NEI 11-04A [Revision 0]

Nuclear Energy Institute

Nuclear Generation Quality Assurance Program Description

(Based on the Requirements of
ASME NQA-1-2008 and NQA-1a-2009 Addenda)

August 2013

ACKNOWLEDGMENTS

This guidance document, *Nuclear Generation Quality Assurance Program Description*, NEI 11-04, was developed by the NEI Quality Assurance Task Force. We appreciate the direct participation of the many utilities and suppliers who contributed to the development of this document and the participation of the balance of the industry that reviewed and submitted comments to improve the document clarity and consistency. The dedicated and timely effort of the many Quality Assurance Task Force participants, including their management's support of the effort, is greatly appreciated.

FOREWORD

In June 2010, the NRC issued Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction), Revision 4. This Regulatory Guide (RG) described methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considered acceptable for complying with the provisions of Title 10, of the *Code of Federal Regulations*, Part 50, "Domestic Licensing of Production and Utilization Facilities" (10 CFR Part 50), and Title 10, of the *Code of Federal Regulations*, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (10 CFR Part 52) which refer to 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," for establishing and implementing a quality assurance (QA) program for the design and construction of nuclear power plants and fuel reprocessing plants.

The issuance of Regulatory Guide 1.28, Revision 4 endorsed the Part I and Part II requirements included in NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications"), for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants as acceptable to the NRC staff and providing an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to specific additions and modifications of NQA-1-2008 and the NQA-1a-2009 Addenda and the regulatory position in RG 1.28, Revision 4.

This guideline has been developed to assist the industry in developing a QAPD for implementing the quality standards endorsed through the issuance of Regulatory Guide 1.28, Revision 4.

This accepted version of NEI 11-04, Revision 0, incorporates the Final Safety Evaluation Report as Appendix 2 and NEI responses to NRC RAIs as Appendix 3. In accordance with NRC guidance, this accepted version is designated NEI 11-04A (with the suffix A indicating NRC acceptance).

EXECUTIVE SUMMARY

NEI 11-04, "Nuclear Generation Quality Assurance Program Description" (QAPD) provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement applicable requirements related to the Quality Assurance Program. This template includes the QA methods and administrative control requirements that meet 10 CFR 50, Appendix B, and 10 CFR Part 52. The template is based on the requirements of ASME NQA-1-2008 and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected Part III appendices, as identified in this document. ASME NQA-1-2008 and NQA-1a-2009 Addenda are the latest NRC approved regulatory positions for a Quality Assurance Program as referenced in Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction) Revision 4, June 2010. Part IV of this template addresses the regulatory positions delineated in RG 1.28, Revision 4. Operational criteria and other related quality positions in this template are as referenced in the Standard Review Plan (NUREG-0800).

NEI 11-04 is structured as a template for use in developing an applicant-specific QAPD required as part of ESP and COL applications. The template consists of two documents: (1) a Policy Statement, and (2) a Quality Assurance Program Description that consists of five parts. The applicant will format their specific QAPD in accordance with their process for developing such documents. The QAPD template contains bracketed text that applicants will modify with specific information as necessary for the ESP or COL application. Following NRC acceptance of the generic NG QAPD, NRC staff review of applicant QAPDs based on NEI 11-04 is expected to focus on the specific information provided to replace the bracketed text in the generic template.

In response to previous NRC comments on NEI 06-14A, Appendix 1 has been retained and updated to provide a roadmap for identifying how Regulatory Guide 1.33, Rev. 2, and ANSI N18.7-1976 requirements are addressed by NQA-1-2008 and NQA-1a-2009 Addenda and this template. It should be noted that Appendix 1 is not part of the template and is only being provided to assist licensees in understanding the basis for the contents of this template and evaluating potential changes to plant-specific QAPDs in accordance with 10 CFR 50.54(a) or 50.55(f).

[Company Name]

POLICY STATEMENT

[Company Name] ([Company Abbreviation - CA]) shall design, procure, construct, and operate the nuclear plant*[s]* in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating License*[s]* and applicable laws and regulations of the state and local governments.

The *[CA] [Nuclear Development]* Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of *[CA]* activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents *[CA]*'s overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. *[Senior management]* establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the *[CA]* QAP.

Signed

[NAME]
[President and Chief Executive Officer]
[CA]

[Date]

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PART I INTRODUCTION

SECTION 1 GENERAL

[NOTE: The QAPD can be used for Early Site Permit (ESP)/Combined Operating License (COL)/ construction/pre-operation and/or operations. When developing a QAPD using this template, the bracketed text should be selected based on the intended application of the QAPD (e.g., ESP, COL, construction phase, operations, or all). Text that is defined as a NOTE is for information only, is not intended to be part of the QAPD, and should be removed.

NOTE: The QAPD template contains bracketed text that the applicants will select or modify with specific information as necessary for the application. When the bracketed text is ***NOT*** *italicized, the text should be included if applicable to the scope without modification. This non-italicized bracketed text is reviewed and approved as part of the standard template approval. See Part II, Section 2, paragraph 3 for an example of the non-italicized bracketed text. When the bracketed text* ***IS*** *italicized, the text is considered to be example text that the applicant/licensee will modify specific to their needs. This italicized text is subject to review by the NRC to determine the acceptability of the QAPD submitted by the applicant. See Part I, Section 1.1 below for an example of the use of italicized bracketed text.]*

[Company (CA)'s] [Nuclear Development] Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for *[ESP/COL/construction/pre-operation and/or operations]* activities conducted by or for *[CA]*. The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and guidance of ASME NQA-1-2008 and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected Part III sections, as identified in this document.

The QA Program (QAP) is defined by the NRC-approved regulatory document that describes the QA elements (i.e., the QAPD), along with the associated implementing documents. Procedures and instructions that control *[Nuclear Development]* activities will be developed prior to commencement of those activities. *[Policies establish high-level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all [CA] organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.]*

1.1 Scope/Applicability

The QAPD applies to *[ESP, COL, construction/pre-operation and/or operations]* activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

Designing	*Storing*	*Operating*
Siting	*Constructing*	*Maintaining*
Procuring	*Erecting*	*Repairing*
Fabricating	*Installing*	*Modifying*
Cleaning	*Inspecting*	*Refueling*
Handling	*Testing*	*Training*
Shipping	*Startup*	*Decommissioning*
Receiving	*Pre-operational activities (including ITAAC)*	

[ITAAC are those Inspections, Tests, Analyses, and Acceptance Criteria the applicant must satisfy as determined by the commission in accordance with 10 CFR Part 52.]

Safety-related SSCs, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

The policy of *[CA]* is to assure a high degree of availability and reliability of the nuclear plant*[s]* while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1–2008 and NQA-1a-2009 Addenda, Part I, Section 400, apply to select terms as used in this document.

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This section describes the *[CA]* organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes *[corporate/support/off-site and]* on-site functions for *[Nuclear Development]* including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

[CA senior management position responsible for the Quality Assurance organization] is responsible to size the Quality Assurance staff commensurate with the duties and responsibilities assigned.

[NOTE: The following information will be utility specific but should follow the SRP for the content. This also includes interface responsibilities for multiple organizations performing quality-related functions. This section should be developed to include the organization that is to implement the phase the QAPD is intended to cover e.g., ESP, COLA, Construction/Pre-operation/Test, and Operations. The description should include levels of authority, interfaces, and functional responsibilities for each position. In addition, for QAPDs that cover activities during both construction and operations, it should include enough detail to distinguish the organizational structure for construction and for operations. Include organization charts that describe the QA organization that is/will be in place for all positions responsible for establishing, maintaining, and implementing QA requirements from corporate positions through plant positions.]

[NOTE: Generic titles (e.g., Nuclear Development, Quality Assurance Manager) may be used in the QAPD. However, the generic titles established in the Organization Section must be used throughout the document.]

[NOTE: Provide a clear illustration of the organization's functional responsibilities, to include preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and issuing instructions, procedures, and procurement documents; purchasing; verifying supplier activities; identifying and controlling acceptable and nonconforming hardware and software; manufacturing; calibrating and controlling measuring and test equipment; qualifying and controlling special processes; constructing; inspecting; testing; startup; operating; performing maintenance; performing the audit function; and controlling records. Also, refer to the same organizational titles throughout the QAPD.]

[NOTE: Structure Section 1, Organization, of the QAPD such that it clearly delineates how the QA program is implemented during all applicable phases such as the construction and testing phase and the operational phase. The transition process from one phase to another must be described. Position descriptions should clearly delineate these roles during each applicable phase as well as the transition period between phases. For example, during the transition from construction to operations, the following text may be appropriate: No later than six months prior to fuel load of the unit, those positions which are identified for

Operations will be staffed and have the appropriate authority required to perform operations activities. It is anticipated that even after fuel load, construction activities will be ongoing. Those positions required to support these activities will retain their applicable construction/preoperation responsibilities until it is deemed that they are no longer necessary. As the construction of systems (or portions thereof) is completed, control and authority (including oversight, configuration, and operations) is transferred from the contractor to the cognizant owner departments in the operational phase. During the transition, responsibilities will be clearly defined in instructions and procedures to ensure appropriate authority is maintained for each SSC.]

[NOTE: The QAPD describes the functions and responsibilities associated with the quality assurance requirements of 10 CFR 50, Appendix B, Criteria I, Organization and Criteria II, Quality Assurance. All positions associated with the establishment, implementation, and verification of quality-related activities should be shown on the organization charts and described in the QAPD. For the operational phase, the level of detail to be included should include roles, responsibilities, and lines of authority for the positions necessary to implement the requirements of 10 CFR 50, Appendix B. (The typical operating structure includes a site executive with overall responsibility for the execution of the administrative controls and quality assurance program at the plant to assure safety. The site executive directs the activities of the plant manager and nuclear support manager. An individual or organizational unit (often designated as QA, Oversight, or Assessment) knowledgeable and experienced in nuclear power plant operational phase activities and quality assurance practices is designated and assigned the responsibility to verify that the program is being effectively implemented. Depending on the organizational structure, this individual or organizational unit may report functionally to onsite plant management or an offsite organization. Reporting to onsite plant management is preferable since such an arrangement usually results in improved communications in identifying problems and initiating corrective action. The individual or organizational unit in this case may receive technical guidance from offsite support groups.) For example, this level of detail will identify where the independent review functions report within the organization. Comparable detail should be provided for the construction/preoperation phase. The onsite operating organization must include one or more individuals knowledgeable in the following fields: nuclear power plant operation; nuclear power plant mechanical, electrical and electronic systems; nuclear engineering; chemistry and radiochemistry; radiation protection; and quality assurance.]

[NOTE: Sufficient detail must be included to fully describe how the organization will perform, manage, and/or oversee activities affecting the quality and performance of safety-related SSCs, including: testing, preoperational activities such as ITAAC, receiving, storing, repairing, decommissioning, refueling, and shipping.]

[NOTE: The applicant/licensee may provide the required organization description by incorporating by reference information from another section of the FSAR but by so doing, the regulatory change process established by 10 CFR 50.54(a) would be applicable to that incorporated section. If incorporation by reference is used, care must be taken to use the appropriate titles from that section in the QAPD in replacing bracketed text.]

[NOTE: Below is an example of a new plant organization, its independence, and its linking within an existing utility. The sample organization presented here is for illustration only. This is not representative of the level of detail sufficient to address all phases of potential applicability.]

[The [CA] [Nuclear Development (ND)] organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup, and operations development activities. Several organizations within [CA] implement and support the QAPD. These organizations include, but are not limited to [Nuclear Development], Technical Services, Corporate Services and Quality Assurance.

Design, engineering, and environmental services are provided to the [CA] [Nuclear Development] organization by two primary contractors in accordance with their QAPDs. These two contractors are [A/E Firm] and [NSSS vendor].

The following sections describe the reporting relationships, functional responsibilities, and authorities for organizations implementing and supporting the [Nuclear Development] QA Program. The [CA] organization and the [Nuclear Development] organization are shown in Figures II.1-1 and II.1-2, respectively.

1.1 President/CEO

The President/CEO is responsible for all aspects of design, construction, and operation of [CA]'s nuclear plants. The President/CEO is also responsible for all technical and administrative support activities provided by [CA] and contractors. The President/CEO directs the Chief Nuclear Officer/Executive Vice President, the [Senior Nuclear Development Officer], the Vice President Corporate Services, and the Vice President Technical Services in fulfillment of their responsibilities. The President/CEO reports to the [CA] Board of Directors with respect to all matters.

1.2 Nuclear Development

[Company name], [Nuclear Development] (ND) organization is responsible for new nuclear plant Licensing, Engineering, Procurement, Construction, Startup, and Operational Development activities.

1.2.1 Senior Nuclear Development Officer

The Senior Nuclear Development Officer (SNDO) reports to the [CA] President/CEO and is responsible for the establishment and implementation of the [Nuclear Development] QAPD. The SNDO also directs the planning and development of the [Nuclear Development] staff, and organization resources. The SNDO is also responsible for establishing and managing the NSSS contract for the development of new nuclear generation.

1.3 Technical Services

The Technical Services organization is responsible for support of [Nuclear Development] organization by providing Engineering, Licensing, and Document Control support where applicable.

1.3.1 Vice President - Technical Services

The Vice President - Technical Services reports to the [CA] President/CEO and is responsible for the administration of engineering, nuclear fuel, and nuclear licensing for the existing plants and may provide support activities for [Nuclear Development] under the QAPD.

1.4 Corporate Services

The Corporate Services organization is responsible for supporting the [Nuclear Development] organization through performing activities related to Procurement, Safety and Health, and Information Technology where applicable.

1.4.1 Vice President Corporate Services

The Vice President Corporate Services, reports to the [CA] President / CEO and is responsible for managing the overall Corporate Service organization including assuring that Supply Chain Management, Safety and Health, and Information Technology support [Nuclear Development] activities in accordance with the QAPD.

1.5 Executive Vice President

The Executive Vice President is the Chief Nuclear Officer (CNO) and is responsible for the safe, reliable, and efficient operation of [CA] nuclear plants. The CNO directs the operating plants' Vice Presidents - Project (xxxx and yyyy), and the Quality Assurance Manager. The Executive Vice President will support [Nuclear Development] activities through the Vice President - xxxx and the Quality Assurance Organization.

1.5.1 Vice President – Project

The Vice Presidents – Project report to the Executive Vice President and are responsible for the overall safe and efficient operation of their operating plant, and for the implementation of quality assurance requirements in the areas specified by the operations QAPD.

For the purposes of this program, the description of the duties of the Vice Presidents – Project and their staff will be limited to those site activities that support the [Nuclear Development] new nuclear generation activities.

1.5.1.1 Site Project Organization

The Site Project Organization is responsible for operations and maintenance of the respective plant site. The Site Project Organization is responsible for quality inspection activities of operations on-site work, including any that support [Nuclear Development] ESP and COL application development, as well as controlling interfaces between the operating units and any preconstruction or construction activities.

1.5.2 Quality Assurance

The [CA] Quality Assurance Organization is responsible for independently planning and performing activities to verify the development and effective implementation of the [CA] QAPDs including but not limited to [Nuclear Development], Engineering, Licensing, Document Control, Corrective Action Program, and Procurement that support new nuclear plant generation.

1.5.2.1 Quality Assurance Manager

The Quality Assurance Manager reports to the Executive Vice President for the

operations activities and to the Senior Nuclear Development Officer for the new reactor activities and is responsible for developing and maintaining the [CA] QAPDs, evaluating compliance to Quality Assurance Program requirements, and managing Quality Assurance Organization resources.

1.5.2.1.1 [Nuclear Development] Quality Assurance Project Manager

The [Nuclear Development] Quality Assurance Project Manager (QAPM) reports administratively to the [CA] QA Manager and functionally to the Senior Nuclear Development Officer, and is responsible for the development and verification of implementation of the QAPD described in this document. The QAPM is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors providing quality services, parts, and materials to [CA] are meeting the requirements of 10 CFR 50, Appendix B through NUPIC or [CA] vendor audits. The QAPM has sufficient independence from other [Nuclear Development] priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas regarding [CA]'s [Nuclear Development] activities as appropriate. The QAPM may make recommendations to the [Nuclear Development] management regarding improving the quality of work processes. If the QAPM disagrees with any actions taken by the [ND] organization and is unable to obtain resolution, the QAPM shall inform the QA Manager and bring the matter to the attention of the Senior Nuclear Development Officer, who will determine the final disposition.

1.6 Nuclear Steam Supply System (NSSS) Supplier

An NSSS Supplier provides engineering services for plant design and licensing of specific plant types on [CA] sites. These engineering services for new nuclear generation include site-specific engineering and design necessary to support development of ESP and COL applications and preconstruction and construction activities.

1.7 Architect/Engineering (A/E) Supplier

An A/E Supplier provides engineering services for the development of the ESP and COL applications. These engineering services include site-specific licensing, engineering, and design activities; including planning and support for preconstruction and construction of new nuclear generation facilities.]

1.8 Authority to Stop Work

Quality Assurance and Quality Control Inspection personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This authority extends to off-site work performed by suppliers that furnish safety-related materials and services to *[CA]*.

1.9 Quality Assurance Organizational Independence

For the *[ESP/COL and/or construction]*, independence shall be maintained between the organization(s) performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design

review/verification.

1.10 NQA-1 Commitment

In establishing its organizational structure, *[CA]* commits to compliance with NQA-1-2008, Requirement 1.

Figure II.1-1

[CA] Organization

[NOTE: This is a sample organization chart and should be replaced by actual organization.]
[NOTE: Organization charts should be included for all phases of applicability of the QAPD. Organization Charts should show on-site and off-site organizations implementing the QA Program.]

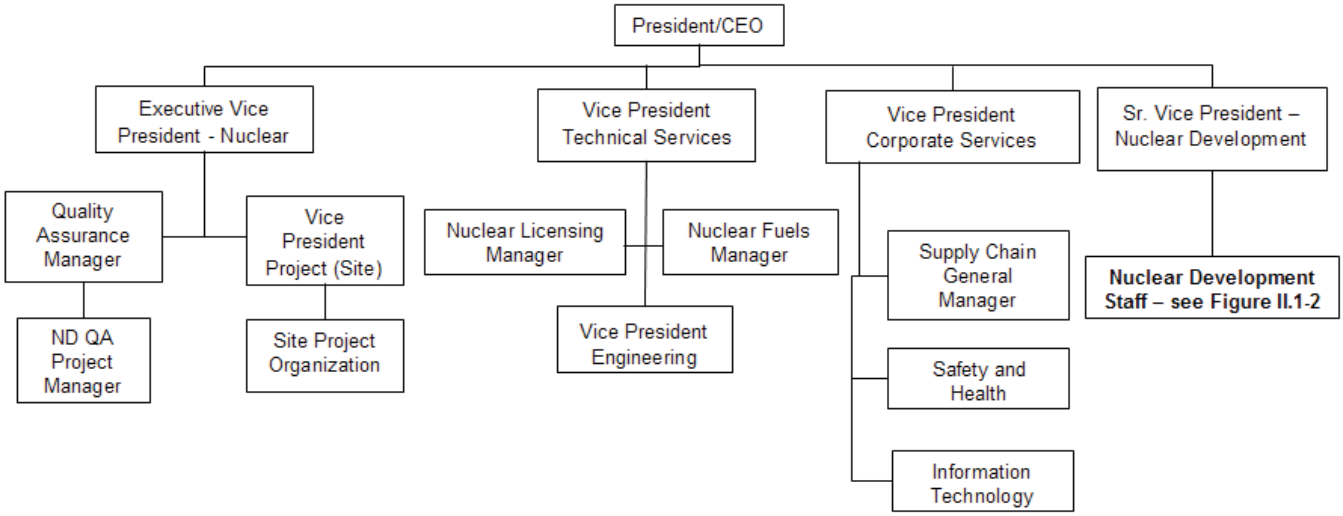
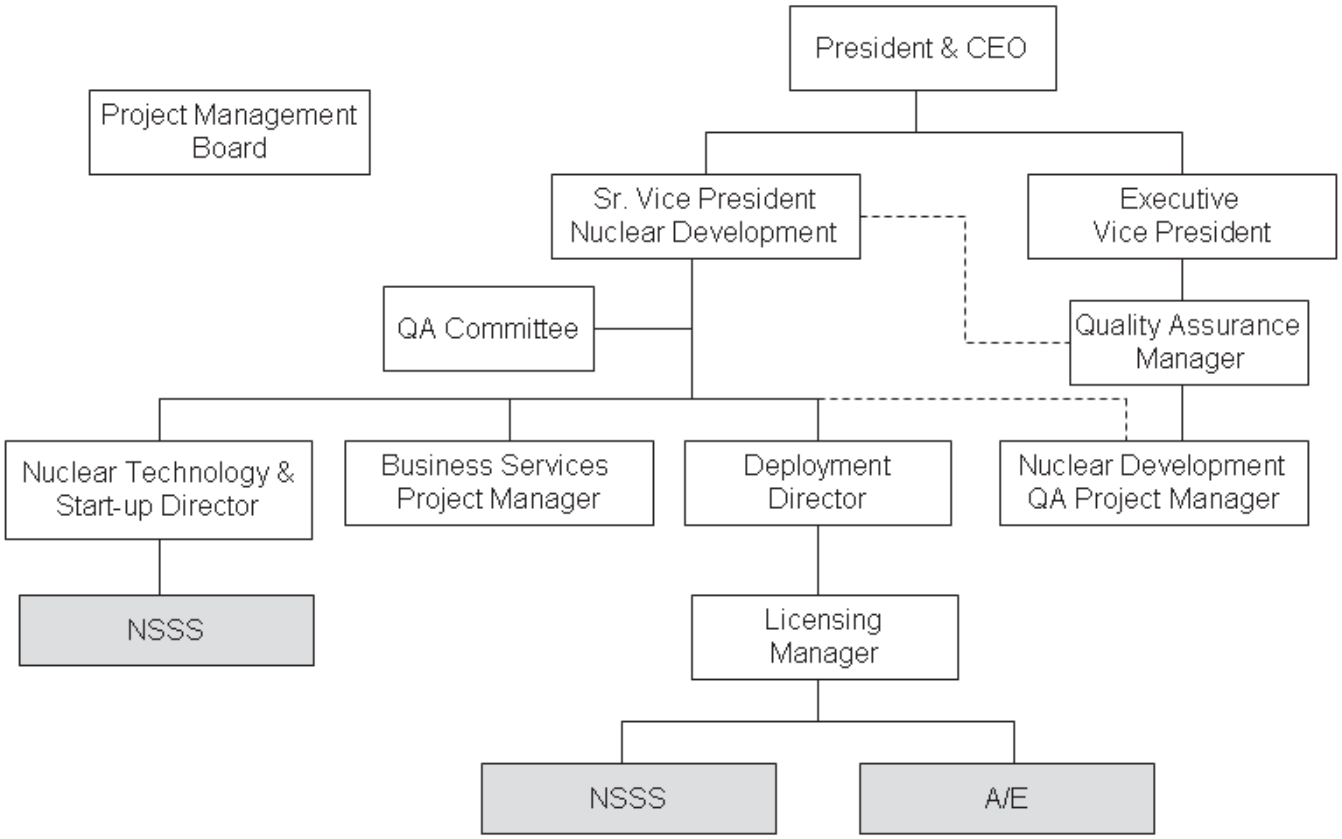


Figure II.1-2

[Nuclear Development] Organization

[NOTE: This is a sample organization chart and should be replaced by actual organization.]
[NOTE: Organization charts should be included for all phases of applicability of the QAPD. Organization Charts should show on-site and off-site organizations implementing the QA Program.]



SECTION 2 QUALITY ASSURANCE PROGRAM

[CA] has established the necessary measures and governing procedures to implement the QAP as described in the QAPD. *[CA]* is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plant*[s]* as described and to the extent delineated in the QAPD. The QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, *[CA]* ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Part II, Section 18.

The objective of the QAP is to assure that *[CA]*'s nuclear generating plant*[s are/is] [designed, constructed, and operated]* in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-2008 and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document. The QAP applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the *[design (excluding Design Certification activities), fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations]. [Examples of ESP/COL program safety-related activities include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis.]* A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility. *[The Design Certification Document]* is used as the basis for this list. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

[As described in Part III of the QAPD, specific program controls are applied to nonsafety-related SSCs that are significant contributors to plant safety, for which 10 CFR 50, Appendix B, is not applicable. The specific program controls, consistent with applicable sections of the QAPD, are applied to those items in a select manner, targeted at those characteristics or critical attributes that qualifies the SSC as a significant contributor to plant safety. *[NOTE: The preceding sentences and Part III do not apply to an ESP-only QAP.]*]

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principal contractor has been approved as a supplier in accordance with the *[CA]* QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

For the *[ESP and/or COL]* applications, the QAPD applies to those *[Nuclear Development]* and *[CA]* activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

[New nuclear plant construction will be the responsibility of [CA]'s [Nuclear Development]

organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD and [NSSS] QA programs prior to commencement of [preconstruction (ESP) and/or construction (COL)] activities. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and, for construction of [a] new plant[s], the interface between nonsafety-related and safety-related SSCs and the placement of seismically-designed backfill. [NOTE: This does not apply to an ESP-only or an Operations-only QAP.]]

In general, the program requirements specified herein are detailed in implementing procedures that are either *[CA]* implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

2.1 Responsibilities

Personnel who work directly or indirectly for *[CA]* are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. *[CA]* personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The *[Quality Assurance Project Manager]* is responsible to verify that processes and procedures comply with QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2 Delegation of Work

[CA] retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Part II, Section 1, may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate based upon their nature and effect, with technical advice or review as appropriate.

2.3 Site-specific Safety-Related Design Basis Activities

Site-specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied. *[NOTE: This does not apply to an Operations-only QAP.]*

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program, or portions thereof, shall assess the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. [However, the period for assessing QA programs during the operational phase may be extended to once every two years. *[NOTE: This does not apply to a non-Operations QAP]*]

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD will be in accordance with [10 CFR 50.55(f) and 10 CFR 50.54(a) *[NOTE: Selection of regulation depends on the scope of the QAP. Select one or both references as appropriate]*]. Changes to the QAPD are evaluated by the *[ND Quality Assurance Project Manager]* to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the *[ESP and COL]* application development process. New revisions to the document will be reviewed, at a minimum, by the *[CA] [Quality Assurance Manager]* and approved by the *[Senior Vice President - Nuclear Development].*

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable requirements of 10 CFR 50, Appendix B will be satisfied. In order to comply with this requirement, the FSAR references the QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD. *[NOTE: This does not apply to a non-Operations QAP.]*

2.6 Personnel Training and Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end, *[CA]* establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the QAPD to achieve initial proficiency, maintain proficiency, and adapt to technology changes, method, or job responsibilities. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities; and include or address the following, as appropriate:

- Education, experience, and proficiency of the personnel receiving training
- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements
- On-the-job training, if direct hands-on applications or experience is needed to achieve and maintain proficiency.

[Plant and support staff minimum qualification requirements are as delineated in the unit Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications. *[NOTE: This does not apply to a non-Operations QAP.]*]

Sufficient managerial depth is provided to cover absences of incumbents. When required

by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable *[CA]* procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed. [Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training. *[NOTE: This does not apply to a non-Operations QAP.]*] Records of personnel training and qualification are maintained.

The minimum qualifications of the *[[Quality Assurance Manager] and the [Nuclear Development Quality Assurance Project Manager]] are* that *[he/each]* holds an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications for the individuals responsible for supervising QA or QC personnel is that each has a high school diploma or equivalent and has a minimum of one year of experience performing quality verification activities. Individuals who do not possess these formal education and experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of individuals that are part of the *[Quality Assurance Group]* responsible for planning, implementing, and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7 NQA-1 Commitment / Exceptions

In establishing qualification and training programs, *[CA]* commits to compliance with NQA-1-2008, Requirement 2 with the following clarifications and exceptions:

- Section 302, Inspection and Test *[NOTE: The applicant may either adopt non-mandatory Appendix 2A-1 as if it were part of the requirement by following Option 1 below or taking exception to Appendix 2A-1 by following Option 2.]*

    - *[Option 1; NQA-1-2008,* Requirement 2 includes use of Appendix 2A-1 guidance as if it were part of the Requirement.] *[NOTE: When applying Option 1, either or both of the following two alternatives may be applied to the implementation of*

this Requirement and Appendix:]

(1) *[In lieu of being certified as Level I, II, or III in accordance with NQA-1-2008, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.]*

(2) *[A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.]*

- *[Option 2 is based on SER ML050700416 and may only be applied during the Operational phase. The post-TMI regulations at 10 CFR 50.34(f)(3)(iii) apply during construction phase.]*

(1) [In lieu of Nonmandatory Appendix 2A-1, [CA] does not establish levels of qualification/certification for inspection personnel. Instead, [CA] establishes initial qualification requirements and determines individual qualification through evaluation of education, training and experience, and through demonstration of capability in performing the type of inspections expected on the job.]

(2) [NOTE: When selecting option 2, the following alternative may be applied to the implementation of Requirement 2.] [Inspections, examinations or tests may be performed by individuals in the same organization as that which performed the work, provided that (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b and c are not met, inspections, examinations, or tests are carried out by individuals certified in accordance with Section 300. Individuals performing visual inspections required by the ASME Boiler and Pressure Vessel Code are qualified and certified according to Code requirements.]

- *[CA]* follows Section 301 for qualification of nondestructive examination personnel, except that *[CA]* will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at *[CA]* sites for the scope of activities governed by these cited

standards.

- Section 400 (a) (8) requires the date of certification expiration be included on the qualification record. *[CA]* considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

SECTION 3 DESIGN CONTROL

[CA] has established and implements a process to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within *[CA]* and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification by inspection and test, as required. Design change processes and the division of responsibilities for design-related activities are detailed in *[CA]* and supplier procedures. Changes to design inputs, final designs, *[and]* field changes*[, and temporary and permanent modifications to operating facilities]* are justified and subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the *[CA]* design organization or by other organizations so authorized by *[CA]*.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.1 Design Verification

[CA] design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item or computer program under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are

identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use.

[CA] normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture, or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2 Design Records

[CA] maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3 Computer Application and Digital Equipment Software

The QAPD governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Computer program acceptability is pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. *[CA]* and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto is documented and approved by *[authorized personnel].* The QAPD is also applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4 Setpoint Control

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

- Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes originally supplied by the *[NSSS supplier, applicant for certification, or DC holder], [the A/E,]* and the plant's technical staff.
- Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.
- Provide for documentation of setpoints, including those determined operationally.

- Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate or maintain plant equipment, develop or revise design documents, or develop or revise accident analyses.

[NOTE: This subsection does not apply to an ESP-only QAP]

3.5 NQA-1 Commitment

In establishing its program for design control and verification, *[CA]* commits to compliance with NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.7 for computer software, NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.14 for Quality Assurance requirements for commercial grade items and services [, and Subpart 2.20 for subsurface investigation requirements]. *[NOTE: Subpart 2.20 does not apply to an Operations-only QAP].*

SECTION 4 PROCUREMENT DOCUMENT CONTROL

[CA] has established the necessary measures and governing procedures to assure that purchased items, computer programs, and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit, and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.

- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under *[CA]*'s approved QA program).

Reviews of procurement documents 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.

4.1 NQA-1 Commitment / Exceptions

In establishing controls for procurement, *[CA]* commits to compliance with NQA-1-2008, Requirement 4, with the following clarifications and exceptions:

- With regard to service performed by a supplier, *[CA]* procurement documents may allow the supplier to work under the *[CA]* QAP, including implementing procedures, in lieu of the supplier having its own QAP.

- Section 300 and 400 of Requirement 4 require the review of technical and Quality Assurance Program requirements of procurement documents prior to award of a contract and for procurement document changes. *[CA]* may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and quality assurance requirements of the procurement.

Procurement documents for Commercial Grade Items that will be procured by *[CA]* for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the *[CA]* QAPD, Section 7, "Control of Purchased Material, Equipment and Services."

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

[CA] has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAPD. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

[CA]'s policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require: (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) the user to have committed the procedure steps to memory, (3) verification of completion of significant steps, by initials or signatures or use of check-off lists. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2 Procedure Content

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2008. In addition, procedures governing tests, inspections, operational activities and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3 NQA-1 Commitment

In establishing procedural controls, *[CA]* commits to compliance with NQA-1-2008, Requirement 5.

SECTION 6 DOCUMENT CONTROL

[CA] has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

- Identification of controlled documents
- Specified distribution of controlled documents for use at the appropriate location
- A method to identify the correct document (including revision) to be used and control of superseded documents
- Identification of individuals responsible for controlled document preparation, review, approval, and distribution
- Review of controlled documents for adequacy, completeness, and approval prior to distribution
- A method to ensure the correct documents are being used
- A method to provide feedback from users to improve procedures and work instructions
- Coordinating and controlling interface documents and procedures

The types of documents to be controlled include:

- *[Drawings such as design, construction, installation, and as-built drawings*
- *Engineering calculations*
- *Design specifications*
- *Purchase orders and related documents*
- *Vendor-supplied documents*
- *Audit, surveillance, and quality verification/inspection procedures*
- *Inspection and test reports*
- *Instructions and procedures for activities covered by the QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing*
- *Technical specifications*
- *Nonconformance reports and corrective action reports]*

[During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.]

6.1 Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. [During the *[ESP or construction phase],* procedures for design, construction, and installation are also reviewed by *[the organization responsible for quality verification]* to

ensure quality assurance measures have been appropriately applied. *[NOTE: This does not apply to an Operations-only QAP.]]* The documented review signifies concurrence.

[During the operational phase, documents affecting the configuration or operation of the station as described in the SAR are screened to identify those that require review by the [IRB/IRC] prior to implementation as described in Part V, Section 2.2.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed, and updated as necessary, based on the following conditions:

- *Following any modification to a system*
- *Following an unusual incident, such as an accident, significant operator error, or equipment malfunction*
- *When procedure discrepancies are found*
- *Prior to use if not used in the previous two years*
- *Results of QA audits conducted in accordance with Part II, Section 18.1.] [NOTE: This does not apply to a non-Operations QAP.]*

Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval. *[Where temporary procedure changes are necessary during the operational phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. [NOTE: This does not apply to a non-Operations QAP.]]* Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. 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 classification shall be clearly delineated in implementing procedures.

6.3 NQA-1 Commitment

In establishing provisions for document control, *[CA]* commits to compliance with NQA-1-2008, Requirement 6.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

[CA] has established the necessary measures and governing procedures to control purchased items and services to assure conformance with specified requirements. Such control provides 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.

7.1 Acceptance of Item or Service

[CA] establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item or service importance to safety, complexity, quantity, and the frequency of procurement. Verification actions include testing, as appropriate, during *[design, fabrication, construction, and operation]* activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly changes the scope, methods, or controls performed by a supplier, an audit of the changes is performed, thus starting a new triennial period.
- *[CA]* may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet *[CA]* requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.
- Controls are imposed for the selection, determination of suitability for intended use

(critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2 NQA-1 Commitment / Exceptions

In establishing controls for purchased items and services, *[CA]* commits to compliance with NQA-1-2008 and NQA-1a-2009, Requirement 7, with the following clarifications and exceptions:

- *[CA]* considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to the *[CA]* plant*[s]* are not required to be evaluated or audited.
- When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

  - The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the *[CA]* QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.

  - The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

  - A documented review of the supplier's accreditation will be performed and will include a verification of the following:

    - The calibration laboratory holds a domestic (United States) accreditation by an NRC-approved domestic (United States) accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

    - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

- For Section 501, *[CA]* considers documents that may be stored in approved electronic media under *[CA]* or vendor control, not physically located on the plant site, but accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to *[CA]* to support operations. The *[CA]* records management system will provide for timely

retrieval of necessary records.

- In establishing commercial grade item requirements, *[CA]* commits to compliance with NQA-1a-2009, Section 700 and Subpart 2.14, with the following clarification:

  - For commercial grade items, quality verification requirements are established and described in *[CA]* documents to provide the necessary assurance an item will perform satisfactorily in service. The *[CA]* documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

  - *[CA]* will assume 10 CFR 21 reporting responsibility for all items that *[CA]* dedicates as safety-related.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

[CA] has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.1 NQA-1 Commitment

In establishing provisions for identification and control of items, *[CA]* commits to compliance with NQA-1-2008, Requirement 8.

SECTION 9 CONTROL OF SPECIAL PROCESSES

[CA] has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1 NQA-1 Commitment

In establishing measures for the control of special processes, *[CA]* commits to compliance with NQA-1-2008, Requirement 9.

SECTION 10 INSPECTION

[CA] has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as *[source, in-process, final, and receipt inspection, as well as construction, installation, maintenance, modification, in-service, and operations]* activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.1 Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at a *[CA]* facility, (3) for final acceptance of fabricated and/or installed items during construction, and (4) upon receipt of items for a facility[, *as well as (5) during maintenance, modification, in-service, and operating activities*].

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2 Inspector Qualification

[CA] has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.3 NQA-1 Commitment / Exceptions

In establishing inspection requirements, *[CA]* commits to compliance with NQA-1-2008, Requirement 10 and Subparts 2.4, 2.5 and 2.8 for establishing appropriate inspection requirements with the following clarifications;

- Subpart 2.4 commits *[CA]* to IEEE 336-1985, which refers to IEEE 498-1985. Both IEEE 336-1985 and IEEE 498-1985 use the definition of "Safety Systems" from IEEE 603-1980. *[CA]* commits to the definition of Safety Systems in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.

- An additional exception to Subpart 2.4 is addressed in Part II, Section 12 of the QAPD.

SECTION 11 TEST CONTROL

[CA] has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory. These programs include criteria for determining when testing is required, such as *[proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests (such as surveillance tests required by Plant Technical Specifications)],* to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

*[*The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs. *[NOTE: This does not apply to an ESP-only QAP]]*

Except for computer program testing, which is addressed in Section 11.1, tests are performed and results documented in accordance with applicable technical and regulatory requirements, including those described in the Technical Specifications and SAR. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2.

11.1 NQA-1 Commitment for Computer Program Testing

[CA] establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end *[CA]* commits to compliance with the requirements of NQA-1a-2009, Requirement 11 and Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, Requirement 3.

11.2 NQA-1 Commitment

In establishing provisions for testing, *[CA]* commits to compliance with NQA-1a-2009, Requirement 11.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

[CA] has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met or information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services are controlled as described in Part II, Section 7.

12.1 Installed Instrument and Control Devices

[For the operational phase of the facilities, *[CA]* has established and implements procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements.] Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device. NOTE: This does not apply to an ESP-only QAP.

12.2 NQA-1 Commitment / Exceptions

In establishing provisions for control of measuring and test equipment, *[CA]* commits to compliance with NQA-1-2008, Requirement 12 with the following clarification and exception:

- NQA-1-2008, Subpart 2.4 refers to ANSI/IEEE Std. 336-1985 for the installation, inspection, and testing requirements for power, instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std. 336-1985 makes reference to the use of IEEE Std. 498-1985 for measuring and test equipment control, *[CA]* will implement the QA requirements of NQA-1-2008, Requirement 12.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

[CA] has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning, and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use.

Operators of special handling and lifting equipment are experienced or trained in the use the equipment. [During the operational phase, *[CA]* establishes and implements controls over hoisting, rigging, and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. *[NOTE: This does not apply to a non-Operations QAP.]*] Where required, *[CA]* complies with applicable hoisting, rigging and transportation regulations and codes.

13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems, and components within the plant. This includes control of cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, and protection of equipment*[, as well as, radioactive contamination control, and storage of solid radioactive waste]*. Housekeeping practices help assure that only proper materials, equipment, processes, and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, and cleaning of control consoles[, and radioactive decontamination] are developed and used. *[NOTE: This does not apply to an ESP-only QAP.]*

13.2 NQA-1 Commitment / Exceptions

In establishing provisions for handling, storage, and shipping, *[CA]* commits to compliance with NQA-1-2008, Requirement 13. [*[CA]* also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: *[NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

[NQA-1a-2009, Subpart 2.1

- *Subpart 2.1, Section 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, [CA] may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. [CA] establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference ADAMS Accession number ML050700416.]]*

NQA-1a-2009, Subpart 2.2

- *[Subpart 2.2, Section 202 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, [CA] may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference ADAMS Accession number ML050700416.]]*

- Subpart 2.2, Section 606, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, *[CA]* documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

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[NQA-1-2008, Subpart 2.3

- *Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, [CA] bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference ADAMS Accession number ML050700416.]]*

NQA-1-2008, Part III, Subpart 3.2

- Subpart 3.2, Appendix 2.1: Only Section 300, "Cleaning Recommendations and Precautions" are being committed to in accordance with RG 1.37. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels.]

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

[CA] has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1 NQA-1 Commitment

In establishing measures for control of inspection, test and operating status, *[CA]* commits to compliance with NQA-1-2008, Requirement 14.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

[CA] has established the necessary measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with *[CA]* procedures, regulatory requirements, and industry standards.

15.1 Interface with the Reporting Program

[CA] has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of *[10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during [ESP/COL design and construction and 10 CFR 21 during operations].*

15.2 NQA-1 Commitment

In establishing measures for nonconforming materials, parts, or components, *[CA]* commits to compliance with NQA-1-2008, Requirement 15.

SECTION 16 CORRECTIVE ACTION

[CA] has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. *[CA]* procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. *[CA]* procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, *[CA]* documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, *[CA]* may delegate specific responsibilities for corrective actions but *[CA]* maintains responsibility for the effectiveness of corrective action measures.

16.1 Interface with the Reporting Program

[CA] has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of *[10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during ESP/COL design and construction, and 10 CFR 21 during operations]*.

16.2 NQA-1 Commitment

In establishing provisions for corrective action, *[CA]* commits to compliance with NQA-1-2008, Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

[CA] has the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for *[CA]* and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for *[design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits]* and their retention times are defined in appropriate procedures. The records and retention times are *[based on Regulatory Position C.1.a.(3) of Regulatory Guide 1.28, Revision 4 for design, construction, and initial start-up. Retention times for operational phase records are based on construction records that are similar in nature.] [NOTE: The applicant/licensee must address the records retention schedule for their plant by either referencing Regulatory Guide 1.28, Rev. 4, or including their specific table in the QAPD]* In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

When using optical disks for electronic records storage and retrieval systems, *[CA]* complies with the NRC guidance in Generic Letter 88-18, "Plant Record Storage on Optical Disks." *[CA]* will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.

17.3 NQA-1 Commitment / Exceptions

In establishing provisions for records, *[CA]* commits to compliance with NQA-1-2008, Requirement 17, and regulatory positions stated in Regulatory Guide 1.28, Rev 4, June 2010.

SECTION 18 AUDITS

[CA] has established the necessary measures an*d* governing procedures to implement audits to verify that activities covered by the QAPD are performed in conformance with the established requirements and performance criteria are met. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of selected aspects of *[licensing, design, construction and operating phase]* activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the early portions of *[Nuclear Development]* activities, audits will focus on areas including, but not limited to, *[site investigation],* procurement, and corrective action. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of internal rules, procedures *[(e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff, corrective actions, and observation of performance of operating, refueling, maintenance, and modification activities, including associated record keeping].*

The audits are scheduled on a formal preplanned audit schedule and in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the *[Quality Manager responsible for the day to day program as documented in Section 1].*

[CA] is responsible for conducting periodic internal to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAPD.

The results of each audit are reported in writing to the responsible *[Senior Executive responsible for the Quality Assurance program at the Site/Plant/Company]*, or designee, as appropriate. Additional internal distribution is made to other concerned management levels and to management of the internal audited organizations or activities in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Audits of suppliers of safety-related components and/or services are conducted as described in Section 7.1.

18.2 Internal Audits

Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

[Internal audits of activities, conducted after placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area within a period of two years. Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.

During the operational phase audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, as a minimum, activities in the following areas:

- The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls.
- The performance, training, and qualifications of the facility staff.
- The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B.
- The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant.
- Other activities and documents considered appropriate by the *[Vice President of Nuclear Operations, or the CNO].*

Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code. *[NOTE: This does not apply to a non-Operations QAP]*]

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of *[construction, fabrication, operating, refueling, maintenance, and modification]* activities including associated record keeping.

18.3 NQA-1 Commitment

In establishing the independent audit program, *[CA]* commits to compliance with NQA-1-2008, Requirement 18 and the regulatory positions stated in Regulatory Guide 1.28, Rev 4.

PART III NONSAFETY-RELATED SSC QUALITY CONTROL

[NOTE: Part III does not apply to an ESP-only QAPD]

SECTION 1 NONSAFETY-RELATED SSCS - SIGNIFICANT CONTRIBUTORS TO PLANT SAFETY

Specific program controls are applied to nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-related SSCs.

1.1 Organization

The verification activities described in this part may be performed by the *[CA]* line organization. The QA organization described in Part II is not required to perform these functions.

1.2 QA Program

[CA] QA requirements for nonsafety-related SSCs are established in the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

1.3 Design Control

[CA] has design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

1.4 Procurement Document Control

Procurement documents for items and services obtained by or for *[CA]* include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5 Instructions, Procedures, and Drawings

[CA] provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6 Document Control

[CA] controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7 Control of Purchased Items and Services

[CA] employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8 Identification and Control of Purchased Items

[CA] employs measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

1.9 Control of Special Processes

[CA] employs process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

[CA] uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11 Test Control

[CA] employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in

accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

1.12 Control of Measuring and Test Equipment (M&TE)

[CA] employs measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

1.13 Handling, Storage, and Shipping

[CA] employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14 Inspection, Test, and Operating Status

[CA] employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15 Control of Nonconforming Items

[CA] employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16 Corrective Action

[CA] employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17 Records

[CA] employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

1.18 Audits

[CA] employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2 NON-SAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS

[NOTE: The applicant should provide an evaluation of conformance with the guidance in NRC regulatory guides in effect 6 months before the submittal date of the application. That evaluation should also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant. Section 2 provides alternative approaches for satisfying the following NRC guidance:

- *Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."*
- *Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in Regulatory Guide 1.155 Revision 0 August 1988, "Station Blackout."]*

[NOTE: The specific program controls identified in Part III, Section1 for nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, are commensurate with the NRC Guidance identified above.]

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related;

- *[CA]* implements quality requirements for the fire protection system in accordance with *[Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Nuclear Power Plants" as identified in FSAR Chapter 1.] [NOTE: The applicant/licensee must address the conformance to Regulatory Guide 1.189. Part III Section 1 may not adequately address regulatory position 1.7 of RG1.189. In reviewing the Regulatory Positions the applicant should reference FSAR Section 9.5.]*

- *[CA]* implements the quality requirements for ATWS equipment in accordance with Part III, Section1.

- *[[CA*] implements quality requirements for SBO equipment in accordance with Part III, Section1.

[NOTE: In addressing applicability of these Regulatory Guides care must be exercised to ensure conformance identified for the design is consistent with the technology specific design as documented in the applicable certified design.]

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the *[CA]* QAPD. *[CA]* complies with these standards to the extent described or referenced. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.

[NOTE: NEI 11-04 was prepared and reviewed to NUREG 0800 Standard Review Plan Section 17.5 March 2007 and RG 1.28, Rev.4 that endorses NQA-1-2008 and NQA-1a-2009; if there is a later version of the guidance, an applicant would need to address conformance to the later revision in the FSAR.]

[NOTE: The applicant should provide an evaluation of conformance with the guidance in NRC regulatory guides in effect six months before the submittal date of the application. That evaluation should also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant. The section on Regulatory Guides below identifies where the template conforms with or provides alternative approaches for satisfying the identified NRC guidance.]

Regulatory Guides:

[See FSAR Chapter 1 for the [CA] evaluation of conformance with the guidance in NRC Regulatory Guides in effect six months prior to the submittal date of the application.]

[NOTE: The notes provide an applicant information to support addressing Regulatory Guide conformance in Chapter 1 of the FSAR consistent with RG 1.206, section C.I.1.9. The formatting of this section assumes the applicant will address conformance with RGs in a single location in Chapter 1 of the FSAR. If an applicant elects to provide the identification of conformance in this section for the identified RGs, conformance, exceptions, or alternatives for all regulatory positions of each RG should be included. Once a QAPD is approved by the NRC and the applicant/licensee makes changes in the RG conformance, such as new or different clarifications or alternatives, the changes must be in accordance with the regulations for making QAPD changes (10 CFR 50.54(a) or 10 CFR 50.55(f).]

[NOTE: The information below identifies where this template conforms with or provides alternatives to the RGs and the indicated regulatory positions. Regulatory Positions determined to not be directly applicable to the QAPD include a pointer to the potentially applicable Chapter of the FSAR. The applicant is responsible to review this information and confirm its accuracy at the time of submittal of an application. In addressing conformance with the Regulatory Guides, the applicant must also consider the status of conformance for design and construction consistent with the referenced DCD. The revisions used below were in effect when this document was prepared. Use the appropriate revisions based on the time of application.]

Regulatory Guide 1.8, *[Rev. 3, May 2000]*, Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This regulatory guide endorses ANSI/ANS-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," with certain additions and exceptions that are listed in the Regulatory Position of this guide. Some of the exceptions are endorsements of certain sections of two other standards, ANSI N18.7-1976 (ANS-3.2), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," and ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants." Rather than to commit to those Standards in the QAPD, appropriate requirements have been directly incorporated into the text if not found in NQA-1-2008 with NQA-1a-2009 Addenda. These requirements are consistent with the identified acceptance criteria in SRP Section 17.5. With regard to cold licensed operators when the selection, training, and qualification requirements of ANSI/ANS-3.1-1993 may not be met, NEI 06-13A, (NRC approval as Rev. 1) (NEI published Rev. 2) provides acceptable alternatives.]

[NOTE: Regulatory Positions C.1.1 through C.1.4 address definitions in ANSI/ANS-3.1-1993. Conformance with ANSI/ANS-3.1-1993 and those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Position C.2.1 (2.1.1, 2.1.2, and 2.1.3) addresses alternatives and substitutions for education and experience for quality assurance personnel. Those alternatives and substitutions are reflected in Part II, Section 2.6 of the QAPD template.]

[NOTE: Regulatory Position C.2.2 through C.2.10 are not directly applicable to quality assurance personnel, but are relevant to the overall quality assurance organization described in Part II, Section 1 of the QAPD and the operating organization described in FSAR Chapter 13. Those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Position C.2.11 addresses ANSI/ANS-3.1-1993 Section 4.5.5, Quality Control. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T.]

[NOTE: Regulatory Position C.2.12 addresses ANSI/ANS-3.1-1993 Section 4.5.6, Quality Assurance. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.S.]

[NOTE: Regulatory Position C.2.13 is not directly applicable to quality assurance personnel, but is relevant to the overall quality assurance organization described in Part II, Section 1 of the QAPD and the operating organization described in FSAR Chapter 13. This Regulatory Position should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Positions C.2.14 and C.2.15 address ANSI/ANS-3.1-1993 Sections 4.7.1 and 4.7.2 relative to Independent Review qualifications. The QAPD identifies an alternative for this regulatory position in Part V, Section 2.2. As documented in SER ML070510300, the QAPD template follows SRP Section 17.5, paragraph II.W for providing guidance to the applicant to establish an independent review program for activities occurring during the operational phase.]

Regulatory Guide 1.26, *[Revision 4, March 2007]* - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This Regulatory Guide provides guidance on establishing quality group classifications for components of the nuclear plant and the appropriate industry standards to apply that ensure proper quality requirements. Regulatory Positions C.1 through C.3 provide guidance in establishing quality group classifications of components that correspond to ASME Section III, Class 2 and 3, and those that are not part of the reactor coolant system but may contain radioactive material. Table 1 of the RG identifies the industry standards that would be applied to establishing appropriate quality requirements. The classification of components would be addressed through the FSAR (and associated DCD) Section 3.2. The application of specific standards would be addressed in the FSAR/DCD sections that describe the identified components.]

Regulatory Guide 1.28, *[Rev. 4, June 2010]*, Quality Assurance Program Criteria (Design and Construction)

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This regulatory guide endorses Part I and Part II requirements in ASME NQA-1-2008, "Quality Assurance Program Requirements for Nuclear Power Plants" and the ASME NQA-1a-2009 Addenda along with the regulatory positions discussed below for the establishment and execution of quality assurance programs during the design and construction phases of nuclear power plants. The QAPD provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-2008 and NQA-1a-2009 Addenda as supplemented by additional regulatory guidance and industry guidance.

[NOTE: Regulatory Position C.1 addresses quality assurance records. In establishing a records program, the QAPD, Part II, Section 17.3 commits the applicant to comply with NQA-1-2008 and NQA-1a-2009 Addenda and the regulatory position as modified by the

noted clarifications and exceptions.}

[NOTE: Regulatory Position C.2 addresses audits. In establishing the independent audit program, the QAPD, Part II, Section 18.3 commits the applicant to comply with NQA-1-2008 and NQA-1a-2009 Addenda and the regulatory position as modified by the noted clarifications and exceptions.}

Regulatory Guide 1.29, *[Revision 4, March 2007]* - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This Regulatory Guide describes an acceptable method for identifying and classifying the features of nuclear power plants that must be designed to withstand the effects of the Safe Shutdown Earthquake (SSE). Regulatory Positions C.1 through C.3 provide guidance in establishing the SSCs, or portions thereof, classified as needing to meet seismic design requirements. The seismic design classification of SSCs would be addressed through the FSAR (and associated DCD) Section 3.2.]

[NOTE: Regulatory Position C.4 addresses the application of the QA requirements of Appendix B to 10 CFR Part 50 to all activities affecting the safety-related functions of those portions of the SSCs that are covered by Regulatory Positions 2 and 3. Those in Regulatory Position 1 are considered safety-related. The QAPD described in Section 17.5 of the FSAR addresses the QA program requirements applied to safety-related activities.]

[NOTE: Regulatory Position C.5 addresses the application of design requirements for portions of the fire protection SSCs as discussed in Regulatory Guide 1.189. The design and quality assurance requirements for fire protection SSCs are addressed in Section 9.5.1 of the FSAR (and associated DCD).]

Regulatory Guide 1.33, *[Revision 2, February 1978]*, Quality Assurance Program Requirements (Operations)

Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This Regulatory Guide endorses ANSI N18.7-1976/ANS-3.2 for complying with the quality assurance program requirements for the operation phase of nuclear power plants, subject to five regulatory positions. Attachment 2 provides a comparison of QA requirements established within NQA-1-2008 and NQA-1a-2009 Addenda and the template to provide an alternate method of meeting 10 CFR 50, Appendix B during the operational phase in lieu of committing to the requirements of ANSI N18.7-1976/ANS-3.2.]

[NOTE: Regulatory Position C.1 addresses "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors." QAPD Part II, Sections 5 and 6, and Part V, Section 3 address requirements for procedures consistent with requirements addressed in SRP 17.5 section II.F and ANSI N18.7-1976.]

[NOTE: Regulatory Position C.2 identifies additional standards referenced by ANSI N18.7-1976/ANS-3.2 and provides a cross reference for a regulatory Guide that addressed each of those standards. The QAPD identifies commitments to ASME NQA-1-2008 with NQA-1a-2009 Addenda instead of the listed ANSI N45.2 series standards listed. Regulatory Guides 1.28, 1.37, 1.38, 1.39, 1.30, 1.94, 1.58, 1.116, 1.88, 1.74, 1.64, and 1.123 are listed for positions on the ANSI N45.2 series standards. RG 1.8, 1.17, and 1.54 are included as addressing other ANSI Standards. RG 1.8, 1.28, and 1.37 have been revised to reference newer standards and are discussed specifically in this section. RG 1.17, 1.38, 1.39, 1.58, 1.64, 1.74, 1.88, 1.94, 1.116 and 1.123 have been withdrawn. For RG 1.30, 1.38, 1.94 and 1.116 the QAPD provides an acceptable alternative using ASME NQA-1-2008 with NQA-1a-2009 Addenda, Subparts 2.2, 2.4, 2.5, and 2.8 as identified in Part II Sections 10.3 and 13.2 and SRP 17.5 Section II.U.2. For RG 1.39 the QAPD provides an acceptable alternative in Part II, Section 13.1, which is consistent with SRP Section 17.5, paragraph II.M. for operations; controls during design and construction are addressed in the commitment in Section 13.2. For applicability of RG 1.54, FSAR Chapter 6 should be consulted.]

[NOTE: Regulatory Position C.3 identifies a position related to Independent Review. The QAPD provides an alternative for this position by addressing Independent Review requirements specifically in Part V, Section 2.2 consistent with SRP 17.5 Section II.W rather than referencing ANSI N18.7. Item 2.2 c. specifically relates to the concern of this regulatory position.]

[NOTE: Regulatory Position C.4 relates to provisions of the audit program. In establishing the independent audit program, the QAPD provides an alternative for this position by committing the applicant to comply with the quality standards described in NQA-1-2008, Requirement 18. Over the years, the utilities have modified their audit programs to provide alternatives to the amplified requirements of this Regulatory Position through risk-informed scheduling or controlling the scope of the scheduled audits. The licensee/applicant will need to provide the NRC with the rationale for any alternative to the amplified frequencies stated in the Regulatory Position. The QAPD template follows SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established.]

[NOTE: Regulatory Position C.5 identifies concerns of the NRC with the usage of the verbs "should" and "shall" in ANSI N18.7-1976. The QAPD provides an alternative to this position by providing adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA-1-2008 with NQA-1a-2009 Addenda, as supplemented by the QAPD. Additional regulatory guidance and industry guidance is identified in SRP Section 17.5.]

Regulatory Guide 1.37, *[Revision 1, March 2007]* – Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants

Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.] [NOTE: Does not apply to ESP-only or Operations-only QAP]*]

[NOTE: This Regulatory Guide finds that the provisions and recommendations included in ASME NQA-1-1994, Part II, Subpart 2.1 are generally acceptable for onsite cleaning of materials and components, cleanness control, and preoperational cleaning and layup of water-cooled nuclear power plant fluid systems with three regulatory positions. The three regulatory positions were addressed in the NQA-1a-2009 Addenda and subsequently accepted by Regulatory Guide 1.28, Rev. 4. QAPD Part II, Section 13.2 addresses the commitment to NQA-1-2008 with NQA-1a-2009 Addenda, Part II, Subpart 2.1.]

[Regulatory Guide 1.54, [Revision 2, October 2010] - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants]

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.

[Note: For applicability of RG 1.54 and any clarifications or alternatives, FSAR Chapter 6 should be consulted.]]

Standards:

ASME NQA-1-2008 Edition with NQA-1a-2009 Addenda - Quality Assurance Requirements for Nuclear Facility Applications

[CA] commits to NQA-1-2008 with NQA-1a-2009 Addenda, Parts I and II, as described in Part*[s]* II *[and V]* of this document with specific identification of exceptions or clarification. *[CA]* commits to NQA-1-2008 with NQA-1a-2009 Addenda, and Part III only as specifically noted in Part*[s]* II *[and V]* of this document.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

[CA] commits to NIRMA TGs as described in Part II, Section 17.

PART V ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE

*[**Note:** This Part is only applicable for Licensees that are submitting their QAPD for the operational phase. This Part does not apply to ESP and Construction phases.]*

*[**Note:** The information in Part V is provided as equivalent requirements for meeting the regulatory positions of Reg. Guide 1.33, Rev. 2, as identified in Appendix 1.]*

[CA] includes the requirements of Part V that follow when establishing the necessary measures and governing procedures for the operational phase of the plant.

SECTION 1 DEFINITIONS

[CA] uses the definitions of terms as provided in Section 4 of the Introduction of NQA-1-2008 with NQA-1a-2009 Addenda in interpreting the requirements of NQA-1 and the other standards to which the QAPD commits. In addition, definitions are provided for the following terms not covered in NQA-1:

administrative controls: rules, orders, instructions, procedures, policies, practices, and designations of authority and responsibility

experiments: performance of plant operations carried out under controlled conditions in order to establish characteristics or values not previously known

independent review: review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review)

nuclear power plant: any plant using a nuclear reactor to produce electric power, process steam, or provide space heating

on-site operating organization: on-site personnel concerned with the operation, maintenance and certain technical services

operating activities: work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the on-site operating organization

operational phase: that period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of initial fuel loading, and ends with plant decommissioning

review: a deliberately critical examination, including observation of plant operation, evaluation of assessment results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions

supervision: direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities they direct or monitor

surveillance testing: periodic testing to verify that safety related structures, systems, and components continue to function or are in a state of readiness to perform their functions

system: an integral part of nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function

SECTION 2 REVIEW OF ACTIVITIES AFFECTING SAFE PLANT OPERATION

2.1 Onsite Operating Organization Review

The *[CA]* onsite organization employs reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews are documented and subjects of potential concern for the independent review described below are brought to the attention of the *[manager responsible for Plant Operations (plant manager)]*. The reviews are part of the normal duties of plant supervisory personnel in order to provide timely and continuing monitoring of operating activities in order to assist the *[manager responsible for Plant Operations (plant manager)]* in keeping abreast of general plant conditions and to verify that day-to-day operations are conducted safely in accordance with the established administrative controls. The *[manager responsible for Plant Operations (plant manager)]* ensures the timely referral of the applicable matters discussed in the reviews to appropriate management and independent reviewers.

2.2 Independent Review

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

- Reviews proposed changes to the facility as described in the safety analysis report (SAR). The *[Independent Review Body (IRB)/Independent Review Committee (IRC)]* also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.
- Reviews proposed tests and experiments not described in the SAR prior to implementation. Verifies the determination of whether changes to proposed tests and experiments not described in the SAR require a technical specification change or license amendment.
- Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.
- Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
- Reviews any matter related to nuclear safety that is requested by the *[Site Vice President, Site Director, Plant Manager,] [NOTE: the generic titles used here must match those established in Part II, Section 1 Organization]* or any *[IRB/IRC]* member.
- Reviews corrective actions for significant conditions adverse to quality.
- Reviews internal audit reports.
- Reviews the adequacy of the internal audit program every 24 months.

[NOTE: Option I or Option II may be used. The generic terms Independent Review Body (IRB) and Independent Review Committee (IRC) may be substituted with the specific company terms.]

[NOTE: Option I]

[Independent Review Body

A group may function as an independent review body (IRB). In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

IRB reviews are supplemented as follows:

- A qualified person, independent of the preparer, reviews proposed changes in the procedures as described in the SAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.
- Audits of selected changes in the procedures described in the SAR are performed to verify that procedure reviews and revision controls are effectively implemented.
- Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.
- The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review supports management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.
    - The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities. The IRB supervisor or chairman has a minimum six (6) years combined managerial and technical support experience. The members of the IRB should have a minimum of five years of experience in their own area of responsibility as applicable to the activities being reviewed (i.e., a minimum of five years of experience in one of the areas listed below:
        - Nuclear power plant operations
        - Nuclear engineering
        - Chemistry and radiochemistry
        - Metallurgy
        - Nondestructive testing
        - Instrumentation and control
        - Radiological safety
        - Mechanical engineering
        - Electrical engineering
        - Administrative control and quality assurance practices
        - Training

  - Emergency plans and related procedures and equipment).
  - The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.
- Results of the review are documented and reported to responsible management.
- Management periodically consider issues they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.
- Management determines the scheduling and scope of review and the composition of the team performing the review.]

[NOTE: Option II]

[Independent Review Committee

A formally established group functions as an Independent Review Committee (IRC). In discharging its review responsibilities, the IRC keeps safety considerations paramount when opposed to cost or schedule considerations. The IRC performs its functions in the following manner:

- An Independent Review Committee is assigned independent review responsibilities and reports to *[CA is to identify a management level above the plant manager as described in the organization in Part II, Section 1]*.
- The Independent Review Committee is composed of no less than 5 persons; no more than a minority of members are from the on-site operating organization.
  - For example, at least 3 of the 5 members must be from off-site if there are 5 members on the committee. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.
- During the period of initial operation, meetings are conducted no less frequently than once per calendar quarter. Afterwards meetings are conduced no less than twice a year.
- Results of the meeting are documented and recorded.
- Consultants and contractors are used for the review of complex problems beyond the expertise of the off site/on site independent review committee.
- Persons on the Independent Review Committee are qualified as follows:

  <u>Supervisor or Chairman of the Independent Review Committee</u>

  - Education: Baccalaureate in engineering or related science
  - Minimum experience: Six (6) years combined managerial and technical support

  Independent Review Committee members

  - Education: Baccalaureate in engineering or related science for those personnel required to review problems in nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering or electrical engineering.

    High school diploma for those independent review personnel required to review

problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.

- Minimum experience: Five (5) years experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, non-destructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment).

SECTION 3 OPERATIONAL PHASE PROCEDURES

The following is a description of the various types of procedures used by *[CA]* to govern the design, operation, and maintenance of its nuclear generating plants. *[CA]* follows the guidance of Appendix A to Regulatory Guide 1.33 in identifying the types of activities that should have procedures or instructions to control the activity. Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process.

3.1 Format and Content

Procedure format and content may vary from one location to the other; however, procedures include the following elements as appropriate to the purpose or task to be described.

Title/Status
Each procedure is given a title descriptive of the work or subject it addresses, and includes a revision number and/or date and an approval status.

Purpose/Statement of Applicability/Scope
The purpose for which the procedure is intended is clearly stated (if not clear from the title). The systems, structures, components, processes or conditions to which the procedure applies are also clearly described.

References
Applicable references, including reference to appropriate Technical Specifications, are required. References are included within the body of the procedure when the sequence of steps requires other tasks to be performed (according to the reference) prior to or concurrent with a particular step.

Prerequisites/Initial Conditions
Prerequisites/initial conditions identify independent actions or procedures that must be accomplished and plant conditions which must exist prior to performing the procedure; including prerequisites applicable to only a specific portion of a procedure.

Precautions
Precautions alert the user to those important measures to be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation during performance of the procedure. Cautionary notes applicable to specific steps are included in the main body of the procedure and are identified as such.

Limitations and actions
Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band are specified.

Main body
The main body of the procedure contains the step-by-step instructions in the degree of detail necessary for performing the required function or task.

Acceptance criteria
The acceptance criteria provide the quantitative or qualitative criteria against which the success or failure (as of a test-type activity) of the step or action would be judged.

Checklists
Complex procedures utilize checklists which may be included as part of the procedure or appended to it.

3.2 Procedure Types

Procedure types may vary from one location to the other based on scope of activities; however, procedures are developed in each of the following categories.

Administrative Control Procedures
These include administrative procedures, directives, policies, standards, and similar documents that control the programmatic aspects of facility activities. These administrative documents ensure that the requirements of regulatory and license commitments are implemented. Several levels of administrative controls are applied ranging from those affecting the entire Company to those prepared at the implementing group level. These documents establish responsibilities, interfaces, and standard methods (rules of practice) for implementing programs. In addition to the administrative controls described throughout this QAPD, instructions governing the following activities are provided:

Operating Orders/Procedures
Instructions of general and continuing applicability to the conduct of business to the plant staff are provided. Examples include, but are not limited to, job turnover and relief, designation of confines of control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions. Provisions are made for periodic review and updating of these documents, where appropriate.

Special Orders
Management instructions, which have short-term applicability and require dissemination, are issued to encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions are made for periodic review, updating, and cancellation of these documents, where appropriate.

Plant Security and Visitor Control
Procedures or instructions developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program is confidential and thus accorded limited distribution. The security and visitor control procedures consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control. Administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for

visitors; emphasis on inspection, observation and challenging of strangers by operating crews; and a program of pre-employment screening for potential employees are also considered.

Temporary Procedures
Temporary procedures may be used to direct operations during testing, refueling, maintenance, and modifications to provide guidance in unusual situations not within the scope of the normal procedures. These procedures ensure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that portions of existing procedures do not apply. Temporary Procedures include designation of the period of time during which they may be used and are subject to the procedure review process as applicable.

Engineering Procedures
These documents provide instructions for the preparation of engineering documents, engineering analysis, and implementation of engineering programs. This includes activities such as designs; calculations; fabrication, equipment, construction, and installation specifications; drawings; analysis and topical reports; and testing plans or procedures. They include appropriate references to industry codes and standards, design inputs, and technical requirements.

Configuration Management Procedures
These documents provide instructions for the responsibility and authority for functions that affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement. *[CA shall establish and document a time or event when configuration management shall be established for the facility.]*

Installation Procedures
These documents provide instructions for the installation of components generally related to new construction and certain modification activities. They include appropriate reference to industry standards, installation specifications, design drawings, and supplier and technical manuals for the performance of activities. These documents include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection and test instructions subject to the requirements for test and inspection procedures below.

System Procedures
These documents contain instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation, and other instructions appropriate for operations of systems related to the safety of the plant. Actions to correct off-normal conditions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure. Separate procedures may be developed for correcting off-normal conditions for those events where system complexity may lead to operator uncertainty. Appropriate procedures will also be developed for the fire protection program.

Start-up Procedures
These documents contain instructions for starting the reactor from cold or hot conditions and establishing power operation. This includes documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned, necessary system procedures, tests and calibrations have been completed; and required approvals have been obtained.

Shutdown Procedures
These documents contain guidance for operations during controlled shutdown and following reactor trips, including instructions for establishing or maintaining hot shutdown/standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the plant are specified, including instructions for such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence for activating or deactivating equipment, requirements for prompt analysis for causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal.

Power Operation and Load Changing Procedures
These documents contain instructions for steady-state power operation and load changing. These type documents include, as examples, provisions for use of control rods, chemical shim, coolant flow control, or any other system available for short-term or long-term control of reactivity, making deliberate load changes, responding to unanticipated load changes, and adjusting operating parameters.

Process Monitoring Procedures
These documents contain instructions for monitoring performance of plant systems to assure that core thermal margins and coolant quality are maintained in acceptable status at all times, that integrity of fission product barriers is maintained, and that engineered safety features and emergency equipment are in a state of readiness to keep the plant in a safe condition if needed. Maximum and minimum limits for process parameters are appropriately identified. Operating procedures address the appropriate nature and frequency of this monitoring.

Fuel Handling Procedures
These documents contain instructions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of neutron flux throughout core loading, periodic data recording, audible annunciation of abnormal flux increases, and evaluation of core neutron multiplication to verify safety of loading increments. Procedures are also provided for receipt and inspection of new fuel, and for fuel movements in the spent fuel storage areas. Fuel handling procedures include prerequisites to verify the status of systems required for fuel handling and movement; inspection of replacement fuel and control rods; designation of proper tools, proper conditions for spent fuel movement, proper conditions for fuel cask loading and movement; and status of interlocks, reactor trip circuits and mode switches. These procedures provide requirements for refueling, including proper sequence, orientation and seating of fuel and components, rules for minimum operable instrumentation, actions for response to fuel damage, verification of shutdown margin, communications between the control room and the fuel handling station, independent verification of fuel and component locations, criteria for stopping fuel movements, and documentation of

final fuel and component serial numbers (or other unique identifiers) and locations.

Maintenance Procedures
These documents contain instructions in sufficient detail to permit maintenance work to be performed correctly and safely, and include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection or test instructions subject to the requirements for test and inspection procedures below. Appropriate referencing to other procedures, standards, specifications, or supplier manuals is provided. When not provided through other documents, instructions for equipment removal and return to service, and applicable radiation protection measures (such as protective clothing and radiation monitoring) will be included. Additional maintenance procedure requirements are addressed in NQA-1-2008, Subpart 2.18, Section 202, Procedures.

Radiation Control Procedures
These documents contain instructions for implementation of the radiation control program requirements necessary to meet regulatory commitments, including acquisition of data and use of equipment to perform necessary radiation surveys, measurements and evaluations for the assessment and control of radiation hazards. These procedures provide requirements for monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; effluent and environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities, and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures to employees and others.

Calibration and Test Procedures
These documents contain instructions for periodic calibration and testing of instrumentation and control systems, and for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. These documents provide for meeting surveillance requirements and for assuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.

Chemical and Radiochemical Control Procedures
These documents contain instructions for chemical and radiochemical control activities and include: the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces, or become sources of radiation hazards due to activation. These documents also provide for the control, treatment and management of radioactive wastes, and control of radioactive calibration sources.

Emergency Operating Procedures
These documents contain instructions for response to potential emergencies so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate actions that are taken in response. Format and content of emergency procedures are based on NUREG and Owner's Group(s) guidance that identify potential emergency conditions and require such procedures to include, as appropriate, a title, symptoms to aid in identification of the nature of the emergency, automatic actions to be expected from protective systems, immediate operator actions for

operation of controls or confirmation of automatic actions, and subsequent operator actions to return the reactor to a normal condition or provide for a safe extended shutdown period under abnormal or emergency conditions.

Emergency Plan Implementing Procedures
These documents contain instructions for activating the Emergency Response Organization and facilities, protective action levels, organizing emergency response actions, establishing necessary communications with local, state and federal agencies, and for periodically testing the procedures, communications and alarm systems to assure they function properly. Format and content of such procedures are such that requirements of each facility's NRC approved Emergency Plan are met.

Test and Inspection Procedures
These documents provide the necessary measures to assure quality is achieved and maintained for the nuclear facilities. The instructions for tests and inspections may be included within other procedures, such as installation and maintenance procedures, but will contain the objectives, acceptance criteria, prerequisites for performing the test or inspection, limiting conditions, and appropriate instructions for performing the test or inspection, as applicable. These procedures also specify any special equipment or calibrations required to conduct the test or inspection and provide for appropriate documentation and evaluation by responsible authority to assure test or inspection requirements have been satisfied. Where necessary, hold or witness points are identified within the procedures and require appropriate approval for the work to continue beyond the designated point. These procedures provide for recording the date, identification of those performing the test or inspection, as-found condition, corrective actions performed (if any), and as-left condition, as appropriate for the subject test or inspection.

SECTION 4 CONTROL OF SYSTEMS AND EQUIPMENT IN THE OPERATIONAL PHASE

Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented. Measures, such as installation of tags or locks and releasing stored energy, are used to ensure personnel and equipment safety. When entry into a closed system is required, *[CA]* has established control measures to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.

Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. In making this determination, attention is given to the potentially degraded degree of protection where one subsystem of a redundant safety system is not available for service. Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; method of emergency core cooling; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.

When systems or equipment are ready to be returned to service, designated operating personnel control placing the items in service and document its functional acceptability. Attention is given to restoration of normal conditions, such as removal of jumpers or signals used in maintenance or testing, or actions such as returning valves, breakers or switches to proper start-up or operating positions from "test" or "manual" positions. Where necessary, the equipment placed into service receives additional surveillance during the run-in period.

Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly. The minimum requirements and standards for using independent verification are established in company documents.

SECTION 5 PLANT MAINTENANCE

[CA] establishes controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related structures, systems and components are maintained in a manner that assures their ability to perform their intended safety function(s). Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant.

In establishing controls for plant maintenance, *[CA]* commits to compliance with NQA-1-2008, Subpart 2.18, with the following clarifications:

- Where Subpart 2.18 refers to the requirements of ANS-3.2, it shall be interpreted to mean the applicable standards and requirements established within the *[ND]* QAPD

- Section 203 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the *[ND]* QAPD, Part II, Section 13.2.

APPENDIX 1

Regulatory Guide 1.33, Rev. 2, ANSI N18.7-1976, NQA-1-2008/NQA-1a-2009 Standards, and NEI 11-04 QAPD Compliance Matrix

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
1. Scope		
This Standard provides requirements and recommendations for an administrative controls and quality assurance program necessary to provide assurance that operational phase activities at nuclear power plants are carried out without undue risk to the health and safety of the public. The requirements of this Standard apply to all activities affecting the safety-related functions of nuclear power plant structures, systems, and components. It is not intended to apply to test mobile and experimental reactors nor reactors not subject to U.S. Nuclear Regulatory Commission licensing. However, applicable sections of this Standard should be used as they apply to related activities. Activities included are: design changes, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling and modifying.	NQA-1, Introduction to Part I NQA-1, Introduction to Part II QAPD, Part I, Introduction QAPD, Part II, Section 2	
It is recommended that the administrative controls and quality assurance provisions of this Standard be applied to other important plant equipment at a level commensurate with the importance of the equipment to reliable and efficient plant operation. However, it is emphasized that this Standard is directed primarily toward administrative controls and quality assurance associated with safety-related activities, equipment and procedures.	NQA-1, Introduction to Part I NQA-1, Introduction to Part II QAPD, Part I, Introduction QAPD, Part II, Section 2	
This Standard incorporates criteria that permit a degree of flexibility, since administrative practices vary among		NQA-1 and the NEI 11-04 are similar in allowing some

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organizations operating nuclear power plants.		flexibility based on importance to safety.
The Nuclear Regulatory Commission (NRC) promulgates regulations applicable to many aspects of the design, construction and operation of nuclear power reactors. This Standard contains criteria for administrative controls and quality assurance for nuclear power plants during the operational phase of plant life. This phase is generally considered to commence with initial fuel loading, except for certain preoperational activities. Certain operating activities may commence prior to fuel loading and certain initial construction activities may extend past fuel loading. Owner organizations should identify clearly those activities that fall in these overlapping time periods and should specify whether the activities are to be considered as operational or as construction activities.	NQA-1 Introduction to Part I NQA-1, Introduction to Part II QAPD, Part I, Introduction QAPD, Part II, Section 2	
This Standard is intended to be consistent with applicable criteria for quality assurance, including those given in Title 10, Code of Federal Regulations, Part 50, "Licensing of Production and Utilization Facilities," Appendix B. [1][1] This Standard fully and completely describes the general requirements and guidelines of American National Standard Quality Assurance Program Requirements for Nuclear Power Plants, N45.2-1971, [2] as those requirements and guidelines apply during the operational phase of plant life.	QAPD Part I, Introduction QAPD, Part II, Section 2 QAPD, Part IV	10 CFR 50, Appendix B, for the operational phase is met through a combination of NQA-1 and the QAPD in lieu of a commitment to implement the requirements of ANSI N18.7-1976/ANS-3.2. (Commitment to industry standards is addressed in nuclear facility's FSAR, [Usually Chapter 1, and QAPD referenced in chapter 17]. Most of the listed standards are updated and

[1] Footnote from N18.7 – "Numbers in brackets refer to corresponding numbers in Section 6, References."

<table>
<tr><th>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</th><th>NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD</th><th>Comments</th></tr>
<tr><td>Reg. Guide 1.33 – C. Regulatory Position, paragraph 1:
The overall quality assurance program requirements for the operation phase that are included in ANSI N18.7-1976/ANS-3.2 are acceptable to the NRC staff and provide an adequate basis for complying with the quality assurance program requirements of Appendix B to 10 CFR Part 50, subject to the following [NOTE: The Regulatory Positions that followed this statement are inserted into the ‘best fit’ sections of the N18.7-1976/ANS-3.2 text in this column of the table.]:
Reg. Guide 1.33 – C. Regulatory Position 2.
Throughout ANSI N18.7-1976/ANS-3.2, other documents required to be included as a part of this standard are identified at the point of reference. The specific acceptability of these standards listed in ANSI N18.7-1976/ANS-3.2 has been addressed in the latest revision of the following regulatory guides:
ANSI Standard Regulatory Guide
N45.2 1.28
N45.2.1 1.37
N45.2.2 1.38
N45.2.3 1.39
N45.2.4 1.30
N45.2.5 1.94
N45.2.6 1.58
N45.2.8 1.116
N45.2.9 1.88
N45.2.10 1.74
N45.2.11 1.64
N45.2.13 1.123</td><td></td><td>incorporated into NQA-1.
For the QAPD the following cross-reference is provided:

N45.2 is replaced by NQA-1-2008 and NQA-1a-2009 Addenda as indicated in Reg. Guide 1.28, Rev. 4.
Table A-3 of RG 1.28 provides a cross-reference between the RGs, ANSI Standard and their location in NQA, as follows:

<table>
<tr><th>RG</th><th>ANSI</th><th>NQA-1</th></tr>
<tr><td>1.30</td><td>N45.2.4</td><td>Subpart 2.4</td></tr>
<tr><td>1.37</td><td>N45.2.1</td><td>Subpart 2.1</td></tr>
<tr><td>1.38 W[1]</td><td>N45.2.2</td><td>Subpart 2.2</td></tr>
<tr><td>1.39 W[1]</td><td>N45.2.3</td><td>Subpart 2.3</td></tr>
<tr><td>1.58 W</td><td>N45.2.6</td><td>Part I</td></tr>
<tr><td>1.64 W</td><td>N45.2.11</td><td>Part I</td></tr>
<tr><td>1.88 W</td><td>N45.2.9</td><td>Part I</td></tr>
<tr><td>1.94 W[1]</td><td>N45.2.5</td><td>Subpart 2.5</td></tr>
<tr><td>1.116 W[1]</td><td>N45.2.8</td><td>Subpart 2.8</td></tr>
<tr><td>1.123 W</td><td>N45.2.13</td><td>Part I</td></tr>
<tr><td>1.144 W</td><td>N45.2.12</td><td>Part I</td></tr>
</table>
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N18.1 1.8 N18.17 1.17 N101.4 1.54 *Note:* N45.2.12 is discussed in NRC documents WASH-1283, "Guidance on Quality Assurance Requirements During Design and Procurement Phase of Nuclear Power Plants," (Grey Book) and WASH-1309, "Guidance on Quality Assurance Requirements During the Construction Phase of Nuclear Power Plants," (Green Book) and will be endorsed by a regulatory guide upon its approval as an ANSI standard.		1.146 W | N45.2.23 | Part I W = Withdrawn Reg. Guide W[1] = Withdrawn Reg. Guide after issuance of RG 1.28, Rev.4, June 2010 • N45.2.10 is now NQA-1-2008 and NQA-1a-2009, Part I, Introduction, Section 400; Reg. Guide 1.74 has been withdrawn • N18.1 is now ANS-3.1 • N18.17 and Reg. Guide 1.17 have been withdrawn and the applicable requirements included in 10 CFR Part 73 • N101.4 has been withdrawn and replaced with several other standards as discussed in RG 1.54, Rev. 2)
2. Definitions		
2.1 Limitations.		
The definitions given below are applicable specifically to this Standard. Other terms and their definitions are contained in American National Standard, Quality Assurance Terms and Definitions, N45.2.10 [3].	NQA-1, Introduction to Part I	NQA-1 replaces N45.2 and daughters, including N45.2.10
2.2 Glossary of Terms		
administrative controls. Rules, orders, instructions,	QAPD, Part V, Section 1	

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procedures, policies, practices and designations of authority and responsibility.		
audit. A formal, independent examination with intent to verify conformance with established requirements.	NQA-1, Introduction to Part I	NQA-1 provides more clarity
emergency procedures. Written procedures which specify actions, including manipulation of plant controls, to reduce the consequence of an accident or potentially hazardous condition which has already occurred, to implement the emergency plan, or to prepare for possible hazardous natural occurrences.	QAPD, Part V, Section 3	The intent of the definition is met by the description of the Emergency Operating Procedures and Emergency Plan Implementing Procedures in the QAPD.
experiments. Performance of those plant operations carried out under controlled conditions in order to establish characteristics or values not previously known.	QAPD, Part V, Section 1	
independent review. Review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review).	QAPD, Part V, Section 1	
inspection. Examination, observation, or measurement to determine the conformance of materials, supplies, components, parts, appurtenances, systems, personnel performance, procedures, processes or structures to predetermined requirements.	NQA-1, Introduction to Part I	
maintenance and modification procedures. Written procedures defining the policies and practices by which structures; mechanical, electrical and instrumentation and control systems; and components thereof of a nuclear power plant are kept in a condition of good repair or efficiency so	NQA-1, Part II, Subpart 2.18, Sections 202 and 404.1 QAPD, Part V, Section 4	

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that they are capable of performing their intended functions. As used in this Standard, these procedures apply to those activities performed by maintenance or contractor personnel to maintain, repair or modify safety-related equipment. Related activities are those actions taken by operating personnel to determine that a planned maintenance activity can be safely performed under the existing plant operating conditions, to authorize the release of equipment to be maintained in accordance with equipment control procedures, and to assure that the equipment has been returned to normal operating status at the completion of the maintenance work including verification of functional acceptability. Procedures for these related activities by operating personnel are considered to be operating procedures, but may be included in maintenance procedures.		
nuclear power plant. Any plant using a nuclear reactor to produce electric power, process steam or space heating.	QAPD, Part V, Section 1	
off-normal condition procedures. Written procedures which specify operator actions for restoring an operating variable to its normal controlled value when it departs from its range or to restore normal operating conditions following a perturbation. Such actions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure.	QAPD, Part V, Section 3	
onsite operating organization. Onsite personnel concerned with operation, maintenance and certain	QAPD, Part V, Section 1	

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technical services.		
operating activities. Work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the onsite operating organization.	QAPD, Part V, Section 1	
operating procedures. Written procedures defining the normal method, means and limits of operation of a nuclear power plant, a plant system or systems, or processes, including actions to be taken by operating personnel for removal from and return to service equipment on which maintenance is to be or has been performed (see also maintenance and modification procedures).	QAPD, Part V, Section 4	
operational phase. That period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of fuel loading, and ends with plant decommissioning.	QAPD, Part V, Section 1	
owner organization. The organization, including the onsite operating organization, which has overall legal, financial and technical responsibility for the operation of one or more nuclear power plants.	NQA-1, Introduction to Part I, Section 400 QAPD, Part II, Section 1	This term is also defined in ANS-3.1
quality assurance. All those planned and systematic actions necessary to provide assurance that a structure, system or component will perform satisfactorily in service. It applies to all activities associated with doing a job correctly as well as verifying and documenting the	NQA-1, Introduction to Part I	

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satisfactory completion of the work.		
review. A deliberately critical examination, including observation of plant operation, evaluation of audit results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions (see independent review).	QAPD, Part V	
shall, should and may. The word "shall" is used to denote a requirement; the word, "should" to denote a recommendation; and the word "may" to denote permission, neither a requirement nor a recommendation.	NQA-1, Introduction to Part I (as part of the definition of guideline)	The word "may" is not defined in NQA-1 or Regulatory Guide 1.33, but used in NQA-1 to denote permission. These words are also defined in ANS-3.1.
supervision. Direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities he directs or monitors.	QAPD, Part V	
surveillance testing. Periodic testing to verify that safety-related structures, systems and components continue to function or are in a state of readiness to perform their functions.	QAPD, Part V	
system. An integral part of a nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function.	QAPD, Part V	
testing. Performance of those steps necessary to determine that systems or components function in accordance with predetermined specifications.	NQA-1, Introduction to Part I	NQA-1 expounds on the definition.

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3. Owner Organization		
3.1 General.		
The owner organization shall establish an administrative controls and QA program which complies with this Standard. The program shall be in effect at all times during the operational phase to assure that operational phase activities are carried out without undue risk to the health and safety of the public. The program shall require that decisions affecting safety are made at the proper level of responsibility and with the necessary technical advice and review. The owner organization may delegate to other organizations the work of establishing and executing the administrative controls and quality assurance program or any part thereof, in accordance with this Standard, but shall retain responsibility.	NQA-1, Requirement 2 QAPD Policy Statement QAPD Part II, Sections 1 and 2	
3.2 Assignment of Authority and Responsibility.		
It is essential that all members … involved in operation of nuclear power plants, including those at the highest management levels, recognize the necessity that plants be operated under a well formulated & detailed administrative controls and QAP to assure safety and efficiency. Lines of authority, responsibility and communication shall be established from the highest management level through intermediate levels to and including the onsite operating organization (including offsite organizations assigned responsibility for procurement, design and construction, QA, and technical support activities). These relationships shall be documented and updated, as appropriate, in	NQA-1, Requirement 1 QAPD, Part I, Section 1	

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organizational charts, functional descriptions of departmental responsibilities and relationships and job descriptions for key personnel positions or equivalent. The owner organization shall specify in writing the authority and responsibility assigned to individuals and organizations involved in establishing, executing and measuring the overall effectiveness of the administrative controls and quality assurance program required by this Standard.		
The persons or organizations responsible for defining and measuring the overall effectiveness of the program shall be designated, shall be sufficiently independent from cost and scheduling considerations when opposed to safety considerations, shall have direct access to responsible management at a level where appropriate action can be accomplished, and shall report regularly on the effectiveness of the program to the plant manager and the cognizant offsite management.	NQA-1, Requirement 1	
Persons or organizations performing functions of assuring that the administrative controls and quality assurance program is established and implemented or of assuring that an activity has been correctly performed shall have sufficient authority and organizational freedom to: identify quality problems; initiate, recommend or provide solutions, through designated channels; and verify implementation of solutions.	NQA-1, Requirement 1	
The organizational structure and the functional responsibility assignments shall be such that: (1) Attainment of program objectives is accomplished by	NQA-1, Requirement 1	

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those … assigned responsibility for performing work. This may include interim examinations, checks, and inspections of the work by the individual performing the work. (2) Verification of conformance to established program requirements is accomplished by a qualified person who does not have responsibility for performing or directly supervising the work. The method and extent of such verification shall be commensurate with the importance of the activity to plant safety and reliability.		
In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. For example, it may be more appropriate for nuclear engineers to perform reviews of plant nuclear engineering activities rather than quality assurance engineers because of the special competence required to perform these reviews. Quality assurance encompasses many functions and activities and extends to various levels in all participating organizations, from the top executive to all workers whose activities may influence quality.	NQA-1, Requirement 1	
3.3 Indoctrination and Training.		
Provisions shall be made for indoctrination and training of those personnel in the owner organization performing activities affecting quality to assure that suitable proficiency is achieved and maintained. Such personnel also shall be provided training concerning the administrative controls and quality assurance program	NQA-1, Requirement 2 QAPD, Part II, Section 2	

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which, as a minimum, shall include the following areas: - Overall company policies, procedures, or instructions which establish the program - Procedures or instructions which implement the program related to the specific job-related activity.		
3.4 Onsite Operating Organization		
3.4.1 General.		
A number of factors influence management in its decision regarding the establishment of an onsite operating organization. These include the owner organization's established staffing policies, the physical size and complexity of the nuclear power plant, the number of units, the extent of assistance provided by offsite technical support organizations, the extent of reliance on consultants and the availability of qualified personnel from other sources to assist in activities, such as initial start-up, refueling, maintenance or modification work. A nuclear power plant onsite operating organization may change with time. For example, the number and qualifications of personnel making up the onsite technical support staff can generally be reduced as a plant progresses through initial operation to operational maturity. Management shall give careful consideration to the timing and extent of such changes.	NQA-1, Requirement 1 QAPD, Part II, Section 1	
3.4.2 Requirements for the Onsite Operating Organization.		
The onsite operating organization shall include one or more individuals knowledgeable in the following fields: nuclear power plant operation; nuclear power plant mechanical,	QAPD, Part II, Section 1	

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electrical and electronic systems; nuclear engineering; chemistry and radiochemistry; radiation protection; and quality assurance.		
Initial incumbents or replacements for members of the onsite operating organization and offsite technical support organizations shall have appropriate experience, training and retraining to assure that necessary competence is maintained in accordance with the provisions of American National Standard for Selection and Training of Nuclear Power Plant Personnel, N18.1-1971. [4] Personnel whose qualifications do not meet those specified in N18.1 and who are performing inspection, examination, and testing activities during the operational phase of the plant, including preoperational and start-up testing, shall be qualified to American National Standard Qualifications of Inspection, Examination, and Testing Personnel for the Construction Phase of Nuclear Power Plants, N45.2.6-1973 [5], except that the QA experience cited for Levels I, II, and III should be interpreted to mean actual experience in carrying out the types of inspection, examination, or testing activity, being performed.	NQA-1, Requirement 2 QAPD, Part II, Section 2 QAPD, Part IV, (by commitment to ANS-3.1)	The facility technical specifications also address commitments for training and qualification of the operating staff. Between NQA-1-2008, NQA-1a-2009 Addenda, and the QAPD content, alternative requirements that meet the intent of ANSI N45.2.6 are established.
The owner organization shall designate those positions in the onsite operating organization which shall be filled by personnel holding NRC reactor operator and senior reactor operator licenses. Requirements for the minimum number of personnel holding such licenses who shall be present at the plant under various operating conditions and situations shall also be specified.	QAPD, Part II, Section 1 QAPD, Part IV (by the commitment to ANS-3.1 where it describes functional positions that require an NRC operator license)	The facility technical specifications establish specific requirements for numbers of personnel requiring NRC licenses based on operating conditions/situations.

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The Plant Manager shall have overall responsibility for the execution of the administrative controls and quality assurance program at the plant to assure safety. An individual or organizational unit knowledgeable and experienced in nuclear power plant operational phase activities and quality assurance practices shall be designated and assigned the responsibility to verify that the program is being effectively implemented. Depending on the organizational structure, the individual or organizational unit may report functionally to onsite plant management or an offsite organization (see also 3.2). Reporting to onsite plant management is preferable since such an arrangement usually results in improved communications in identifying problems and initiating corrective action. The individual or organizational unit in this case may receive technical guidance from offsite support groups. This individual's or organizational unit's duties and responsibilities shall be such that the required attention can be devoted, as required, to verifying that the program is being effectively executed. The individual or organizational unit shall report on the effectiveness of the program to the Plant Manager and to other cognizant management as may be designated. Their activities shall be periodically audited by designated offsite personnel.	NQA-1, Requirement 1 NQA-1, Requirement 2 QAPD, Part II, Section 1 QAPD, Part II, Section 18 for assessing and reporting on the effectiveness of the QA program implementation	

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4. Reviews and Audits		
4.1 General.		
Programs for reviews and for audits of activities affecting plant safety during the operational phase shall be established by the owner organization to:	NQA-1, Requirement 18 QAPD, Part II, Sections 1, 2, 3, 5, and 18 QAPD, Part V, Section 2	
(1) Verify that these activities are performed in conformance with this Standard and with company policy and rules, approved operating procedures and license provisions.	NQA-1, Requirement 18 QAPD, Part II, Sections 1, 2, 3, 5, 18 QAPD, Part V, Section 2	
(2) Review significant proposed plant changes, tests and procedures	QAPD, Part II, Sections 5,18 QAPD, Part V, Section 2	
(3) Verify that reportable events, which require reporting to NRC in writing within 24 hours, are promptly investigated and corrected in a manner which reduces the probability of recurrence of such events	QAPD, Part V, Section 2	
(4) Detect trends which may not be apparent to a day-to-day observer	QAPD, Part II, Section 18 QAPD, Part V, Section 2	
These programs for reviews and audits shall, themselves, be periodically reviewed for effectiveness by management of the owner organization.	QAPD, Part II, Section 18.2	
The programs provided for reviews and audits may take different forms. For example, the owner organization may assign these functions to separate established units independent of the onsite operating organization, or appoint a committee comprised of individuals from within		This paragraph contains general guidance and historical information, no requirements are specified.

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or outside the owner organization to perform reviews and exercise overview of audits. Historically, a committee approach was used to provide both review and audit capability …. This approach was employed to make the most efficient use of personnel with pertinent experience and qualifications. In the ensuing period, the availability of competent personnel has significantly increased as the nuclear power industry has expanded and the sources of trained manpower have responded to the resulting demand. This growing pool of talent in the aggregate, is sufficient to encourage alternative approaches to the review and audit committees commonly used in the past.		
In general, the time required of individuals serving as members of independent review groups is a function of the number of nuclear power plants an owner organization has in operation. For this reason, owner organizations contemplating rapid growth and an expanding commitment to nuclear power should regard the use of committees to meet the independent review functions as an interim approach for effective utilization of available technical expertise. In addition, such owner organizations should include in their expansion planning, provisions for early establishment of organizational units to provide independent review, for recruitment of staff, and for an orderly transition to such an organizational structure in the event a committee approach has been used previously to meet the independent review function		This paragraph provides general guidance information, no requirements are specified.
An independent offsite organizational unit may be assigned review responsibilities including responsibility for reviewing audit reports provided by onsite staff members,		This paragraph provides general guidance information, no requirements are specified.

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or both functions may be assigned to an organizational unit that is independent of line responsibility for operating activities. This Standard does not specify an organizational structure for meeting the review and audit functions, but in lieu thereof delineates essential elements of satisfactorily comprehensive programs for review and for audit in the manner best suited to the owner organization involved.		
4.2 Program Description.		
Written programs for both audits and independent reviews shall be prepared that contain: (1) Subjects to be audited and independently reviewed. (2) Responsibility and authority of those supervising audits and conducting independent reviews. These responsibilities shall include the identification of problems and the verification of corrective action. Additional responsibilities may include recommendations to appropriate management of solutions to problems and the approval or disapproval of contemplated actions. (3) Mechanisms for initiating audit and independent review activities. (4) Provisions for use of specialists or subgroups. (5) Authority to obtain access to the nuclear power plant operating records and operating personnel to perform audits and independent reviews. (6) Requirements, for distribution of reports and other records to appropriate staff members and managers in the owner organization. (7) Identification of the management position (or positions, if auditors and reviewers have different reporting chains) to	NQA-1, Requirement 18 QAPD, Part II, Section 18 QAPD, Part V, Section 2	

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which auditors and independent reviewers report. (8) Provisions for assuring that personnel responsible for audit and independent review are kept informed on a timely basis of matters within their scope of responsibility. (9) Provisions for follow-up action, including re-audit of deficient areas where indicated. (10) Other provisions required for effective audits and independent reviews.		
4.3 Independent Review Program.		
Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading.	QAPD, Part V, Section 2	
4.3.1 Personnel.		
Personnel assigned responsibility for independent reviews shall be specified, in both number and technical disciplines, and shall collectively have the experience and competence required to review problems in the following areas: (1) Nuclear power plant operations (2) Nuclear engineering (3) Chemistry and radiochemistry (4) Metallurgy (5) Nondestructive testing (6) Instrumentation and control (7) Radiological safety (8) Mechanical and electrical engineering	QAPD, Part V, Section 2	

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(9) Administrative controls and quality assurance practices (10) Other appropriate fields associated with the unique characteristics of the nuclear power plant involved. An individual may possess competence in more than one specialty area. If sufficient expertise is not available from within the owner organization, independent reviews shall be supplemented through outside consultants or organizations. Provisions shall be made to assure that appropriate expertise is brought to bear in reviews of operational phase activities.		
4.3.2 Standing Committees Functioning as Independent Review Bodies		
4.3.2.1 Committee Composition.		
When a standing committee is responsible for the independent review program, it shall be composed of no less than five persons, of whom no more than a minority are members of the onsite operating organization. Competent alternates are permitted if designated in advance. The use of alternates shall be restricted to legitimate absences of principals.	QAPD, Part V, Section 2	
4.3.2.2 Meeting Frequency.		
Formal meetings of personnel assigned to a standing committee functioning as an independent review group shall be scheduled as needed. During the period of initial operation such meetings should be held no less frequently than 1/calendar quarter. Subsequently, the meeting frequency shall not be less than twice a year.	QAPD, Part V, Section 2	

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4.3.2.3 Quorum.		
A quorum for formal meetings of the committee held under the provisions of 4.3.2.2 shall consist of not less than a majority of the principals, or duly appointed alternates, and shall be subject to the following constraints: the chairman (or his duly appointed alternate) shall be present for all formal meetings; and no more than a minority of the quorum shall have line responsibility for operation of the plant.	QAPD, Part V, Section 2	
4.3.2.4 Meeting Records.		
Committee meeting minutes shall be prepared and retained, and disseminated promptly to appropriate members of management having responsibility in the area reviewed. All documentary material reviewed should be identified. Committee decisions and recommendations shall be documented. (See also Section 5.2.12.)	QAPD, Part V, Section 2	
4.3.3 Organizational Units Functioning as Independent Review Bodies.		
An organizational unit assigned responsibility for review of operational phase activities shall report to designated management with authority and responsibility for effective functioning of the unit and not immediately responsible for the performance of the activities to be reviewed. The supervisor of such an organizational unit should schedule periodic formal meetings of his staff, or of appropriate subparts thereof, for the purpose of fostering interaction in reviews of specific operational phase activities.	QAPD, Part V, Section 2	

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4.3.3.1 Documentation of Reviews.		
Written records of reviews shall be prepared and retained. All documentary material reviewed should be identified. Results of reviews … including recommendations and proposed actions shall be subject to approval of the supervisor of the unit, and shall be disseminated promptly to management with responsibility in the area reviewed. (See also Section 5.2.12.)	QAPD, Part V, Section 2	
4.3.4 Subjects Requiring Independent Review.		
The following subjects shall be reviewed by the independent review body:	QAPD, Part V, Section 2	
(1) Written safety evaluations of changes in the facility as described in the Safety Analysis Report, changes in procedures as described in the Safety Analysis Report and tests or experiments not described in the Safety Analysis Report which are completed without prior NRC approval under the provisions of 10 CFR 50.59(a)(1). [1] This review is to verify that such changes, tests or experiments did not involve a change in the technical specifications or an unreviewed safety question as defined in 10 CFR 50.59(a)(2). [1]	QAPD, Part V, Section 2	
(2) Proposed changes in procedures, proposed changes in the facility, or proposed tests or experiments, any of which involves a change in the technical specifications or an unreviewed safety question as defined in 10 CFR 50.59(c). [1] Matters of this kind shall be referred to the independent review body by the onsite operating organization (see 4.4) following its review, or by other functional organizational units within the owner organization, prior to	QAPD, Part V, Section 2	Note – change in 50.59 language ("unreviewed safety question" no longer used) – but otherwise covered in QAPD, Part V, Section 2.2

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implementation.		
(3) Changes in the technical specifications or license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously reviewed proposed change. **Reg. Guide 1.33** – C. Regulatory Position 3. Section 4.3.4, "Subjects Requiring Independent Review," Item (3) states, in part, that changes to the technical specifications or license amendments related to nuclear safety are required to be reviewed by the independent review body prior to implementation. It should be noted that proposed changes to technical specifications or license amendments should be reviewed by the independent review body prior to their submittal to the Commission for approval.	QAPD, Part V, Section 2	
(4) Violations, deviations and reportable events, which require reporting to the NRC in writing within 24 hours, such as:	QAPD, Part V, Section 2	Regulations for reporting have changed, but the intent of this is addressed in QAPD, Part V, Section 2.2
(a) Violations of applicable codes, regulations, orders, technical specifications, license requirements or internal procedures or instructions having safety significance	QAPD, Part V, Section 2	
(b) Significant operating abnormalities or deviations from normal or expected performance of plant safety-related structures, systems, or components	QAPD, Part V, Section 2	
(c) Reportable events, which require reporting to the NRC in writing within 24 hours, as defined in the plant technical specifications Review of events covered under this Section	QAPD, Part V, Section 2	Regulations for reporting have changed, but the intent of this is addressed in QAPD, Part V,

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shall include the results of any investigations made and the recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.		Section 2.2
(5) Any other matter involving safe operation of the nuclear power plant which an independent reviewer deems appropriate for consideration, or which is referred to the independent reviewers by the onsite operating organization or by other functional organizational units within the owner organization.	QAPD, Part V, Section 2	
4.4 Review Activities of the Onsite Operating Organization.		
The onsite operating organization shall provide, as part of the normal duties of plant supervisory personnel, timely and continuing monitoring of operating activities to assist the Plant Manager in keeping abreast of general plant conditions and to verify that the day-to-day operating activities are conducted safely and in accordance with applicable administrative controls. These continuing monitoring activities are considered to be an integral part of the routine supervisory function and are important to the safety of plant operation.	QAPD, Part V, Section 2	
The onsite operating organization <u>should</u> perform reviews periodically and as situations demand, to evaluate plant operations and to plan future activities. The important elements of the reviews <u>should</u> be documented. Such reviews serve a useful purpose but shall not take the place of the reviews and audits described in Sections 4.3 and 4.5, respectively. The onsite operating organization should screen subjects of potential concern to independent	QAPD, Part V, Section 2	

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reviewers and perform preliminary investigations (see 4.3.4). The Plant Manager, in carrying out his responsibility for overall safety of plant operations, shall be responsible for timely referral of appropriate matters to management and independent reviewers. **Reg. Guide 1.33** – C. Regulatory Position 5.a. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: a. Section 4.4–The guidelines concerning review activities of the onsite operating organization, except the guideline that refers to screening subjects of potential concern. [**NOTE**: The affected "should" words are underlined in the N18.7 excerpt above.]		
4.5 Audit Program.		
A comprehensive system of planned and documented audits shall be carried out to verify compliance with all aspects of the administrative controls and quality assurance program.	NQA-1, Requirement 18 QAPD, Part II, Section 7 QAPD, Part II, Section 18.	
Audits of selected aspects of operational phase activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of all safety-related functions is completed within a period of two years. Audits shall include as a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (for example, operating, design,	QAPD, Part II, Section 18	The utilities' have modified their audit programs over the years to include risk-informed scheduling and controlling the scope of the audits as alternate methods of satisfying the amplified requirements stated in RG 1.33 for specific elements to be

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procurement, maintenance, modification, refueling, surveillance, test, security and radiation control procedures and the emergency plan), regulations and license provisions; programs for training, retraining, qualification and performance of operating staff; corrective actions taken following abnormal occurrences; and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping. **Reg. Guide 1.33** – C. Regulatory Position 4. Section 4.5, "Audit Program," of ANSI N18.7-1976/ANS-3.2 states that audits of selected aspects of operational phase activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to ensure that an audit of all safety-related functions is completed within a period of 2 years. In amplification of this requirement, the following program elements should be audited at the indicated frequencies: a. The results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or method of operation-at least once per 6 months. b. The conformance of facility operation to provisions contained within the technical specifications and applicable license conditions-at least once per 12 months. c. The performance, training, and qualifications of the facility staff-at least once per 12 months.		audited more frequently than every two years.
Written reports of such audits shall be reviewed by the independent review body and by appropriate members of	NQA-1, Requirement 18	

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management including those having responsibility in the area audited.	QAPD, Part II, Section 18 QAPD, Part V, Section 2.2	
Those performing the audits may be members of the audited organization; however, they shall not audit activities for which they have immediate responsibility. While performing the audit, they shall not report to a management representative who has immediate responsibility for the activity being audited.	NQA-1, Requirement 18	
Appropriate and timely follow-up action, including re-audit of deficient areas, shall be taken.	NQA-1, Requirement 18	
Periodic review of the audit program shall be performed by the independent review body or by a management representative at least semiannually to assure that audits are being accomplished in accordance with requirements of technical specifications and of this Standard.	QAPD, Part V, Section 2	Audits are no longer addressed in the technical specifications. Based on SRP 17.5, the period for evaluating the audit program is two years rather than every six months.
Further guidance on requirements for auditing of quality assurance programs for nuclear power plants exists in draft form.[2]		
5. Program, Policies and Procedures		
5.1 Program Description.		
The total program for providing administrative controls and quality assurance during the operational phase may be described in many diverse documents. For example,	QAPD, Part I, Introduction QAPD, Part II, Section 6	

[2] Footnote from N18.7 "Requirements for auditing of Quality Assurance Programs for Nuclear Power Plants," Proposed American National Standard N45.2.12, trial use (Draft 4, Revision 2) January 1 1976; correspondence should be sent to: Secretary, American National Standards Committee N45, The American Society of Mechanical Engineers, United Engineering Center, 345 East 47 street, New York, NY 10017. The provisions of this draft standard shall be used for audits performed under this section except the audit frequency specified herein shall be used."

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operating procedures may be compiled in one manual, maintenance procedures in a second manual and Quality Assurance procedures in a third. It is not intended that all source documents be compiled in one master document. However, a summary document shall be compiled by each owner organization to identify the sources, to index such source documents to the requirements of this Standard and to provide a consolidated base for description of the program.		
The owner organization shall identify in the program description those structures, systems and components to be covered by the program and the major organizational units and their responsibilities. The program shall provide control over activities affecting the quality of the structures, systems and components to an extent consistent with their importance to safety. The program shall take into account the need for special controls, processes, tests, equipment, tools, and skills to attain the required quality and the need for verification of quality by inspections, evaluation or test.	NQA-1, Requirement 2 QAPD, Part II, Section 2	The applicable licensee's SAR provides more detail on the SSCs and their importance to safety. In most cases this will refer back to the list in the referenced DCD.
5.2 Rules of Practice.		
The owner organization shall establish rules and instructions pertaining to personnel conduct and control, including consideration of job-related factors which influence the effectiveness of operating and maintenance personnel, including such factors as number of hours at duty station, availability on call of professional and supervisory personnel, method of conducting operations, and preparing and retaining plant documents. These rules and instructions should provide a clear understanding of	QAPD, Policy QAPD, Part V	

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operating philosophy and management policies.		
5.2.1 Responsibilities and Authorities of Operating Personnel.		
The responsibilities and authorities of the plant operating personnel shall be delineated. These shall include, as a minimum: (1) The reactor operator's authority and responsibility for shutting the reactor down when he determines that the safety of the reactor is in jeopardy or when operating parameters exceed any of the reactor protection system setpoints and automatic shutdown does not occur. (2) The responsibility to determine the circumstances, analyze the cause, and determine that operations can proceed safely before the reactor is returned to power after a trip or an unscheduled or unexplained power reduction. (3) The senior reactor operator's responsibility to be present at the plant and to provide direction for returning the reactor to power following a trip or an unscheduled or unexplained power reduction. (4) The responsibility to believe and respond conservatively to instrument indications unless they are proved to be incorrect. (5) The responsibility to adhere to the plant's Technical Specifications. (6) The responsibility to review routine operating data to assure safe operation.	QAPD, Part I Section 1 QAPD, Part V	QAPD provides overall responsibilities in general terms. The specific responsibilities described here are located in the organizational standards and administrative controls, Technical Specifications and reinforced through the systematic training programs.
5.2.2 Procedure Adherence.		
Procedures shall be followed, and the requirements for use	NQA-1, Requirements 5 & 6	

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of procedures shall be prescribed in writing. Rules shall be established which provide methods by which temporary changes to approved procedures can be made, including the designation of a person or persons authorized to approve such changes.	QAPD, Part II, Sections 5 & 6	
Temporary changes which clearly do not change the intent of the approved procedure, shall as a minimum be approved by two members of the plant staff knowledgeable in the areas affected by the procedures. At least one of these individuals shall be the supervisor in charge of the shift and hold a senior operator's license on the unit affected. Such changes shall be documented and, if appropriate, incorporated in the next revision of the affected procedure. In the event of an emergency not covered by an approved procedure, operations personnel shall be instructed to take action so as to minimize personnel injury and damage to the facility and to protect health and safety.	QAPD, Part II, Sections 5 & 6	The QAPD requirements only allow temporary changes that do not change the intent of the procedure. All other changes must be done in accordance with the document control program.
Guidance should be provided to identify the manner in which procedures are to be implemented. Examples of such guidance include identification of those tasks that require: (1) The written procedure to be present and followed step by step while the task is being performed (2) The operator to have committed the procedural steps to memory (3) Verification of completion of significant steps, by initials or signatures of check-off lists.	QAPD, Part II, Section 5	
The types of procedures that shall be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, e.g., reactor	QAPD, Part II, Section 5.1	

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start-up, tasks which are infrequently performed, and tasks in which operations must be performed in a specified sequence. Procedural steps for which actions should be committed to memory include, for example, immediate actions in emergency procedures. Routine procedural actions that are frequently repeated may not require the procedure to be present. Copies of all procedures shall be available to appropriate members of the plant staff. If documentation of an action is required, the necessary data shall be recorded as the task is performed. Examples of procedures requiring verification are furnished in 5.3.4.1 and 5.3.4.2.		
5.2.3 Operating Orders.		
A mechanism shall be provided for dissemination to the plant staff of instructions of general and continuing applicability to the conduct of business. Such instructions, sometimes also referred to as standing orders or standard operating procedures, should deal with job turnover and relief, designation of confines of control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions, or other such matters. Provisions should be made for periodic review and updating of standing orders. **Reg. Guide 1.33** – C. Regulatory Position 5.b. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of	QAPD, Part V, Section 3.2	

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the standard: b. Section 5.2.3–The guideline concerning review and updating of standing orders. [**NOTE**: The affected "should" word is underlined in the N18.7 excerpt above.]		
5.2.4 Special Orders.		
A mechanism shall be provided for issuing management instructions which have short-term applicability and which require dissemination. Such instructions, sometimes referred to as a special orders, should encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions should be made for periodic review, updating and cancellation of special orders. **Reg. Guide 1.33** – C. Regulatory Position 5.c. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: c. Section 5.2.4–The guideline concerning review, updating, and cancellation of special orders. [**NOTE**: The affected "should" word is underlined in the N18.7 excerpt above.]	QAPD, Part V, Section 3.2	
5.2.5 Temporary Procedures.		
Temporary procedures may be issued during the operational phase: to direct operations during testing,	QAPD, Part V, Section 3.2	

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refueling, maintenance and modifications; to provide guidance in unusual situations not within the scope of the normal procedures; and to insure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that portions of existing procedures do not apply. Temporary procedures shall include designation of the period of time during which they may be used and shall be subject to the review process prescribed in 4.3 and 5.2.15 as applicable.	Also, temporary procedures for Maintenance activities are covered under NQA-1, Part II, Subpart 2.18, Section 202.	
Temporary procedures shall be approved by the management representative assigned approval authority	QAPD, Part V, Section 3.2	
5.2.6 Equipment Control.		
Permission to release equipment or systems for maintenance shall be granted by designated operating personnel. Prior to granting permission, such operating personnel shall verify that the equipment or system can be released, and determine how long it may be out of service. Granting of such permission shall be documented. Attention shall be given to the potentially degraded degree of protection when one subsystem of a redundant safety system has been removed for maintenance.	NQA-1, Requirement 14 NQA-1, Part II, Subpart 2.18, Section 205 QAPD, Part V, Section 4	
After permission has been granted to remove the equipment from service, it shall be made safe to work on. Measures shall provide for protection of equipment and workers. Equipment and systems in a controlled status shall be clearly identified. Strict control measures for such equipment shall be enforced.	NQA-1, Requirement 14 QAPD, Part V, Section 4	

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Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; method of emergency core cooling; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.	NQA-1, Part II, Subpart 2.18, Section 205 QAPD, Part V, Section 4	
When entry into a closed system is required, control measures shall be established to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.	NQA-1, Subpart 2.3 QAPD, Part II, Section 13 QAPD, Part V, Section 4	
Procedures shall be provided for control of equipment, as necessary, to maintain personnel and reactor safety and to avoid unauthorized operation of equipment. These procedures shall require control measures such as locking or tagging to secure and identify equipment in a controlled status. The procedures shall require independent verifications, where appropriate, to ensure that necessary measures, … , have been implemented correctly.	NQA-1, Requirement 14 QAPD, Part V, Section 4	
Temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings, shall be controlled by approved procedures which shall include a requirement for independent verification. A log shall be maintained of the current status of such temporary modifications.	QAPD, Part II, Section 3 QAPD, Part II, Section 14	
The procedures shall also require that the status of inspections and tests performed upon individual items on	NQA-1, Requirement 14	

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the nuclear power plant be indicated by the use of markings such as stamps, tags, labels, routing cards, or other suitable means. Suitable means include identification numbers which are traceable to records of the status of inspections and tests.		
Procedures shall also provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. In cases where required documentary evidence is not available, the associated equipment or materials must be considered nonconforming in accordance with Section 5.2.14. Until suitable documentary evidence is available to show the equipment or material is in conformance, affected systems shall be considered to be inoperable and reliance shall not be placed on such systems to fulfill their intended safety functions.	NQA-1, Requirement 14 QAPD, Part II, Section 14	
When equipment is ready to be returned to service, operating personnel shall place the equipment in operation and verify and document its functional acceptability. Attention shall be given to restoration of normal conditions, such as removal of jumpers or signals used in maintenance or testing or such as returning valves, breakers or switches to proper start-up or operating positions from "test" or ”manual" positions. When placed into service, the equipment should receive additional surveillance during the run-in period.	NQA-1, Requirement 14 NQA-1, Part II, Subpart 2.18, Section 202 QAPD, Part V, Section 4	
5.2.7 Maintenance and Modifications.		
Maintenance or modifications which may affect functioning of safety-related structures, systems, or components shall	NQA-1, Introduction to Part II NQA-1, Part II, Subpart 2.18	

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be performed in a manner to ensure quality at least equivalent to that specified in original design bases and requirements, materials specifications and inspection requirements. A suitable level of confidence in structures, systems, or components on which maintenance or modifications have been performed shall be attained by appropriate inspection and performance testing (see also 5.2.17 and 5.3.5).	QAPD, Part V, Section 5	
Maintenance or modification of equipment shall be preplanned and performed in accordance with written procedures, documented instructions or drawings appropriate to the circumstances which conform to applicable codes, standards, specifications, and criteria. Skills normally possessed by qualified maintenance personnel may not require detailed step-by-step delineations in a written procedure.	NQA-1, Requirement 5 NQA-1, Part II, Subpart 2.18, Section 202 QAPD, Part II, Section 5	
Means for assuring quality of maintenance and modification activities (for example, inspections, measurements, tests, welding, heat treatment, cleaning, nondestructive examination and worker qualifications in accordance with applicable codes and standards) and measures to document the performance thereof shall be established. This documentation shall be retained as specified in Section 5.2.12.	NQA-1, Requirement 2 NQA-1, Requirement 3 NQA-1, Requirement 9 NQA-1, Requirement 10 NQA-1, Requirement 11 NQA-1, Requirement 17 NQA-1, Part II, Subpart 2.1 NQA-1, Part II, Subpart 2.3 QAPD, Part II, Sections 2, 3, 9, 10, 11, and 17	
Measures shall be established and documented to identify the inspection and test status of items to be used in	NQA-1, Requirement 14 QAPD, Part II, Section 14	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
maintenance and modification activities. Normally, the point of control for such items should be the plant storage area.		
The following standards contain useful guidance concerning design and construction-related activities associated with modifications and shall be applied to those activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during initial plant design and construction: American National Standard Installation, Inspection and Testing of Instrumentation and Electric Equipment During the Construction of Nuclear Power Generation Station, N45.2.4-1972 (IEEE 336-1972) [6]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants, N45.2.5-1974 [7]; American National Standard Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants N45.2.6-1973 [5]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for Construction Phase of Nuclear Power Plants, N45.2.8-1975 [8] American National Standard Quality Assurance Requirements for the Design of Nuclear Power Plants, N45.2.11-1974 [9]; and American National Standard Quality Assurance for Protective Coating Applied to Nuclear Facilities N101.4-1972 [10]. Considerable care is required in assessing which operational phase activities are comparable in nature and	QAPD, Part IV	ANSI N101.4 has been withdrawn and RG 1.54 revised in October 2010 to address the acceptability of the replacement ANSI Standards.

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extent to activities normally associated with design and construction.		
5.2.7.1 Maintenance Programs.		
A maintenance program shall be developed to maintain safety-related structures, systems and components at the quality required for them to perform their intended functions.	NQA-1, Part II, Subpart 2.18, Section 100	
Maintenance shall be scheduled and planned so as not to compromise the safety of the plant. Planning shall consider the possible safety consequences of concurrent or sequential maintenance, testing or operating activities. Equipment required to be operable for the prevailing mode shall be available, and maintenance shall be performed in a manner such that license limits are not violated. Planning for maintenance shall include evaluation of the use of special processes, equipment and materials in performance of the task, including assessment of potential hazards to personnel and equipment.	NQA-1, Introduction to Part II NQA-1, Part II, Subpart 2.18, Section 201	
General rules for the development of procedures under a maintenance program which is consistent with the provisions of 5.2.7 shall be written before start-up. These general rules shall form the basis for developing the repair or replacement procedures at the time of failure. Procedures required for maintenance of equipment expected to require recurring maintenance should be written prior to plant operation. As experience is gained in operation of the plant, routine maintenance should be altered to improve equipment performance, and procedures for repair of equipment shall be improved as appropriate.	NQA-1, Part II, Subpart 2.18 QAPD, Part V, Section 3	

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Approved procedures shall be available for repair of safety-related equipment prior to the performance of such repairs (see also Sections 5.2.2 and 5.2.7).		
A preventive maintenance program including procedures as appropriate for safety-related structures, systems and components shall be established and maintained which prescribes the frequency and type of maintenance to be performed. A preliminary program based on service conditions and experience with comparable equipment should be developed prior to fuel loading. The program should be revised and updated as experience is gained with the equipment.	NQA-1, Part II, Subpart 2.18, Section 300	
The causes of malfunctions shall be promptly determined, evaluated and recorded (see also Sections 4.3 and 4.4). Experience with the malfunctioning equipment and similar components shall be reviewed and evaluated to determine whether a replacement component of the same type can be expected to perform its function reliably. If evidence indicates that common components in safety-related systems have performed unsatisfactorily, corrective measures shall be planned prior to replacement or repair of all such components. Replacement components should have received adequate testing or should be of a design for which experience indicates a high probability of satisfactory performance. Consideration shall be given to phased replacement to permit inservice performance of the new component to be evaluated and thereby minimize the possibility of a hidden deficiency producing a systematic failure. An augmented testing and inspection program should be implemented following a large scale component	NQA-1, Requirement 16 NQA-1, Part II, Subpart 2.18, Section 400	

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replacement (or repair) until such time as a suitable level of performance has been demonstrated. **Reg. Guide 1.33** – C. Regulatory Position 5.d. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: d. Section 5.2.7.1–The guidelines that address adequate design and testing of replacement parts. [**NOTE**: The affected "should" words are underlined in the N18.7 excerpt above.]		
5.2.7.2 Modifications.		
Design activities associated with modifications of safety-related structures, systems, and components shall be accomplished in accordance with N45.2.11-1974. [9]	NQA-1, Requirement 3 QAPD, Part II, Section 3	
5.2.8 Surveillance Testing and Inspection Schedule.		
A surveillance testing and inspection program shall be prescribed to insure that safety-related structures, systems, and components will continue to operate, keeping parameters within normal bounds, or will act to put the plant in a safe condition if they exceed normal bounds.	NQA-1, Requirement 10 NQA-1, Requirement 11 QAPD, Part II, Section 11	
Provisions shall be made for performing required surveillance testing and inspections, including ISI. Such provisions shall include the establishment of a master surveillance schedule reflecting the status of all planned in plant surveillance tests and inspections. Frequency of surveillance tests and inspections may be related to the	NQA-1, Requirement 10 NQA-1, Requirement 11 QAPD, Part II, Section 11	

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results of reliability analyses, the frequency and type of service, or age of the item or system, as appropriate.		
Additional control procedures shall be instituted, as necessary, to assure timely conduct of surveillance tests and inspections and appropriate documentation, reporting, and evaluation of the results. Surveillance testing which may increase the probability of plant trips or major transients with accompanying safety concerns should be deferred to periods when such plant trips or transients have a minimum impact on safety and reliability.	NQA-1, Requirement 11	
5.2.9 Plant Security and Visitor Control.		
Procedures shall be developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program shall be confidential and thus accorded limited distribution. The security and visitor control procedures should consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control. Also to be considered are administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation and challenging of strangers by operating crews; and a program of pre-employment screening for potential employees. See American National Standard Industrial Security for Nuclear Power Plants, N18.17-1973, for guidance and provisions for security measures adequate		Administrative controls are established through the security measures required by regulation (10 CFR 73) and NRC orders. These regulatory requirements have superseded the requirements of ANSI N18.7.

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to protect nuclear power plants. [11]		
5.2.10 Housekeeping and Cleanliness Control.		
Housekeeping practices shall be utilized recognizing requirements for the control of radiation zones and the control of work activities, conditions and environments that can affect the quality of important parts of the nuclear plant. Housekeeping encompasses all activities related to the control of cleanness of facilities, materials, equipment fire prevention and protection including disposal of combustible material and debris and control of access to areas, protection of equipment, radioactive contamination control and storage of solid radioactive waste. Housekeeping practices shall assure that only proper materials, equipment, processes and procedures are utilized and that the quality of items is not degraded as a result of housekeeping practices or techniques.	NQA-1, Part II, Subpart 2.3 QAPD, Part IV	
Where necessary, procedures and work instructions needed to assure compliance with specific requirements shall be available; e.g., inspection and cleaning of electrical bus and control centers, cleaning of control consoles, radioactive decontamination. Particular attention should be given to housekeeping in work and storage areas where important items are handled and stored to preclude damage or contamination. American National Standard Housekeeping During the Construction Phase of Nuclear Power Plants, N45.2.3-1973 [12] shall be applied to those activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction.	NQA-1, Requirement 2 NQA-1, Requirement 5 NQA-1, Part II, Subpart 2.3 NQA-1, Part II, Subpart 2.18 QAPD, Part II, Sections 2 QAPD, Part II, Section 5	NQA-1, Subpart 2.3 replaces ANSI N45.2.3

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During maintenance or modification activities, certain portions of safety-related systems may be subject to potential contamination with foreign materials. To prevent such contamination, control measures, including measures for access control, shall be established. Immediately prior to closure an inspection shall be conducted to assure cleanness and the result of such inspection shall be documented. American National Standard Cleaning of Fluid Systems and Associated Components during Construction Phase of Nuclear Power Plant, N45.2.1-1973 [13] shall be applied to activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction. Measures for minimizing the introduction of foreign materials during maintenance or modification, or cleaning following maintenance or modification of radioactively contaminated systems or of equipment of high radiation fields require special consideration.	NQA-1, Part II, Subpart 2.1 NQA-1, Part II, Subpart 2.18, Section 203	NQA-1, Subpart 2.1 replaces N45.2.1
5.2.11 Corrective Actions.		
The program shall provide measures to ensure that conditions adverse to plant safety, such as failure, malfunctions, deficiencies, deviations, defective material and equipment, abnormal occurrences, and nonconformances are promptly identified and corrected.	NQA-1, Requirement 16 NQA-1, Part II, Subpart 2.18 QAPD, Part II, Section 16	
In the case of significant conditions adverse to safety, the measures shall assure that the cause of the condition is determined and corrective action taken shall be documented and reported to appropriate levels of management and for independent review in accordance	NQA-1, Requirement 16 NQA-1, Part II, Subpart 2.18, Section 403.2 QAPD, Part II, Section 16 QAPD, Part V, Section 2	

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with Section 4.3.		
5.2.12. Plants Records Management.		
Provisions shall be made for preparation and retention of plant records as appropriate.	NQA-1, Requirement 17 QAPD Part II, Section 17.1	
The responsibility for maintaining records and storing them at a specified location or locations shall be assigned.	NQA-1, Requirement 17	
Retention periods of sufficient duration to assure the ability to reconstruct significant events and satisfy any statutory requirements which apply shall be specified.	NQA-1, Requirement 17, Section 400 QAPD, Part II, Section 17.1	NQA-1, Requirement 17 with the information in Reg. Guide 1.28, Rev. 4 for NQA-1 Part III, Nonmandatory Appendix 17A-1, "Guidance on Quality Assurance Records," in Paragraph 200, "List of Typical Lifetime Records," is equivalent to ANSI N45.2.9
American National Standard Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants, N45.2.9-1974, shall be used for management of plant records during the operational phase. [14]	NQA-1, Requirement 17 QAPD, Part II, Section 17.1	NQA-1, Requirement 17 with the information in Reg. Guide 1.28, Rev. 4 for NQA-1 Part III, Nonmandatory Appendix 17A-1, "Guidance on Quality Assurance Records," in Paragraph 200, "List of Typical Lifetime Records," is equivalent to ANSI N45.2.9
5.2.13 Procurement and Materials Control.		
Measures shall be provided for procurement, documentation and control of those materials and components including spare and replacement parts necessary for plant operation, refueling, maintenance and	NQA-1, Requirement 4 NQA-1, Requirement 8 NQA-1, Requirement 15	NQA-1 Requirements 4 and 7 are equivalent to the requirements of N45.2.13 and replace that standard.

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modification. These measures shall utilize American National Standard Quality Assurance Requirements for the Control of Procurement of Items and Services for Nuclear Power Plants, N45.2.13-1976. The Appendix to N45.2.13 is particularly useful in determining the quality assurance requirements depending on the complexity or safety of the item. [15]. Procedures shall be established and implemented to ensure that purchased materials and components associated with safety-related structures or systems are: (1) Purchased to specifications and codes equivalent to those specified for the original equipment, or those specified by a properly reviewed and approved revision. (In those cases where the original item or part is found to be commercially "off the shelf or without specifically identified quality assurance requirements spare and replacement parts may be similarly procured but care shall be exercised to assure at least equivalent performance. In those cases where the QA requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall assure that interfaces, interchangeability, safety, fit and function are not adversely affected or contrary to applicable regulatory or code requirements. The results of this evaluation shall be documented); (2) Produced or fabricated under requirements at least equivalent to that of the original equipment, or those specified by a properly reviewed and approved revision; (3) Packaged and transported in a manner that will ensure	NQA-1, Part II, Subpart 2.2 QAPD, Part II, Section 4 QAPD, Part II, Section 8 QAPD, Part II, Section 15	

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that the quality is not degraded during transit; (4) Properly documented to show compliance with applicable specifications, codes and standards; (5) Properly inspected, identified and stored to protect against damage, deterioration or misuse; (6) Properly controlled to ensure the identification, segregation and disposition of nonconforming material. Special nuclear material and sources shall be shipped and stored as specified in the U.S. Nuclear Regulatory Commission (NRC) fuel license and other applicable regulatory documents.		
5.2.13.1 Procurement Document Control.		
Measures shall be provided to assure that applicable regulatory requirements, design bases and other requirements which are necessary to assure adequate quality are included or referenced in the procedures for procurement of items and services.	NQA-1, Requirement 4	See Requirement 2, paragraph 202, Technical Requirements.
To the extent necessary, procurement documents shall require suppliers to provide a quality assurance program consistent with the pertinent requirements of American National Standard Quality Assurance Program Requirements for Nuclear Power Plants, N45.2-1971. [2]	NQA-1, Requirement 4	The QA requirements of NQA-1-1994 are equivalent to those of ANSI N45.2-1971. See Requirement 2, paragraph 203, Quality Assurance Program Requirements.
Where changes are made to procurement documents, they shall be subject to the same degree of control as was used in the preparation of the original documents.	NQA-1, Requirement 4	See Requirement 2, paragraph 400, Procurement Document Changes.
Procurement documents shall include provisions for the following, as applicable:	NQA-1, Requirement 4	See Requirement 2, paragraph 203, Quality Assurance Program

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(1) Supplier Quality Assurance Program. Identification of quality assurance requirements applicable to the items or services procured.		Requirements.
(2) Basic Technical Requirements. Where specific technical requirements apply, such as drawings, specifications, and industrial codes and standards, they shall be identified by titles and dates of issue in such a way as to clearly set forth the applicable documents. Where procedural requirement apply, in such areas as test and inspection needs, fabrication, cleaning, erecting, packaging, handling, shipping and storage, they too, shall be identified clearly and in such a way as to avoid uncertainty as to source and need.	NQA-1, Requirement 4	See Requirement 2, paragraph 202, Technical Requirements.
(3) Source Inspection and Audit. Provisions for access to the supplier's facilities and records for source inspection and audit when the need for such inspection or audit has been determined.	NQA-1, Requirement 4	See Requirement 2, paragraph 204, Right of Access.
(4) Documentation Requirements. Records to be prepared, maintained, submitted or made available for review, such as drawings, specifications, procedures, procurement documents, inspection and test records, personnel and procedure qualifications, and material, chemical, and physical test results. Instruction on record retention and disposition shall be provided.	NQA-1, Requirement 4	See Requirement 2, paragraph 205, Documentation Requirements.
(5) Lower Tier Procurement. Provisions for extending applicable requirements to lower tier subcontractors and suppliers, including purchaser's access to facilities and records.	NQA-1, Requirement 4	See Requirement 2, paragraph 203, Quality Assurance Program Requirements and paragraph 204, Right of Access.

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5.2.13.2 Control of Purchased Material, Equipment and Services.		
Measures shall be provided to assure that purchased items and services, whether purchased directly or through contractors, conform to the procurement documents.	NQA-1, Requirement 7	
These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection and audit at the source and examination of items upon delivery.	NQA-1, Requirement 7	
Measures for evaluation and selection of procurement sources include the use of historical quality performance data, source surveys or audits, or source qualification programs.	NQA-1, Requirement 7	See Requirement 7, paragraph 200, Supplier Evaluation and Selection.
Source inspection or audit shall be performed as necessary to assure the required quality of an item. Source inspection or audit may not be necessary when the quality of the item can be verified by review of test reports, inspection upon receipt, or other means.	NQA-1, Requirement 7 QAPD, Part II, Section 7.1	See Requirement 7, paragraph 200, Supplier Evaluation and Selection and paragraph 5, Acceptance of Item or Service.
Where required by code, regulation, or contract requirements documentary evidence that items conform to procurement requirements shall be available at the nuclear power plant site prior to installation or use of such items.	NQA-1, Requirement 7	See Requirement 7, paragraph 501, General.
This documentary evidence shall be retrievable and shall be sufficient to identify the specific requirements such as codes, standards and specifications met by the purchased item.	NQA-1, Requirement 7	See Requirement 7, paragraph 400, Control of Supplier Generated Documents and paragraph 800, Records.
Where not precluded by other requirements, such documentary evidence may take the form of written	NQA-1, Requirement 7	See Requirement 7, paragraph 502, Methods of Acceptance.

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certifications of conformance which identify the requirements met by the items, provided means are available to verify the validity of such certifications.		
The effectiveness of the control of quality shall be assessed by the purchaser at intervals consistent with the importance, complexity and quality of the item or service.	NQA-1, Requirement 7 QAPD, Part II, Section 7.1	See Requirement 7, paragraph 200, Supplier Evaluation and Selection.
5.2.13.3 Identification and Control of Materials, Parts and Components.		
Measures shall be provided for the identification and control of materials, parts, and components including partially fabricated subassemblies.	NQA-1, Requirement 8	
These procedures shall be implemented to provide insurance that only correct and accepted items are used and installed, and relating an item of production (batch, lot, component, part) at any stage, from initial receipt through fabrication, installation, repair or modification, to an applicable drawing, specification, or other pertinent technical document.	NQA-1, Requirement 8	See Requirement 8, paragraph 201, Item Identification.
Physical identification shall be used to the maximum extent possible. Where physical identification is either impractical or insufficient, physical separation, procedural control or other appropriate means shall be employed.	NQA-1, Requirement 8	See Requirement 8, paragraph 202, Physical Identification.
Identification may be either on the item or on records traceable to the item, as appropriate.	NQA-1, Requirement 8	
Where identification marking is employed, the marking shall be clear, unambiguous and indelible, and shall be applied in such a manner as not to affect the function of the item.	NQA-1, Requirement 8	See Requirement 8, paragraph 202, Physical Identification,

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Markings shall be transferred to each part of an item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.	NQA-1, Requirement 8	See Requirement 8, paragraph 202, Physical Identification,
When codes, standards or specifications require traceability of materials, parts or components to specific inspection or test records, the program shall be designed to provide such traceability.	NQA-1, Requirement 8	See Requirement 8, paragraph 301, Identification and Traceability of Items.
5.2.13.4 Handling, Storage and Shipping.		
Measures shall be provided to control handling, storage and shipping, including cleaning, packaging and preservation of material and equipment in accordance with established instructions, procedures or drawings, to prevent damage, deterioration and loss.	NQA-1, Requirement 13	See Requirement 13, paragraph 100, Basic,
When necessary for particular items, special coverings, special equipment and special protective environments, such as inert gas atmosphere, specific moisture content levels and temperature levels shall be specified, provided, and their existence verified.	NQA-1, Requirement 13	See Requirement 13, paragraph 300, Procedures,
For critical, sensitive, perishable or high value articles, specific written procedures for handling, storage, packaging, shipping and preservation should be used.	NQA-1, Requirement 13	See Requirement 13, paragraph 300, Procedures,
Special handling tools and equipment <u>should</u> be provided and controlled as necessary to ensure safe and adequate handling. **Reg. Guide 1.33** – C. Regulatory Position 5.e. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections	NQA-1, Requirement 13	See Requirement 13, paragraph, 300, Procedures.

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have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: e. Section 5.2.13.4–The guideline concerning special handling tools and equipment. [**NOTE**: The affected "should" word is underlined above.]		
Special handling tools and equipment shall be inspected and tested in accordance with written procedures and at specified times, to verify that the tools and equipment are adequately maintained.	NQA-1, Requirement 13	See Requirement 13, paragraph 300, Procedures.
Attention shall be given to providing adequate instructions for marking and labeling of items for packaging, shipment and storage. Marking shall be adequate to identify, maintain and preserve the shipment, including indication of the presence of special environments or the need for special control.	NQA-1, Requirement 13	See Requirement 13, paragraph 600, Marking or Labeling
American National Standard for Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants (During the Construction Phase), N45.2.2-1972, shall be applied to those activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction. [16]	NQA-1, Part II, Subpart 2.2	NQA-1, Subpart 2.2 is equivalent to the cited ANSI N45.2.2 standard.
5.2.14 Nonconforming Items.		
Measures shall be provided to control items, services or activities which do not conform to requirements (see also Section 5.2.6).	NQA-1, Requirement 15	

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These procedures shall include as appropriate, instructions for identification, documentation, segregation, disposition and notification to affected organizations.	NQA-1, Requirement 15 QAPD, Part II, Section 15	
Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.	NQA-1, Requirement 15	See Requirement 15, paragraph 404, Disposition.
The responsibility and authority for the disposition of nonconforming items shall be defined.	NQA-1, Requirement 15	See Requirement 15, paragraph 402, Responsibility and Authority.
Repaired and reworked items shall be re-inspected in accordance with applicable procedures.	NQA-1, Requirement 15	See Requirement 15, paragraph 404, Disposition.
Measures which control further processing, delivery or installation of a nonconforming or defective item pending a decision on its disposition shall be established and maintained. Nonconforming items may be: - Dispositioning the item as accept "as is" after evaluation - Scrapping the defective item - Repairing the defective item - Reworking the defective item to complete or correct the item to a drawing or specification. Such measures shall provide assurance that the item is identified as nonconforming and controlled. The measures shall require documentation verifying the acceptability of nonconforming items which have the disposition of "repair" or "use as is." A description of the change, waiver or deviation that has been accepted shall be documented to record the change and denote the as-built condition.	NQA-1, Requirement 15	See Requirement 15, paragraph 200, Identification and paragraph 400, Disposition.

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As a guideline, control of nonconforming items by tagging, marking or other means of identification is acceptable where physical segregation is not practical, although physical segregation and marking are preferred.	NQA-1, Requirement 15	See Requirement 15, paragraph 300, Segregation.
5.2.15 Review, Approval and Control of Procedures.		
The administrative controls and quality assurance program shall provide measures to control and coordinate the approval and issuance of documents, including changes thereto, which prescribe all activities affecting quality. Such documents include those which describe organizational interfaces, or which prescribe activities affecting safety-related structures, systems, or components. These documents also include operating and special orders, operating procedures, test procedures, equipment control procedures, maintenance or modification procedures, refueling, and material control procedures.	NQA-1, Requirement 6 QAPD, Part II, Section 6	
These measures shall assure that documents, including revisions or changes, are reviewed for adequacy by appropriately qualified personnel and approved for release by authorized personnel; and are distributed in accordance with current distribution lists and used by the personnel performing the prescribed activity, and that procedures are provided to avoid the misuse of outdated or inappropriate documents. Procedures for operational phase activities of a nuclear power plant reflect the conditions that exist at the time the procedures are written. These conditions include the technical information available, industry experience, and in the case of the initial procedures for a new plant,	NQA-1, Requirement 6 QAPD, Part II, Section 6	

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assumptions made regarding the detailed behavior of the plant that may not be fully known prior to operation. In order to ensure that the procedures in current use provide the best possible instructions for performance of the work involved, systematic review and feedback of information based on use is required. Each procedure shall be reviewed and approved prior to initial use. The frequency of subsequent reviews shall be specified and may vary depending on the type / complexity of the activity involved, and may vary with time as a given plant reaches operational maturity. Applicable procedures shall be reviewed following an unusual incident, such as an accident, an unexpected transient, significant operator error, or equipment malfunction. Applicable procedures shall be reviewed following any modification to a system. Plant procedures shall be reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every two years to determine if changes are necessary or desirable. A revision of a procedure constitutes a procedure review. Procedures shall be approved as designated by the owner organization before initial use. Rules shall be established which clearly delineate the review of procedures by knowledgeable personnel other than the originator and the approval of procedures and procedure changes by authorized individuals.		
Changes to documents shall be reviewed and approved by the same organizations that perform the original review and approval unless the owner organization designates another qualified organization.	NQA-1, Requirement 6	See Requirement 6, paragraph 301, Major Changes.

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The reviewing organizations shall have access to pertinent background information upon which to base its approval and shall have adequate understanding of requirements and intent of the original document.	NQA-1, Requirement 6	See Requirement 6, paragraph 301, Major Changes.
Those participating in any activity shall be made aware of, and use, proper and current instructions, procedures, drawings, and engineering requirements for performing the activity. Participating organizations shall have procedures for control of the document and changes thereto to preclude the possibility or use of outdated or inappropriate documents.	QAPD, Part II, Section 6	
Document control measures shall provide for: (1) Identification of individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and revisions thereto (2) Identifying the proper documents to be used in performing the activity (3) Coordination and control of interface documents (4) Ascertaining that proper documents are being used (5) Establishing current and updated distribution lists	NQA-1, Requirement 6 QAPD, Part II, Section 6	See Requirement 6, paragraph 200, Document Control.
5.2.16 Measuring and Test Equipment.		
The method and interval of calibration for each installed instrument and control device shall be defined and shall be based on the type of equipment, stability and reliability characteristics, required accuracies and other conditions affecting calibration.	NQA-1, Requirement 12	
Tools, instruments, testing equipment and measuring devices used for measurements, tests and calibration shall	NQA-1, Requirement 12	See Requirement 12, paragraph 200, Selection and paragraph

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be of the proper range and type and shall be controlled, calibrated and adjusted and maintained at specified intervals or prior to use to assure the necessary accuracy of calibrated devices.		300, Calibration and Control.
When calibration, testing, or other measuring devices are found to be out of calibration, an evaluation shall be made and documented concerning the validity of previous test and the acceptability of devices previously tested from the time of the previous calibration.	NQA-1, Requirement 12	See Requirement 12, paragraph 303, Control.
If any calibration, testing or measuring device is consistently found to be out of calibration, it shall be repaired or replaced.	NQA-1, Requirement 12	See Requirement 12, paragraph 302, Control.
It is not the intent of this Standard to imply a need for special calibration and control measures on rulers, tape measures, levels and other such devices if normal commercial practices provide adequate accuracy.	NQA-1, Requirement 12	See Requirement 12, paragraph 304, Commercial Devices.
Special calibration shall be performed when the accuracy of either installed or calibrating equipment is questionable.	NQA-1, Requirement 12	See Requirement 12, paragraph 302, Control
Records shall be made and equipment suitably marked to indicate calibration status.	NQA-1, Requirement 12	See Requirement 12, paragraph 400, Records.
American National Standard N45.2.4-1972 shall be applied to those activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction. [6]	NQA-1, Part II, Subpart 2.4	NQA-1, Part II Subpart 2.4 (ANSI/IEEE Std. 336-1985 IEEE) is equivalent to ANSI N45.2.4. NQA-1, Part II, Subpart 2.16 consists of IEEE Std. 498-1985; however, IEEE has withdrawn this standard. The primary

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		requirements from this standard are included in NQA-1 Requirement 12.
5.2.17 Inspections.		
A program for inspection of activities affecting safety shall be established and executed by or for the organization performing the activity to verify conformance with applicable documented instructions, procedures, and drawings.	NQA-1, Requirement 10 QAPD, Part II, Section 10	
Inspections, examinations, measurements, or tests of material, products, or activities shall be performed for each work operation where necessary to assure quality.	NQA-1, Part II, Subparts 2.1, 2.2, 2.3, 2.4, 2.5, 2.8, and 2.15 establish specific inspections to be performed	
Such inspections shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected. Inspection of operating activities (work functions associated with normal operation of the plant, routine maintenance, and certain technical services routinely assigned to the onsite operating organization) may be conducted by second-line supervisory personnel or by other qualified personnel not assigned first-line supervisory responsibility for conduct of the work. These independent inspections, i.e., those performed by individuals not assigned first-line supervisory responsibility for the conduct of the work, are not intended to dilute or replace the clear responsibility of first-line supervisors for the quality of work performed under their supervision.	NQA-1, Requirement 10 QAPD, Part II, Section 10 (Note exemption in the QAPD.)	

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For modifications and non-routine maintenance, inspections shall be conducted in a manner similar (frequency, type, and personnel performing such inspections) to that associated with construction phase activities (see also Section 5.2.7).	NQA-1, Requirement 10	See Requirement 10, paragraph 603, Modifications, Repairs and Replacements.
Inspections of safety-related activities shall be performed in accordance with approved written procedures, which set forth the requirements and acceptance limits and specify the inspection responsibilities.	NQA-1, Requirement 10	See Requirement 10, paragraph 200, Inspection Requirements.
If mandatory inspection hold points are required, the specific hold points shall be indicated in appropriate documents.	NQA-1, Requirement 10	See Requirement 10, paragraph 300, Inspection Hold Points.
Information concerning inspection shall be obtained from the related design drawings, specifications and/or other controlled documents.	NQA-1, Requirement 10	See Requirement 10, paragraph 200, Inspection Requirements.
When inspection techniques require specialized qualifications or skills, personnel performing the inspection shall meet applicable licensing requirements, codes, and standards appropriate to the discipline involved (see also Sections 5.2.7, 5.2.6 and 5.3.10).	NQA-1, Requirement 10 NQA-1, Requirement 2	
If inspection is impossible or disadvantageous, indirect control by monitoring processing methods, equipment and personnel shall be provided.	NQA-1, Requirement 10	See Requirement 10, paragraph 500, In-process Inspection.
Both inspection and process monitoring shall be provided when control is inadequate without both. In cases where documented verification of quality implied by the above requirements is not possible or feasible, the extent of inspection or performance testing to verify adequacy of	NQA-1, Requirement 10	See Requirement 10, paragraph 500, In-process Inspection.

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structures, systems, or components for service should be, in general, greater than otherwise required.		
The owner organization shall evaluate inspection results along with test results (see Section 5.2.19) to determine whether the individual inspection and test programs demonstrate that the plant can be operated safely and as designed.	NQA-1, Requirement 10 NQA-1, Requirement 11 NQA-1, Part II, Subpart 2.18, Section 202	
Records shall be kept in sufficient detail to permit adequate confirmation of the inspection program. The person recording the data as well as the person approving the inspection results shall be identified. Deviations, their cause, and any corrective action completed or planned as a result of the deviations shall be documented. Inspection records shall be identified as such and shall be retrievable (see also Section 5.2.12).	NQA-1, Requirement 10 NQA-1, Requirement 11	Inspection records under NQA-1 may be a part of the work documents. See Requirement 10, paragraph 800, Records and Requirement 11, paragraph 600, Test Records.
5.2.18 Control of Special Processes.		
Measures shall be established and documented to assure that special processes, accomplished under controlled conditions in accordance with applicable codes, standards, specifications, criteria, and other special requirements, use qualified personnel and procedures.	NQA-1, Requirement 9	See Requirement 9, paragraph 200, Process Controls
Qualification of personnel, procedures, and equipment shall comply with the requirements of applicable codes and standards.	NQA-1, Requirement 9 NQA-1, Requirement 2	See Requirement 9, paragraph 201, Special Processes.
Special processes are those that require interim in process controls in addition to final inspection to assure quality including such processes as welding, heat treating, chemical cleaning, and nondestructive examination.	NQA-1, Requirement 9 QAPD, Part II, Section 9	

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For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established codes or standards, the necessary qualifications of personnel, procedures, or equipment shall be defined.	NQA-1, Requirement 9	See Requirement 9, paragraph 203, Special Requirements.
5.2.19 Test Control.		
A test program shall be established to assure that testing required to demonstrate that the item will perform satisfactorily in service is identified and documented, and that the testing is performed in accordance with written test procedures which incorporate or reference the requirements and acceptance limits contained in applicable design documents.	NQA-1, Requirement 11 NQA-1, Part II Subpart 2.18 establishes programmatic controls for testing NQA-1, Part II Subparts 2.1, 2.4, 2.5, and 2.8 establish specific testing requirements that apply to the operational phase	
The test program shall cover all required tests including: (1) Tests during the preoperational period to demonstrate that performance of plant systems is in accordance with design intent and that the coordinated operation of the plant as a whole is satisfactory, to the extent feasible. (2) Tests during the initial operational phase to demonstrate the performance of systems that could not be tested prior to operation and to confirm those physical parameters, hydraulic or mechanical characteristics that need to be known, but which could not be predicted with the required accuracy, and to confirm that plant behavior conforms to design criteria. The initial start-up test program shall be planned to permit safe fuel loading and start-up; to increase power in safe increments; and to	NQA-1, Requirement 10 NQA-1, Requirement 11 NQA-1, Part II, Subpart 2.4, ANSI/IEEE Std. 336-1985, Section 7 NQA-1, Part II, Subpart 2.8, Section 500 NQA-1, Part II, Subpart 2.18, Section 207 QAPD, Part II, Section 11	See Requirement 10, paragraph 700, Inspections During Operations. See Requirement 11, paragraph 200, Test Requirements.

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perform major testing at specified power plateaus. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted shall be prescribed. Prerequisites and record keeping shall be given attention and the scope of the testing shall demonstrate insofar as practicable that the plant is capable of withstanding the design transients and accidents. The suitability of plant operating procedures should be checked to the maximum extent possible during the preoperational and initial start-up test programs. **Reg. Guide 1.33** – C. Regulatory Position 5.f. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: f. Section 5.2.19(2)–The guideline for checking plant operating procedures during the testing program. [**NOTE**: The affected "should" word is underlined in the N18.7 excerpt above.] (3) Surveillance tests during the operational phase to provide assurance that failures or substandard performance do not remain undetected and that the required reliability of safety-related systems is maintained (see Section 5.2.8). (4) Tests during design, fabrication and construction activities associated with plant maintenance and modifications during the operational phase and the demonstration of satisfactory performance following plant		

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maintenance and modifications or procedural changes (see Section 5.2.7).		
5.2.19.1 Preoperational Tests.		
Preoperational tests are generally performed sequentially in accordance with written procedures. Procedures should ensure that prerequisite steps for equipment testing, such as completion of necessary construction, prior testing, safety precautions, and measures to preserve equipment status have been or will be performed (see also Sections 5.2.17 and 5.3.10). A detailed prescribed physical inspection of equipment components and facilities should be performed to ensure readiness for operation. Typical items to be covered include cleanliness, lubrication, setting of limit switches, calibration of instruments, and presence of safety devices. The test procedure should list the checks to be made and include acceptance criteria and reference sources, such as vendor's literature, engineering drawings or plant specifications. A component test is a functional, operational or performance test of an individual piece of equipment or unit system under prescribed conditions. Typical parameters to be examined are direction of rotation, bearing temperatures, vibration, time delays, and ability to operate with remote and local controls. The procedure should list checks to be made and provide acceptance criteria. Consideration should also be given to providing a run-in period to minimize early failures during operation of the plant.	NQA-1, Requirement 11 NQA-1, Part II, Subpart 2.4, ANSI/IEEE Std. 336-1985, Section 7 NQA-1, Part II, Subpart 2.8, paragraph 500 QAPD, Part II, Section 11	NQA-1, Part II Subpart 2.8 is equivalent to the requirements of ANSI N45.2.8 See Requirement 11, paragraph 300, Test Procedures.

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Individual system tests establish the functional adequacy by operation under prescribed conditions. The tests shall be designed to permit evaluation of system performance including, for example, the measurement of flow, temperature, pressure, response time and vibration, transfer of power supply to emergency power and accuracy and response of control devices. The preoperational testing program should demonstrate, as nearly as can be practicably simulated, the overall integrated operation of the plant systems at rated conditions, including simultaneous operation of auxiliary systems. It may be necessary to defer portions of these tests until nuclear heat is available. The procedures used should be similar to those discussed in 5.3.3 and 5.3.4, and they should be modified to require variation in control parameters, such as pump stops and restarts, cycling valves and varying flows so that system performance can be evaluated. For additional requirements in matters relating to preoperational test programs, American National Standard N45.2.8-1975 is generally applicable. [8] **Reg. Guide 1.33** – C. Regulatory Position 5.g. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: g. Section 5.2.19.1–The guidelines for preoperational tests, except the guideline that refers to a run-in period		

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for equipment. In addition to these guidelines, the prerequisite steps for each equipment test should be completed prior to the commencement of the preoperational test. [**NOTE**: The affected "should" words are underlined in the N18.7 excerpt above.]		
5.2.19.2 Tests Prior to and During initial Plant Operation.		
Prior to placing a nuclear power plant into operation, a preoperational test program shall be performed to demonstrate the functional adequacy of plant components, systems and structures. Following fuel loading an initial start-up test program shall be conducted to evaluate plant performance as the start-up progresses.	NQA-1, Requirement 11, NQA-1, Part II, Subpart 2.8, paragraph 500 QAPD, Part II, Section 11	
Responsibilities		
The ultimate responsibility for the preparation and execution of adequate preoperational and initial start-up test programs rests with the owner organization. If design or construction is performed by other than the owner organization, design organizations involved should participate in definition of the programs, and the construction organization involved may supply manpower or supervision for execution of part or all of the program, but the owner organization shall determine that the program is adequate and that the results are satisfactory.	QAPD, Part II, Section 1	
Scheduling		
A schedule shall be provided and maintained to provide assurance that all necessary tests are performed and	QAPD, Part II, Section 11	

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properly evaluated on a timely basis. Testing shall be scheduled so that the safety of the plant is never dependent on the performance of an untested system (see also Section 5.2.8).		
5.2.19.3 Tests Associated with Plant Maintenance, Modifications or Procedure Changes.		
Tests shall be performed following plant modifications or significant changes in operating procedures to confirm that the modifications or changes reasonably produce expected results and that the change does not reduce safety of operations.	NQA-1, Requirement 11 NQA-1, Part II, Subpart 2.18, paragraph 200 QAPD, Part II, Section 11	See Requirement 11, paragraph 200, Test Requirements.
5.3 Preparation of Instructions and Procedures.		
The administrative controls and quality assurance program shall be carried out throughout plant life in accordance with written procedures. Activities affecting safety at nuclear power plants shall be described by written procedures of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions and procedures. **Reg. Guide 1.33** – Regulatory Position C, Item 1 ANSI N18.7-1976/ANS-3.2 requires the preparation of many procedures to carry out an effective quality assurance program. Appendix A, "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors," to this regulatory guide should be used as guidance to ensure minimum procedural coverage for plant operating activities, including related maintenance activities. Appendix A lists typical safety-related activities that should be covered by written	NQA-1, Requirement 5 QAPD, Part II, Section 5; Part V, Section 3	

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procedures but does not provide a complete listing of needed procedures. Many other activities carried out during the operation phase of a nuclear power plant require written procedures not included in Appendix A. Appendix A may also contain procedures that are not applicable to an applicant because of the configuration of the nuclear power plant. The procedures listed in Appendix A may be combined, separated, or deleted to conform to the applicant's procedures plan.		
These procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. These procedures shall provide an approved preplanned method of conducting operations. Procedures shall be prepared and approved prior to implementation as required by 4.3 and 5.2.15.	NQA-1, Requirement 5	
5.3.1 Procedure Scope.		
Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process.	QAPD, Part V, Section 3	
5.3.2 Procedure Content.		
The format of procedures may vary from plant to plant, depending on the policies of the owner organization. However, procedures shall include, as appropriate, the following elements:	QAPD, Part V, Section 3	
(1) Title. Each procedure <u>should</u> contain a title descriptive of the work or system or unit to which it applies, a revision	QAPD, Part V, Section 3.1	

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number or date, and an approval status.		
(2) Statement of Applicability. The purpose for which the procedure is intended should be clearly stated; for example, for use during reactor or plant start-up. If the purpose is not clear from the title, a separate statement of applicability should be provided, which may identify the reasons for particular operations.	QAPD, Part V, Section 3.1	
(3) References. References, including reference to technical specifications, should be included in procedures as applicable. References should be identified within the body of procedures when the sequence of steps requires other tasks to be performed prior to or concurrent with a particular step within that task.	NQA-1, Introduction to Part II, NQA-1, Part II, Subpart 2.18, paragraph 202 QAPD, Part V, Section 3.1	
(4) Prerequisites. Each procedure should identify those independent actions or procedures which shall be completed and plant conditions which shall exist prior to its use. Prerequisites applicable only to certain sections of a procedure should be so identified.	NQA-1, Introduction to Part II, NQA-1, Part II, Subpart 2.18, paragraph 202 QAPD, Part V, Section 3.1	
(5) Precautions. Precautions should be established to alert the individual performing the task to those important measures which should be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation. It may be convenient to specify precautions separately. Cautionary notes applicable to specific steps in the procedure should be included in the main body of the procedure and should be identified as such.	NQA-1, Introduction to Part II, NQA-1, Part II, Subpart 2.18, paragraph 202 QAPD, Part V, Section 3.1	
(6) Limitations and Actions. Limitations on the parameters being controlled and appropriate corrective measures to	QAPD, Part II, Section 5	

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return the parameter to the normal control band should be specified. It may be convenient to specify limitations and setpoints in a separate section. Where appropriate, quantitative control guides should be provided; for example, an appropriate step of a procedure should say "Manually adjust the feedwater flow controller to maintain the reactor water level at x feet," rather than "Manually adjust the feedwater flow to maintain water level."	QAPD, Part V, Section 3.1	
(7) Main Body. The main body of a procedure should contain step-by-step instructions in the degree of detail necessary for performing a required function or task.	NQA-1, Introduction to Part II NQA-1, Part II Subpart 2.18, paragraph 202 QAPD, Part V, Section 3.1	
(8) Acceptance Criteria. Procedures should contain, where applicable, acceptance criteria against which the success or failure of test-type activity would be judged. In some cases there would be qualitative criteria, i.e., a given event does or does not occur. In other cases quantitative values would be designated.	NQA-1, Introduction to Part II NQA-1, Part II, Subpart 2.18, paragraph 202 QAPD, Part V, Section 3.1	

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(9) Checkoff Lists. Complex procedures should have checkoff lists. These lists may be included as part of the procedure or may be appended to the procedure. **Reg. Guide 1.33** – C. Regulatory Position 5.h. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: h. Section 5.3.2-The guidelines that describe the content (excluding format) of procedures, except for the guidelines that address (1) a separate statement of applicability in Section 5.3.2(2), (2) inclusion of references in procedures, as applicable, in Section 5.3.2(3), and (3) inclusion of quantitative control guides in Section 5.3.2(6). [**NOTE**: The affected "should" words are underlined in the N18.7 excerpts above.]	NQA-1, Introduction to Part II NQA-1, Part II Subpart 2.18, paragraph 202 QAPD, Part V, Section 3.1	
5.3.3 System Procedures.		
Instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation and other instructions appropriate for operations of systems related to the safety of the plant shall be delineated in system procedures. Procedures for correcting off-normal conditions shall be developed for those events where system complexity may lead to operator uncertainty. System procedures shall contain checkoff lists where appropriate.	QAPD, Part V, Section 3.2	

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5.3.4 General Plant Procedures.		
General plant procedures provide instructions for the integrated operations of the plant. In addition to the characteristics of procedures presented in 5.3.1 and 5.3.2, details concerning specific general plant procedures are emphasized in the following sections.	QAPD, Part V, Section 3.2	
5.3.4.1 Start-up Procedures.		
Start-up procedures shall be provided that include starting the reactor from cold or hot conditions and establishing power operation, with the generator synchronized to the line. Recovery from reactor trips shall be in accordance with the start-up procedure and shall be subject to the determinations set forth in 5.2.1. (1) Prerequisites. Start-up procedures shall include provisions for documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned; necessary systems procedures, tests and calibrations have been completed; and required approvals have been obtained. Checkoff lists are normally used for this purpose. (2) Main Body. The main body of the start-up procedures shall include the major steps of the start-up sequence, including reference to appropriate system procedures. Such major steps shall include or reference detailed instructions for their performance, for example, minimum instrumentation requirements coverage of control rod withdrawal sequence or soluble poison dilution, manipulation of controls, establishment of feed and steam	QAPD, Part V, Section 3.2	

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flow and turbine start-up and synchronization. Checkoff lists should be used for the purpose of confirming completion of major steps in proper sequence.		
5.3.4.2 Shutdown Procedures.		
Shutdown procedures shall be provided to guide operations during and following controlled shutdown or reactor trips and shall include instructions for establishing or maintaining hot standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the plant shall be specified, including detailed instructions for the performance of such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence of activating or deactivating equipment, requirements for prompt analyses of causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal. Checkoff lists should be used for the purpose of confirming completion of major steps in proper sequence.	QAPD, Part V, Section 3.2	
5.3.4.3 Power Operation and Load Changing Procedures.		
Procedures for steady-state power operation and load changing shall be provided that include, for example, provisions for use of control rods, chemical shim, coolant flow control or any other system available for long-or-short term control of reactivity, making deliberate load changes, responding to unanticipated load changes and adjusting operating parameters.	QAPD, Part V, Section 3.2	

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5.3.4.4 Process Monitoring Procedures.		
Procedures for monitoring performance of plant systems shall be required to assure that core thermal margins and coolant quality are maintained at all times, that integrity of fission product barriers is maintained at all times and that engineered safety features and emergency equipment are in a state of readiness to maintain the plant in a safe condition if needed. The limits (maximum and minimum) for significant process parameters shall be identified. The nature and frequency of this monitoring shall be covered by operating procedures, as appropriate.	QAPD, Part V, Section 3.2	
5.3.4.5 Fuel-Handling Procedures.		
Fuel-handling operations shall be performed in accordance with written procedures. These procedures shall specify actions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of the neutron flux throughout core loading, periodic recording of data, audible annunciation of abnormal flux increases and evaluation of core neutron multiplication to verify the safety of loading increments. Provisions shall be made for preparing specific procedures for each refueling outage and for receipt and shipment of fuel. Plant procedures should, nonetheless, prescribe the general preplanning for the fuel-handling program and its associated safety measures and should identify those aspects of the program for which procedures are to be prepared for each refueling outage. (1) Prerequisites**.** Prerequisites shall be provided in the	QAPD, Part V, Section 3.2	

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fuel-handling procedures that include, for example, the status of plant systems required for refueling; inspection of replacement fuel, control rods, poison curtains and internals; designation of proper tools; proper conditions for spent fuel movement; proper conditions for fuel cask loading and movement; and status of interlocks, reactor trip circuits and mode switches. (2) Main Body. The main body of fuel handling procedures shall include requirements for refueling; for example, the status of the core, instructions for proper sequence, orientation, and seating of fuel and components, rules for minimum operable instrumentation, actions to be followed in the event of fuel damage, rules for periods when refueling is interrupted, verification of the shutdown margin and the frequency of determination, communications between control room and the fuel loading station, independent verification of fuel and component location, criteria for stopping refueling and for reducing the size of the fuel loading increment, and a containment evacuation plan and its associated safety measures. Documentation of final fuel and component serial numbers and locations shall be maintained.		
5.3.5 Maintenance Procedures.		
Maintenance procedures shall contain applicable items listed under 5.3.2 and, in addition, measures to cover the features of maintenance described below. (1) Preparation for Maintenance**.** Maintenance procedures shall reflect considerations listed under 5.2.6. Adherence to applicable radiation protection measures shall be prescribed. These measures shall specify protective clothing	NQA-1, Part II, Subpart 2.18, paragraph 200 QAPD, Part V, Section 3.2	

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and radiation monitoring needed to assure safety. (2) Performance of Maintenance. The procedures shall contain enough detail to permit the maintenance work to be performed correctly and safely, and shall include provisions for conducting and recording results of required tests and inspections. References should be made to vendor manuals, plant procedures, drawings and other sources as applicable. (3) Post Maintenance Check Out and Return to Service. Instructions shall be included, or referenced, for returning the equipment to its normal operating status. (4) Supporting Maintenance Documents. Where appropriate sections of related documents, such as vendor manuals, equipment operating and maintenance instructions, or approved drawings with acceptance criteria provide adequate instructions to assure the required quality of work, the applicable sections of the related documents shall be referenced in the procedure, or may, in some cases, constitute adequate procedures in themselves. Such procedures shall receive the same level of review and approval as operating procedures.		
5.3.6 Radiation Control Procedures.		
Procedures shall be provided for implementation of a radiation control program to meet applicable program requirements. The radiation control program involves the acquisition of data and provision of equipment to perform necessary radiation surveys, measurements and evaluations for the assessment and control of radiation hazards associated with a nuclear power plant. Procedures shall be developed and implemented for: monitoring both	QAPD, Part V, Section 3.2	

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external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities; and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures of employees and others.		
5.3.7 Calibration and Test Procedures.		
Procedures shall be provided for periodic calibration and testing of safety-related instrumentation and control systems. Procedures shall also be provided for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. The procedures shall provide for meeting surveillance schedules and for assuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.	QAPD, Part V, Section 3.2	
5.3.8 Chemical-Radiochemical Control Procedures.		
Procedures shall be provided for chemical and radiochemical control activities. They should include, for example, the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces or become sources of radiation hazards due to activation. Procedures shall also be provided for the control, treatment and management of radioactive wastes and control of radioactive calibration sources.	QAPD, Part V, Section 3.2	

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5.3.9 Emergency Procedures.		
Procedures shall be provided to guide operations during potential emergencies. They shall be written so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate action he should take. Since emergencies may not follow anticipated patterns, the procedures should provide sufficient flexibility to accommodate variations. Emergency procedures that cover actions for manipulations of controls to prevent accidents or lessen their consequences should be based on a general sequence of observations and actions. Emphasis should be placed on operator responses to observations and indications in the control room; that is, when immediate operator actions are required to prevent or mitigate the consequences of a serious condition, procedures should require that those actions be implemented promptly. The emergency procedure format given in 5.3.9.1 provides a basis for coping with emergencies and is an acceptable format for prescribing operator observations and actions. Emergency procedures may contain supplemental background information to further aid operators in taking proper emergency actions, but this information shall be separated from the procedural actions. It is extremely difficult to distinguish between procedures prepared for the purpose of correcting off-normal conditions which in themselves do not constitute actual emergency situations, but which conceivably can degenerate into true emergencies in the absence of positive corrective action, and procedures required for coping with true emergencies	QAPD, Part V, Section 3.2	Requirements for Emergency Procedures have been updated through the years through industry initiatives and lessons learned.

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
that have already occurred. Some owner organizations choose the term "Off-normal Procedures" for the same purpose that others choose "Emergency Procedures." When initially available intelligence provided to operating personnel via instrument readings, physical conditions, and personal observations may not clearly indicate the difference between a simple operational problem and a serious emergency, the actions outlined in the emergency procedures shall be based on a conservative course of action by the operating crew. Considerable judgment on the part of competent personnel is required before departing from the emergency procedure. **Reg. Guide 1.33** – C. Regulatory Position 5.i. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: i. Section 5.3.9–The guideline concerning emergency procedures requiring prompt implementation of immediate operator actions when required to prevent or mitigate the consequences of a serious condition. [**NOTE**: The affected "should" words are underlined in the N18.7 excerpt above.]		
5.3.9.1 Emergency Procedure Format and Content.		
Emergency procedures shall include, as appropriate, the following elements: (1) Title. The title <u>should</u> be descriptive of the emergency	QAPD, Part V, Section 3.2	Requirements for Emergency Procedures have been updated through the years through industry initiatives and lessons

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
for which the procedure is provided. (2) Symptoms. Symptoms should be included to aid in the identification of the emergency. They should include alarms, operating conditions and probable magnitudes of parameter changes. If a condition is peculiar only to the emergency under consideration, it should be listed first. (3) Automatic Actions. The automatic actions that will probably occur as a result of the emergency should be identified. (4) Immediate Operator Actions. These steps should specify immediate actions for operation of controls or confirmation of automatic actions that are required to stop the degradation of conditions and mitigate their consequences. Examples include the following: (a) The verification of automatic actions. This step is based on equipment operating as designed and the sequence of events following an expected course. Since variations from the expected course may occur, operators should be prepared to manipulate controls as necessary to cope with the problem. However, the procedure should caution the operator not to place systems in "manual" unless misoperation in "automatic" is apparent, and should require him to make frequent checks for proper operation of systems placed in manual control. (b) Assurance that reactor is in a safe condition. This step usually means shutdown of the reactor with sufficient reactivity margin and establishment of required core cooling. (c) Notification to plant personnel of the nature of the		learned.

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
emergency. (d) Determination that the reactor coolant system pressure boundary is intact. (e) Confirmation of the availability of adequate power sources. (f) Confirmation that containment and exhaust systems are operating properly in order to prevent uncontrolled release of radioactivity. (5) Subsequent Operator Actions. Steps should be included to return the reactor to a normal condition or to provide for a safe extended shutdown period under abnormal or emergency conditions. **Reg. Guide 1.33** – C. Regulatory Position 5.j. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: j. Section 5.3.9.1–The guidelines that describe the content (excluding format) for: the title in Section 5.3.9.1(1); the inclusion of symptoms to aid in identification in Section 5.3.9.1(2); automatic actions in Section 5.3.9.1(3); immediate operator action, excluding those guidelines contained in the examples, in Section 5.3.9.1(4); and subsequent operator actions in Section 5.3.9.1(5). [**NOTE**: The affected “should” words are underlined in the N18.7 excerpt above.]		

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
5.3.9.2 Events of Potential Emergency.		
Potential emergency conditions shall be identified and procedures for coping with them shall be prepared. The following categories of events may, depending upon the design of the plant, be considered as examples of potential emergencies for which procedures are written and for which immediate action is indicated: (1) Loss of coolant from identified and unidentified sources, from small loss to design-basis-accident loss (2) Reactor transients and excursions (3) Failure of vital equipment (4) Loss or degradation of vital power sources (5) Civil disturbances (6) Abnormally high radiation levels (7) Excessive release of radioactive liquid or gaseous effluent (8) Malfunction of reactivity control system (9) Loss of containment integrity (10) Conditions that require use of standby liquid poison systems (11) Possible natural occurrences (12) Fires	QAPD, Part V, Section 3.2	The list contained in N18.7 is provided as examples and is not stated in the QAPD. NRC regulatory guidance and the applicable facility SAR and Emergency Plans will provide the basis for what procedures are necessary.
5.3.9.3 Procedures for Implementing Emergency Plan.		
Implementing procedures for emergency plan actions shall contain, as appropriate, the following elements: (1) Individual assignment of authorities and responsibilities for performance of specific tasks to specific	QAPD, Part V, Section 3.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
individuals or staff positions. (2) Protective action levels and protective measures outlined for the emergency identified. (3) Specific actions to be taken by coordinating support groups. (4) Procedures for medical treatment and handling of contaminated individuals. (5) Special equipment requirements for items such as medical treatment, emergency personnel removal, specific radiation detection, personnel dosimetry and rescue operations, procedures for making this equipment available, plus operating instructions for such equipment, and provisions for its periodic inspection and maintenance. (6) Identification of emergency communications network, including communications required for personnel identification and effective coordination of all support groups. (7) Description of alarm signals in each facility. At sites with multiple units, alarm signals should be consistent from one unit to another. (Signals for initiating protective measures should be clear and distinct from process or operational alarm system to avoid confusion.) (8) Procedures required to restore the plant to normal conditions following an emergency. (9) Requirements for periodically testing of procedures, communications network and alarm systems to assure that they function properly.		

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	NQA-1-2008, NQA-1a-2009 Addenda or NEI 11-04 QAPD	Comments
See also U.S. Nuclear Regulatory Commission (NRC) "Guide to the Preparation of Emergency Plans for Production and Utilization Facilities." [17]		
5.3.10 Test and Inspection Procedures.		
Test and inspection procedures shall contain a description of objectives; acceptance criteria that will be used to evaluate the results; prerequisites for performing the tests or inspections including any special conditions to be used to simulate normal or abnormal operating conditions; limiting conditions; and the test or inspection procedure. These procedures shall also specify any special equipment or calibrations required to conduct the test or inspection.	NQA-1, Requirement 11 NQA-1, Part II, Subpart 2.18, paragraph 200 QAPD, Part V, Section 3.2	See Requirement 11, paragraph 300, Test Procedures.
Test and inspection results shall be documented and evaluated by responsible authority to assure that test and inspection requirements have been satisfied.	NQA-1, Requirement 10 NQA-1, Requirement 11 QAPD, Section 5.4	
Where tests and inspections are to be witnessed, the procedure shall identify hold points in the testing sequence to permit witnessing. The procedure shall require appropriate approval for the work to continue beyond the designated hold point. The test and inspection procedures shall require recording the date, identification of those performing the test or inspection, as found condition, corrective actions performed, if any, and as-left condition.	NQA-1, Requirement 10 NQA-1, Requirement 11 NQA-1. Part II, Subpart 2.18, paragraph 200 QAPD, Part V, Section 3.2	See Requirement 10, paragraph 300, Inspection Hold Points, and paragraph 800, Records. See Requirement 1, paragraph 300, Test Procedures; paragraph 500, Test Results; and paragraph 600, Test Records.

APPENDIX 2 – NRC Safety Evaluation Report on NEI 11-04, Revision 0

(ML13023A051)

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May 9, 2013

Mr. Russell J. Bell, Director
New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1201 F Street, NW, Suite 1100
Washington, DC 20004

SUBJECT: FINAL SAFETY EVALUATION FOR TECHNICAL REPORT NEI 11-04, "QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 0

Dear Mr. Bell:

By letter dated May 27, 2011, the Nuclear Energy Institute (NEI) submitted Draft Revision 0 of NEI 11-04, "Quality Assurance Program Description. NEI 11-04 provides a Quality Assurance Program Description (QAPD) template for applicants of Part 52 permits or licenses to use in meeting the requirements in Title 10 of the *Code of Federal Regulation* (10 CFR) Parts 50 and 52. In a safety evaluation report dated July 13, 2010, the U.S. Nuclear Regulatory Commission (NRC) previously endorsed NEI 06-14 "Quality Assurance Program Description, Revision 9," which is based on American Society of Mechanical Engineers NQA-1-1994. NEI 11-04 updates the NEI generic QAPD template to reflect the requirements of NQA-1-2008 and the NQA-1a-2009 Addenda, which the NRC endorsed in Regulatory Guide (RG) 1.28, Revision 4.

By letter dated February 8, 2012, the NRC requested additional information to complete its review of NEI 11-04. A teleconference was held September 5, 2012, to promote a better understanding of the NEI responses to the NRC's request for addition information (RAI). By a letter dated September 13, 2012, NEI submitted NEI 11-04, Revision 0, which incorporates NEI responses to NRC staff comments on NEI 11-04.

The NRC staff has reviewed the NEI submittal and supporting documentation. On the basis of its review, the staff concludes that the QAPD template can be used by applicants of 10 CFR Part 52 permits or licenses, as applicable, for establishing a quality assurance program that complies with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Parts 50 and 52.

CONTACT: Wesley Held, NRO/DARR
301-415-1583

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 11-04 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in Standard Review Plan Section 17.5. Key areas that an applicant is required to address include:

- The organizational description addressed in Part II, Section 1 of NEI 11-04, Revision 0.
- Record retention criteria addressed in Part II, Section 17.1 of NEI 11-04, Revision 0.
- Regulatory commitments addressed in Part IV of NEI 11-04, Revision 0.

To ensure all quality assurance requirements for the operating phase are addressed, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-2008 and the NQA-1a-2009 Addenda by explicitly addressing the provisions in NEI 11-04, Revision 0, Part V and Appendix 1, or otherwise by including a commitment to RG 1.33, “Quality Assurance Program Requirements (Operation),” Revision 2 in Part IV of the QAPD.

Enclosed is the NRC staff’s SER which defines the basis for acceptance of NEI 11-04, Revision 0. The NRC staff finds that for combined license applications (COLAs), NEI 11-04, Revision 0, provides an acceptable template for describing a quality assurance program.

Our acceptance applies only to material provided in NEI 11-04, Revision 0. We do not intend to repeat our review of the acceptable material described in NEI 11-04, Revision 0, when referenced in a COLA. Licensing requests that deviate from NEI 11-04, Revision 0, will be subject to a plant-specific or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC Web site, we request that NEI publish the accepted version of NEI 11-04, Revision 0 within 3 months of receipt of this letter. The accepted version should incorporate this letter and the enclosed SER. The accepted version should also contain historical review information, including NRC RAIs and your responses. The accepted versions shall include a “-A” (designating accepted) following the report identification symbol.

If future changes to the NRC’s regulatory requirements affect the acceptability of NEI 11-04A, NEI will be expected to revise NEI 11-04A appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Wesley W. Held at (301) 415-1583 or via email at Wesley.Held@nrc.gov.

Sincerely,

/RA/

Joseph Colaccino, Branch Chief
Policy Branch
Division of Advanced Reactors and Rulemaking
Office of New Reactors

Project No.: 689

Enclosure:
Safety Evaluation Report

cc w/encl: See next page

If you have any questions, please contact Wesley W. Held at (301) 415-1583 or via email at Wesley.Held@nrc.gov.

Sincerely,

/RA/

Joseph Colaccino, Branch Chief
Policy Branch
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Safety Evaluation Report

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SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS
TECHNICAL REPORT NEI 11-04,
"QUALITY ASSURANCE PROGRAM DESCRIPTION" REVISION 0

1.0 Introduction

By letter dated October 19, 2006 (Ref. 1), the Nuclear Energy Institute (NEI) submitted an industry quality assurance program description (QAPD) template for review and approval by the U.S. Nuclear Regulatory Commission (NRC) staff. In its letter dated January 7, 2007, NEI revised the QAPD template in technical report NEI 06-14, "Quality Assurance Program Description," that provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement NRC regulatory requirements related to quality assurance (QA) programs. NEI 06-14 is based on American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as supplemented by quality assurance and administrative control requirements specific to the operations phase. NEI 06-14 provides a common format for applicants when making commitments to comply with Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (Appendix B), and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

The QAPD template was initially released in May 2008, as NEI 06-14A, Revision 0, the 'A' denoting NRC staff approval as documented by NRC safety evaluation (SE) dated April 25, 2007 (Ref. 2). Its most recent Revision, NEI 06-14A, Revision 7, received NRC staff approval as documented by NRC SE dated July 13, 2010 (Ref. 3).

In June 2010, the NRC issued Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 4. This RG described methods that the NRC staff considered acceptable for complying with the provisions of 10 CFR Part 50, 10 CFR Part 52 which refer to 10 CFR Part 50, Appendix B for establishing and implementing a QA program for the design and construction of nuclear power plants and fuel reprocessing plants.

RG 1.28, Revision 4, endorsed the Part I and Part II requirements included in NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants as acceptable to the NRC staff. The NEI template provides an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to specific additions and modifications of NQA-1-2008 and the NQA-1a-2009 Addenda and the regulatory position in RG 1.28, Revision 4.

By letter dated May 27, 2011, the NEI submitted Draft Revision 0, (Ref. 4) to NEI 11-04 for staff review and approval. NEI 11-04 updated the NEI generic QAPD template to reflect the requirements of NQA-1-2008 and the NQA-1a-2009 Addenda.

Enclosure

By letter dated February 8, 2012 (Ref. 5), the NRC requested additional information to complete its review of NEI 11-04. A teleconference was held September 5, 2012 to promote understanding of the NEI responses to the NRC requests for additional information (RAIs). By letter dated September 13, 2012 (Ref. 6), NEI submitted NEI 11-04, Revision 0, which incorporates NEI responses to NRC staff comments on NEI 11-04. This safety evaluation report (SER) documents the basis for the NRC staff's acceptance of NEI 11-04, Revision 0, as an acceptable basis for developing a QAPD that meets Appendix B to 10 CFR Part 50 requirements.

2.0 Background

The QAPD template provides guidance for establishing a top-level policy document that defines QA policy and assigns major QA program functional responsibilities. This QAPD template can be used for ESP, COL, construction, preoperational, and/or operation activities, as applicable, that affect the quality and performance of safety-related structures, systems, and components (SSCs).

The QAPD template includes brackets throughout the document to allow for user-specific text for statements that are scope dependent, are not applicable to combined license applications (COLAs) with an approved ESP, or are applicable only to ESP applications. In addition, the QAPD template uses brackets to provide guidance to users on how to address areas that are specific to the application. Brackets are also used to provide the user with different alternatives that satisfy the requirements of Appendix B to 10 CFR Part 50.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 11-04 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in Standard Review Plan (SRP), Section 17.5, "Quality Assurance Program Description, Design Certification, Early Site Permit, and New License Applicants."

3.0 Discussion and Evaluation

3.1 Regulatory Evaluation

The Commission's regulatory requirements related to QA programs are set forth in 10 CFR Part 50, Appendix B. Appendix B establishes QA requirements for the design, fabrication, construction, and testing of the SSCs of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

10 CFR 52.17 establishes the technical information requirements for ESP applications. Section 52.17(a)(1)(xi) requires that ESP applications provide a description of the QA program applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site.

10 CFR 52.79 establishes the technical information requirements for COLAs. Section 52.79(a)(25) requires that COLAs provide a description of the QA program applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility. Further, 10 CFR 52.79(a)(25) requires that the description of the QA program include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, and also include a discussion of how the QA program will be implemented. Finally, 10 CFR 52.79(a)(27) requires that the application contain information on the managerial and administrative controls to be used to assure safe operation consistent with the requirements of Appendix B to 10 CFR Part 50 and a discussion of how such requirements will be satisfied.

3.2 Evaluation

In evaluating the adequacy of the QAPD template, the staff followed SRP Section 17.5 (Ref. 7), that provides guidance to NRC staff for evaluating QA program descriptions submitted under 10 CFR Part 52. SRP Section 17.5 is based on ASME standard NQA-1, 1994 Edition; RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3; RG 1.28; and RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2. An evaluation of the applicant's conformance with these RGs is included in Part IV of the QAPD template.

3.2.1 Organizational Description

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.A, by providing an example of an organizational description for a new plant license, independence of working and checking organizations, and providing interrelationships of new plant and existing utility organizations. The template provides adequate guidance for ESP and COL applicants to describe an organizational structure that clearly delineates those management positions responsible for establishing, maintaining, and implementing regulatory requirements from corporate through operating plant positions. The QAPD template provides guidance for applicants to describe functional responsibilities and position descriptions during the construction, preoperational, and operations phases, as well as characterizing control and transitions between phases. It allows management to size the QA organization commensurate with its assigned duties and responsibilities. Information in Part II, Section 1 of NEI 11-04, Revision 0, is applicant-specific and will be reviewed and approved by the staff on a case-by-case basis.

In addition, the QAPD template commits the applicant to the QA standards described in NQA-1-2008, Requirement 1.

3.2.2 Quality Assurance Program

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.B for establishing the necessary measures to implement a QA program to ensure that the design, construction, and operation of nuclear power plants are in accordance with governing regulations and license requirements. The QA program comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, including certain

nonsafety-related SSCs and activities that are significant contributors to plant safety, as described in the ESP site safety analysis report or the COL final safety analysis report. A listing or system identifying SSCs and activities within the scope of the QA program is maintained by the applicant at an appropriate facility.

The QAPD template provides measures to assess the adequacy of the QAPD and to ensure its effective implementation at least once each year or at least once during the life of a quality related activity, whichever is shorter. The period for assessing the QAPD during the operations phase may be extended to once every 2 years. In addition, consistent with SRP Section 17.5, paragraph II.B.8, a grace period of 90 days is applied to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity may be reset backwards when an activity is performed early.

The QAPD template follows the guidance of SRP Section 17.5, paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure task-related proficiency is maintained. Plant technical specifications delineate the minimum qualifications for plant and support staff. The QAPD has personnel completing training for positions identified in 10 CFR 50.120, "Training and Qualification of Nuclear Plant Personnel," according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD template provides the minimum training requirements for managers responsible for QAPD implementation and for the manager responsible for planning, implementing, and maintaining the QAPD.

The QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 2 with the following clarifications and exceptions:

- *Section 302, Inspection and Test [NOTE: The applicant may either adopt nonmandatory Appendix 2A-1 as if it were part of the requirement by following Option 1 below or taking exception to Appendix 2A-1 by following Option 2.]*

  - [*Option 1; NQA-1-2008, Requirement 2 includes use of Appendix 2A-1 guidance as if it were part of the Requirement.] [NOTE: When applying Option 1, either or both of the following two alternatives may be applied to the implementation of this Requirement and Appendix:]*

  (1) *[In lieu of being certified as Level I, II, or III in accordance with NQA-1-2008, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.]* This alternative is consistent with SRP Section 17.5, paragraph II.T.5.

(2) *[A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.]* The staff's review determined that there is no conflict with regulatory guidance, NQA-1-2008, or other industry guidance in this subject area.

- *[Option 2 is based on the SER under Agencywide Documents Access and Management System (ADAMS) Accession No. ML050700416 and may only be applied during the Operational phase. The post-Three Mile Island (TMI) regulations at 10 CFR 50.34(f)(3)(iii) apply during construction phase.]*

a) *[In lieu of Nonmandatory Appendix 2A-1, [CA] does not establish levels of qualification/certification for inspection personnel. Instead, [CA] establishes initial qualification requirements and determines individual qualification through evaluation of education, training and experience, and through demonstration of capability in performing the type of inspections expected on the job.]* The staff determined that this exception is acceptable as documented in a previous SE under ADAMS Accession No. ML050700416 and is only applicable during operations, because the TMI regulations at 10 CFR 50.34(f)(3)(iii) apply during the construction phase.

b) *[NOTE: When selecting Option 2, the following alternative may be applied to the implementation of Requirement 2.] [Inspections, examinations or tests may be performed by individuals in the same organization as that which performed the work, provided that (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b and c are not met, inspections, examinations, or tests are carried out by individuals certified in accordance with Section 300. Individuals performing visual inspections required by the ASME Boiler & Pressure Vessel (BPV) Code are qualified and certified according to Code requirements.]* This alternative is consistent with SRP Section 17.5, paragraph II.T.5 and 6.

- *[CA] follows Section 301 for qualification of nondestructive examination personnel, except that [CA] will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME BPV Code approved by the NRC for use at [CA] sites for the scope of activities governed by these cited standards.* The regulation in 10 CFR 50.55a, "Codes and Standards," requires use of the latest edition and addenda of Sections III and XI endorsed in 10 CFR 50.55a. Therefore, the staff finds the use of Sections III and XI of the ASME BPV Code for qualification of nondestructive examination personnel acceptable.

- *Section 400(a)(8) requires the date of certification expiration be included on the qualification record. [CA] considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.* The date of certification establishes the expiration date, when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization's procedure; therefore because having both dates on the form is redundant, the staff determined that this exception is acceptable.

3.2.3 Design Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.C, for establishing the necessary measures to control design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items within the scope of the QAPD. The QAPD template includes measures to control design inputs, outputs, changes, interfaces, records, and organizational interfaces among the applicant and its suppliers. These provisions ensure that the design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the QAPD template provides for individuals knowledgeable in QA principles to review design documents to ensure that they contain the necessary QA requirements.

The QAPD template commits the applicant to the quality standards for its program in design control and verification described in NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.7 for computer software, Subpart 2.14 for QA requirements for commercial-grade items and services and Subpart 2.20 for subsurface investigation requirements. [NOTE: Subpart 2.20 does not apply to an Operations-only QAP].

3.2.4 Procurement Document Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.D, for establishing the necessary administrative controls and processes to ensure that procurement documents include or reference applicable regulatory, technical, and QA program requirements. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and the regulation at 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for procurement of items and services.

The QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 4, with the following clarifications and exceptions:

- *With regard to service performed by a supplier, [CA] procurement documents may allow the supplier to work under the [CA] QAP, including implementing procedures, in lieu of the supplier having its own QAP.* Criterion IV of Appendix B requires suppliers to have a QA program consistent with Appendix B. Therefore, the staff determined this clarification to be acceptable, because it is consistent with SRP Section 17.5, paragraph II.D.2.d..

- *Sections 300 and 400 of Requirement 4 require the review of technical and QA program requirements of procurement documents prior to award of a contract and for procurement document changes. [CA] may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and QA requirements of the procurement.* The staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change, which is consistent with SRP Section 17.5, paragraph II.D.3. Therefore, the staff concluded that this alternative is acceptable.

- *Procurement documents for commercial-grade items that will be procured by [CA] for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with the [CA] QAPD, Section 7, "Control of Purchased Material, Equipment and Services.*" This alternative is consistent with staff guidance in Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989, and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

3.2.5 Instructions, Procedures, and Drawings

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.E, for establishing necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, and drawings.

The QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 5, for establishing procedural controls.

3.2.6 Document Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance, and changes of documents that specify quality requirements or prescribe measures for controlling activities affecting quality, including organizational interfaces. The template provides measures to ensure that the same organization that performed the original review and approval also reviews and approves revisions or changes to documents, unless other organizations are specifically designated. A listing of all controlled documents identifying the current approved revision or date is maintained so that personnel can readily determine and access current and applicable documents for specific applications.

To ensure effective and accurate procedures during the operational phase, procedures are reviewed and updated as necessary, consistent with the guidance provided in SRP Section 17.5, paragraph II.F.8. During the operational phase, temporary changes to a procedure that clearly do not alter the intent of the procedure may be implemented, provided that two members of the operations staff knowledgeable in the areas affected by the procedure approve the changes.

These temporary changes include a specific period of time during which the revised procedure may be used.

In establishing provisions for document control, the QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 6.

3.2.7 Control of Purchased Material, Equipment, and Services

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.G, for establishing necessary measures and governing procedures that control procurement of items and services to ensure conformance with specified requirements. The controls include measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, controls include auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions, such as source verification, receipt inspection, pre- and post-installation tests and review of documentation, such as certificates of conformance, to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (components, spares, and replacement parts necessary for plant operation, refueling, maintenance, and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment, or specified by properly reviewed and approved revisions to design documentation, to ensure that the items are suitable for their intended service and are of acceptable quality, consistent with their effect on safety.

In establishing procurement verification control, the QAPD template commits the applicant to the quality standards described in NQA-1-2008 and NQA-1a-2009, Requirement 7, with the following clarifications and exceptions:

- *[CA] considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection (ANI) Agencies, National Institute of Standards and Technology(NIST), or other State and Federal agencies which may provide items or services to the [CA] plant[s] are not required to be evaluated or audited.*

  The staff acknowledges that 10 CFR Part 50 and Part 52 licensees, ANI agencies, the NIST, and other State and Federal agencies perform work under acceptable quality programs, and no additional audit or evaluation is required. The staff determined that this exception is acceptable as documented in a previous SE under ADAMS Accession No. ML052710224. The applicant or holder is still responsible for ensuring that the items or services conform to its Appendix B program, applicable ASME BPV Code requirements, and other regulatory requirements and commitments. The applicant or holder is also responsible for ensuring that the items or services are suitable for the intended application and for documenting this evaluation. The proposed exception is acceptable on the basis that it provides an appropriate level of quality and safety.

- *When purchasing commercial-grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:*

  - *The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the [CA] QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.*

  - *The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.*

  - *A documented review of the supplier's accreditation will be performed and will include a verification of the following:*

    - *The calibration laboratory holds a domestic (United States) accreditation by an NRC approved domestic (United States) accrediting bodies, recognized by the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.*

    - *The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."*

    - *The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.*

  The staff determined that the provisions of this exception are consistent with the regulatory guidance provided in SRP Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications and as documented in a previous SE under ADAMS Accession No. ML052710224. The staff expects full conformance to the guidance in SRP Section 17.5, paragraph II.L.8, and subparagraph h, that "The alternative method is limited to the domestic calibration service suppliers."

- *For Section 501, [CA] considers documents that may be stored in approved electronic media under [CA] or vendor control, not physically located on the plant site, but accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to [CA] to support operations. The [CA] records management system will provide for timely retrieval of necessary records.*

  The staff determined that this alternative meets the requirements of Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services." Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, this provision, which would allow for accessing and reviewing the necessary procurement documents at the site before installation and use, would meet this requirement.

- *In establishing commercial-grade item requirements, QAPD template commits to compliance with NQA-1a-2009, Section 700 and Subpart 2.14, with the following clarification:*

  - *For commercial-grade items, quality verification requirements are established and described in [CA] documents to provide the necessary assurance an item will perform satisfactorily in service. The [CA] documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.*

  - *[CA] will assume 10 CFR Part 21 reporting responsibility for all items that [CA] dedicates as safety-related.*

  The staff determined that the provisions of this exception are consistent with the regulatory requirements of 10 CFR Part 21 and regulatory guidance provided in SRP Section 17.5, paragraphs II.U.1.d and II.U.1.e.

3.2.8 Identification and Control of Materials, Parts, and Components

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.H, for establishing necessary measures for identification and control of items such as materials, including consumables, and items with limited shelf life, parts, components, and partially fabricated subassemblies. Identification of items is maintained throughout fabrication, erection, installation, and use so that the item is traceable to its documentation.

In establishing provisions for identification and control of items, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 8.

3.2.9 Control of Special Processes

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.I, for establishing and implementing programs, procedures, and processes to ensure that special processes requiring interim process controls to ensure quality, such as welding, heat treating, chemical cleaning, and nondestructive examinations, are controlled in accordance with applicable codes, specifications, and standards for the specific application.

In establishing measures for the control of special processes, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 9.

3.2.10 Inspection

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.J, for establishing necessary measures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to documented specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the

frequency of inspection, and identifying special tools needed to perform the inspection. Qualified personnel perform the inspections and are independent of those who performed or directly supervised the work

In establishing inspection requirements, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 10, and Subparts 2.4, 2.5 and 2.8 for establishing appropriate inspection requirements with the following clarifications;

- *Subpart 2.4 commits [CA] to Institute of Electrical and Electronics Engineers (IEEE) Std 336-1985, which refers to IEEE Std 498-1985. Both IEEE Std 336-1985 and IEEE Std 498-1985 use the definition of "Safety Systems" from IEEE Std 603-1980. [CA] commits to the definition of Safety Systems in IEEE Std 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.* The clarification is to reinforce the fact that the QAPD is not committing to the entirety of IEEE Std 603-1980. The staff determined that the use of the definition of safety systems equipment in the context of Subpart 2.4 is acceptable because it is an accurate clarification of the definition.

3.2.11 Test Control

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.K, for establishing necessary measures and governing provisions to demonstrate that items within the scope of the QAPD will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant, as a whole, is satisfactory.

[CA] establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end [CA] commits to compliance with the requirements of NQA-1a-2009, Requirement 11 and Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, Requirement 3.

In establishing provisions for testing, QAPD template commits the applicant to the quality standards described in NQA-1a-2009, Requirement 11.

3.2.12 Control of Measuring and Test Equipment

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.L, for establishing necessary measures to control the calibration, maintenance, and use of measuring and test equipment that provides information important to safe plant operation. In establishing provisions for control of measuring and test equipment, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 12 with the following clarification and exception:

NQA-1-2008, Subpart 2.4 refers to American National Standards Institute (ANSI)/IEEE Std 336-1985 for the installation, inspection, and testing requirements for power,

instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std 336-1985 makes reference to the use of IEEE Std 498-1985 for measuring and test equipment control, [CA] will implement the QA requirements of NQA-1-2008, Requirement 12. The staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, paragraph II.L.3.

3.2.13 Handling, Storage, and Shipping

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.M, for establishing necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

In establishing provisions for handling, storage, and shipping, the QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 13. *[CA] also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: [NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

[NQA-1a-2009, Subpart 2.1

- *Subpart 2.1, Sections 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, [CA] may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. [CA] establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference under ADAMS Accession No. ML050700416.]]* The staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, and was approved previously in *ADAMS Accession No. ML050700416.*

NQA-1a-2009, Subpart 2.2

- *[Subpart 2.2, Section 202 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, [CA] may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference under ADAMS Accession No. ML050700416.]]* The

staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, and was approved previously in *ADAMS Accession No. ML050700416.*

- *Subpart 2.2, Section 606, "Storage Records." This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, [CA] documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.* The staff determined that this proposed alternative is acceptable, on the basis that these records do not meet the classification of a quality record as defined in NQA-1-2008, Requirement 17.

[NQA-1-2008, Subpart 2.3

- *Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, [CA] bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference under ADAMS Accession No. ML050700416.]* The staff finds that this alternative is consistent with the staff guidance provided in SRP Section 17.5, and was approved previously in *ADAMS Accession No. ML050700416.*

NQA-1-2008, Part III, Subpart 3.2

- *Subpart 3.2, Appendix 2.1: only Section 300, "Cleaning Recommendations and Precautions" are being committed to in accordance with RG 1.37 "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," Revision 1. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels.* The staff determined that this proposed clarification is acceptable, on the basis that these precautions are consistent with the regulatory positions of RG 1.37, Revision 1.

3.2.14 Inspection, Test, and Operating Status

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.N, for establishing necessary measures to identify the inspection, test, and operating status of items and components within the scope of the QAPD to maintain personnel and reactor safety and avert inadvertent operation of equipment.

In establishing measures for control of inspection, test, and operating status, the QAPD template commits the applicant to compliance with NQA-1-2008, Requirement 14.

3.2.15 Nonconforming Materials, Parts, or Components

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.O, for establishing necessary measures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Nonconformances are evaluated for their impact on operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation or maintenance of the item or service. Results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to upper management in accordance with applicable procedures.

In addition, the QAPD template provides for establishing the necessary interfaces between the QA program for identification and control of nonconforming material, parts, and components and the non-QA reporting program that satisfy the applicable requirements of 10 CFR 50.55(e), and/or 10 CFR Part 21 during design, construction and operations.

In establishing measures for nonconforming materials, parts, or components, the QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 15.

3.2.16 Corrective Action

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.P, for establishing necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD template requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality are documented and reported to responsible management. In the case of suppliers working on safety-related activities or similar situations, the applicant or holder, as applicable, may delegate specific responsibility for the corrective action program, but the applicant or holder maintains responsibility for the program's effectiveness.

In addition, the QAPD template provides for establishing the necessary interfaces between the QA corrective actions program and the non-QA reporting program to identify, evaluate, and report defects and noncompliances to satisfy the applicable requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21.

In establishing provisions for corrective action, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 16.

3.2.17 Quality Assurance Records

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.Q, for establishing necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

Regulatory position C.1.a of RG 1.28, Revision 4 provides record retention times for lifetime and nonpermanent records. In establishing the retention time for records, the QAPD template provides ESP and COL applicants the guidance to base the retention on regulatory position C.1.a of RG 1.28, Revision 4 or by including their specific table in the QAPD. The NRC staff will evaluate the adequacy of records retention times as site-specific information when an ESP or COL applicant submits their application.

Concerning the use of electronic records storage and retrieval systems, the QAPD template provides for compliance with NRC guidance given in GL 88-18, "Proposed Final NRC Generic Letter 88-18, Supplement 1," "Guidance on Managing Quality Assurance Records in Electronic Media," dated September 13, 1999; Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000; and associated Nuclear Information and Records Management Association (NIRMA) guidelines TG 11-1998, TG 15-1998, and TG 21-1998.

In establishing provisions for records, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 17, and regulatory positions stated in RG 1.28, Revision 4.

3.2.18 Audits

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.R, for establishing necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the established requirements. The effectiveness of the audit program is reviewed as part of the overall audit process. The QAPD provides for the applicant or holder, as applicable, to conduct periodic internal and external audits. Internal audits are conducted to determine the adequacy of the program and its procedures and to determine if they are meaningful and comply with the QAPD requirements. Internal audits are performed with a frequency commensurate with safety significance and in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of 2 years after the initial determination that the audit program has been soundly established. External audits determine the adequacy of a supplier's or contractor's QA program. Responsible management reviews audit results; these reviews are documented. Management responds to all audit findings and initiates corrective action where indicated. Where corrective actions are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify that corrective action have been adequately implemented.

In establishing the independent audit program, QAPD template commits the applicant to the quality standards described in NQA-1-2008, Requirement 18 and the regulatory positions stated in RG 1.28, Revision 4.

3.3 Nonsafety-Related SSC Quality Assurance Control

3.3.1 Nonsafety-Related SSCs—Significant Contributors to Plant Safety

The QAPD template follows the guidance of SRP Section 17.5, paragraph II.V.1, for establishing specific program controls applied to nonsafety-related SSCs that are significant

contributors to plant safety and to which Appendix B does not specifically apply. Specific applicable QAPD controls are used in a prescribed manner, targeting those characteristics or critical attributes that make the SSC a significant contributor to plant safety consistent.

3.3.2 Nonsafety-Related SSCs Credited for Regulatory Events

In establishing quality requirements for nonsafety-related SSCs credited for regulatory events, the QAPD template follows the guidance of SRP Section 17.5, paragraph II.V.2, and commits the applicant to comply with the following regulatory guidance:

- The applicant or holder shall implement quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants," issued April 2001.

- The applicant or holder shall implement quality requirements for anticipated transient without scram (ATWS) equipment in accordance with GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued January 1985.

- The applicant or holder shall implement quality requirements for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG1.155, Station Blackout," issued August 1988.

3.4 Regulatory Commitments

Commitments to NRC RGs identified in COL and ESP applications are listed in Chapter 1 of the Final Safety Analysis Report (FSAR). An applicant must make a specific statement for evaluation of conformance to the following RGs related to an applicant's QA program. These RGs are typically identified in Chapter 1 of the FSAR and their inclusion is consistent with RG 1.206, Section C.I.1.9.

- RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," issued May 2000.

- RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued March 2007.

- RG 1.28, Revision 4, "Quality Assurance Program Requirements (Design and Construction)," issued June 2010.

- RG 1.29, Revision 4, "Seismic Design Classification," issued March 2007.

- RG 1.33, Revision 2, "Quality Assurance Program Requirements (Operations)," issued February 1978. (Exception to RG 1.33 see Section 3.4.1 of SER)

- RG 1.37, Revision 1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants,” issued March 2007.

- RG 1.54, Revision 2, “Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants,” issued October 2010.

Applicants must provide an evaluation for conformance to the RGs identified in Part IV of the QAPD template, in the bracketed text, by either including a commitment to the RGs or by providing an alternative or exception to be reviewed for adequacy by the NRC staff. The NRC staff will review the adequacy of commitments to these RGs on an applicant-specific basis.

The QAPD template includes regulatory commitments to the following industry guidance related to QA:

- ASME NQA-1-2008 Edition with NQA-1a-2009 Addenda, “Quality Assurance Requirements for Nuclear Facility Applications.” The QAPD template commits to NQA-1-2008 with NQA-1a-2009 Addenda, Parts I and II, as described in Part[s] II [and V] of the QAPD template with specific identification of exceptions or clarification and commits to NQA-1-2008 with NQA-1a-2009 Addenda, and Part III only as specifically noted in Part[s] II [and V] of the QAPD template.

- NIRMA technical guides, as described in Section 3.2.17 of this SER.

3.4.1 Alternative for Commitment to RG 1.33

RG 1.33, Revision 2, describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. The requirements for administrative controls of ANSI N18.7-1976 are incorporated into the text of the NEI 11-04, Revision 0, QAPD template in Part V. The principal difference between ANSI N18.7-1976 and NQA-1-2008 with NQA-1a-2009 Addenda is that administrative controls, required during the operational phase of a nuclear power plant, were not incorporated into NQA-1-2008 with NQA-1a-2009 Addenda. Therefore, in order to satisfy Appendix B to Part 50 requirements during the operations phase, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-2008 with NQA-1a-2009 Addenda by explicitly addressing the provisions in NEI 11-04, Revision 0, Appendix 1, while also completing Part V of the QAPD template or, otherwise, by including an explicit commitment to RG 1.33 in Part IV of the QAPD. A commitment to RG 1.33 indicates the applicant will comply with the provisions of ANSI N18.7-1976, as supplemented or modified by the regulatory positions in RG 1.33. The NRC staff will review the adequacy of alternatives for commitment to RG 1.33 on an applicant-specific basis.

4.0 Conclusion

Based on its review of NEI 11-04, Revision 0, in accordance with the guidance of SRP Section 17.5, the NRC staff concludes that the QAPD template provides an acceptable format

and adequate guidance for establishing a QA program that complies with Appendix B to 10 CFR Part 50. The QAPD template is based on ASME NQA standard NQA-1-2008 with NQA-1a-2009 Addenda, as supplemented by additional regulatory guidance and industry guidance applicable to administrative and quality controls during nuclear power plant operation. Accordingly, the staff concludes that the QAPD template can be used, by applicants for 10 CFR Part 52 permits or licenses, as applicable, for establishing a QA program description required by the provisions of 10 CFR 52.17(a)(1)(xi) for an ESP application and 10 CFR 52.79(a)(25) for a COL application.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 11-04 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in SRP Section 17.5. Key areas that an applicant is required to address include:

- The organizational description addressed in Part II, Section 1 of NEI 11-04.
- Record retention criteria addressed in Part II, Section 17.1 of NEI 11-04.
- Regulatory commitments addressed in Part IV of NEI 11-04.

To ensure all quality assurance requirements for the operating phase are addressed, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-2008 with NQA-1a-2009 Addenda by explicitly addressing the provisions in NEI 11-04, Revision 0, Appendix 1, or otherwise by including a commitment to RG 1.33 in Part IV of the QAPD.

5.0 REFERENCES

1. Heymer, A. P., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report on Template for an Industry Quality Program Description," October 19, 2006. (ADAMS Accession No. ML062990149.)

2. U.S. NRC, Office of New Reactors, Final Safety Evaluation for Technical Report NEI 06-14, "Quality Assurance Program Description," April 25, 2007. (ADAMS Accession No. ML070510300.)

3. U.S. NRC, Office of New Reactors, Final Safety Evaluation for Technical Report NEI 06-14, "Quality Assurance Program Description," Revision9, July 13, 2010. (ADAMS Accession No. ML101800497.)

4. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report 11-04, *Quality Assurance Program Description*, Draft Revision 0," May 27, 2011. (ADAMS Accession No. ML111940285.)

5. U.S. NRC, Office of New Reactors, to the NEI, "Request for Additional Information

Regarding Nuclear Energy Institute Technical Report 11-04, Quality Assurance Program Description, Draft Revision 0," dated February 8, 2012, (ADAMS Accession No. ML12026A803.)

6. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report 11-04, *Quality Assurance Program Description*, Revision 0," September 13, 2012. (ADAMS Accession No. ML 12258A358.)

7. NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," March 2007. (ADAMS Accession No. ML06310019.)

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APPENDIX 3 – NEI Responses to NRC RAIs

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Response to Request for Additional Information Regarding Review of NEI 11-04, "Nuclear Generation Quality Assurance Program Description," Draft Revision 0

The following responses are provided with respect to the request for additional information concerning Nuclear Energy Institute 11-04, "Nuclear Generation Quality Assurance Program Description," Draft Revision 0 communicated by the NRC by letter on February 8, 2012.

RAI-1

The Nuclear Energy Institute (NEI) 11-04 Quality Assurance Program Description (QAPD) template commits to compliance with NQA-1-2008, Requirement 2 with the following clarification:

> As an alternative to Section 303.3 that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years the following may be used for qualification of experienced individuals: "A Prospective Lead Auditor that has related industry experience and previously demonstrated ability to properly implement the audit process shall participate in one nuclear quality assurance audit within the year prior to qualification." [NOTE: This alternative is not allowed for Lead Auditors conducting audits of activities involving Section III, Article NCA-4000 of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code; including supplier qualification audits.]

However, NQA-1-2008, Requirement 2, Section 303.3 provides for participation in independent assessments as another means of satisfying the requisite number of quality assurance audits, and supplies the acceptance criteria for use of these activities toward lead auditor qualification.

As such, the U.S. Nuclear Regulatory Commission (NRC) staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NEI 11-04 given that NQA-1-2008, Requirement 2, Section 303.3, already contains an alternative means for qualifying prospective lead auditors beyond participation in a minimum of five audits in the previous three years. Please provide a justification for this clarification and for the bracketed text.

RAI-1 Response

NEI 11-04 Section 2.7 will be revised to remove the Lead Auditor qualification alternative defined in Section 303.3 which will result in full implementation of the quality standards as described in NQA-1-2008, Requirement 2, Sections 100 through 500, without any exceptions.

RAI-2

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 2 with the following exception:

> Section 400 (a) (8) requires the date of certification expiration be included on the qualification record. [CA] considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

The NRC staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NEI 11-04, please provide a justification for this exception.

RAI-2 Response
The inclusion of this exception in NEI 11-04 is a clarification for changes to the NQA-1 Standard as a result of the consolidation of Requirement 2 that introduced data that was slightly different from the individual personnel documentation requirements. The date of certification establishes the expiration date, when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization's procedures. Therefore, to have both dates on the form is redundant.

Additionally, in NQA-1-2008, Part III, Nonmandatory Appendix 2A-3, Figure 2A-3.1 Sample Form for Record of Lead Auditor Qualification, the form does not contain a blank for the inclusion of certification expiration date. Therefore, if this form were used "as is" it would not be in strict compliance with NQA-1-2008, Requirement 2, Section 400(a)(8). This information has been sent to the NQA Committee by NEI and the NQA Committee is addressing the issue in a future revision of the Standard.

RAI-3
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.7 for computer software[, and Subpart 2.20 for subsurface investigation requirements]. [NOTE: Subpart 2.20 does not apply to an Operation –only QAP].

The dedication of commercial grade items or services for use as safety-related applications is a design control activity. Subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services” provides the requirements for commercial-grade items and services and should be committed to in Section 3 of the NEI 11-04 QAPD template.

Based on the above, please add Subpart 2.14 to Section 3.5, NQA-1 Commitment.

RAI-3 Response
NEI 11-04 Section 3.5 will be revised to reference to NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.14 for Quality Assurance requirements for commercial grade items and services.

RAI-4
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 4, with the following clarifications and exceptions:

> Section 203 requires the purchaser to specify the quality assurance requirements in the procurement documents. To meet this requirement, [CA] may require suppliers to have a documented QAP that meets the applicable requirements of Title 10 of the Code of Federal Regulations Part 50, Appendix B, as appropriate to the circumstances of the procurement.

Technical and quality requirements are provided in Sections 202 and 203 of NQA-1-2008, Requirement 4, respectively. As such, it is not clear to the staff why an exception or clarification to NQA-1-2008, Requirement 4, Section 203, is necessary given that provisions regarding the information are contained in NQA-1-2008 and NQA-1a-2009 Addenda, please provide a justification for this clarification.

RAI-4 Response
NEI 11-04 Section 4.1 will be revised to remove the Section 203 exception noted.

RAI-5
Section 6, "Document Control," of NEI 11-04, states the following:

> [CA] has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

The above section in the previous revision, NEI 06-14A REV 7, states the following:

> [CA] has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

Please provide clarification of the correct paragraph to be used for this section.

RAI-5 Response
The noted difference is the result of efforts to improve wording in this revised section to be clearer and grammatically correct. There is no change of intent.

RAI-6
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008 and NQA-1a-2009, Requirement 7, with the following clarifications and exceptions:

> A documented review of the supplier's accreditation will be performed and will include a verification of the following:
>
> > The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):
> >
> > (1) National Voluntary Laboratory Accreditation Program (NVLAP)
> > (2) American Association for Laboratory Accreditation (A2LA)
> > (3) ACLASS Accreditation Services (ACLASS)
> > (4) International Accreditation Service (IAS)
> > (5) Laboratory Accreditation Bureau (L-A-B)

The NRC has approved other laboratory accrediting bodies not listed above. Please provide clarification if it is the intent to only account for the five above or to also include "other NRC-approved Laboratory accrediting bodies."

RAI-6 Response
NEI 11-04 Section 7.2 exception will be revised to state the following:

- A documented review of the supplier's accreditation will be performed and will include a verification of the following:

  The calibration laboratory holds a domestic (United States) accreditation by an NRC-approved domestic (United States) accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

RAI-7
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 10 and Subparts 2.4, 2.5 and 2.8 for establishing appropriate inspection requirements with the following clarifications;

> Subpart 2.4 commits [CA] to Institute of Electrical and Electronics Engineers (IEEE) 336-1985, which refers to IEEE 498-1985. Both IEEE 336-1985 and IEEE 498-1985 use the definition of "Safety Systems" from IEEE 603-1980. [CA] commits to the definition of Safety Systems in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.
>
> An additional exception to Subpart 2.4 is addressed in Part II, Section 12 of the QAPD.

The previous version of NEI 11-04, NEI 06-14A Rev 7, in addition to the above also contains the following clarification:

> *[NOTE: This in an optional alternative for those sites where the reporting independence of NQA-1-1994, Supplement 10S-1, Section 3.1 may not be met. Refer to accession number ML052490337.] Where inspections at the operating facility are performed by persons within the same organization (e.g., Maintenance group), [CA] takes exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1, the inspectors report to the [quality control management] while performing those inspections.]*

Although NQA-1-2008 no longer contains a specific section for reporting independence it still provides the following in Section 100, which states, "Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected." This was the original basis for the acceptance of the alternative as refer to in accession number ML052490337.

The NRC staff was unable to ascertain why this clarification to NQA-1-2008 is not included for NEI 11-04 as in its previous version, please provide a justification for this clarification.

RAI-7 Response
The reason for the Alternative Position has been removed in NQA-1-2008. As a result, there is no reason to take an exception to a position that is no longer applicable. The wording in Section 100 of NQA-1-2008 applies in all cases.

RAI-8
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 12, with the following clarification and exception:

> The out of calibration conditions described in Section 303.2 refers to when the M&TE is found out of the required accuracy limits (i.e., out of tolerance) during calibration and not overdue for calibration.

Previous excepted alternatives for this requirement have not included "not overdue for calibration." The NRC staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NEI 11-04, please provide a justification for this exception.

RAI-8 Response
NEI 11-04 Section 12.2 will be revised to remove the exception noted. The clarification is no longer needed due to the distinction has been appropriately addressed in NQA-1-2008 between expired due dates and out of tolerance conditions for measuring and test equipment.

RAI-9
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 12, with the following clarification and exception:

> Measuring and test equipment are not required to be marked with the calibration status, as described in section 303.6, where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-2008, Subpart 2.4 (See Section 7.2.1 of ANSI/IEEE Std. 336-1985).

The NRC staff notes that NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 12, Section 303.6, as written, already provides for measuring and test equipment to be "otherwise identified" to indicate calibration status and establish traceability to calibration records. As such, it is not clear to the staff why an alternative to NQA-1-2008, Requirement 12, Section 303.6 is necessary. Please provide a justification for this clarification.

RAI-9 Response
NEI 11-04 Section 12.2 will be revised to identify the following exception:

- NQA-1-2008, Subpart 2.4 refers to ANSI/IEEE Std. 336-1985 for the installation, inspection, and testing requirements for power, instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std. 336-1985 makes reference to the use of IEEE Std. 498-1985 for measuring and test equipment control, *[CA]* will implement the QA requirements of NQA-1-2008, Requirement 12.

RAI-10
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 13. The NEI 11-04 QAPD template also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and

Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: *[NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

> [As an alternative to Subpart 2.2, Section 405, Shipments from Countries outside the United States, [CA] may elect to establish special requirements that address the appropriate quality requirements and applicable United States Customs and Border Protection/Department of Homeland Security requirements.]

The NRC staff was unable to ascertain why this clarification to NQA-1-2009a is included, please provide a justification for this clarification.

RAI-10 Response

NEI 11-04 Section 13.2 will be revised to delete the reference to NQA-1a-2009, Subpart 2.2, Subpart 2.2, Section 405, "Shipments from Countries Outside the United States" until further resolution is provided by the NQA Committee.

NEI understands that the recent changes in US shipping law may prevent full compliance with NQA-1 a-2009 Addenda, Subpart 2.2, Section 405, "Shipments from Countries outside the United States," as written. The NRC has brought this topic to the attention of the NQA Committee and a resolution is currently under development by the Committee that may delete or modify Subpart 2.2, Section 405.

RAI-11

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 13. The NEI 11-04 QAPD template also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: *[NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

> Subpart 2.2, Section 701 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging, and transporting of items for the nuclear power plant[s] during construction.

Nowhere is subpart 2.15 does it state that the requirements for hoisting, rigging, and transporting of items for the nuclear power plants only apply during construction. The NRC staff was unable to ascertain why this clarification to NQA-1-2009a is included, please provide a justification for this clarification.

RAI-11 Response

NEI 11-04 Section 13.2 will be revised to remove the reference to Subpart 2.15 as this clarification point is no longer needed.

RAI-12
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 17, and regulatory positions stated in Regulatory Guide (RG) 1.28, Rev 4, June 2010, with the following clarifications and exceptions:

> In establishing the provisions for a list of records, [CA] commits to comply with Regulatory Guide 1.28, Revision 4, position C.1.a.(3) with the following clarifications; *[Note: [CA] should use either Option 1 or Option 2 below]*
>
> > *[[Note: Option 1][CA] commits to develop a list of typical QA records and their retention periods using the guidance of NQA-1-2008, Part III, Nonmandatory Appendix 17A-1, Section 200, for the lifetime records recognizing that the record name may vary and the list may not be all-inclusive. For records not listed, the record that most nearly describes the record in question will be followed regarding retention. [CA] commits to maintain sufficient records to furnish evidence of activities affecting quality.]*
> >
> > *[[Note: Option 2][CA] commits to develop a list of QA records and their retention periods and to maintain sufficient records to furnish evidence of activities affecting quality.]*

The NRC staff was unable to ascertain why this clarification to RG 1.28, Rev 4, June 2010 is included, please provide a justification for this clarification.

RAI-12 Response
NEI 11-04 Section 17.3 will be revised to remove the clarification as it is not needed.

RAI 13
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 18, and regulatory positions stated in RG 1.28, Rev 4, with the following clarifications and exceptions:

> *[CA]* annual evaluation of the supplier in NRC position C. 2. b. (4). (a), (b), and (c) shall only be required to consider activities related to *[CA]* procurement activities.

The NRC staff was unable to ascertain why this clarification to RG 1.28, Revision 4, is necessary given that the relationships with suppliers, and the related evaluation requirements, are already based on procurement activities and the associated documentation. Please provide a justification for the clarification.

Furthermore, compliance with NQA-1-2008, Requirement 18 is based on internal audits. External audits/supplier evaluations are described in Section 7 of the NEI 11-04 QAPD template. Please explain why the above clarification, if retained, is listed in Section 18.3 versus Section 7.2.

In addition, please provide a justification for the exclusion of NRC position C. 2. b. (4)(d) from the above clarification.

RAI-13 Response
NEI 11-04 Section 17.3 will be revised to remove the clarification as it is not needed.

RAI-14

Section 18.1 of NEI 11-04 QAPD template provides reference to external and internal audits. External audits or audits of suppliers are described and documented in Section 7 of NEI 11-04, and Requirement 7 of NQA-1-2008. Please provide clarification as to why external audits are mentioned in Section 18.1.

RAI-14 Response

NEI 11-04 Section 18.1 will be revised to remove references to External or Supplier Audits.