DOE - EM - SRP - 2010
2nd Edition

Environmental Management

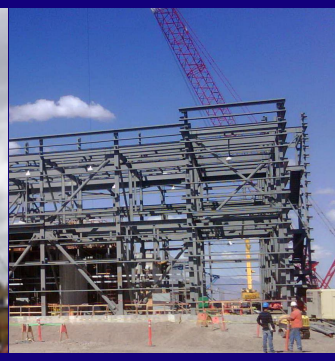
Safety ▪ Performance ▪ Cleanup ▪ Closure

Standard Review Plan (SRP)

Protocol for QAP/QIP Review







Corporate Critical Decision (CD) Review and Approval Framework Associated with Nuclear Facility Capital and Major Construction Projects

March 2010

Office of Environmental Management
U.S. Department of Energy
Washington D. C. 20585

EM Environmental Management

safety ❖ performance ❖ cleanup ❖ closure

Protocol for EM Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/ Quality Implementation Plans (QIPs)

February 2010

Office of Standards and Quality Assurance (EM-23)
Office of Environmental Management
U.S. Department of Energy
Washington D.C. 20585

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Protocol for EM-HQ Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)

1.1 Overview

The corporate priority in carrying out the Office of Environmental Management's (EM) diverse mission is to "do work safely and correctly." This mandate is more important today than it has ever been. The additional EM investments and resources made possible as the result of the American Recovery and Reinvestment Act (ARRA) have resulted in creation of thousands of new jobs. It has also made it possible for EM to accelerate completion of its mission.

The Office of Environmental Management issued its Corporate Quality Assurance Program (QAP), EM-QA-001, in November 2008. The EM Corporate Quality Assurance Program serves as the QA roadmap to ensure that EM mission gets accomplished safety, correctly, and efficiently.

Using a graded approach[1], each HQ and Field organization is required to prepare a Quality Assurance Implementation Plan (QIP) identifying procedures and documents that directly implement the applicable requirements of the QAP. The QIP is expected to demonstrate how the QAP requirements are being implemented. Appendix G of EM Corporate QAP presents an acceptable template for preparation of a site-specific Quality Assurance Implementation Plan.

The graded approach provides site management and project managers with the programmatic flexibility to develop and cost-effectively implement a project-specific QA program that best meets the needs, complexities, and anticipated risks associated with planned activities.

1.2 Purpose

The purpose of this document is to present the review protocol and lines of inquiry (LOIs) that are used as basis for EM-HQ technical review and approval of site-specific QAP/QIPs. This is intended to ensure EM-wide technical consistency, transparency, stability, and clarity of QA requirements and expectations in corporate review and decision making process.

The review protocol and lines of inquiry are based on governing Department of Energy (DOE) and EM specific quality assurance requirements and expectations. These include DOE O 414.1C, *Quality Assurance*; 10 CFR 830, Subpart A; *Quality Assurance Requirements*; ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications (QA)*; and EM Management Expectations

[1] Relative to Contractor-specific QAP/QIP, DOE O 414.1C, Attachment 2, Contractor Requirements Document (CRD), Paragraph2.a.1, states that: "*A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following. (1) Implements QA criteria as defined in paragraph 3 of this CRD, S/CI prevention requirements as defined in paragraph 4, and safety software as defined in paragraph 5, using a graded approach and describing how the QA criteria and graded approach are applied. See paragraph 2 of this CRD for guidance on compliance*"

The review protocol and LOIs are also designed to be used by EM Field Offices, sites, and projects to conduct internal self-assessment of effectiveness of their QAP/QIP development and implementation.

The following elaborates on the relationship between the EM QAP, DOE O 414.1C, and the QA Rule. *As stated in Section 7.0 of EM QAP, "EM QA Program," the EM HQ, EM Field/ Project Offices, and EM contractors shall prepare a site-specific QAP or adopt the EM QAP. Each organization shall prepare a QIP that demonstrates how the EM QAP requirements are met and implemented. EM segregated the QAP requirements contained in DOE O 414.1C and 10 CFR 830 Subpart A into "requirements" and "implementation." Nothing in this approach affects the contractor's legal liability to comply with 10 CFR 830.*

The EM QAP meets DOE O 414.1C and 10 CFR 830 Subpart A requirements in the following way:

- *EM Secretarial Officer (i.e., Program Secretarial Officer [PSO]) develops and provides an approved corporate QAP;*

- *DOE Field/Projects and/or their contractors can adopt this "approved" QAP and write a QIP describing how the EM QAP requirements will be implemented, and process the QIP for approval as described in EM QAP, Section 6.0; or*

- *DOE Field/Projects and/or their contractors can develop their own site-specific QAP describing how the requirements contained in the EM QAP are being met, develop a QIP describing how the site-specific QAP will be implemented, and submit the QAP and QIP for approval as described in EM QAP, Section 6.0; or*

- *If the site-specific QAP integrates both the EM QAP and QIP requirements, only a cover memo attached to the integrated site-specific QAP requesting approval per EM QAP Section 6.0 is required.*

1.3 EM-HQ Corporate Review Process

The EM-HQ review and approval of site-specific QAP/QIP consists of two distinct phases.

Phase 1 is focused on *Approval for Implementation of QAP/QIP*. Phase 2 is focused on *Verification and Validation (V&V) of QAP/QIP implementation.*

1.3.1 Phase 1: EM-HQ Approval for Implementation of QAP/QIP

The Phase 1 review consists of programmatic/desktop review of submitted QAP/QIP. It addresses the following key areas:

- Format and content
- Applicability and Scope
- Reasonableness of graded approach

Table 1 provides the review protocol that will be used to perform the Phase 1 review. The results of EM-HQ review can potentially fall into three (3) categories:

1. Approved—this category indicates that the submitted QAP/QIP is approved for implementation by the site.

2. Conditional Approval— this category indicates that the submitted QAP/QIP is approved for implementation by the site subject to specified areas that need to be strengthened or further clarified.

3. Needs Significant Revision—this category indicates that the submitted QAP/QIP is in need of significant upgrade and revision prior to being approved for implementation by the site.

It should be noted that Phase 1 review does not assess the implementation aspects of QAP/QIP including adequacy of the implementing procedures, effectiveness of program execution, or the degree to which QA is effectively graded, integrated and institutionalized at the site. These issues will be verified and validated as part of Phase 2 review.

1.3.2 Phase 2: EM-HQ Verification and Validation (V&V) of QAP/QIP Implementation

The Phase 2 review consists of onsite review of program implementation and addresses the following key areas:

- Adequacy of implementing procedures and processes; and

- Maturity and effectiveness of program implementation.

In addition to the above, Phase 2 onsite review process will examine the following:

- Status of issues identified as part of Phase 1 programmatic review of QAP/QIPs. The expectation is that by the time an onsite visit is scheduled, the site has fully addressed these issues.

- High priority and cross-cutting QA issues such as the adequacy of QA oversight associated with the ARRA projects, Commercial Grade Dedication (CGD), Code of Record, Suspect/Counterfeit Items (S/CI), Procurement, and flow down to subcontractors and Venders.

The lines of inquiry and protocol for the Phase 2 review are organized consistent with the ten program criterion listed in the EM Corporate QAP. Each criterion is based on the requirements of DOE O 414.1C; 10 CFR 830, Subpart A; NQA-1-2004; and EM Management Expectations. Specifically;

- Table 2 presents the LOIs for each of the 10 EM Corporate QAP Criteria.

- Table 3 presents the relationship between the EM QAP performance criterions to ASME NQA-1-2004 requirements.

- Table 3 provides supporting LOIs and performance expectations associated with the eighteen (18) ASME NQA-1 Part 1 Requirements and the Subpart 2.7 Requirement on Computer Software.

The LOIs presented in Tables 2 and 4 are consistent with the Quality Assurance Review Module of EM Standard Review Plan (SRP) that provides the technical framework to support Critical Decision (CD) Reviews associated with implementation of DOE O 413.3A, Change 1, *and Program and Project Management for the Acquisition of Capital Asset*.

The outcome of EM-HQ Phase 2 review falls into two (2) potential categories:

1. Satisfactory—this category indicates that EM-HQ V&V of implementation of the QIP found that the site QA program meets the intent and requirements of Corporate EM QAP as documented in its approved site-specific QAP/QIP.

2. Needs Improvement - this category indicates that EM-HQ V&V of the QIP found that the site QA program does not fully meet intent and requirements of Corporate EM QAP as documented in its approved site-specific QAP/QIP. Site must develop and implement corrective actions to address specific weaknesses identified as part of V&V.

1.4 Contact Information

For any assistance or more information regarding QAP/QIP, please contact Mr. Kriss Grisham, Office of Standards and Quality Assurance, EM-23, at Kriss.Grisham@em.doe.gov or (301) 903-8478.

For any assistance or more information regarding Phase 2 onsite reviews or self-assessments, please contact Mr. Robert Toro, office of Standards and Quality Assurance, EM-23, at Robert.Toro@em.doe.gov or (202) 586-3359.

Robert Murray, Acting Director
Office of Standards and Quality Assurance, EM-23
Robert.Murray@em.doe.gov
(202) 586-7267

Phase 1: EM-HQ Approval for Implementation of Quality Assurance Program/Implementation Plan (QAP/QIP)

Field/Site:

Organization(s)/Project(s):

Document Number/Rev/Date:

Lead Reviewer:

Table 1. Protocol for EM-HQ Phase 1 Review EM-HQ Approval for Implementation of QAP/QIP

Review Area	Comments
Review Area: Format and Content	
1. Did the site submit a separate Site-Specific Quality Assurance Plan (QAP)? *Note: If a site adopts the Corporate EM QAP, EM-QA-001, a separate Site Specific QAP is not required and the answer to this block will be NO.* *Note: Please cite the document title, revision, and date.*	
2. Did the site submit a Site-Specific Quality Assurance Implementation Plan (QIP) *Note: Please cite the document title, revision, and date.*	
3. Does the site-specific QIP address the content in the template provided in Attachment G of EM-QA-001?	
4. Did the site submit an integrated Site-Specific QAP/QIP? *Note: If the site-specific QAP integrates both the EM QAP and QIP requirements, only a cover memo attached to the integrated site-specific QAP requesting approval per EM QAP Section 6.0 is required.* *Note: Please cite the document title, revision, and date.*	
5. List any other documents/attachments submitted by the Site (e.g., additional documents to support the QIP, Variance Form, etc) *Note: Please cite the document title, revision, and date.*	

Review Area	Comments
Review Area: Applicability	
1. **Does the QAP and/or QIP adopt or state that it was developed to meet the requirements of Corporate EM-QAP consisting of NQA-1-2004; DOE O 414.1C/10 CFR 830, Subpart A; and Management Expectations?**	
2. Does the QAP/QIP reference the RW QARD and WIPP programs, for sites involved in TRU, SNF, and/or HLW? (i.e., site specific programs)	
3. Does the scope of QAP/QIP cover all EM mission related activities including activities funded by the American Recovery and Reinvestment Act (ARRA)?	
4. Is there a request or indication of exceptions and/or exemptions to the Corporate EM QAP? *If yes, is there a formal exception/exemption analysis included? (see EM-23 risk-informed exception/exemption request process)*	
Review Area: Reasonableness of Graded Approach	
1. Is the application of graded approach to develop the QAP/QIP reasonable relative to known site specific factors such as magnitude of hazards, complexity of work/mission, life-cycle of projects/facilities, and other programmatic considerations?[2] **2. Have appropriate sections of NQA-1 Part 2 been incorporated?**	

[2] Relative to Contractor-specific QAP/QIP, DOE O 414.1C, Attachment 2, Contractor Requirements Document (CRD), Paragraph 2.a.1, states that: "*A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following. (1) Implements QA criteria as defined in paragraph 3 of this CRD, S/CI prevention requirements as defined in paragraph 4, and safety software as defined in paragraph 5, using a graded approach and describing how the QA criteria and graded approach are applied. See paragraph 2 of this CRD for guidance on compliance*"

Outcome of Phase 1: EM-HQ Approval for Implementation of Quality Assurance Implementation Plan (QIP)

Field/Site:

Organization(s)/Project(s):

Document Number/Rev/Date:

Lead Reviewer:

Summary Comment/Observations:

Outcome of EM-HQ Phase 1 Review		
Name/Signature/Date of Lead EM-23 Review Staff	**Name/Signature/Date of Lead EM-23 Peer Review Staff**	
Approved Name/Signature/Date	**Conditional Approval Name/Signature/Date**	**Needs Significant Revision Name/Signature/Date**

Sample Memorandum

MEMORANDUM FOR [*Insert name*]
MANAGER
[*Insert Field Site/Project*]

FROM: DR. STEVEN L. KRAHN
DEPUTY ASSISTANT SECRETARY FOR
SAFETY AND SECURITY PROGRAM
ENVIRONMENTAL MANAGEMENT

SUBJECT: Environmental Management-Headquarters Review of [*Insert QAP/QIP Document Title and Date*]

The Office of Standards and Quality Assurance, EM-23, has reviewed the *[INSERT QAP/QIP Document Title and Date]*, consistent with the review process documented in *Protocol for EM-HQ Review/Field Self-Assessment of Site-Specific Quality Assurance Program (QAP) and Quality Assurance Implementation Plan (QIP),* dated February 2010**.**

The Office of Environmental Management (EM) *Corporate Quality Assurance Program (QAP),* EM-QA-001, requires each HQ and Field organization, using a graded approach, to prepare a Quality Assurance Implementation Plan (QIP) identifying procedures and documents that directly implement the applicable requirements of the QAP. The QIP will demonstrate how the QAP requirements are being implemented. Appendix G of EM Corporate QAP, EM-QA-001, presents an acceptable template for preparation of a QIP.

Based on the EM-23 staff review of the *[Insert QAP/QIP Document Title and Date]*, the document is [*Insert review outcome: Approved, Conditionally Approved**,** or Needs Significant Revision**]*.** A summary of the EM-HQ review results and any applicable comments are attached. If you have any questions, please contact me at (202) 586-5151, or have your staff contact Robert Murray at (202) 586-7267.

Attachment

cc:
D. Chung, EM-2
F. Marcinowski, EM-3
R. Murray, EM-23
K. Grisham, EM-23
L. Perkins, EM-23
M. Gilbertson, EM-50
[*Insert Site QA Manager*]

Phase 2: EM-HQ Verification and Validation (V&V) of QAP/QIP

Table 2. EM QAP QA Criteria and Lines of Inquiry (LOIs)

Criterion 1 – Program		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP describe the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work?	
	▪ Has the organization designated the senior management position responsible for the development and maintenance of the QAP/QIP?	
	▪ Are the senior managers listed in the Federal (and contractor) organizational charts responsible for assuring planning, scheduling, and providing adequate resources?	
	▪ Is there an explicit set of criteria used in applying a graded approach to the QAP/QIP? Do these criteria include meets to past quality performance?	
	▪ Does the QAP/QIP describe the relations of the roles and responsibilities, levels of authority, and interfaces in the organizational structures of both the Federal and contractor organizations that are explicitly addressed in a FRAM?	
	▪ Are senior management expectations for implementation defined and delineated?	
	▪ Are the requirements of ISM addressed and integrated into the QAP/QIP?	
	▪ Is the responsibility for integrating quality into work activities described for all workers?	
	▪ Does the QAP/QIP establish authority, direct access to management, organizational freedom, and access to work to perform their function for those personnel responsible for verifying quality achievement?	
	▪ Does the scope of QAP/QIP cover all EM mission related activities including activities funded by the American Recovery and Reinvestment Act (ARRA)?	

Criterion 1 – Program		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Are the responsibilities interface, and authority of each organization clearly defined when more than one organization is involved in the execution of activities?	
	Does the QAP/QIP describe the management processes including planning, scheduling, and providing resources for the work?	
	▪ Does the program address control over activities affecting quality to an extent consistent with their importance?	
	▪ Has the management established processes and procedures for project mission-related activities in a controlled manner?	
	▪ Are processes described to make employees aware of management expectations through initial indoctrination and periodic training?	
	Does the QAP/QIP define a process for grading the application of QA requirements for activities that identify consequences, requirements, and depth/extent/rigor necessary in application of those requirements?[3]	
	▪ Is the graded approach consistent with DOE O 414.1C, Section 4.a.(1) stating that each DOE organization must develop and implement a QAP that addresses QA criteria as defined in paragraph 4b using a graded approach and describing how the criteria and graded approach are applied?	
	▪ Does the QAP/QIP cite DOE G 414.1-2a, Section 4.1.3, that the grading process should be used to evaluate hazards or risks and to determine the appropriate controls to address those hazards or risks?	

[3] Relative to Contractor-specific QAP/QIP, DOE O 414.1C, Attachment 2, Contractor Requirements Document (CRD), Paragraph 2.a.1, states that: "*A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following. (1) Implements QA criteria as defined in paragraph 3 of this CRD, S/CI prevention requirements as defined in paragraph 4, and safety software as defined in paragraph 5, using a graded approach and describing how the QA criteria and graded approach are applied. See paragraph 2 of this CRD for guidance on compliance*"

Criterion 1 – Program		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP include Suspect/Counterfeit Items (S/CI) Prevention process commensurate with the facility/activity hazards and mission impact?	
	▪ Does the QAP/QIP apply to identifying and analyzing S/CIs, removing them, and preventing S/CIs from being supplied to DOE/[National Nuclear Security Administration]NNSA and its contractors per DOE O 414.1C, Attachment 3 (Contractor Requirements Document, Attachment 2, paragraph 4)?	
	▪ Are there specific work processes that are developed and implemented using available S/CI information per DOE O 414.1C, Attachment 3 (Contractor Requirements Document, Attachment 2, and Paragraph 4)?	
	Is the process for determining the quality requirements applicable to subcontractors/suppliers and passing those requirements down through contracts clearly defined? Is it applicable to all contracts?	
	Does the QAP/QIP address integrated Management system requirements as defined in DOE O 414.1C, the S/CI Prevention process (Attachment 3), the Corrective Action Management Program (Attachment 4), and Safety Software Quality Requirements (Attachment 5) with other quality or management system requirements in DOE directives and external requirements, including as applicable:	
	▪ DOE P 450.4, Safety Management System Policy;	
	▪ DOE P 226.1A, Department of Energy Oversight Policy;	
	▪ NNSA, Quality Management Policy, QC-1 (quality management system for the nuclear weapons complex and weapons-related activities);	
	▪ *DOE/RW-0333P DOE Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description; and*	

Criterion 1 – Program		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ *DOE/CBFO-94-1012, DOE Carlsbad Field Office, Quality Assurance Program Description, (for the Waste Isolation Pilot Plant and related activities)?*	
	Is the QAP/QIP developed and maintained using the guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 1 on Organization?	
	▪ Requirement 2 on Quality Assurance Program?	

Criterion 2 – Personnel Training and Qualification		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP identify the methodology for establishing requirements *to train and qualify personnel so that they are capable of performing their assigned work?*	
	▪ Is there a process to ensure that indoctrination and training commensurate with scope, complexity, importance of the activities, education, experience, and proficiency of the person?	
	▪ Is there a process for initial indoctrination and training of new hires?	
	Is there evidence that the organization has an established and documented training plan *in providing continuing training to personnel to maintain job proficiency?*	
	Is there a process in place to ensure that adequate resources been identified to support the selection, training, and qualification of personnel conducting work?	
	Does the training and qualification program describe the positions and functions to which it applies?	
	Is there a process in place to ensure employee-specific training needs are documented and updated as required to ensure the maintenance of competencies required by the position?	
	Is a specific organizational member responsible for operating the technical qualification program?	
	Are there provisions in the training program for further enhancement of employee skills beyond minimum requirements through independent reading or off-site training?	
	Are positions with specialized certification of skills identified, with responsibilities for achieving certification assigned?	

Criterion 2 – Personnel Training and Qualification		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Are processes in place to ensure that there is sufficient redundancy of personnel with critical skills to allow the organization's mission to be accomplished during occasional absences due to vacations and sick leave?	
	Is there a list of all skills, competencies, and personnel certifications needed for each position within the organization?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: • **Requirement 2 on Quality Assurance Program?** ***(see Table 4 for relevant NQA-1 lines of inquiry)***	

Criterion 3 – Quality Improvement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that the organization has *established, implemented, and documented processes to detect and prevent any conditions adverse to quality?*	
	▪ Do work processes and procedures call for identification and reporting of quality problems?	
	▪ Does senior management policy encourage problem detection and prevention?	
	▪ Are there processes for communicating lessons leaned and performance information?	
	▪ Is there a method for categorizing the significance of quality problems?	
	▪ Is there a requirement for management to set performance goals and standards?	
	▪ Is there a process for management to establish metrics that monitor performance to identify processes needing improvement?	
	▪ Are goals and standards set by management required to be communicated to those responsible for meeting them, and is there a process for this communication?	
	▪ Is there a process for measuring and documenting quality performance to identify items, services and processes capable of improvement?	
	Does the QAP/QIP *establish an approach to identify, control, and correct items, services, and processes that do not meet established requirements* adequately described?	
	▪ Does this approach include the requisite discipline involvement to adequately evaluate and disposition the nonconforming item, service, or process?	
	▪ Does this approach address the identification and control of nonconforming items such that is prevents inadvertent use consistent with DOE G 414.1-3?	
	▪ Does the QAP/QIP address documentation and correction of quality problems associated with services and processes?	

Criterion 3 – Quality Improvement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Is there a procedure for removing defective or suspect equipment and materials from the workplace to prevent inadvertent use with assigned responsibilities?	
	▪ Are personnel injuries, equipment failures, and other off-normal events included in the quality problem process?	
	Does the QAP/QIP provide *for the identification of the causes of conditions adverse to quality and work to pre vent recurrence as part of correcting the problem*?	
	▪ Are corrective/preventive actions developed and implemented for problems/findings related to item characteristics, process implementation, or services?	
	▪ Are managers assigned responsibility for determining root causes of problems, where these problems are of sufficient severity (see DOE G 231.1-2), and pursuing a search for all occurrences related to the problem (extent of condition)?	
	▪ Are deficiencies identified as “significant" (as defined in NQA-1) documented, extent of conditions identified, and corrective/preventative actions implementation verified?	
	▪ Are completed corrective/preventative actions independently verified for implementation and closure?	
	Does the QAP/QIP describe methods for addressing cause, extent, and remedial and preventative actions for quality problems?	
	Is a process identified to *review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement?*	
	▪ Is there a quality performance analysis system?	
	▪ Does the performance analysis system provide a mechanism for feedback to affected and related entities in the organization?	

Criterion 3 – Quality Improvement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 2 on Quality Assurance Program?	
	▪ Requirement 15 on Control of Nonconforming Items?	
	▪ Requirement 16 on Corrective Action?	

Criterion 4 - Documents and Records		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that the organization has a document control system to *prepare, review, approve issue, use and revise documents to prescribe processes, specify requirements, or establish design*?	
	▪ Do approved documents, such as procedures, describe key functions relating to quality criterion?	
	▪ Do documents prescribe internal processes as well as processes to oversee contractors and suppliers?	
	▪ Are policies, procedures, and plans maintained current and deployed in a manner that makes the documents readily available to users?	
	▪ Do procedures identify records that need to be created and maintained?	
	Does the QAP/QIP address how the organization *specifies, prepares reviews, approves, and maintains records*?	
	▪ Are new or revised requirements analyzed to determine impact on implementing procedures and/or contracts?	

Criterion 4 - Documents and Records		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Are policies, procedures, and plans maintained current and deployed in a manner that makes the documents readily available to the users?	
	▪ Are procedures developed for identifying records that need to be created and maintained?	
	▪ Are records maintained until they are transferred to permanent storage?	
	▪ Are records transferred to permanent storage in a timely manner when they are no longer needed by the organization?	
	▪ Is there an assigned responsibility for electronic records management?	
	▪ Is there an assigned responsibility for creating and implementing a disaster recovery plan?	
	▪ Are there established locations for maintaining records, and documents, and a system for searching and retrieving data from them?	
	▪ Is there an established set of criteria for classifying documents and records to establish which must be duplicated to assure preservation and which may be transferred to permanent storage or destroyed after set periods of time?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 5 on Instructions, Procedures and Drawings?	
	▪ Requirement 6 on Document Control?	
	▪ Requirement 17 on Quality Assurance Records?	

Criterion 5 - Work Processes		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP provide a method for ensuring work that *is performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.?*	
	▪ Are the core functions and guiding principles of the DOE ISMS addressed?	
	▪ Do the approved documents meet regulatory or contract requirements?	
	▪ Are management processes that are routinely performed incorporated in the QAP/QIP?	
	Does the QAP/QIP *provide methods to identify and control items to ensure their proper use*?	
	▪ Is the process consistent with DOE G 414.1-3 for suspect/counterfeit items?	
	▪ Are there documented procedures and assigned personnel dedicated to the generation, revision, review and approval of instructions and work processes?	
	▪ Are there documented procedures for periodic inventory surveys and inspections to ensure work items are controlled and used properly?	
	▪ Is there an assigned responsibility for maintaining and executing emergency management plans?	
	Is there a method to *maintain items to prevent their damage, loss, or deterioration adequately described?*	
	▪ Does the method address the requirements of DOE O 433.1?	
	Does the QAP/QIP describe an adequate *calibration and maintenance system for equipment used for process monitoring or data collection?*	
	Does the process for development, use, control, and oversight of software include elements that are consistent with those described in the DOE Directives and NQA-1?	

Criterion 5 - Work Processes		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Is safety software managed and controlled in accordance with the requirements of DOE 414.1C, Attachment 2, section 5 (EM Contractors) and Attachment 5 (EM HQ and EM Field/Project offices)	
	▪ Are non-safety, quality-related software for nuclear facility or EM mission critical applications managed and controlled in accordance with the requirements of NQA-1-2004 Part II, Subpart 2.7, and "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications"?	
	▪ Do safety and quality-related software have the appropriate controls in place as required by DOE O 414.1C and NQA-1 2004, even if it is off-the-shelf?	
	Are procedures adequately developed, controlled and executed by employees?	
	▪ Do documents clearly establish the roles and responsibilities for employees?	
	▪ Do employees follow approved processes written to accomplish the EM mission, meeting regulatory and contract requirements when performing assigned tasks?	
	▪ Do employees identify and assist in making changes that improve project processes and documents?	
	Are resources assigned and scheduled established for the maintenance and calibration of equipment used to monitor work processes or data collection?	
	Are managers responsible for collecting and analyzing worker suggestions for improvements?	
	Is there an assigned responsibility for cyber security?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 5 on Instructions, Procedures, and Drawings?	
	▪ Requirement 8 on Identification and Control of Items?	

Criterion 5 - Work Processes		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Requirement 9 on Control of Special Processes?	
	▪ Requirement 12 on Control of Measuring and Test Equipment?	
	▪ Requirement 13 on Handling, Storage, and Shipping?	
	▪ Requirement 14 on Inspection, Test and Operating Status?	

Criterion 6 - Design		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that the design inputs correctly translated into design documents in a timely manner?	
	▪ *Has the design been developed using sound engineering/scientific principles and appropriate standards?*	
	▪ Is the design *incorporates applicable requirements and design bases*?	
	▪ Does the design provide for appropriate acceptance, inspection, testing, and maintenance criteria to ensure continuing reliability and safety of the items? (DOE G 414.1-2A)	
	▪ Are the design inputs specified to the level of detail necessary to permit design activities to be correctly carried out and to provide a consistent basis for making design decisions, accomplishing design verification activities, and evaluating design changes?	
	▪ *Are applicable requirements and design bases incorporated in design work and design changes?*	
	Are the changes to design controlled in a manner commensurate with the original design?	
	▪ Are the design and specification changes, including field changes, subject to the same design controls that were applicable to the original design?	
	Is there a verification and validation process for the design?	
	▪ Is there a process to define the responsibilities of personnel verifying the design, the areas and features that require design verification, the pertinent considerations to be verified, and the extent of documentation required to document verification?	

Criterion 6 - Design		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Are the guidelines or criteria established and described for determining the method of design verification (design review, alternate calculations, or tests)?	
	▪ *Have the design products been verified or validated by individuals or groups other than those who performed the design work?*	
	▪ *Has the design been verified or validated before approval and implementation of the design*? (DS-3.4)	
	Are the *design control interfaces identified and controlled?*	
	Does the QAP/QIP specify that independent design reviews shall be implemented?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 3 for relevant NQA-1 lines of inquiry)***	
	▪ *Requirement 3 on Design Control?*	
	▪ *Part II, Subpart 2.7 on Computer Software for Nuclear Facility Applications?*	

Criterion 7 - Procurement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify a documented procedures for Acquisition Planning, Vendor Surveys, Bid Evaluations, Contractor Oversight, Contract Administration, Source Evaluation and establishing requirements to be met by approved suppliers (integrated acquisition strategy), and is there an assigned responsibility for the oversight of these procedures?	
	Does the QAP/QIP specify that appropriate personnel assigned the responsibility of creating and maintaining an approved supplier list?	
	Does the QAP/QIP specify an explicit delegation of procurement authorities to specific employees?	
	Does the QAP/QIP specify an assigned responsibility for monitoring and oversight of contractor performance, including activities funded by the Americal Recovery and Reinvestment Act (ARRA) funds, with sufficient authority to assure correction of deficiencies?	
	▪ Does the QAP/QIP specify that oversight shall focus on verifying that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished?	
	Does the QAP/QIP specify how the requirements for the procurement of items and services are established, including provisions for Commercial Grade Dedication GDC) items?	
	▪ *Does the process ensure that items and services procured meet established requirements and perform as specified?*	
	Are procurement document changes managed and controlled at the same level as the original?	
	▪ Does this process require design authority approval of changes to their requirements?	

Criterion 7 - Procurement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Is there a system to evaluate and select prospective suppliers based on specified criteria?	
	Is there a system for identification of potential suspect/counterfeit items (S/CI) and prevention of their procurement is developed and implemented in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program?	
	▪ Does the organization have standard contract clauses for this purpose?	
	Is supplier documentation managed and controlled?	
	Does QAP/QIP address how established processes ensure that approved suppliers continue to provide acceptable items (including Commercial Grade Dedication) and services established and implemented?	
	▪ Is it graded to ensure safety-related items and mission critical items are subject to more rigorous methods?	
	▪ Does oversight focus on verifying that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished?	
	▪ Are government-furnished services/items (GFS/I) provided according to contract provisions?	
	Does the QAP/QIP have a defined process to ensure that procured items and services meet established requirements and perform as specified?	
	Does the QAP/QIP define a software quality assurance process that is implemented and executed in accordance with the Corporate DOE Office of Environmental Management Quality Assurance Program?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	

Criterion 7 - Procurement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Requirement 4 on Procurement Document Control?	
	▪ Requirement 7 on Control of Purchased Items and Services?	

Criterion 8 - Inspection and Acceptance Testing		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP include a clear statement of specifications to be met by procured items, and are the qualifications of those able to develop those specifications described?	
	Does the QAP/QIP specify that personnel assigned to receive deliveries have the training and resources necessary to assure that the delivered items meet specifications? These include products and services provided under the ARRA funds.	
	Is there an assigned responsibility for assuring that Federal personnel involved in contractor oversight have the data, equipment and skills needed to assess contractor performance?	
	Does the QAP/QIP specify the process used to conduct inspections and tests to verify the physical and functional aspects of items, services, and processes to meet performance criteria and that systems and components are fit for use and acceptable? These include Commercial Grade Dedication items.	
	Does the QAP/QIP specify an oversight or assessment process of the contractor's program to ensure acceptability of work or items related to inspection and testing?	
	Does the QAP/QIP specify how inspections and tests specified for items, services, and processes should be performed?	
	▪ How are acceptance and performance criteria established and used?	
	Are inspection and acceptance tests planned and controlled consistent with DOE G 414.1-3?	
	Is there a system for documenting the results of inspections and tests?	
	▪ Are the procedures that address the inspection and testing process identified in the project QIP? (IT-3.1)	

Criterion 8 - Inspection and Acceptance Testing		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Is inspection and test equipment controlled by a process to ensure it is calibrated and maintained?	
	Does the contractor conduct inspections and tests to verify the physical and functional aspects of items, services, and processes to meet requirements and that systems and components are fit for use and acceptable?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 8 on Identification and Control of Items?	
	▪ Requirement 10 on Inspection?	
	▪ Requirement 11 on Test Control?	
	▪ Requirement 12 on Control of Measuring and Test Equipment?	
	▪ Requirement 14 on Inspection, Test and Operating Status?	

Criterion 9 - Management Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP describe how managers, at all levels, assess their management processes?	
	▪ *Are the management processes assessed to identify and correct problems that hinder the organization from achieving its objectives?*	
	▪ Are management assessments one of the means for identifying areas needing correction and/or improvement?	
	▪ Are management assessments performed by managers knowledgeable in the subject area and trained in assessment techniques?	
	▪ Do the assessments address their organization's performance with regards to such things as safety, quality, mission completion and performance against technical and financial goals and objectives?	
	▪ Are specific managers assigned the responsibility of recording, tracking and analyzing operating experience?	
	▪ Are the responsibilities for conducting a program of lessons learned and implementing its recommendations assigned?	
	▪ Are the responsibilities for scheduling and documenting assessments assigned?	
	▪ Are managers responsible for providing written procedures for assessments and for developing measures of performance?	
	Does the QAP/QIP provide for the identification and correction of problems that hinder the organization from achieving its objectives?	
	▪ Are results of management assessments documented and deficiencies tracked with corrective actions taken until corrective actions have been completed and verified?	
	Do managers take responsibility for, and directly participate in the assessments?	

Criterion 9 - Management Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the project Management Assessment process implement the intent, focus and concepts described in DOE Guide, G 414.1-1B, Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A, and DOE O 414.1C, Quality Assurance; DOE M 450.4-1, Integrated Safety Management System Manual; and DOE O 226.1A, Implementation of Department of Energy Oversight Policy?	
	Does management consolidate the Integrated Safety Management System (ISMS) and QA annual validation and declaration activities?	
	Does the QAP/QIP specify that senior management should be informed of the assessment results and engaged in ensuring responsible management response to identified issues?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 2 on Quality Assurance Program?	
	▪ Requirement 18 on Audits?	

Criterion 10 - Independent Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify an independent assessment process?	
	▪ Does the QAP/QIP specify that guidance provided in DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*, should be used to develop independent assessment strategy?	
	▪ Does the independent assessment process constitute a comprehensive plan and schedule to independently assess and conduct audits of reporting organizations against technical, programmatic, administrative and quality program requirements?	
	***Are independent assessments planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement*?**	
	***Does the group performing independent assessments have sufficient authority and freedom from line management*?**	
	***Are the personnel conducting independent assessments technically qualified and/or knowledgeable in the areas being assessed* including lead auditors qualified in accordance with NQA-1?**	
	Is there a process to obtain independent technical and subject matter experts for assessments when they are not available in the organization?	
	Independent assessment implements the intent, focus and concepts, described in DOE Guide 414.1-1B, Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A, and DOE O 414.1C, Quality Assurance; DOE M 450.4-1, Integrated Safety Management System Manual; and DOE O 226.1A, Implementation of Department of Energy Oversight Policy and DOE O 414.1C	

Criterion 10 - Independent Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Is there a system for reporting assessment results to responsible management, and for them to assure that action has been taken place to correct identified issues and that they will be tracked to completion/verification?	
	▪ Are deficiencies identified as "significant (as defined in NQA-1) documented, extent of conditions identified, and corrective/preventative actions implementation verified? (IA-6.1)	
	Does the QAP/QIP meet the requirements of ASME NQA-1 for: ***(see Table 4 for relevant NQA-1 lines of inquiry)***	
	▪ Requirement 1 on Organization?	
	▪ Requirement 2 on Quality Assurance Program?	
	▪ Requirement 10 on Inspection?	
	▪ Requirement 11 on Test Control?	
	▪ Requirement 15 on Control of Nonconforming Items?	
	▪ Requirement 16 on Corrective Action?	
	▪ Requirement 18 on Audits?	

Table 3. The Relationship between the EM QAP Performance Criterions to NQA-1-2004 Requirements

DOE O 414.1C		ASME NQA-1		
Performance Criterion		**Requirement Number and Title**		**LOI ID**
1	Program	1 2	Organization Quality Assurance Program	ORG QAP
2	Personnel Training & Qualification	2	Quality Assurance Program	QAP
3	Quality Improvement	2 15 16	Quality Assurance Program Control of Nonconforming Items Corrective Action	QAP NCI COR
4	Documents & Records	5 6 17	Instructions, Procedures & Drawings Document Control Quality Assurance Records	IPD DOC QAR
5	Work Processes	5 8 9 10 12 13 14	Instructions, Procedures & Drawings Identification & Control of Items Control of Special Processes Inspection Control of Measuring & Test Equipment Handling, Storage and Shipping Inspection, Test & Operating Status	IPD ICI CSP INS MTE HSS ITO
6	Design	3	Design Control	DSN
7	Procurement	4 7	Procurement Document Control Control of Purchased Items & Services	PDC PUR
8	Inspection & Acceptance Testing	8 10 11 12 14 15	Identification & Control of Items Inspection Test Control Control of Measuring & Test Equipment Inspection, Test & Operating Status Control of Nonconforming Items	ICI INS TST MTE ITO CNI
9	Management Assessment	2 18	Quality Assurance Program Audits	QAP AUD
10	Independent Assessment	1 2 10 11 15 16	Organization Quality Assurance Program Inspection Test Control Control of Nonconforming Items Corrective Action	ORG QAP INS TST NCI COR

DOE O 414.1C		ASME NQA-1		
Performance Criterion		**Requirement Number and Title**		**LOI ID**
		18	Audits	AUD
	Safety Software Quality Requirements	Sub part 2.7	QA Requirements for Computer Software for Nuclear Facility Applications	SQA

Table 4. ASME NQA-1-2004 Requirements and Lines of Inquiry

NQA-1 Requirement 1 - Organization	
ID #	**Lines of Inquiry**
NQA-1/ ORG-1	Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority and lines of communications for activities affecting quality shall be documented.
NQA-1/ ORG-2	The organizational structure and responsibility assignments shall be such that: (a) Senior management establishes overall expectations for effective implementation of the quality assurance program and is responsibility for obtaining the desired end result; (b) Quality is achieved and maintained by those assigned responsibility for performing work; (c) Quality achievement is verified by those not directly responsible for performing the work; and (d) Those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations.
NQA-1/ ORG-3	The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefore.
NQA-1/ ORG-4	Where more than one organization involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.
NQA-1/ ORG-5	The external interfaces between organizations and the internal interfaces between organizational units, and changes there too, shall be documented.

NQA-1 Requirement 2 - Program	
ID #	**Lines of Inquiry**
NQA-1/ PRG-1	A documented quality assurance program shall be planned, implemented, and maintained in accordance with this part (Part 1), or portions thereof.
NQA-1/ PRG-2	The program shall provide control over activities affecting quality to an extent consistent with their importance.
NQA-1/ PRG-3	The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactory and shall be established at the earliest time consistent with the schedule for accomplishing the activities.
NQA-1/ PRG-4	The program shall provide for planning and accomplishment of activities affecting quality under suitable controlled conditions.
NQA-1/ PRG-5	The controlled conditions shall include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied.
NQA-1/ PRG-6	The program shall provide for any special controls, process, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality.
NQA-1/ PRG-7	The organization shall establish and implement processes to detect and correct quality problems.
NQA-1/ PRG-8	The program shall provide for indoctrination and training, and qualification as necessary of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.
NQA-1/ PRG-9	Management shall regularly assess the adequacy and effective implementation of the quality assurance program.
NQA-1/ PRG-10	Indoctrination and training shall be commensurate with scope, complexity, important of the activities, and education, experience, and proficiency of the person.
NQA-1/ PRG-11	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.
NQA-1/ PRG-12	The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods or job responsibilities.
NQA-1/ PRG-13	The responsible organization shall designate those activities that require qualification of personnel and the minimum requirements for such personnel.

NQA-1 Requirement 2 - Program	
ID #	**Lines of Inquiry**
NQA-1/ PRG-14	The responsible organization shall establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform these activities.
NQA-1/ PRG-15	This section specifies requirements for the qualification of RT, MP, UT, PT, ET, NR, LT, AE, and VT personnel to verify conformance to the specified requirements.
NQA-1/ PRG-16	The American Society of Nondestructive Testing (ASNT) Recommended Practices or Standards provide acceptable qualification requirements for NDE Personnel. Applicable Codes and Standards or design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement.
NQA-1/ PRG-17	The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.
NQA-1/ PRG-18	The job performance of inspection and test personnel shall be reevaluated at periodic interval not exceed 3 years and reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of Section 200 of this Requirement.
NQA-1/ PRG-19	If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated.
NQA-1/ PRG-20	Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated.
NQA-1/ PRG-21	The Lead Auditor organizes and directs audits; reports audit findings, and evaluate corrective action.
NQA-1/ PRG-22	The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

NQA-1 Requirement 2 - Program	
ID #	**Lines of Inquiry**
NQA-1/ PRG-23	Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including: (a) Knowledge and understanding of this standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable; (b) General structure of quality assurance programs as a whole and applicable elements as defined in this Standard; (c) Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out of audit findings; (d) Planning audits of activities affecting quality; and (e) On-the-job training to include applicable elements of the audit program.
NQA-1/ PRG-24	Prospective Lead Auditors shall participate in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to date of qualification; one audit of which shall be a nuclear quality assurance audit within the year prior to qualification.
NQA-1/ PRG-25	Prospective Lead Auditors shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.
NQA-1/ PRG-26	Lead Auditors shall maintain their proficiency through one or more of the following: • regular and active participation in the audit process; • review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; and • or participation in training program(s).
NQA-1/ PRG-27	Based on annual assessment, management may extend the qualification, require retraining, or require requalification.
NQA-1/ PRG-28	Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with para.303.2 of this Requirement, reexamination in accordance with para.303.4 of this Requirement and participation as an Auditor in a at least one nuclear quality assurance audit.

NQA-1 Requirement 2 - Program	
ID #	**Lines of Inquiry**
NQA-1/ PRG-29	Auditors are participants in an audit. Auditors shall have or be given appropriate training and orientation to develop their competence for performing audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods: (a) Orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting issues; (b) General and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of qualify auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings; or (c) On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor and such training shall include planning, performing, reporting, and follow up action involved in conducting audits.
NQA-1/ PRG-30	The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish auditing of quality assurance programs.
NQA-1/ PRG-31	The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information: 1. Employer's name; 2. Identification of person being certified; 3. Activities certified to perform; 4. Basis of qualification (education experience, indoctrination and training; test results where applicable; capability demonstration results); 5. Results of periodic evaluation; 6. Results of physical examination, when required; 7. Signature of employer's designate representative who is responsible for certification; and 8. Date of certification or recertification and certification expiration.
NQA-1/ PRG-32	The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.
NQA-1/ PRG-33	Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records and are records of qualification, including requalification for auditors and Lead Auditors and for inspection and test personnel shall be established and maintain by the employer and for indoctrination and training.

ID#	NQA-1 Requirement 3 - Design Control Lines of Inquiry
NQA-1/ DSN-1	The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.
NQA-1/ DSN-2	Design documents shall support facility design, construction, and operation.
NQA-1/ DSN-3	Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.
NQA-1/ DSN-4	The design methods, materials, parts, equipment and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.
NQA-1/ DSN-5	Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.
NQA-1/ DSN-6	The final design shall: (1) Be relatable to the design input by documentation in sufficient detail to permit design verification; (2) Specify required inspections and tests and include or reference appropriate acceptance criteria; and (3) Identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.
NQA-1/ DSN-7	Characteristics to be verified are those which provide reasonable assurance that the item will perform its intended function. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirement that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.
NQA-1/ DSN-8	Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.
NQA-1/ DSN-9	To the extent required in paragraphs 401(a) and (b) of this Requirement, computer program acceptability shall be pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs shall be controlled in accordance with the requirements of these Standards.
NQA-1/ DSN-10	The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
NQA-1/ DSN-11	The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

ID#	NQA-1 Requirement 3 - Design Control Lines of Inquiry
NQA-1/ DSN-12	Documentation of design analyses shall include: (a) The objective of the analysis; (b) The design inputs and their sources; (c) Results of literature searches or other applicable background data; (d) Assumptions and indication of those assumptions that must be verified as the design proceeds; (e) Identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to specific physical problem, and (f) Review and approval.
NQA-1/ DSN-13	The responsible design organization shall identify and document the particular design verification method(s) used.
NQA-1/ DSN-14	The results of the design verification shall be document with the identification of the verifier clearly indicated.
NQA-1/ DSN-15	Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization.
NQA-1/ DSN-16	Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled.
NQA-1/ DSN-17	In all cases, the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.
NQA-1/ DSN-18	If the design is modified to resolve verification findings, the modified design shall be verified prior to release for use.
NQA-1/ DSN-19	The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs.
NQA-1/ DSN-20	Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.
NQA-1/ DSN-21	Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable the following: (a) Were design inputs correctly selected? (b) Are assumptions necessary to perform the design activity adequately described and reasonable, where necessary, are the assumptions identified for subsequent re-verifications when detailed design activities are completed? (c) Were appropriate design methods and computer programs used? (d) Were the design inputs correctly incorporated in to the design? (e) Is the design output reasonable compared to the design inputs? (f) Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions?

ID#	NQA-1 Requirement 3 - Design Control Lines of Inquiry
	(g) Have suitable materials, parts, processes, and inspection testing criteria been specified?
NQA-1/ DSN-22	Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program, its associated computer hardware and system software, or other calculation methods shall also be reviewed.
NQA-1/ DSN-23	Qualification testing shall demonstrate adequacy of performance under condition that stimulate the most adverse design conditions.
NQA-1/ DSN-24	Change control shall be handled in accordance with the following: (a) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design. (b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. (c) Where a signification design change is necessary because of an incorrect design, the design process and verification procedure shall be review and modified as necessary.
NQA-1/ DSN-25	Procedures implementation configuration management requirements shall be documented at the earliest practical time prior to facility operation.
NQA-1/ DSN-26	These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing and procurement.
NQA-1/ DSN-26	Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.
NQA-1/ DSN-28	The configuration shall be established and approved at the earliest time practical prior time to initial operation.
NQA-1/ DSN-29	The configuration shall be established and approved at the earliest time practical prior time to initial operation of the facility and maintained for the life of the facility.
NQA-1/ DSN-30	The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements and other applicable sources.
NQA-1/ DSN-31	Interface controls shall include the integration of activities of organizations that can affect the approved configuration.
NQA-1/ DSN-32	Documentation shall identify the design bases and the approved configuration for the approved modes of operation.
NQA-1/ DSN-33	Measures shall be established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design basis.

ID#	NQA-1 Requirement 3 - Design Control Lines of Inquiry
NQA-1/ DSN-34	The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.
NQA-1/ DSN-35	Approval by the design authority shall be required prior to implementation of a change to the design bases.
NQA-1/ DSN-36	The configuration of the facility shall be documented in drawings, specifications, procedures and other documents which reflect the operational status of the facility.
NQA-1/ DSN-37	The process utilized to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of the operation.
NQA-1/ DSN-38	Design information transmitted across interfaces shall identify the status of the design information or documents provided, and identify incomplete items which require further evaluation, review or approval.
NQA-1/ DSN-39	Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.
NQA-1/ DSN-40	The software design process shall be documented, approved by the responsible design organization, and controlled.
NQA-1/ DSN-41	Software design requirements shall be identified and documented and their selection reviewed and approved.
NQA-1/ DSN-42	Software design requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.
NQA-1/ DSN-43	The software design shall be documented and shall define the computational sequence necessary to meet the software requirements.
NQA-1/ DSN-44	The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures and the applicable relationships between data structures and process structures.
NQA-1/ DSN-45	The software design shall be translated into computer program(s) using the programming organization's or design organization's programming standards and conventions.
NQA-1/ DSN-46	Software design verification shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. The results of verification shall be documented with the identification of the verifier indicated.
NQA-1/ DSN-47	The results of verification shall be documented with the identification of the verifier indicated.
NQA-1/ DSN-48	Software verification methods shall include any one or a combination of design reviews, alternate calculations and tests performed during computer program development. The extent of verification and the methods chosen are a function of: (a) the complexity of the software; (b) the degree of standardization; (c) the similarity with previously proved software; and (d) the importance to safety.

ID#	NQA-1 Requirement 3 - Design Control Lines of Inquiry
NQA-1/ DSN-49	Computer program testing shall be performed and accomplished in accordance with Requirement 11.
NQA-1/ DSN-50	Software configuration management includes, but is not limited to, configuration identification, change control, and status control.
NQA-1/ DSN-51	Configuration items shall be maintained under configuration management until the software is retired
NQA-1/ DSN-52	A software baseline shall be established at the completion of each activity of the software design process.
NQA-1/ DSN-53	Approved changes created subsequent to a baseline shall be added to the baseline.
NQA-1/ DSN-54	A baseline shall define the most recently approved software configuration.
NQA-1/ DSN-55	A labeling system for configuration items shall be implemented that: (a) uniquely identifies each configuration item; (b) identifies changes to configuration items by revision; and (c) provides the ability to uniquely identify each configuration of the revised software available for use.
NQA-1/ DSN-56	Changes to software shall be formally documented to include: (a) a description of the change; (b) the rationale for the change; and (c) the identification of affected software baselines.
NQA-1/ DSN-57	The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes.
NQA-1/ DSN-58	Only authorized changes shall be made to software baselines.
NQA-1/ DSN-59	Changes to software shall be formally documented to include: (d) a description of the change; (e) the rationale for the change; and (f) the identification of affected software baselines.
NQA-1/ DSN-60	The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes.
NQA-1/ DSN-61	Only authorized changes shall be made to software baselines.
NQA-1/ DSN-62	Appropriate verification activities shall be performed for the change.
NQA-1/ DSN-63	The change shall be appropriately reflected in documentation and traceability of the change to the software design requirement shall be maintained.
NQA-1/ DSN-64	Appropriate acceptance testing shall be performed for the change.
NQA-1/ DSN-65	The status of configuration items resulting from software design shall be maintained current. Configuration item changes shall be controlled until they are incorporated into the approved product baseline.

ID#	NQA-1 Requirement 3 - Design Control Lines of Inquiry
NQA-1/ DSN-66	The control shall include a process for maintaining the status of changes which are proposed and approved, but not implemented.
NQA-1/ DSN-67	The controls shall also provide for notification of this information to affected organizations.
NQA-1/ DSN-68	Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents; but also documentation which identifies the important steps in the design process, including sources of design inputs that support the final design.

ID#	NQA-1 Requirement 4 -- Procurement Document Control Lines of Inquiry
NQA-1/ PD-1	Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.
NQA-1/ PD-2	To the extent necessary, procurement documents shall require suppliers to have a quality assurance program consistent with the applicable requirements of this standard.
NQA-1/ PD-3	Procurement documents issues at all tiers of procurement shall include provisions for the following as deemed necessary by the purchaser.
NQA-1/ PD-4	Procurement documents shall include a statement of the scope of the work to be performed by the supplier
NQA-1/ PD-5	Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures or instructions, including revisions thereto that describe the items or services to be furnished.
NQA-1/ PD-6	The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.
NQA-1/ PD-7	Quality assurance program requirements shall be specified in the procurement documents.
NQA-1/ PD-8	These requirements shall be consistent with importance and/or complexity of the item or service being procured.
NQA-1/ PD-9	The procurement documents shall require the supplier to incorporate appropriate quality assurance program requirements in sub tier procurement documents.
NQA-1/ PD-10	The procurement documents shall provide for access to the supplier's and sub tier supplier's facilities and records for surveillance, inspection, or audit by the purchaser, its designated representative, and others authorized by the purchaser.
NQA-1/ PD-11	The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. The time of submittal shall also be established
NQA-1/ PD-12	When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.
NQA-1/ PD-13	The procurement documents shall specify the purchaser's requirements for the supplier's reporting of nonconformances.

ID#	NQA-1 Requirement 4 -- Procurement Document Control Lines of Inquiry
NQA-1/ PD-14	The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.
NQA-1/ PD-15	A review of the procurement documents and changes thereto, shall be made and documented prior to award to assure documents transmitted to prospective supplier(s) include appropriate provisions to assure that items or services will meet specified requirements.
NQA-1/ PD-16	Technical or quality assurance program changes made as a result of bid evaluations or negotiations shall be incorporated into procurement documents prior to their issuance to the supplier.
NQA-1/ PD-17	Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.
NQA-1/ PD-18	Procurement document changes affecting technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

ID#	NQA-1 Requirement 5 - Instructions, Procedures, and Drawings Lines of Inquiry
NQA-1/ IN-1	Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.
NQA-1/ IN-2	The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.
NQA-1/ IN-3	The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

ID#	NQA-1 Requirement 6 -- Document Control Lines of Inquiry
NQA-1/ DO-1	The preparation, issue and change of documents that specify quality requirements, or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to assure correct documents are being employed.
NQA-1/ DO-2	Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.
NQA-1/ DO-3	The following controls shall be applied to documents and changes thereto: (a) The identification of controlled documents; (b) the specified distribution of controlled documents for use at the appropriate location; (c) the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents; (d) the review of controlled documents for completeness, and approval prior to distribution; (e) a method to ensure the correct documents is being used.
NQA-1/ DO-4	Changes to documents, other than those defined as minor changes, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.
NQA-1/ DO-5	The reviewing organization shall have access to pertinent background data or information upon which to base their approval.
NQA-1/ DO-6	Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents same review and approval as the original documents.
NQA-1/ DO-7	To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

ID#	NQA-1 Requirement 7 - Control of Purchased Items & Services Lines of Inquiry
NQA-1/ PI-1	The procurement of items and services shall be controlled to assure conformance with specified requirements.
NQA-1/ PI-2	Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion.
NQA-1/ PI-3	Prior to award of a contract, the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents and the results and there from shall be documented and shall include one or more of the following: (a) Supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability. (b) Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated. (c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the supplier's quality assurance program.
NQA-1/ PI-4	If bids are solicited, the bid evaluation shall include a determination of the supplier's capability to conform to the technical and quality assurance requirements.
NQA-1/ PI-5	Prior to the award of the contract, the purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation.
NQA-1/ PI-6	Controls shall be implemented to assure that the submittal and evaluation of supplier-generated documents are accomplished in accordance with the procurement document requirements.
NQA-1/ PI-7	The controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.
NQA-1/ PI-8	Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements
NQA-1/ PI-9	The extent of the verification activities by the Purchaser shall be a function of the relative importance, complexity, and quality of the item or services procured and the Supplier's quality performance.
NQA-1/ PI-10	Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

ID#	NQA-1 Requirement 7 - Control of Purchased Items & Services Lines of Inquiry
NQA-1/ PI-11	Purchaser methods used to accept an item or service from a supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or post installation test at the nuclear facility site, or a combination of these methods.
NQA-1/ PI-12	A Certificate of Conformance shall meet the following minimum requirements: (a) The certificate shall identify the purchased material or equipment, such as by the purchase order number; (b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment; (c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances; (d) The certificates shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function & position are described in the Purchaser's or Supplier's quality assurance program; (e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program; (f) Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier's or independent inspection or test of items. The Purchaser shall conduct such verification at intervals commensurate with the supplier's past quality performance.
NQA-1/ PI-13	When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities.
NQA-1/ PI-14	Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points.
NQA-1/ PI-15	Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.
NQA-1/ PI-16	When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the supplier
NQA-1/ PI-17	Receiving inspection shall verify by objective evidence such features as configuration; identification; dimensional; physical; and other characteristics; freedom from shipping damage; and cleanliness.

ID#	NQA-1 Requirement 7 - Control of Purchased Items & Services Lines of Inquiry
NQA-1/ PI-18	Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.
NQA-1/ PI-19	When post installation testing is used, post installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.
NQA-1/ PI-20	In cases involving procurement of services only, such as third party inspection; engineering and consulting services; auditing; and installation, repair, overhaul or maintenance work, the Purchaser shall accept the service by any or all of the following methods: (a) Technical verification of data produced; (b) Surveillance and/or audit of the activity; (c) Review of objective evidence for conformance to the procurement document requirements.
NQA-1/ PI-21	Methods for control and disposition of Supplier non-conformances for items and services that do not meet procurement documentation requirements shall include: (a) Evaluation of non-conforming items; (b) Submittal of non-conformance notice to Purchaser by Supplier as directed by the Purchaser. The submittals shall include supplier recommended disposition for use-as-is and repair along with technical justification. Non-conformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition: 1. technical or material requirement is violated; 2. requirement in supplier documents, which has been approved by the purchaser, is violated; 3. non-conformance cannot be corrected by continuation of the original manufacturing process or by rework; and 4. the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired; (c) Purchaser disposition of supplier recommendation; and (d) Verification of the implementation of the disposition; maintenance of records of supplier-submitted non-conformances.
NQA-1/ PI-22	Where the design utilizes commercial grade items, the purchaser can utilize the following requirements of an acceptable alternative to other requirements of this section for procuring and accepting items: (a) The commercial grade item is identified in an approved design output document or an alternate commercial grade item may be applied, provided the cognizant design organization provides verification that the alternate commercial grade item will perform the intended function and will met design requirements applicable to both the replaced item and its application; (b) Source evaluation and selection, where determined necessary by the Purchaser based on complexity and importance to safety, shall be in accordance with section 200 of this requirement;

ID#	NQA-1 Requirement 7 - Control of Purchased Items & Services Lines of Inquiry
	(c) Commercial grade items shall be identified in the purchase order by the manufacturer's published product description; (d) One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance: 1. special tests or inspections or both; 2. commercial grade survey of the supplier; 3. source verification; 4. acceptable supplier/item performance records; and (e) Prior to acceptance of a commercial grade item the Purchaser shall determine that: 1. Damage was not sustained during shipment; and 2. The item has satisfied the specified acceptance criteria; and specified documentation, as applicable to the item, was received and is acceptable.

ID#	NQA-1 Requirement 8 - Identification & Control of Items Lines of Inquiry
NQA-1/ CI-1	Controls shall be established to assure that only correct and acceptable items are used or installed.
NQA-1/ CI-2	Identification shall be maintained on the item or in documents traceable to the item, or in a manner which assures that identification is established and maintained.
NQA-1/ CI-3	Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use.
NQA-1/ CI-4	This identification shall relate an item to an applicable design or other pertinent specifying document.
NQA-1/ CI-5	Physical identification shall be used to the maximum extent possible.
NQA-1/ CI-6	Where physical identification on the item is either impractical or insufficient; physical separation, procedural control, or other appropriate means shall be employed
NQA-1/ CI-7	Identification markings shall be applied using materials and methods, which provide a clear and legible identification and does not degrade the function or service life of the item.
NQA-1/ CI-8	Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.
NQA-1/ CI-9	When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability controls.
NQA-1/ CI-10	Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.
NQA-1/ CI-11	Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as: (a) Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (b) Protection of identification on items subject to excessive deterioration due to environmental exposure; and (c) Provisions for updating existing plant records.

ID#	NQA-1 Requirement 9 - Control of Special Processes Lines of Inquiry
NQA-1/ SP-1	Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.
NQA-1/ SP-2	Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means and shall include or reference procedure, personnel, and equipment qualification requirements.
NQA-1/ SP-3	Conditions necessary for accomplishment of the process shall include proper equipment, controlled parameters of the process, specified environment and calibration requirements.
NQA-1/ SP-4	The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions.
NQA-1/ SP-5	For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.
NQA-1/ SP-6	It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.
NQA-1/ SP-7	Records shall be maintained as appropriate for the currently qualified personnel, processes and equipment of each special process.

ID#	NQA-1 Requirement 10 - Inspection Lines of Inquiry
NQA-1/ IS-1	Inspections required verifying conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed.
NQA-1/ IS-1	Characteristics subject to inspection and inspection methods shall be specified and inspection results shall be documented.
NQA-1/ IS-3	Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.
NQA-1/ IS-4	Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.
NQA-1/ IS-5	If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents.
NQA-1/ IS-6	Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.
NQA-1/ IS-7	Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.
NQA-1/ IS-	Sampling procedures, when used, shall be based upon valid statistical methods.
NQA-1/ IS-8	Inspection of items under construction or otherwise in-process shall be performed as necessary to verify quality. When it is impossible or disadvantageous to inspect processed items, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.
NQA-1/ IS-9	Both inspection and process monitoring shall be provided when control is inadequate without both.
NQA-1/ IS-10	Final inspections shall include a records review of results and resolution of non-conformances identified by prior inspections.
NQA-1/ IS-11	Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.
NQA-1/ IS-12	Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.
NQA-1/ IS-13	Appropriate records shall be established, maintained and, as a minimum identify the following: (a) Item inspected; (b) Date of inspection; (c) Inspector; (d) Type of observation; (e) Results or acceptability; and (f) Reference to information on action taken in connection with non-

ID#	NQA-1 Requirement 10 - Inspection Lines of Inquiry
	conformances.

ID#	NQA-1 Requirement 11 - Test Control Lines of Inquiry
NQA-1/ TC-1	Tests required collecting data such as for siting or design input, to verify conformance of an item or computer program to specified requirements or to demonstrate satisfactory performance for service shall be planned and executed.
NQA-1/ TC-2	Characteristics to be tested and test methods to be employed shall be specified.
NQA-1/ TC-3	Test results shall be documented and their conformance with test requirements and acceptance criteria evaluated.
NQA-1/ TC-4	Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, operational tests, and computer program tests such as software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled.
NQA-1/ TC-5	Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.
NQA-1/ TC-6	The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.
NQA-1/ TC-7	Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.
NQA-1/ TC-8	If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.
NQA-1/ TC-9	Test procedures (other than for computer programs) shall include or reference the test configuration and test objectives and also include provisions for assuring the following: • Prerequisites and suitable environmental conditions are met • Adequate instrumentation is available and used & appropriate tests and equipment are used; and • Necessary monitoring is performed. Prerequisites shall include the following, as applicable: • Calibrated instrumentation; • Appropriate equipment; • Trained personnel;

ID#	NQA-1 Requirement 11 - Test Control Lines of Inquiry
	• Condition of test equipment and the item to be tested; • Suitable environmental conditions; and • Provisions for data acquisition.
NQA-1/ TC-10	As an alternative to the above, appropriate sections of related documents, such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used
NQA-1/ TC-11	Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements.
NQA-1/ TC-12	For those computer programs used in design activities, computer program test procedures shall provide for assuring that the computer program produces correct results.
NQA-1/ TC-13	For those computer programs used for operational control, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process.
NQA-1/ TC-14	The procedures shall also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.
NQA-1/ TC-15	In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.
NQA-1/ TC-16	In-use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system.
NQA-1/ TC-17	Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hard-ware failures, or instrument drift can affect required performance.
NQA-1/ TC-18	Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied.
NQA-1/ TC-19	Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization.
NQA-1/ TC-20	Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.
NQA-1/ TC-21	Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602 **601 Test Records** *(a)* item tested *(b)* date of test *(c)* tester or data recorder

ID#	NQA-1 Requirement 11 - Test Control Lines of Inquiry
	(d) type of observation *(e)* results and acceptability *(f)* action taken in connection with any deviations *(g)* person evaluating test results **602 Computer Program Test Records** *(a) Verification Test Records* (1) computer program tested (2) computer hardware tested (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) simulation models used, where applicable (7) test problems (8) results and applicability (9) action taken in connection with any deviations noted *(10)* person evaluating test results *(b) In-Use Test Records* (1) computer program tested (2) computer hardware tested (3) test equipment and calibrations, where applicable (4) date of test (5) tester or data recorder (6) acceptability

ID#	NQA-1 Requirement 12 - Control of Measuring and Test Equipment Lines of Inquiry
NQA-1/ EQ-1	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and calibrated at specified periods, adjusted, and maintained to required accuracy limits.
NQA-1/ EQ-2	Selection of measuring and test equipment shall be based on the type, range, accuracy and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.
NQA-1/ EQ-3	Measuring and test equipment shall be calibrated at prescribed time periods or usage and whenever the accuracy of the equipment is suspect.
NQA-1/ EQ-4	Calibration shall be against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration shall be documented.
NQA-1/ EQ-5	Calibration procedures shall identify or reference required accuracy. Procedures shall define methods and frequency of checking accuracy.
NQA-1/ EQ-6	The calibration method and interval of calibration for measuring and test equipment shall be defined based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting capability.
NQA-1/ EQ-	Out-of-calibration devices shall be tagged or segregated, or both, and not used until they have been recalibrated.
NQA-1/ EQ-7	Measuring or test equipment consistently found to be out of calibration shall be repaired or replaced.
NQA-1/ EQ-8	When measuring and test equipment are found to be out of calibration, an evaluation, commensurate with the significance of the condition, shall be made and documented including the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.
NQA-1/ EQ-9	Measuring and test equipment shall be properly handled and stored to maintain accuracy.
NQA-1/ EQ-10	Equipment shall be suitably marked or otherwise identified to indicate calibration status.
NQA-1/ EQ-11	Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform their intended function.

ID#	NQA-1 Requirement 13 - Handling, Storage, and Shipping Lines of Inquiry
NQA-1/ SH-1	Handling, storage, cleaning, packaging, shipping and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.
NQA-1/ SH-2	These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions or other pertinent documents or procedures specified for use in conducting the activity.
NQA-1/ SH-3	When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.
NQA-1/ SH-4	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.
NQA-1/ SH-5	Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling.
NQA-1/ SH-6	Special handling tools and equipment shall be inspected and tested periodically or prior to use as necessary to assure performance.
NQA-1/ SH-7	Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment.
NQA-1/ SH-8	Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

ID#	NQA-1 Requirement 14 - Inspection, Test, and Operating Status Lines of Inquiry
NQA-1/ ST-1	The status of inspection and test activities shall be identified either on the item or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed.
NQA-1/ ST-2	The status of inspection and test activities shall be identified either on the item or in documents traceable to the items to assure that items which have not passed the required inspections or tests are not inadvertently installed, used or operated.
NQA-1/ ST-3	Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records or other suitable means.
NQA-1/ ST-4	The authority for application and removal of tags, markings, labels, and stamps shall be specified.
NQA-1/ ST-5	Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches to prevent inadvertent operation.

ID#	NQA-1 Requirement 15 - Control on Nonconforming Items Lines of Inquiry
NQA-1/ NC-1	Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.
NQA-1/ NC-2	Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.
NQA-1/ NC-3	Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item.
NQA-1/ NC-4	Identification shall be made either on the item, the container or the package containing the item.
NQA-1/ NC-5	Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.
NQA-1/ NC-6	When segregation is impractical or impossible, due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.
NQA-1/ NC-7	Nonconforming items shall be evaluated and recommended dispositions shall be proposed.
NQA-1/ NC-8	Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.
NQA-1/ NC-9	The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.
NQA-1/ NC-10	The responsibility and authority for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.
NQA-1/ NC-11	Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, and have adequate understanding of the requirements and access to pertinent background information.
NQA-1/ NC-12	Personnel performing evaluations to determine a disposition shall have adequate understanding of the requirements, and have access to pertinent background information.

ID#	NQA-1 Requirement 15 - Control on Nonconforming Items Lines of Inquiry
NQA-1/ NC-13	A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented.
NQA-1/ NC-14	Technical justification for the acceptability of a nonconforming item dispositioned as repair or use-as-is shall be documented.
NQA-1/ NC-15	Nonconformance to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.
NQA-1/ NC-16	Required as-built records shall reflect the use-as-is or repair condition.
NQA-1/ NC-17	Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.
NQA-1/ NC-18	Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

ID#	NQA-1 Requirement 16 - Corrective Action Lines of Inquiry
NQA-1/ CA-1	Conditions adverse to quality shall be identified promptly and corrected as soon as practical.
NQA-1/ CA-2	In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.
NQA-1/ CA-3	The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.
NQA-1/ CA-4	Completion of corrective actions shall be verified.

ID#	NQA-1 Requirement 17 - QA Records Lines of Inquiry
NQA-1/ QR-1	Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.
NQA-1/ QR-2	Quality Assurance records shall be identified, generated, authenticated, and maintained and their final disposition specified.
NQA-1/ QR-3	Requirements and responsibilities for these activities shall be documented.
NQA-1/ QR-4	The term, records, used throughout this section, is to be interpreted as quality assurance records.
NQA-1/ QR-5	(a) Records shall be legible; and (b) traceable to associated items and activities and accurately reflect the work accomplished or information required.
NQA-1/ QR-6	Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.
NQA-1/ QR-7	Records shall be classified as lifetime or nonpermanent in accordance with paragraphs 401 and 402 of this Requirement.
NQA-1/ QR-8	Lifetime records meet one or more of the following criteria: (a) Those which would be of significant value in demonstrating capability for safe operation; (b) Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; (c) Those which would be of significant value in determining the cause of an accident or malfunction of an item; (d) Those which provide required baseline data for in-service inspections.
NQA-1/ QR-9	Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.
NQA-1/ QR-10	Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.
NQA-1/ QR-11	Records shall be retained in accordance with the above classifications.
NQA-1/ QR-12	The retention periods for nonpermanent records shall be established in writing.
NQA-1/ QR-13	Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records and the designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

ID#	NQA-1 Requirement 17 - QA Records Lines of Inquiry
NQA-1/ QR-14	Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: 1) natural disasters such as winds, floods, or fires; 2) environmental conditions such as high and low temperatures and humidity; and 3) infestation of insects, mold or rodents.
NQA-1/ QR-15	Dual facilities, containers, or a combination thereof shall be provided for records storage if a single facility, container, or combination thereof is not capable of providing adequate protection.
NQA-1/ QR-16	Record retention periods shall be documented.
NQA-1/ QR-17	Records shall be maintained for their retention period.
NQA-1/ QR-18	Records shall be protected from damage or loss.
NQA-1/ QR-19	Records shall be retrievable.
NQA-1/ QR-20	Methods for record changes shall be documented.
NQA-1/ QR-21	Provisions shall be made for specially processed records (such as radiographs, photographs, negatives, microfilm, and magnetic and optical media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity.

ID#	NQA-1 Requirement 18 - Audits Lines of Inquiry
NQA-1 AD-1	Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program.
NQA-1 AD-2	These audits shall be performed in accordance with written procedures or checklists.
NQA-1 AD-3	These audits shall be performed by personnel who do not have direct responsibility for performing the activities being audited.
NQA-1 AD-4	Audit results shall be documented and reported to and reviewed by responsible management.
NQA-1 AD-5	Follow-up action shall be taken where indicated.
NQA-1 AD-6	Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity.
NQA-1 AD-7	Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.
NQA-1 AD-8	The auditing organization shall develop an audit plan for each audit.
NQA-1 AD-9	This plan shall identify audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule and written procedures or checklists.
NQA-1 AD-10	Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.
NQA-1 AD-11	An audit team shall be identified prior to the beginning of each audit.
NQA-1 AD-12	An audit team shall contain one or more auditors, one being designated Lead Auditor who organizes and directs the audit.
NQA-1 AD-13	The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.
NQA-1 AD-14	Elements selected for audit shall be evaluated against specified requirements.

ID#	NQA-1 Requirement 18 - Audits Lines of Inquiry
NQA-1 AD-15	Elements selected for audit shall be evaluated with objective evidence being examined to the depth necessary to determine if these elements are being implemented effectively.
NQA-1 AD-16	Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.
NQA-1 AD-17	The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization.
NQA-1 AD-18	The contents of the report shall: (a) describe the audit scope, (b) identify Auditors and persons contacted, (c) summarize audit results, including a statement on the effectiveness of the elements audited, and (d) describe each reported adverse audit finding.
NQA-1 AD-19	Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality and notify the appropriate organization in writing of action taken or planned.
NQA-1 AD-20	Audit responses shall be evaluated by or for the auditing organization.
NQA-1 AD-21	Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.
NQA-1 AD-22	Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

ID#	NQA-1 Subpart 2.7 Requirement - Computer Software Lines of Inquiry
NQA-1/ SQ-1	**GENERAL REQUIREMENTS** The following general requirements shall be applied to the software engineering elements described in paragraph 101 of this subpart (see a – d below): The scope of software engineering activities include the following elements, as appropriate: a) Software acquisition method(s) for controlling the acquisition process for software and software services; b) Software engineering method(s) used to manage the software life-cycle activities; c) Application of standards, conventions, and other work practices that support the software life cycle; and Controls for support software used to develop, operate, and maintain computer programs
NQA-1/ SQ-2	**Documentation** The appropriate software engineering elements, described in para.101 of this Subpart, shall define the baseline documents that are to be maintained as records, in accordance with Part 1, Requirement 17. Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents.
NQA-1/ SQ-3	**Review** The appropriate software engineering elements, described in paragraph 101 of this Subpart, shall define the control points and associated reviews. Reviews of software shall assure compliance with the approved software design requirements. Although multiple review requirements are specified within this Subpart, the reviews may be performed and documented separately or combined, as appropriate, to the defined software engineering method.
	The following two reviews are required:
NQA-1/ SQ-4	a) One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification.
NQA-1/ SQ-5	b) The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review.
NQA-1/ SQ-6	Reviews shall identify the participants and their specific review responsibilities.
NQA-1/ SQ-7	Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software.

ID#	NQA-1 Subpart 2.7 Requirement - Computer Software Lines of Inquiry
NQA-1/ SQ-8	Comments not incorporated and their disposition shall be retained until the software is approved for use.
NQA-1/ SQ-9	When review alone is not adequate to determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle.