes in work activities, technology, and job responsibilities;
- The organization's management system requirements;
- Technical and/or managerial skills needed;
- Certification requirements;
- Training required by regulations;
- Training required for specific job location or project.

Managers will determine the qualification programs that apply to their employees. For those employees chosen to participate, managers ensure that appropriate time and training opportunities are made available to achieve qualification.

The NA-10 QAPIP expresses several commitments in Section 4.2, *Training and Qualification*, which will assist the establishment and implementation of the NA-10 QAP.

7.3 **Quality Improvement**

This section describes correction and prevention of quality-related problems within NA-10 and how the continuous improvement of quality occurs.

DOE O 414.1C Requirements

- Establish and implement processes to detect and prevent quality-related problems.
- Identify, control, and correct items, services, and processes that do not meet established requirements.
- Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.
- Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

Management leads the implementation of the quality improvement process for their organizations to ensure problem prevention, detection, correction, and continuous improvement. The NA-10 QAPIP expresses several commitments within Section 4.3, *Quality Improvement*, which will establish and implement improvement in quality. In the interim, NA-10 organizations will continue to use existing work processes and work methods to detect and correct quality-related problems and make improvements.

7.4 **Documents & Records**

This section describes NA-10 document and record processes in order to establish and maintain formal document and records control.

DOE O 414.1C Requirements

- Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- Specify, prepare, review, approve, and maintain records.

NA-10 follows the NNSA Policy (NAP) Letters expressed in NAP-1, *Establishment of a Policy Letter System for Managing Policy, Directives, and Business Practices Within the National Nuclear Security Administration* and NNSA Business and Operating Policy Letter BOP-4.001, *NNSA Records Management Business and Operating Policy*, to establish business management and operating guidance for the creation, disposition, maintenance, and referencing of NNSA records. NAP-1 is the guiding directive for documents to prescribe processes, specify requirements, or establish design and NA-10 will develop Business and Operating Policy (BOP) letters per the NA-10 QAPIP, as required. BOP-4.001 is the guiding NNSA directive for specification, preparation, review, approval, and maintenance of records. Records applicable to the NA-10 quality

assurance program will be identified within NA-10 Business and Operating Policies (BOPs) as defined by BOP-10.

NA-10 approves BOP-10 and all subsequent BOPs that establish policy, requirements, and/or processes for Defense Programs. Each Assistant Deputy Administrator within NA-10 approves supplemental documents, as needed to support BOPs and/or NAPs that establish policy, requirements and/or procedures for their organization. As appropriate, each Assistant Deputy Administrator within NA-10 and their Office Directors have the responsibility for implementing NAPs, BOPs, and all related supplemental documents. These documents will be identified and conveyed to all personnel through an electronic library.

Records will be established in accordance with Federal Laws and DOE Directives as guided by BOP-4.001 and NA-10 BOPs to provide evidence of conformity to requirements and of the effective operation of the QA Program. Record requirements are necessary for such items as: training, product certification, product nonconformity, design review, supplier evaluation, management assessments, independent assessments, corrective and preventive actions. Each organization within NA-10 works with a system of documents and records that are complete, accurate, retrievable, and maintained. Retention and disposition of records occurs via National Archive and Records Administration guidance. Records in storage are protected from damage, loss, or deterioration.

The NA-10 QAPIP expresses several commitments in Section 4.4, *Documents and Records*, which will assist the establishment and implementation of the NA-10 QAP.

7.5 Work Processes

The purpose of this section is to identify the systems in place to control, manage or oversee work process within all NA-10 organizations.

DOE O 414.1C Requirements

- Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.
- Identify and control items to ensure their proper use.
- Maintain items to prevent their damage, loss, or deterioration.
- Calibrate and maintain equipment used for process monitoring or data collection.
(Exempt)

All levels of NA-10 have the responsibility to ensure that applicable customer and other requirements, acceptance criteria, and technical standards are used to perform work. Prior to performing work, NA-10 personnel must be knowledgeable with applicable requirements and standards, and implement needed controls.

NA-10 identifies and controls sensitive and capital assets, such as accountable government property in their possession consistent with Federal and DOE Property Management Regulations and DOE directives.

NA-10 adheres to the principles set forth in DOE's policy on Integrated Safety Management established in DOE Policy 450.4, "Safety Management System". NA-10 management endorses the ISM concept that quality and safety are part of every work process.

The NA-10 QAPIP identifies commitments within Section 4.5, *Work Processes*, to fully comply with this criterion.

7.6 Design

This section describes how design authority expectations are defined within NA-10 organizations.

DOE O 414.1C Requirements

- Design items and processes using sound engineering/scientific principles and appropriate standards.
- Incorporate applicable requirements and design bases in design work and design changes.
- Identify and control design interfaces.
- Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.
- Verify/validate work before approval and implementation of the design.

NA-10 organizations do not perform any direct design work, but provide oversight and guidance to contractor design activities. Part of the oversight and guidance given to contractors by NA-10 organizations is to ensure that design and development activities are planned and responsibilities assigned and documented by project plans, task agreements, DOE memoranda, statements of work, or work authorizations as appropriate for the design effort. These actions are further defined and discussed in the NA-10 Defense Programs – Program Management Manual (NA13-PMM-04-0001).

For capital projects required to meet DOE O 413.1, NA-10 organizations directly support the verification and validation of design adequacy and its implementation through ESAAB activities. As appropriate, NA-10 organizations will either directly participate in peer review of designs or acquire the required expertise to act on their behalf for the review.

The NA-10 QAPIP identifies commitments within Section 4.5, *Work Processes*, to fully comply with this criterion.

7.7 **Procurement**

This section describes how the procurement of items or services supports NA-10 missions.

DOE O 414.1C Requirements

- Procure items and services that meet established requirements and perform as specified.
- Evaluate and select prospective suppliers on the basis of specified criteria.
- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

NA-10 interfaces with the primary procurement organizations for support service contracts (NNSA Service Center – development and execution) and for M&O contracts (NNSA Management and Administration organization – development, Site Offices - execution). NA-10 ensures that procured items and services comply with documented requirements and perform acceptably. Additionally, NA-10 complies with the following requirements based on external relationships defined above:

- Procure items or services in compliance with the Federal Acquisition Regulations (48 CFR 1) and the DOE Acquisition Regulations (48 CFR 9), and
- Ensure that the selection of suppliers and/or the purchase of commercial-grade materials are evaluated per DOE Guide 440.1-6, Section 4.1 to prevent the procurement of suspect/counterfeit items.

The NA-10 QAPIP identifies commitments within Section 4.5, *Work Processes*, to fully comply with this criterion.

7.8 **Inspection & Acceptance Testing**

This section describes how NA-10 verifies that the development, manufacturing, repair, or modification of items and services provided to the NA-10 organizations have used acceptable processes, inspection, and testing procedures, and equipment.

DOE O 414.1C Requirements

- Inspect and test specified items, services, and processes using established acceptance and performance criteria.
- Calibrate and maintain equipment used for inspections and tests. (Exempt)

Each NA-10 organization will inspect and develop acceptance criteria, as appropriate, to ensure the quality of items, services, and processes that are managed or produced by NA-10.

The NA-10 QAPIP identifies commitments within Section 4.5, *Work Processes*, to fully comply with this criterion.

7.9 Management Assessment

This section describes how NA-10 plans and conducts periodic management assessments.

DOE O 414.1C Requirements

- Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

NA-10 retains the overall responsibility for management assessments (also referred to as self assessment in both this document and the QAPIP) within Defense Programs. Each Assistant Deputy Administrator within NA-10 and their Office Directors have responsibility for planning and conducting management assessments within their organizations. The planning and conducting of such assessments will be in accordance with Appendix N of this QAP. Management assessment also applies to NA-10 management systems. Assessments identify quality problems affecting achievement of organizational objectives and initiate corrective actions (see Section 7.3) that will improve quality, increase customer satisfaction, and/or increase organizational effectiveness.

The NA-10 QAPIP expresses several commitments in Section 4.6, *Assessments*, which will assist the establishment and implementation of the NA-10 QAP.

7.10 Independent Assessment

This section describes how appropriate independent reviews of NA-10 activities are conducted.

DOE O 414.1C Requirements

- Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance, and to promote improvement.
- Establish sufficient authority and freedom from line management for independent assessment teams.
- Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Independent assessments may be conducted by outside groups such as: National Academy of Sciences (NAS); JASONS; Foster Panel; Office of Independent Oversight and Assessment (OA); Defense Nuclear Facilities Safety Board (DNFSB); Inspector General (IG); Government Accounting Office (GAO); Office of Secure Transportation Program Office of Independent Oversight, etc. NA-10 may also establish independent teams. The planning and conduct of such assessments will be in accordance with Appendix O of this QAP.

NA-10 personnel who participate in independent assessments of NA-10 organizations will be knowledgeable of the activity being assessed. Assessors will not be involved with or have responsibility for the operation, program, process, or system being assessed, and

will have sufficient authority and freedom to carry out their assessment responsibilities. NA-10 organizations are responsible to work with independent assessment teams for successful planning and conduct of assessments. The independent assessment team will report assessment results to the Assistant Deputy Administrator. NA-10 organizations are responsible to resolve identified problems, including the verification of satisfactory corrective action.

Additionally, independent assessment results shall be tracked and further distributed within NA-10, as appropriate, by the appointed Office Director for the organization's action.

The NA-10 QAPIP expresses several commitments in Section 4.6, *Assessments*, which will assist the establishment and implementation of the NA-10 QAP.

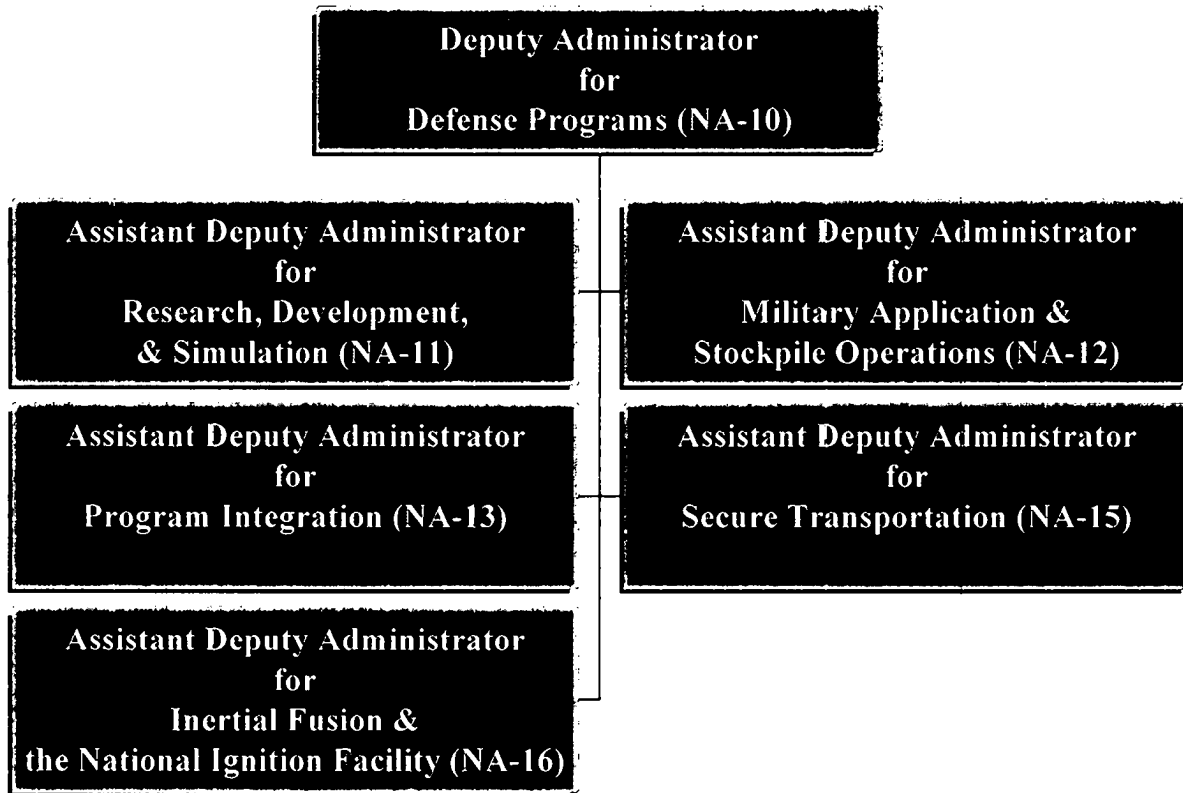
8 Exclusions

Section 7.5 Work Processes: calibrate and maintain equipment used for process monitoring or data collection is excluded as a requirement since NA-10 does not own such equipment.

Section 7.8 Inspection and Acceptance Testing: calibrate and maintain equipment used for inspections and tests is excluded as a requirement since NA-10 does not own M&TE equipment.

Appendix A – Organizational Structure

Office of Defense Programs



NA-10 Mission

Achieve national security objectives established by the President for nuclear weapons and assist in reducing the global nuclear danger by planning for and maintaining a safe, secure, and reliable stockpile of nuclear weapons and associated materials, capabilities, and technologies in a safe, environmentally sound, and cost-effective manner.

NA-11 Mission

The Office of Research, Development, and Simulation develops, directs, maintains, and oversees the research, development, and computer simulation activities in support of maintaining the safety and reliability of the nuclear weapons stockpile. The organization is also responsible for maintaining the readiness to test and develop new warheads if required.

NA-12 Mission

The Assistant Deputy Administrator for Military Application and Stockpile Operations leads the engineering and production development, manufacturing, quality, surety, and production support portion of the stockpile stewardship program to achieve a safe, secure, reliable, stockpile today and tomorrow. The office provides the planning, direction, and resources for stockpile

operations materials, infrastructure, capabilities, and technologies in a safe, secure, environmentally sound and cost-effective manner, through a system of scientific, engineering, and industrial facilities. These support development and production of certified components necessary to extend the lifetime or enhance the surety and reliability of the nuclear weapons stockpile. NA-12 works in close coordination with the Office of Research, Development and Simulation and ultimately the Department of Defense (DoD). The program ensures stockpile readiness by maintaining: the core competency of the stockpile workforce; an applied science and technology base; and the capability to build new weapons, as required, or components found to render weapons unreliable. This program manages and directs the implementation of the tritium readiness program to enable the development of a new tritium production source to assure availability of tritium for the nuclear weapons stockpile as needed. The Office manages the development and execution of the strategy and plans for reconstituting pit manufacturing within the nuclear weapons complex, and meeting stockpile requirements for manufactured pits supporting the Office of Research, Development, and Simulation Pit Program Office.

NA-13 Mission

The Office of Program Integration provides studies, analyses, and recommendations for NA-10 decision-making; integrates all aspects of planning, programming, budgeting and program execution across NA-10; establishes (with input from NA-10 organizations and customers) strategic objectives and measures for NA-10; advises NA-10 regarding program risk and balance in the context of NA-10 strategic objectives; and provides the policies, processes, procedures, and formats for all aspects of NA-10 planning, program management, budgeting, and contractor evaluation. This Office also provides a resource for the conduct, management, or oversight of priority initiatives that crosscut the organizational structure of NA-10.

NA-15 Mission

The Office of Secure Transportation (OST) provides for the safe and secure transportation of nuclear weapons and components, special nuclear materials, selected non-nuclear weapons components, and Limited-Life Components (LLCs) to and from military locations and among nuclear weapon complex facilities, and conduct other missions supporting the national security of the United States of America.

NA-16 General Statement of Function

Develop, direct, and manage a successful Inertial Confinement Fusion (ICF) research and development program that supports the Stockpile Stewardship Program, including the National Ignition Facility Project and achievement of inertial fusion ignition and burn in the laboratory. Lead development of a long-term (10 to 20 years) strategic plan for the use of ICF ignition in support of NNSA and national goals. Participate in the national effort on the High Energy Density Physics (HEDP) program activities and serve on related interagency discussion groups. Provide technical and programmatic input for the budgeting and funding processes, which includes supporting the preparation of testimony and responses to Congressional inquiries. Direct reviews and evaluations of ongoing programs of the weapons laboratories that are being carried out in support of NA-16. Participate in international activities and maintain liaisons with universities, industry, and international organizations on HEDP related issues. Respond to executive, legislative, industrial, and NGO stakeholders on matters related to the ICF Program and NIF Project.

Appendix B – NA-10 Risk Management Process

NOTE: The current information in this appendix will be replaced by the NA-10 Risk Management Process once it is developed. See the NA-10 QAPIP for schedule. Until that time, users can use any of the following to determine their risk and thereby their graded approach: 1) NA-10 Defense Programs Program Management Manual, Section 5.10, Manage Risk and Integration and its supplemental references, 2) NA-12-PD-03-0002 Risk Management Process Description and NA-12-02-0034, Systems Engineering Methodology Guidance Manual, Appendix B, or 3) the information provided below.

It is NA-10's policy that risk assessment be used as the primary driver to applying a graded approach to quality for NA-10 activities. Higher risk items are afforded greater attention to quality to increase the potential that they will perform as intended. As the risk level goes down, the rigor of the assessment can be reduced in a graded fashion because lower risk items do not justify the same effort to ensure conformance to requirements.

Risk is an outcome of an event that might happen to the detriment of a program, project, or activity. It is described by the probability that it will occur (likelihood of occurrence) and the consequence (impact) of the occurrence. The risk or risk factor is equal to the likelihood of occurrence times the impact/consequence of the event (Risk Factor = $P_o \times P_c$).

Risk management is a process that provides a pro-active management approach to understand and control uncertainty throughout the life cycle of a program, project, or activity. Risk management is also a continuing process of planning, identifying, quantifying, responding to, and controlling risks to maximize the potential for success of an activity. One version of a generic risk management process involves seven key steps and is shown graphically in Figure 1 below.

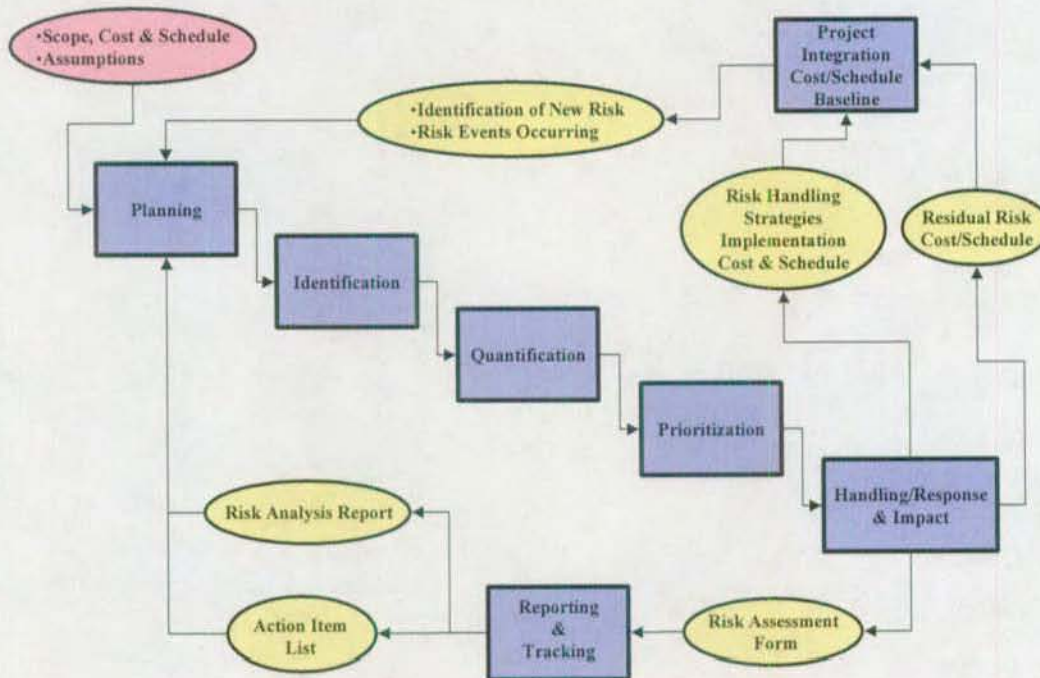


Figure 1 – Risk Management Process

Risk identification is an organized approach to determine events that are likely to affect activities and why those events are considered risks. Risks are identified against assessable elements. Assessable elements essentially are “what we are planning to do now”. The statement of risk considers the assessable element and identifies what can go wrong with what we are planning to do (the event), why it can go wrong (the basis), and defines what happens if it does go wrong (the risk). Once a risk has been identified, the risk type (i.e., programmatic, technical) and category (i.e., management, design, procurement, etc.) can be determined. Table 1 at the end of this section provides an example listing of possible risk categories.

Risk quantification is the process of evaluating the likelihood that a risk event will occur and assessing the range of possible consequences of that risk to the program. There are a number of schemes for determining the likelihood and the consequences. One common method is to use a guideline table to assist in the determination. Table 2 at the end of this section provides a guideline example for addressing the likelihood of occurrence. Table 3 at the end of this section provides a guideline example for addressing consequences.

Once the likelihood and consequence are determined for each risk, the risk grading/ranking can be determined using a risk exposure level matrix. Figure 2 provides an example of a risk exposure level matrix.

Once a risk grade or ranking has been established, an appropriate risk handling strategy should be applied to determine the quality level to be applied. Risk handling is the identification of the course of action or inaction that can be taken for the purpose of effectively managing a given risk. Risk handling strategies are developed with the purpose of eliminating, or at least reducing, the likelihood and/or consequences of an identified risk. The handling strategies are then evaluated and the effects of the risks and the implementation of the handling strategy or risk mitigation alternatives are quantified so the optimum risk handling strategy can be selected. One of four risk handling strategies is to be applied for responding to risks: Accept, Avoid, Transfer, or Mitigate.

Accept – Accepting a risk is essentially a “no action” strategy, and accepts the risk “as is” thus accepting the risk and its consequences. The selection of this strategy is based upon the decision that it is more cost effective to continue the program as planned with no resources specifically dedicated to addressing the risk. The residual risk for this handling strategy equals the initial risk because no action is taken to reduce the risk level. In addition, because this is a “no action” strategy, there should be no handling strategy implementation cost and/or schedule impacts to the program. Low-level risks are examples of the types of risks that are normally subject to being accepted. For some of the low level risks that will be accepted with moderate consequences, it would be prudent to identify a good set of trigger events to monitor and develop contingency plans that can be used if the risk is going to be realized.

Avoid – This strategy is directed at avoiding the risk by either eliminating the potential that the risk event can occur or by eliminating the consequences of that risk event. Therefore, by definition, the residual risks for this handling strategy will be zero. Restructuring the program, design, or selecting an alternative approach or design not containing the particular risk item may accomplish avoiding risk. In general, this handling strategy involves actions that will impact the

cost and/or schedule of the program, and consequently, these impacts must be determined and documented in the overall program plan.

Transfer – This strategy is used when the risk item can be transferred to another program, project, organization or entity that can more appropriately handle the risk. In many cases, the program or project may not have any control or authority over the risk, and the ability to mitigate the risk is not feasible. In these cases, the risk may be transferred to the organization or entity that directly controls or has authority to influence the risk. If a risk is successfully transferred (i.e. – risk is accepted by the receiving entity), the residual risk will be zero to the transferring entity. If this handling strategy involves actions that will impact the cost and/or schedule of the program, then these impacts must be determined and documented in the overall program plan.

Mitigate – The primary objective of risk mitigation is not necessarily to eliminate but to reduce risks to an acceptable level. This is accomplished by either reducing the likelihood of occurrence, reducing the severity of the consequences, or both. The process of mitigating risk involves developing mitigation options and/or strategies. The following are common mitigation strategies:

- Early initiation of activities
- Initiation of parallel development
- Implementation of abatement measures or control
- Implementation of additional extensive analysis and testing

The final graded approach will depend on the selection of the risk handling strategy. Overall, the application rigor of QA requirements to activities will be dependent upon (1) an event's likelihood of occurrence, (2) the consequence of occurrence, and (3) the risk handling strategy employed.

The following examples (Table 1, 2, and 3, and Figure 2) illustrate the concepts that will be encompassed by the risk assessment process

Table 1: Example Risk Categories

Design

- Undefined, Incomplete, Unclear Functions or Requirements
- Complex Design Features
- Numerous or Unclear Assumptions or Bases
- Reliability
- Inspectability
- Maintainability
- Maturity
- Errors and Omissions in Design

Resource/Conditions

- Material/Equipment Availability
- Specialty Resources Required
- Support Services Availability
- Resources Not Available
- Manufacturing Complexities
- Personnel Training & Qualifications
- Tools, Equipment Controls & Availability
- Experience with system/component (design, operations, maintenance)
- Training Required
- Research and Development Support
- Multiple Project/Facility Interface
- Facility Work Control Priorities

Safeguards & Security

- Security Requirements
- Category I nuclear materials
- Classified process / information

Technology

- New Technology
- Existing Technology Modified
- New Application of Existing Technology
- Unknown or Unclear Technology

Procurement

- Procurement Strategy
- First-use Subcontractor/Vendor
- Vendor Support

Testing

- Testability
- Operability

Safety

- Criticality Potential
- Exposure Contamination Potential
- Hazardous Material Involved
- Confinement Strategies

Interfaces

- Multiple Agencies, Contractors
- Multiple components/subsystems
- Multiple Customers

Management

- Funding uncertainties
- Stakeholders Program Strategy Changes
- Infrastructure influence

Facilities

- Not available
- Under construction
- Upgrades needed
- Startup

Table 2 – Likelihood Criteria

Likelihood	Criteria
Very Low	Programmatic: No external, environment, safety, and health (ES&H), security or regulatory issues. Qualified personnel, resources, and facilities are available. Technical: Non-challenging requirements. Simple design or existing design. Few and simple components. Existing technology. Well-developed process.
Low	Programmatic: Minor potential for external, ES&H, security or regulatory issues. Minor redirection of qualified personnel, resources, or facilities modification is necessary. Technical: Low requirements challenge. Minor design challenge or minor modification to existing design. Moderate number or complex components. Existing technology with minor modification. Existing process with minor modification.
Moderate	Programmatic: Moderate potential for external, ES&H, security or regulatory issues. Moderate redirection of qualified personnel, resources, or facilities modification is necessary. Technical: Moderate requirements challenge with some technical issues. Moderate design challenge or significant modification to existing design. Large number or very complex components. Existing technology with significant modification. Existing process with significant modification.
High	Programmatic: Significant potential for external, ES&H, security or regulatory issues. Significant redirection of qualified personnel, resources, or facilities modification is necessary. Technical: Significant requirements challenge with major technical issues. Significant design challenge or major modification to existing design. Large number and very complex components. New technology. New process.
Very High	Programmatic: Major potential for external, ES&H, security or regulatory issues. Major redirection of qualified personnel, resources, or facilities modification is necessary. Technical: Major requirements challenge with possibly unsolvable technical issues. Major design challenge or no existing design to modify. Extreme number and extremely complex components. Possibly no technology available. Possibly no process available.

Table 3 – Example Consequence Criteria

Consequence	Criteria
Very Low	Cost: Negligible impact on cost. Impact is contained within the strategic unit and results in neither under or over costing of spend plan. Performance: Negligible impact on function or performance. Requirements are clearly met. Schedule: Negligible impact on schedule. Impact is managed within the strategic unit. Results in no impact to critical path and no impact to other strategic units. Milestones are clearly met.
Low	Cost: Minor impact on cost. Impact is contained within the strategic unit and results in less than 5% under or less than 5% over costing of spend plan. Performance: Minor impact on function or performance. Requirements are clearly met. Schedule: Minor impact on schedule. Impact may be managed within the strategic unit. Results in no impact to critical path and no impact to other strategic units. Milestones are clearly met.
Moderate	Cost: Recognizable impact on cost. Impact is not contained within the strategic unit and may result in less than 5% under or greater than 5% over costing of spend plan. Performance: Recognizable impact on function or performance. Requirements may not all be met. Schedule: Recognizable impact on schedule. Impact may not be managed within the strategic unit. May result in impact to critical path or may impact other strategic units. Milestones may not be met.
High	Cost: Significant impact on cost. Impact is not contained within the strategic unit and may result in less than 10% under or greater than 10% over costing of spend plan. Performance: Significant impact on function or performance. Requirements will not all be met. Schedule: Significant impact on schedule. Impact will not be managed within the strategic unit. Will result in impact to critical path or will impact other strategic units. Milestones will not be met.
Very High	Cost: Major impact on cost. Impact will not be contained within the strategic unit and will result in less than 10% under or greater than 10% over costing of spend plan. Performance: Major impact on function or performance. Requirements cannot be met. Schedule: Major impact on schedule. Impact cannot be managed within the strategic unit. Will result in failure in critical path or will significantly impact other strategic units. Milestones cannot be met.

Figure 2 – Example Risk Exposure Level Matrix

Likelihood	Very High	5					
	High	4				HIGH	
	Moderate	3			MEDIUM		
	Low	2	LOW				
	Very Low	1					
				1	2	3	4
			Very Low	Low	Moderate	High	Very High
			Consequence				

Appendix C – Requirements Crosswalk

DOE O 414.1C		QC-1, Revision 10	
Section Number	Section Title	Section Number	Section Title
		1.1	Scope
		2.1	Risk-Based Program
4. a.	QAP Requirements		
		2.2	Quality Management Program
4. b.	Quality Assurance Criteria		
4. b. (1)	Management/Criterion 1-Program		
		2.2	Quality Management Program
		2.3	Organization
		2.6	Planning
4. b. (2)	Management/Criterion 2-Personnel Training and Qualification		
		3.2	Training
4. b. (3)	Management/Criterion 3-Quality Improvement		
		2.7	Metrics
		3.1	Quality Improvement
		3.1.1	Continuous Improvement Process
		3.1.2	Prevention versus Detection
		3.1.3	Quality Cost Management
		3.12	Nonconformance
		3.12.1	Nonconforming Item Control
		3.12.2	Nonconforming Item Disposition
		3.13	Corrective Action
4. b. (4)	Management/Criterion 4-Documents and Records		
		3.5	Document Control
		3.14	Records
4. b. (5)	Performance/Criterion 5-Work Processes		
		3.4	Instructions, Procedures and Drawing
		3.7	Identification, Control and Status of Items
		3.8	Control of Processes
		3.8.1	Process Control Methods
		3.8.2	Special Processes
		3.10	Control of Measuring and Test Equipment
		3.11	Handling, Storage, Packaging and Delivery
		3.11.1	Government-Furnished Material
		3.11.2	NNSA-Accepted Material
		3.16	Software Quality Assurance
4. b. (6)	Performance/Criterion 6-Design		
		2.4	Early and Continuous Application of Quality Principles
		2.5	Establishing and Validating Requirements
		3.3	Design
		3.3.1	Design input
		3.3.2	Design Process
		3.3.3	Design Verification
		3.3.4	Design Documents
		3.3.5	Design Change Control and Configuration Management
		3.3.6	Interface Control
		3.3.7	Records
4. b. (7)	Performance/Criterion 7-Procurement		
		3.6	Procurement
		3.6.1	Supplier Evaluation, Selection and Monitoring
		3.6.2	Procurement Documentation
		3.6.3	Acceptance of Procured Items, Materials and Services
		3.6.4	Certificate of Conformance
4. b. (8)	Performance/Criterion 8-Inspection and Acceptance Testing		
		3.9	Inspection, Test and Acceptance
4. b. (9)	Assessment/Criterion 9-Management Assessment		
		3.15	Assessments
		3.15.2	Scheduling
		3.15.3	Planning
		3.15.4	Performance
		3.15.5	Reporting
4. b. (10)	Assessment/Criterion 10-Independent Assessment		
		3.15	Assessments
		3.15.1	Assessor Qualification
		3.15.2	Scheduling
		3.15.3	Planning
		3.15.4	Performance
		3.15.5	Reporting

Appendix D – NA-10 Organizational Charters

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix E – Maintaining NA-10 Quality Requirements

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix F – NA-10 Training and Qualification Process

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix G – NA-10 Continuous Improvement

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix H – NA-10 Non-Conformance Reporting

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix I – NA-10 Corrective Action/Preventive Action

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix J – NA-10 Management Review

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix K – NA-10 Metric Development and Maintenance

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix L – NA-10 Lessons Learned

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix M – NA-10 Self Assessment

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix N – NA-10 Independent Assessment

This appendix is to be developed as part of the Quality Assurance Program Implementation Plan activities.

Appendix O – Definitions

- a. **Assessment.** A review, evaluation, inspection, test, check, surveillance, or audit, to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.
- b. **Document.** Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a record until it meets the definition of a record.
- c. **Graded Approach.** The processes of ensuring that the level of analyses, documentation, and actions used to comply with requirements are commensurate with:
 - (1) The relative importance to safety, safeguards, and security;
 - (2) The magnitude of any hazard involved;
 - (3) The life-cycle stage of a facility or item;
 - (4) The programmatic mission of a facility;
 - (5) The particular characteristics of a facility or item;
 - (6) The relative importance to radiological and non-radiological hazards, and
 - (7) Any other relevant factors.
- d. **Item.** An all-inclusive term used in place of, but not limited to, any of the following: assembly, component, equipment, hardware, material, part, process, product, service, software, subsystem, system, or vehicle.
- e. **Process.** A series of actions that achieves an end result.
- f. **Quality.** The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.
- g. **Quality Assurance (QA).** All those actions that provide confidence that quality is achieved.
- h. **Quality Assurance Program (QAP).** The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.
- i. **Record.** A completed document or other media that provides objective evidence of an item, service, or process. In accordance with 44 United States Code 3301 this includes "...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 data in them."

- j. **Risk.** A qualitative or quantitative expression of possible loss that considers both probability that an undesired event will occur and the consequences of that event.
- k. **Service.** Work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, safety software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, and installation.
- l. **Suspect/Counterfeit Items (S/CI).** An item is suspect when visual inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):
 - (1) Defects resulting from inadequate design or production quality control;
 - (2) Damage during shipping, handling, or storage;
 - (3) Improper installation; deterioration during service;
 - (4) Degradation during removal;
 - (5) Failure resulting from aging or misapplication; or
 - (6) Other controllable causes.
- m. **Validation/Verification.** The act of independently confirming that items, processes or documents conform to specified requirements,
- n. **Work.** Process for performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

Appendix P – References

- a. DOE O 414.1C, "Quality Assurance," dated 06/15/05.
- b. United States of America, Code of Federal Regulations (CFR), Title 10, Chapter III, Part 830, Subpart A, January 1, 2003
- c. Federal Acquisition Regulations (48 CFR 1-99)
- d. DOE Acquisition Regulations (48 CFR 900-999)
- e. "DOE/NNSA Weapon Quality Policy (QC-1)," dated 02/10/04
- f. DOE M 411.1-1C, "Safety Management Functions, Responsibilities, and Authorities Manual," dated 12-31-03.
- g. "Safety Management Functions, Responsibilities, and Authorities Manual (NNSA FRAM), Rev. 0," October 15, 2003
- h. ISO 9001:2000, "Quality Management Systems – Requirements"
- i. DOE O 200.1, "Information Management Program," dated 9-30-96.
- j. DOE O 413.1A, "Management Control Program," dated 04-18-02
- k. DOE G 414.1-1A, "Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line ES&H Oversight Policy," dated 5-31-01.
- l. DOE G 414.1-2, "Quality Assurance Management System Guide for Use with 10 CFR 830.120 and DOE O 414.1," dated 6-17-99.
- m. DOE O 440.1A, "Worker Protection Management for DOE Federal and Contractor Employees," dated 03/27/98.
- n. DOE G 440.1-6, "Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6c, Quality Assurance," dated 6-30-97.
- o. DOE P 450.4, "Safety Management System Policy," dated 10/15/96.
- p. DOE P 450.5, "Line Environment, Safety and Health Oversight," dated 06-26-97;
- q. NNSA Policy Letter, NAP-1, "Establishment of a Policy Letter System for Managing Policy, Directives, and Business Practices Within the National Nuclear Security Administration," dated 5/21/02
- r. NNSA Policy Letter, BOP-004.001, "NNSA Records Management Business and Operating Policy," dated 11/24/03
- s. NA13-PMM-04-0001, "NA-10 Defense Programs – Program Management Manual," dated 12/30/04

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National Nuclear Security Administration

Office of Defense Programs

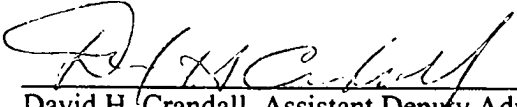
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Program**


Implementation Plan

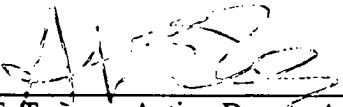
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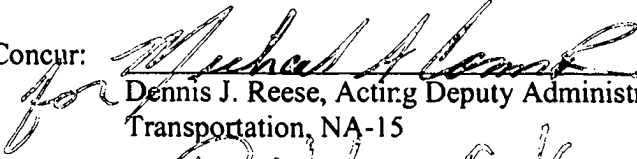
November 2005


Approvals


Concur:  Date: 10/24/05
David H. Crandall, Assistant Deputy Administrator for Research, Development and Simulation, NA-11

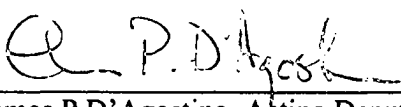
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Foreword

It should be noted that scope, schedule, and assigned parties for activities listed in this implementation plan might change due to the development and issuance of a NNSA QAP and associated QAP Implementation Plan (QAPIP). The NNSA QAP and QAPIP are expected to be issued late in the first quarter of CY 2006. If necessary, the NA-10 QAPIP will be revised to reflect changes driven by the NNSA QAP and QAPIP.

NA-10 QAPIP Change Log			
Revision No.	Date	Change Description	Pages Modified
Rev.0	11/05	Initial publication of NA-10 QAPIP.	All

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Appendices

Appendix A: NA-10 Quality Assurance Program, Rev. 0, November 2005 19

1.0 Background

The Department of Energy (DOE)/National Nuclear Security Administration (NNSA) "Weapon Quality Policy (QC-1)," Revision 10 was issued on March 5, 2004. Each Site Office was instructed to prepare and submit a Quality Assurance Program (QAP) or Weapon Quality Assurance Program, and associated implementation plan for any QC-1 requirements for which their program is not in compliance by September 30, 2004. Site Offices were also instructed to have NNSA M&O Contractors comply with this direction.

The headquarters organization for Defense Programs (DP) headed by the Deputy Administrator for Defense Programs (NA-10) is also implementing this direction with the joint approval of the NA-10 Quality Assurance Program, Rev. 0 (see Appendix A) and this Implementation Plan. Prior to the Deputy Administrator for Defense Programs issuing QC-1, Rev. 10 and the NA-10 QAP, DOE already had quality assurance requirements in place via regulation (10 CFR 830.120) and the directives system (DOE O 414.1C). The NA-10 QAP and this Implementation Plan address all QA requirements and further supplements the NNSA's Quality Assurance Program defined in the NNSA FRAM, dated October 15, 2003.

2.0 Underlying Need

While several initiatives within NNSA and the DOE have made significant improvement to the QA requirements, guidance, and associated implementation, there is not an integrated infrastructure within NA-10, NNSA or the DOE to ensure the consistent implementation of quality assurance in a rigorous, risk-based fashion. The infrastructure needs for NA-10 include development and application of organizational methods to strengthen the existing quality management system in several important areas, including document and records management, assessment, corrective action, and non-conformance reporting.

Defense Programs recognizes the need to establish an effective quality assurance program within headquarters. In addition to the infrastructure needs identified above, an evaluation of the current set of mission oriented work processes is needed to identify and implement additional necessary processes. Also, more effective implementation of existing work processes, such as training and qualification is needed. Finally, an effective communication/training plan is needed to convey the quality management system to the organization to realize a lasting and continual improvement of organizational work.

3.0 Baseline Assumptions

Defense Programs made the following baseline assumptions in developing the NA-10 QAP Implementation Plan (IP):

- IP execution will be based on target-level funding approved by Congress in an atmosphere of stable mission requirements.
- Actions identified in this IP are those necessary to meet quality assurance requirements. These requirements include customer (DoD) requirements, internal (QC-1) requirements,

and DOE requirements. NA-10 may take additional actions outside of this IP to implement quality improvement requirements.

- Actions identified in this IP will be implemented with full consideration of national and international consensus standards. ISO 9001:2000 will be a primary resource.
- Actions identified in the QAPIP are based on the future risk-based applications of quality assurance to NA-10 functions, activities and facility operations.

4.0 Quality Assurance Issue Resolution

The scope of this IP encompasses responsibilities for quality assurance by NA-10 headquarters. Quality assurance, as defined by this IP, includes weapons and weapons related quality assurance activities and other work activities performed by NA-10 employees that provide products/services to customers within or external to DP and that require quality assurance as determined by risk-based grading. Facilities quality assurance activities within NA-15 is fully implemented through the NA-15 Quality Assurance Program Plan.

Each commitment within this Implementation Plan is supported by an Issue Description describing the background and a Resolution Approach summarizing the approach for the collection of commitments within the Deliverables/Milestones for each sub-section. The following sections describe the actions that will be taken to ensure the integrity of quality assurance at Defense Programs headquarters offices.

4.1 Quality Assurance Program

Issue Description

NA-10 is hard at work accomplishing the many objectives in the NA-10 mission. This work is often planned and accomplished with quality assurance tools, and organizational responsibilities and requirements that have been defined or communicated locally as a result of not having an effective management system infrastructure for the entire organization. The development and description of such an infrastructure is the first step towards accomplishing necessary work activities more effectively.

Resolution Approach

The development of the NA-10 QAP and this Implementation Plan resolve the underlying need. The primary focus now is to communicate the QAP to the organization and complete several foundational elements for the program to function effectively. Communicating the QA Program to the organization will include developing practical applications to establish relevance, addressing the future plans laid out in this implementation plan, and performing tabletop sessions with all organizations within NA-10 for feedback on specific applications of the program.

Foundational elements to be addressed will include the definition of organizational charters, applicable requirements to work activities, and graded approach for determining the application of quality assurance to work activities. First, organizational charters will be developed or updated to formally convey the necessary interfaces that are already informally established within and external to NA-10 for the major sub-organizations. Second, a formal means to identify and maintain the applicable requirements within NA-10's defined management system

and QAP will be established. Finally, NA-10 will establish a QAP appendix to define the risk management process to be used for determining to what extent the QAP applies to specific work activities.

The QAP will also require periodic updating as the program matures and as management processes are applied to firmly establish a culture of continuous improvement within the work NA-10 accomplishes.

Deliverables/Milestones

Commitment 4.1.1: Establish and implement a Communication Plan to support NA-10 implementation of a quality program.

Lead Responsibility: NA-13.

Deliverable: Develop briefings to provide a general employee training to all employees on the QAP and Implementation Plan, and carry out table-top sessions with NA-10 organizations to obtain feedback on needed or existing processes and enlist specific support.

Due Date: April 14, 2006.

Commitment 4.1.2: Establish and implement an appendix in the QAP to specify the NA-10 Organizational Charters process. The organizational charters will define mission, functions, roles/responsibilities, internal and external interfaces, and structure at the Director's organization level.

Lead Responsibility: NA-13 for appendix in the QAP and each ADA for Organizational Charters.

Deliverable: Appendix in the QAP and Organizational Charters.

Due Date: June 16, 2006, appendix in the QAP developed.

Due Date: September 8, 2006, Organizational Charters developed.

Commitment 4.1.3: Establish and implement an appendix in the QAP to describe how NA-10 will monitor and maintain the quality requirements matrix and ensure a necessary and sufficient set of requirements for NA-10 HQ.

Lead Responsibility: NA-13.

Deliverable: Appendix in the QAP.

Due Date: March 16, 2007, appendix in the QAP developed.

Due Date: June 15, 2007, appendix in the QAP implemented.

Commitment 4.1.4: Establish and implement an appendix in the QAP to define the NA-10 Risk Management process.

Lead Responsibility: NA-12.

Deliverable: Appendix in the QAP.

Due Date: June 9, 2006, appendix in the QAP developed.

Due Date: September 15, 2006, appendix in the QAP implemented.

Commitment 4.1.5: Update the NA-10 Quality Assurance Program.

Lead Responsibility: NA-13.

Deliverable: Updated NA-10 Quality Assurance Program.

Due Date: November 1, 2006, and at least annually thereafter.

4.2 Training and Qualification

Issue Description

NA-10 already has the fundamental means to accomplish training and qualification through DOE directives and tools; however, implementation has been sporadic within the organization.

Resolution Approach

NA-10 will specify the expectations for training and qualification within the organization by developing and implementing an appendix in the QAP. Continuing training will be defined and implemented by the expectations within sub-section 4.1 and 4.3. NA-10 positions requiring either training or qualification to competently perform the duties and responsibilities of the positions will be identified and such requirements will be pursued, if not already in place. Finally, self-assessment and management review defined in sub-sections 4.6 and 4.3 respectively, will be developed and implemented with respect to training and qualification.

Deliverables/Milestones

Commitment 4.2.1: Establish and implement an appendix in the QAP to define the NA-10 Training and Qualification process.

Lead Responsibility: NA-12.

Deliverable: Appendix in the QAP.

Due Date: November 3, 2006, appendix in the QAP developed.

Due Date: June 8, 2007, appendix in the QAP implemented.

Commitment 4.2.2: Identify NA-10 positions needing specific qualification to be identified and define qualification requirements for all positions specified.

Lead Responsibility: All ADA's.

Deliverable: Listing of NA-10 Positions needing qualification and identification of applicable qualification standards.

Due Date: September 8, 2006.

4.3 Quality Improvement

Issue Description

NA-10 is lacking a formal means of effectively managing problem prevention, self-assessment, issues management, and continuous improvement. Quality improvement activities will require a culture change within the organization to pursue deliberate and formal means to identify areas for improvement and to follow through with meaningful improvement and appropriate objective evidence where appropriate.

Resolution Approach

Quality improvement will be addressed in three primary areas. First, DP policy will be established on quality improvement and the policy will be implemented as part of a continuing training plan. Second, a series of appendices in the QAP will be established and implemented for fundamental QA procedures involving non-conformance reporting, corrective and preventive actions, metrics, and lessons learned. These procedures will be tailored to DP work activities. The final area of emphasis will involve integrated safety management functions. Once the QA program has had an opportunity to develop a number of appendices in the QAP, Phase III implementation will conduct a gap analysis of the developed management system to determine how ISM functions can be better addressed and implemented.

Deliverables/Milestones

Commitment 4.3.1: Establish an appendix in the QAP expressing the Policy for Continuous Improvement and implement a Communication Plan across NA-10.

Lead Responsibility: NA-13.

Deliverable: Appendix in the QAP.

Due Date: March 16, 2007, appendix in the QAP developed.

Due Date: June 15, 2007, appendix in the QAP implemented.

Commitment 4.3.2: Establish and implement an appendix in the QAP for Non-Conformance Reporting.

Lead Responsibility: NA-12.

Deliverable: Appendix in the QAP.

Due Date: November 3, 2006, appendix in the QAP developed.

Due Date: March 9, 2007, appendix in the QAP implemented.

Commitment 4.3.3: Establish and implement an appendix in the QAP for Corrective Action/Preventive Action.

Lead Responsibility: NA-16.

Deliverable: Appendix in the QAP.

Due Date: March 16, 2007, appendix in the QAP developed.

Due Date: June 15, 2007, appendix in the QAP implemented.

Commitment 4.3.4: Establish and implement an appendix in the QAP for Management Review.

Lead Responsibility: NA-11.

Deliverable: Appendix in the QAP.

Due Date: November 3, 2006, appendix in the QAP developed.

Due Date: March 9, 2007, appendix in the QAP implemented.

Commitment 4.3.5: Establish and implement an appendix in the QAP for metric development and maintenance (QC-1 requirement).

Lead Responsibility: NA-12.

Deliverable: Appendix in the QAP.

Due Date: July 7, 2006, appendix in the QAP developed.

Due Date: September 8, 2006, appendix in the QAP implemented.

Commitment 4.3.6: Establish and implement an appendix in the QAP for Lessons Learned.

Lead Responsibility: NA-16.

Deliverable: Appendix in the QAP.

Due Date: March 16, 2007, appendix in the QAP developed.

Due Date: September 21, 2007, appendix in the QAP implemented.

Commitment 4.3.7: Establish and implement a plan for developing a NA-10 procedure to fully develop ISM functions within the DP management system.

Lead Responsibility: NA-13.

Deliverable: ISM Implementation Plan.

Due Date: January 12, 2007, Implementation Plan.

Due Date: September 14, 2007, Implementation complete.

4.4 Documents and Records

Issue Description

A primary need within NA-10 is to use a management system that is comprised of two infrastructure elements: (1) document system to establish direction/guidance/methods and (2) records system to establish objective evidence. This is an issue requiring culture change and a commitment to move away from disseminating policy, direction and/or guidance by e-mail/memo and instead, formulate a system that organizes and archives documents for more effective operations. NA-10 adheres to the NNSA Policy (NAP) Letters expressed in NAP-1, *Establishment of a Policy Letter System for Managing Policy, Directives, and Business Practices Within the National Nuclear Security Administration* and NNSA Business and Operating Policy Letter BOP-4.001, *NNSA Records Management Business and Operating Policy*, and these are used as guides in the establishment of records in accordance with Federal Laws and DOE Directives.

Resolution Approach

Establish a NA-10 procedure (BOP) for document management and records management, including a means for all employees to access the document management system. The purpose of a document management system will be to centralize the policy, direction, and guidance of Defense Programs in a single, accessible location. The NA-10 procedure for documents and records will provide definition and control to the identification, review, approval, maintenance, and disposition of such matters within DP.

Deliverables/Milestones

Commitment 4.4.1: Establish and implement a NA-10 procedure (BOP) for managing NA-10 BOPs.

Lead Responsibility: NA-13.
 Deliverable: NA-10 BOP.
 Due Date: April 28, 2006, NA-10 BOP developed.
 Due Date: July 21, 2006, NA-10 BOP implemented.

Commitment 4.4.2: Develop and maintain an electronic document management system to make QAP documents available to all NA-10 employees.

Lead Responsibility: NA-11.
 Deliverable: NA-10 electronic document management system.
 Due Date: January 19, 2007.

4.5 Work Processes

Issue Description

Defense Programs has not formally defined necessary work processes to fully address Criteria 5-8 in DOE O 414.1C and related criteria in QC-1. DP needs to define and then implement work processes consistent with a risk-based approach to quality assurance. These work processes need to be directed at DP's mission objectives and quality objectives.

Resolution Approach

The program offices (NA-11, NA-12, NA-15, and NA-16) will identify additional work processes required in an Implementation Plan during Phase II of this Implementation Plan and implement the plan during Phase III.

Deliverables/Milestones

Commitment 4.5.1: NA-10 and each ADA will identify work processes to achieve NA-10 quality objectives and establish plans to develop, train and implement work processes that are specific to their organization or broadly applicable to NA-10 for the purpose of meeting QA criteria related to work processes, design, procurement, and inspection, testing and acceptance.

Lead Responsibility: Each ADA.
 Deliverable: ADA Work Processes Implementation Plans.
 Due Date: November 3, 2006, Implementation Plans developed.
 Due Date: September 7, 2007, Implementation complete.

4.6 Assessments

Issue Description

Defense Programs does not have an effective self-assessment program and expectations for interface with independent assessments are not defined.

Resolution Approach

An appendix in the QAP will be established and implemented for both self-assessment (management assessment) and independent assessment. Implementation for self-assessment will include a commitment to establish annual self-assessment plans during Phase III conducted by each ADA, and to implement those plans within the ensuing year.

Deliverables/Milestones

Commitment 4.6.1: Establish and implement an appendix in the QAP for Self-Assessment. This self-assessment will use a standardized form that will be developed as a part of this deliverable.

Lead Responsibility: NA-15.

Deliverable: Appendix in the QAP.

Due Date: November 3, 2006, appendix in the QAP developed.

Due Date: January 5, 2007, appendix in the QAP implemented.

Commitment 4.6.2: Establish and implement annual self-assessment plans for each ADA and for NA-10's established processes.

Lead Responsibility: Each ADA.

Deliverable: ADA self-assessment plans with NA-10 approval.

Due Date: January 12, 2007, self-assessment plans and annually thereafter.

Commitment 4.6.3: Establish and implement an appendix in the QAP for Independent Assessment.

Lead Responsibility: NA-11.

Deliverable: Appendix in the QAP.

Due Date: November 3, 2006, appendix in the QAP developed.

Due Date: April 6, 2007, appendix in the QAP implemented.

5.0 Organization and Management

Overall execution of this IP is the responsibility of the Assistant Deputy Administrator for Program Integration (NA-13). A responsible manager within NA-13 will be assigned to ensure individuals responsible for deliverables and commitments identified within this IP complete their actions. However, responsibility for implementing quality assurance and providing necessary resources rests with line management (NA-10, NA-11, NA-12, NA-15, and NA-16).

5.1 Change Control

Complex, long-range plans require sufficient flexibility to accommodate changes in commitments, actions, or completion dates that may be necessary due to additional information, improvements, or changes in baseline assumptions. Prior written notification to the Deputy Administrator for Defense Programs (NA-10) is required on the status of any IP commitment that will not be completed by the planned milestone date, and NA-10 will approve all revisions and bases for revisions to this IP.

Fundamental changes to the IP's strategy, scope, or schedule will be accomplished through formal revision and re-issuance of the IP. Other changes to the scope or schedule of planned commitments will be formally submitted in appropriate correspondence approved by NA-10, with the appropriate bases for change and corrective actions.

5.2 Reporting

To ensure all Assistant Deputy Administrators implementing the Quality Assurance Program remain informed of the status of plan implementation, progress reports will be provided every six months.

Commitment 5.2.1: The Assistant Deputy Administrator for Program Integration (NA-13) will brief the NA-10 Management Team on the status of completing actions identified in the IP.

Lead Responsibility: NA-13.

Deliverable: Briefings.

Due Date: May 9, 2006, and every six months thereafter until implementation of QAPIP activities is complete.

Table 1: Summary of Implementation Plan Commitments and Deliverables/Milestones

Number	Commitment	Deliverable	Due Date	Responsibility
1.	Commitment 4.1.1: Establish and implement a Communication Plan to support NA-10 implementation of a quality program.	Develop briefings to provide a general employee training to all NA-10 employees on the QAP and QAPIP, and carry out tabletop sessions with NA-10 organizations to obtain feedback on needed or existing processes and enlist specific support.	4/14/06	NA-13
2.	Commitment 4.1.2: Establish and implement a QAP appendix to specify the NA-10 Organizational Charters process. The organizational charters will define mission, functions, roles/responsibilities, internal and external interfaces, and structure at the Director's organization level.	QAP appendix and Organizational Charters	Appendix 6/16/06 Charters 9/8/06	Appendix NA-13 Charters ADAs
3.	Commitment 4.1.3: Establish and implement a QAP appendix to describe how NA-10 will monitor and maintain the quality requirements matrix and ensure a necessary and sufficient set of requirements for NA-10 HQ.	QAP appendix	Appendix 3/16/07 Implemented 6/15/07	Appendix NA-13 Implementation ADAs
4.	Commitment 4.1.4: Establish and implement a QAP appendix to define the NA-10 risk management process.	QAP appendix	Appendix 6/9/06 Implemented 9/15/06	Appendix NA-12 Implementation ADAs
5.	Commitment 4.1.5: Update the NA-10 Quality Assurance Program.	Update the NA-10 Quality Assurance Program	11/1/06 and at least annually thereafter.	NA-13

Number	Commitment	Deliverable	Due Date	Responsibility
6.	Commitment 4.2.1: Establish and implement a QAP appendix to define the NA-10 Training and Qualification process.	QAP appendix	Appendix 11/3/06 Implemented 6/8/07	Appendix NA-12 Implementation ADAs
7.	Commitment 4.2.2: Identify NA-10 positions needing specific qualification to be identified and define qualification requirements for all positions specified.	Listing of NA-10 Positions needing qualification and identification of applicable qualification standards	9/8/06	ADAs
8.	Commitment 4.3.1: Establish a QAP appendix expressing the Policy for Continuous Improvement and implement a Communication Plan across NA-10.	QAP appendix	Appendix 3/16/07 Implemented 6/15/07	Appendix NA-13 Implementation ADAs
9. 333	Commitment 4.3.2: Establish and implement a QAP appendix for Non-Conformance Reporting.	QAP appendix	Appendix 11/3/06 Implemented 3/9/07	Appendix NA-12 Implementation ADAs
10.	Commitment 4.3.3: Establish and implement a QAP appendix for Corrective/Preventive Action.	QAP appendix	Appendix 3/16/07 Implemented 6/15/07	Appendix NA-16 Implementation ADAs
11.	Commitment 4.3.4: Establish and implement a QAP appendix for Management Review.	QAP appendix	Appendix 11/3/06 Implemented 3/9/07	Appendix NA-11 Implementation ADAs
12.	Commitment 4.3.5: Establish and implement a QAP appendix for metric development and maintenance (QC-1 requirement).	QAP appendix	Appendix 7/7/06 Implemented 9/8/06	Appendix NA-12 Implementation ADAs
13.	Commitment 4.3.6: Establish and implement a QAP appendix for Lessons Learned.	QAP appendix	Appendix 3/6/07 Implemented 9/21/07	Appendix NA-16 Implementation ADAs

Number	Commitment	Deliverable	Due Date	Responsibility
14.	Commitment 4.3.7: Establish and implement a plan to fully develop ISM functions within the DP management system.	ISM Implementation Plan	Plan 1/12/07 Implemented 9/14/07	Plan NA-13 Implementation ADAs
15.	Commitment 4.4.1: Establish and implement a NA-10 procedure (BOP) for managing NA-10 BOPs.	NA-10 BOP	BOP 4/28/06 Implemented 7/21/06	BOP NA-13 Implementation ADAs
16.	Commitment 4.4.2: Develop and maintain an electronic document management system to make QAP documents available to all employees.	NA-10 electronic document management system	1/19/07	NA-11
17.	Commitment 4.5.1: NA-10 and each ADA will identify work processes to achieve NA-10 quality objectives and establish plans to develop, train and implement work processes that are specific to their organization or broadly applicable to NA-10 for the purpose of meeting QA criteria related to work processes, design, procurement, and inspection, testing and acceptance.	ADA Work Processes Implementation Plans	Plan 11/3/06 Implemented 9/7/07	ADAs
18.	Commitment 4.6.1: Establish and implement a QAP appendix for Self-Assessment.	QAP appendix	Appendix 11/3/06 Implemented 1/5/07	Appendix NA-15 Implementation ADAs
19.	Commitment 4.6.2: Establish and implement annual self-assessment plans for each ADA and for NA-10's established processes.	ADA self-assessment plans with NA-10 approval	1/12/07 and annually thereafter	ADAs
20.	Commitment 4.6.3: Establish and implement a QAP appendix for Independent Assessment.	QAP appendix	Appendix 11/3/06 Implemented 4/6/07	Appendix NA-11 Implementation ADAs

Number	Commitment	Deliverable	Due Date	Responsibility
21.	Commitment 5.2.1: The ADA for Program Integration will brief the NA-10 Management Team on the status of completing actions identified in the IP.	Briefings	5/9/06, and every six months thereafter until IP is implemented.	NA-13

Appendix A:

NA-10 Quality Assurance Program, Rev. 0, November 2005