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Nuclear

10 CFR 50.54(a)

RS-02-071

April 9, 2002

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Braidwood Station, Units 1 and 2
Facility Operating License Nos. NPF-72 and NPF-77
NRC Docket Nos. STN 50-456 and STN 50-457

Byron Station, Units 1 and 2
Facility Operating License Nos. NPF-37 and NPF-66
NRC Docket Nos. STN 50-454 and STN 50-455

Clinton Power Station, Unit 1
Facility Operating License No. NPF-62
NRC Docket No. 50-461

Dresden Nuclear Power Station, Units 1, 2 and 3
Facility Operating License Nos. DPR-2, DPR-19 and DPR-25
NRC Docket Nos. 50-10, 50-237, 50-249 and 72-37

LaSalle County Station, Units 1 and 2
Facility Operating License Nos. NPF-11 and NPF-18
NRC Docket Nos. 50-373 and 50-374

Limerick Generating Station, Units 1 and 2
Facility Operating License Nos. NPF-39 and NPF-85
NRC Docket Nos. 50-352 and 50-353

Oyster Creek Generating Station
Facility Operating License No. DPR-16
NRC Docket Nos. 50-219 and 72-15

Peach Bottom Atomic Power Station, Units 1, 2 and 3
Facility Operating License Nos. DPR-12, DPR-44 and DPR-56
NRC Docket Nos. 50-171, 50-277, 50-278 and 72-29

Three Mile Island Nuclear Station, Unit 1
Facility Operating License No. DPR-50
NRC Docket No. 50-289

Quad Cities Nuclear Power Station, Units 1 and 2
Facility Operating License Nos. DPR-29 and DPR-30
NRC Docket Nos. 50-254 and 50-265

A001

Zion Nuclear Power Station, Units 1 and 2
Facility Operating License Nos. DPR-39 and DPR-48
NRC Docket Nos. 50-295 and 50-304

Subject: Request for Approval of Quality Assurance Program Changes for Exelon Generation Company, LLC, and AmerGen Energy Company, LLC, Nuclear Power Plants.

Exelon Generation Company, LLC (Exelon), and AmerGen Energy Company, LLC (AmerGen), are submitting a common Quality Assurance Topical Report (QATR) for your review and approval in accordance with the provisions contained in 10 CFR 50.54(a)(3). This common Exelon/AmerGen QATR is an update to the current NRC approved Quality Assurance Program (QAP) described in Exelon Generation Company, LLC, QATR EGC-1A, Revision 69, which endorses ASME NQA-1-1989 as the quality standard and is applicable to the following Exelon stations: Braidwood Station, Byron Station, Dresden Nuclear Power Station, LaSalle County Station and Quad Cities Nuclear Power Station.

Exelon's Limerick Generating Station and Peach Bottom Atomic Power Station, and AmerGen's Clinton Power Station, Oyster Creek Generating Station, and Three Mile Island Nuclear Station are adopting QATR EGC-1A, Revision 70, in lieu of their currently docketed site-specific Quality Assurance Programs. In particular, Exelon/AmerGen QATR EGC-1A will replace: the Clinton Power Station QAP as described in the Clinton Power Station Quality Assurance Manual; the Limerick Generating Station QAP as described in Updated Final Safety Analysis Report (UFSAR), Section 17.2; the Oyster Creek QAP as described in Operational Quality Assurance Plan (OQAP) 2000-PLN-7200.01; the Peach Bottom Atomic Power Station QAP as described in UFSAR, Appendix D.11; and Three Mile Island, Unit 1, QAP as described in OQAP 1000-PLN-7200.01. This change adds 7 nuclear generating units to QATR EGC-1A for a total of 17 operating nuclear units under one Quality Assurance Program which encompasses the entire Exelon/AmerGen nuclear fleet. Attachment 1 to this letter provides the common Exelon/AmerGen QATR EGC-1A, Revision 70. This approach was previously discussed with the Nuclear Regulatory Commission (NRC) staff.

Once implementation of the Exelon/AmerGen QATR is complete, Limerick Generating Station UFSAR, Section 17.2, and Peach Atomic Power Station UFSAR, Appendix D.11, will refer to Exelon/AmerGen QATR EGC-1A as containing the Quality Assurance Program for the respective station. The Clinton Power Station Quality Assurance Manual, Oyster Creek Generating Station OQAP and Three Mile Island, Unit 1, OQAP are incorporated by reference in each respective site's UFSAR. Once implementation of the Exelon/AmerGen QATR is complete, these references will be revised to appropriately reference Exelon/AmerGen QATR EGC-1A.

As part of the Exelon/AmerGen QATR implementation process, reviews were performed that compared the positions and requirements contained in the common Exelon/ AmerGen QATR to each facility's docketed Quality Assurance Program. The reviews were performed using guidance contained in NUREG-0800, "Standard Review Plan," Section 17.1, "Quality Assurance During Design and Construction Phases," and Section 17.2, "Quality Assurance During the Operations Phase," and, as permitted under the requirements of 10 CFR 50.54(a)(3)(ii), using quality assurance alternatives or exceptions approved by NRC Safety Evaluations for changes to other facility Quality Assurance Programs. The specific NRC Safety Evaluation Reports used during the reviews are identified below.

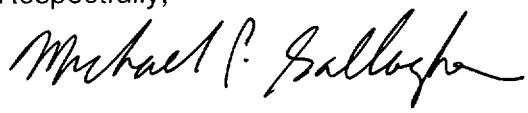
- Safety Evaluation, Nuclear Quality Assurance Plan TVA-NQA-PLN89-A, Elimination of Independent Safety Engineering Group, Tennessee Valley Authority – Browns Ferry, Watts Bar, and Sequoyah Nuclear Plants, dated August 26, 1999.
- Safety Evaluation, Revision 1 to the FirstEnergy Nuclear Operating Company Quality Assurance Program Manual - Beaver Valley Power Station, Unit Nos. 1 and 2, Davis-Besse Nuclear Power Station, Unit 1, Perry Nuclear Power Plant, Unit 1, dated December 19, 2001.
- Safety Evaluation, Proposed Revisions to the Quality Assurance Program Descriptions, Power Authority of the State of New York, Indian Point Nuclear Generating, Unit No. 3, and James A. Fitzpatrick Nuclear Power Plant, dated March 25, 1999.
- Safety Evaluation, Quality Assurance Program in Operations Policy Document, Revision 13, Nebraska Public Power District, Cooper Nuclear Station, dated July 20, 1998.
- Safety Evaluation, Operational Quality Assurance Program (OQAP) Change, Wolf Creek Nuclear Operating Corporation, Wolf Creek Generating Station, dated March 30, 1998.
- Safety Evaluation, Operational Quality Assurance Program Description, Revision 26, Washington Public Power Supply System, Nuclear Project No. 2, dated December 30, 1998.
- Safety Evaluation, Operational Quality Assurance Program Description, Revision 29, Washington Public Power Supply System, Nuclear Project No. 2, dated December 21, 1998.
- Safety Evaluation, Quality Assurance Program Description Changes, Toledo Edison Company, Centerior Service Company, and the Cleveland Electric Illuminating Company, Davis-Besse Nuclear Power Station, Unit No. 1, dated July 15, 1998.
- Safety Evaluation, Proposed Revision 26 To The Rochester Gas And Electric Corporation Quality Assurance Program For Station Operation, R. E. Ginna Nuclear Power Plant, dated April 6, 1999.
- Safety Evaluation, Quality Assurance Topical Report CE-1A Changes, Revision 67a, Commonwealth Edison Company, dated March 13, 2001.

As a result of these reviews, several site-specific clarifications and exceptions that are unique to each site are being added to the existing program. These clarifications and exceptions are noted in applicable appendices of the common Exelon/AmerGen QATR. These exceptions and clarifications will be maintained as site unique as we continue to make our programs common, and will be deleted as commonality is achieved. Also, several changes were identified as reductions in commitment that require prior NRC review and approval pursuant to 10CFR 50.54(a)(4). These reductions in commitment are specific to Oyster Creek Generating Station, Peach Bottom Atomic Power Station, and Three Mile Island, Unit 1. The details and bases for the site-specific reductions in commitment requiring review are contained in Attachments 2 through 4 of this letter.

We are also requesting NRC review and approval for the use of ASME NQA-1-1994 as the basis for the common Exelon/AmerGen Quality Assurance Program versus the NRC endorsed ANSI/ASME NQA-1-1983. Attachment 5 to this letter provides a comparison of standards of ANSI/ASME NQA-1-1983 to ASME NQA-1-1994. Additionally, the NRC previously approved the use of ASME NQA-1-1994 as the quality standard for a nuclear fuels vendor, although not a nuclear facility licensee, to effectively implement the requirements of 10 CFR 50, Appendix B.

If you have any questions or require additional information, please contact Dennis Winchester, Nuclear Oversight at 610-765-5845 or Glenn Stewart, Licensing at 610-765-5529.

Respectfully,



M. P. Gallagher
Director – Licensing
Mid-Atlantic Regional Operating Group

Attachments:
Attachment 1: Quality Assurance Topical Report EGC-1A, Revision 70
Attachment 2: Reductions in Commitment – Oyster Creek Generating Station
Attachment 3: Reduction in Commitment – Peach Bottom Atomic Power Station
Attachment 4: Reductions in Commitment – Three Mile Island Nuclear Station, Unit 1
Attachment 5: Comparison between NQA-1-1983-1a and NQA-1-1994

cc: Regional Administrator – NRC Region I w/attachments
Regional Administrator – NRC Region III "
NRC Senior Resident Inspector – Braidwood Station "
NRC Senior Resident Inspector – Byron Station "
NRC Senior Resident Inspector – Clinton Power Station "
NRC Senior Resident Inspector – Dresden Nuclear Power Station "
NRC Senior Resident Inspector – LaSalle County Station "
NRC Senior Resident Inspector – Limerick Generating Station "
NRC Senior Resident Inspector – Oyster Creek Generating Station "
NRC Senior Resident Inspector – Peach Bottom Atomic Power Station "
NRC Senior Resident Inspector – Three Mile Island Nuclear Station "
NRC Senior Resident Inspector – Quad Cities Nuclear Power Station "
Director, Bureau of Nuclear Engineering, New Jersey Department of Environmental Protection "
Director, Bureau of Radiation Protection – Pennsylvania Department of Environmental Resources "

Attachment 1

Exelon Generation Company, LLC
AmerGen Energy Company, LLC

Quality Assurance Topical Report EGC-1A, Rev. 70

Exelon Generation Company, LLC
AmerGen Energy Company, LLC

QUALITY ASSURANCE TOPICAL REPORT EGC-1A

Revision 70

Exelon Nuclear

Corporate Headquarters

4300 Winfield Road
Warrenville, IL 60555

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1. POLICY STATEMENT

The Quality Assurance Topical Report (QATR) EGC-1A is the highest tiered document that assigns major functional responsibilities for either plants owned or operated by Exelon Generation Company, LLC and AmerGen Energy Company, LLC (AmerGen) collectively. Implementing documents assign more specific responsibilities and tasks and define the organizational interfaces involved in conducting activities and tasks within the scope of this Plan. These requirements apply to those organizations and positions, which manage and perform activities within its scope.

The Company organization is structured on the basis that the attainment of the objectives of this Plan relies on those who manage, perform, and support the performance of activities within the scope of this plan. Assurance of this attainment relies on those who have no direct responsibility for managing or performing the activity.

The Company will maintain and operate its nuclear plants in a manner that will ensure the health and safety of the public and our workers. All facilities shall be at a minimum compliance with the requirements on the Code of Federal Regulations, NRC Operating Licenses, and the applicable laws and regulations of the state and local governments.

2. APPLICABILITY

All Company personnel who work directly, or indirectly, for the Company are responsible for the achievement of quality in their work. Accordingly, all Company personnel and its contractors engaged in supporting nuclear generation activities shall comply with the requirements of our Quality Assurance Program (QAP).

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CHAPTER 1, ORGANIZATION

CHAPTER 2, QUALITY ASSURANCE PROGRAM

CHAPTER 3, DESIGN CONTROL

CHAPTER 4, PROCUREMENT DOCUMENT CONTROL

CHAPTER 5, INSTRUCTIONS, PROCEDURES, AND DRAWINGS

CHAPTER 6, DOCUMENT CONTROL

CHAPTER 7, CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

CHAPTER 9, CONTROL OF SPECIAL PROCESSES

CHAPTER 10, INSPECTION

CHAPTER 11, TEST CONTROL

CHAPTER 12, CONTROL OF MEASURING AND TEST EQUIPMENT

CHAPTER 16, CORRECTIVE ACTION

CHAPTER 17, QUALITY ASSURANCE RECORDS

CHAPTER 18, ASSESSMENTS

APPENDIX A, AUGMENTED QUALITY

APPENDIX B, ASSESSMENT FREQUENCY

APPENDIX C, CODES, STANDARDS, AND GUIDES

APPENDIX D, DEFINITIONS

APPENDIX E, CONTROL OF RADIOACTIVE WASTE OR MATERIALS (SITE SPECIFIC)

APPENDIX F, GRADED APPROACH (SITE SPECIFIC)

APPENDIX G, SUPPLEMENTAL APPLICATIONS (SITE SPECIFIC)

1. SCOPE

This chapter identifies those portions of the Company organization as it applies to the Quality Assurance Program (QAP), and defines the responsibility and authority for establishing, executing, and verifying its implementation. The responsibility for the program is retained and executed by the Company exclusively.

Organizational responsibilities are described for assuring that activities affecting quality are prescribed and implemented by documented instructions, procedures, and drawings. The achievement of quality in the performance of quality related activities are the responsibility of each individual in support of nuclear operations.

The requirements and commitments contained in the QAP are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations.

2. REQUIREMENTS

Note: Minor variations may occur between the titles contained herein and those used in practice. Equivalent AmerGen positions are described with brackets. Specific position descriptions may be contained in approved Company documents.

2.1. Organization

The organizational structure of the Company consists of corporate functions, which include Regional Operating Groups (ROGs) and the nuclear facilities. Organizational titles for the quality assurance functions described are identified in Company policies and procedures.

Lines of authority and responsibility are established from the highest management level through intermediate levels to the implementing personnel. The responsibility, authority, and relationships of the various personnel and organizations are documented and maintained current.

The authority to accomplish the quality assurance functions described herein may be delegated to the incumbent's staff as necessary to fulfill the identified responsibilities.

2.2. Corporate Organization

2.2.1. Chairman, President, and Chief Executive Officer

The Chairman, President, and Chief Executive Officer (CEO), Exelon Generation, is responsible for overall corporate policy and provides executive direction and guidance for the corporation as well as promulgates corporate policy through the Company 's senior management staff. Overall responsibility for the implementation of the QAP is delegated to the President and Chief Nuclear Officer, Exelon Nuclear.

2.2.2. President and Chief Nuclear Officer [Chairman, Chief Executive Officer, Chief Nuclear Officer - AmerGen]

The President and Chief Nuclear Officer (CNO) reports to the CEO of Exelon Generation and has overall responsibility for the safe and reliable operation of the Company's nuclear stations including management oversight and support of the day-to-day operations of the stations and the ROGs. This is the senior executive responsible for setting and implementing policies, objectives, expectations, and priorities to ensure activities are performed in accordance with QAP and other requirements. The following management positions and committees report to the CNO:

1. The management position responsible for nuclear services provides oversight and support and is accountable for defining standard programs, processes, policies, procedures, delivering effective services and support, providing technical oversight of program implementation, and supporting the deployment and sharing of best practices throughout the nuclear organization in accordance with the QAP, regulatory requirements, and the ASME Code. Reporting to this position is a staff of supervisory, administrative, and technical personnel. Functional areas of responsibility includes:
   - engineering that provides support to the nuclear stations, design authority under the ASME Code, configuration management programs, special processes, generic programs for technical and regulatory issues, and appoints the NDE Lead Level III. A support staff provides the necessary discipline and expert support for setting technical policy, developing design standards, and performing engineering discipline reviews. This staff develops and supports common approaches for technical and regulatory engineering issues, as well as develops and coaches engineers.
   - laboratory services for implementing metrology related programs including calibration and maintenance of measuring and test equipment, technical services, and marketing.
   - nuclear fuels management providing BWR/PWR nuclear fuel procurement and fabrication services, technical support to monitor fuel reliability and certain in-core components, design and licensing analyses for core reloads, safety analyses, and high level waste strategy.

This position is responsible for reactivity management oversight and corporate support of reactor operations to ensure safe and reliable plant operations, as the manager of nuclear materials, and for controls and reports associated with special nuclear material accountability.

- outage planning and services.
- project and asset management.
- records management.
- ROG level nuclear services.
- security (authorization, in-processing programs, technical support, and planning).
- training (regulation and accreditation, programs and processes, programs and assessment, and technology).
- decommissioning activities for Dresden 1 that include the safe storage and handling of irradiated spent nuclear fuel, operations, maintenance, and decommissioning activities.

2. The management position responsible for Nuclear Oversight (NOS) activities is independent of production and assures that an appropriate QAP is established, maintained, and effectively executed throughout the nuclear organization. This position provides overall direction for the implementation of the QAP and for the effective implementation of quality assurance functions that verify activities affecting safety-related functions. The management position responsible for NOS must meet the educational and experience requirements of ANSI/ANS 3.1. A staff of supervisory, administrative, and technical personnel supports assessment and quality verification. Functional responsibilities include:

- employee concern program activities.
- establishing quality assurance practices and policies.
- independent assessment and quality verification activities.
- initiating stop work, ordering unit shutdown, or request any other actions deemed necessary to avoid unsafe plant conditions or a significant violation of the QAP.
- initiating, trending, and recommending solutions for deficiencies identified by NOS.
- maintaining a trained and qualified staff of personnel within the NOS organization.
- maintenance and approval of revisions to the Quality Assurance Topical Report (QATR) and the program for employee concerns.
- overseeing ROG and nuclear site NOS activities.
- participation in joint membership groups.
- periodic assessments to determine that the Quality Assurance Policy is being carried out.
- periodic review of the independent assessment program.

- periodically apprising the President and CNO and the Nuclear Safety Review Board of the status of the quality assurance aspects at Company facilities and immediately apprise them of significant problems affecting quality.
- periodically conducting an independent effectiveness review of NSRB activities (not to exceed 2 years).
- settling disputes between NOS and other organizations.
- the certifying authority for NOS assessment personnel.
- the internal assessment program.
- the management assessment program.
- verifying implementation of solutions for significant conditions adverse to quality identified by NOS.

A. Reporting to the management position responsible for NOS is a management position in each ROG responsible to head and oversee NOS activities at the plants. The ROG position is also responsible to prioritize and communicate regional quality issues to appropriate senior management and for the resolution of these issues. A position responsible for implementation of site level NOS activities reports through the ROG NOS.

B. Also reporting to the management position responsible for NOS is a management position responsible for establishing, maintaining, and interpreting Company quality assurance policies and procedures; providing training on quality assurance subjects; establishing the requirements for assessment/auditor and inspector certification; and controlling and maintaining the QATR. This position also provides an offsite point of contact for station Quality Verification personnel if assistance is necessary for quality verification activities and manages implementation of the program for employee concerns.

3. The management position responsible for business operations provides integrated support to senior management and the nuclear sites for all business functions. Reporting to this position is a staff of supervisory, administrative, and technical personnel. Functional areas of responsibility includes:
   - business planning and process improvement.
   - management and supervision of information systems related services and activities. This includes the software quality assurance program and creating, obtaining, and enhancing computer hardware, communication, and software systems to support operational requirements.
   - procurement engineering that provides overall coordination and guidance of the nuclear organization's procurement engineering process and technical operations. This includes parts evaluations, upgrading of stock material, equivalent item evaluation, and

examination and testing in accordance with the applicable ASME Code and Federal Regulations.

- a supply organization that is responsible for establishment of priorities and providing operational control of the purchase of non-fuel goods and services required for nuclear operations. This organization is also responsible for the areas of material procurement, procurement engineering, services procurement, supply programs, inventory management, investment recovery, and a supplier audit program. Supply establishes policies, common administrative controls and processes to ensure compliance with applicable requirements and effective use of resources.
  - supplier evaluation that provides for the conduct of supplier assessments, audits, or surveys (including their sub-tier suppliers) as required by the QAP. The management position responsible, or his designee, verifies that the supplier's quality assurance program complies with Company requirements and has the authority and responsibility for QA activities applicable to supplier evaluation including, stop work as deemed necessary when a violation of the QAP is identified. Stop work authority is delegated by the management position responsible for Nuclear Oversight to this position holder. This group is independent of procurement activities.

4. The Nuclear Safety Review Board (NSRB) is an offsite committee that reports to and advises the President and CNO of the results of their independent oversight of plant operations related to safe operation of the station and the Company's nuclear program relative to nuclear safety. The NSRB is responsible for the independent safety review function and functions in accordance with written procedures and instructions which delineates committee composition, responsibility, authority, member qualifications, meeting frequency, subjects to be reviewed, reporting requirements, and administrative controls under which the board operates. The NSRB:
   - conducts independent reviews of station performance and operations to determine if the facility is being operated and maintained in a manner that promotes safety and provides feedback to the organization on suggested improvements.
   - focuses primarily in the areas of Operations, Maintenance, Engineering, Plant Support, Regulatory and Nuclear Oversight, or other matters relating to safety.
   - reviews station materials and activities and advises the CNO and management responsible for NOS on the following activities:
     - any issue potentially affecting the safe operation of the facility.

- station nuclear safety performance determined by discussion and interviews with station, ROG, and Exelon Nuclear individuals, plant tours, oversight of meetings, and review of documents distributed for NSRB review.
- effectiveness of the station program for oversight including audits, assessments, and self-assessments.
- corrective actions for degraded or non-conforming conditions involving violations of the NRC license requirements, plant transients or forced shutdowns, or the submission of a Licensee Event Report (LER).
- oversight of activities of the on-site safety review function.

5. A management position heads each ROG and is responsible for providing overall direction and management oversight for plant operations and Zion Station decommissioning activities. This position establishes and implements policies, goals, and objectives, in accordance with the QAP and other requirements, to assure the safe and reliable operation of the nuclear stations within the ROGs. Leadership and direction is provided to implement industry best practices.
   - management positions for operations support are accountable for defining standard programs and processes, delivering effective services and support, providing technical oversight of program implementation, and supporting the deployment and sharing of best practices throughout the nuclear organization in accordance with the QAP and other requirements, as applicable. Reporting to this position is a staff of supervisory, administrative, and technical personnel. Functional areas of responsibilities include:
     - ROG level operations support (chemistry, environmental, industrial safety, maintenance and work control, operations, operations centers, radiation protection, and radioactive waste).

6. A management position responsible for licensing and regulatory affairs provides organizational support and management oversight of the stations to ensure prompt and proper disposition of regulatory issues, develops regulatory positions and advises senior management on priorities and activities affecting regulatory issues at the nuclear sites. Other responsibilities include developing policies and standardized processes and procedures for the maintenance of the licensing basis, the preparation of submittals to the NRC and other regulatory organizations, the dissemination of regulatory and operational experience information, NSRB, and the administration of the Corrective Action Program.
   - a management position for emergency planning heads each ROG and is responsible for providing overall direction and management oversight.

7. A management position responsible for the oversight of operations promotes the understanding and practice of fundamentals. Other responsibilities include acting as peer group lead for operations as well as participating as a peer group member at the plant management level.

8. A management position responsible for licensing projects including special projects and new technology.

9. A management position responsible for operational projects.

2.3. Site Organization

A management position for each nuclear site reports through a ROG level management position to the CNO and is responsible for overall plant nuclear safety and the implementation of the Company's QAP. This position is also responsible for the station compliance with its NRC operating license, governmental regulations, and ASME Code requirements. Day to-day direction and management oversight of activities associated with the safe and reliable operation of a nuclear station is provided. The following site management positions report to this position:

2.3.1. The management position responsible for plant operations assures the safe, reliable, and efficient operation of the plant within the constraints of applicable regulatory requirements, operating license, and the QAP. Supervisory direction is provided for the Technical Review Program, including approval of individuals as technical reviewers, and the Plant Operations Review Committee (PORC). During periods that exceed three months, when unavailable, responsibility is designated in writing to an established alternate who satisfies the experience requirements of this position. Functional areas of responsibility include:

- chemistry activities, laboratory and system processes, related procedures and programs.
- emergency preparedness.
- environmental services.
- fuel handling (receipt, movement, and storage).
- health physics/radiological protection.
- operations and support including:
  - a management position responsible for safe, reliable, and efficient plant operations within the constraints of the operating license and regulatory requirements. This position is also responsible for the development and implementation of appropriate controls in accordance with the QAP and other requirements.
  - management position(s) responsible for operations shift crews and administration, direction and supervision of operating staff. This position is also responsible for routine plant operations activities and evolutions that are performed within the constraints of the operating license, the QAP, and other requirements. Typically this

position is the senior individual on site who holds a Senior Reactor Operator license.

- management position(s) responsible for the day-to-day operation of the nuclear unit(s) and overall command and control of shift activities including operations of the radioactive waste system.
- management position(s) responsible for supervision for control of work and of the plant and field supervision that coordinates and/or assists in the control of shift operations. This position directs control room personnel, field operations, has the primary responsibility for authorizing removal and restoration of systems to support maintenance activities and holds a Senior Reactor Operator License.
- a management position responsible for advisory technical support to shift management in the areas of thermal hydraulics, reactor engineering and plant analysis with regards to the safe operations of the facility. In addition, this position shall meet the qualifications as specified by the NRC.

- radioactive waste.
- radiological environmental monitoring.
- security.

2.3.2. The management position for engineering and design has the responsibility and authority for day-to-day engineering support activities, develops and maintains engineering programs, policies, procedures, and provides engineering services in accordance with the QAP. A staff of supervisory, technical, and administrative personnel supports maintenance activities. Functional areas of responsibility include:

- design engineering.
- document control.
- engineering administration.
- modifications and their implementation.
- plant configuration control.
- quality assurance records management.
- reactor engineering.
- system engineering.
- system testing.
- technical support.

2.3.3. Management position(s) for maintenance are responsible for the performance of corrective, predictive and preventive maintenance, cleanliness controls and modification installation of mechanical and electrical equipment and instrumentation in accordance with the QAP and other requirements. A staff of supervisory, technical, administrative, and contract personnel supports day-to-day maintenance of equipment within their functional area.

2.3.4. Management position(s) responsible for project management and control of work coordinate, administer, execute, and monitor daily and outage work schedules. This position is also responsible for material management and site supply, which coordinates parts requirements, specifies and evaluates parts, procures all materials for the site, ships and receives material, and controls the onsite inventory.

2.3.5. The management position responsible for regulatory assurance maintains an interface and liaison between the station and federal and state regulators and is also responsible for the overall administration of the station's corrective action program and associated activities.

2.3.6. The management position responsible for training provides direction, control, and overall supervision of personnel as required by regulations and training for all site personnel as required. Functional areas of responsibility include:

- learning services.
- maintenance technical training.
- operations training.

2.3.7. The Plant Operations Review Committee (PORC) is a multi-disciplined committee responsible for review of activities that affect nuclear safety, reports to, and advises the management position responsible for plant operation on matters related to nuclear safety. The PORC shall ensure that plant activities are conducted safely and do not require NRC review and approval prior to implementation or changes to the Technical Specifications. The PORC functions in accordance with written instructions which delineate committee composition, responsibility, authority, member qualifications, meeting frequency, subjects to be reviewed, reporting requirements, and administrative controls under which the group operates.

2.3.8. The management position responsible for site NOS activities reports to the management position responsible for NOS through a ROG level NOS management position. This position has the organizational freedom and authority to identify problems, has a reporting relationship with the senior management position responsible for overall plant nuclear safety, and ensures compliance with QAP and nuclear safety requirements.

Significant safety or quality issues requiring escalated action will be directed through the ROG NOS management position to the President and CNO. Functional responsibilities include:

- authority and responsibility to escalate matters.
- approving the agenda, checklist, findings, and report of each assessment.
- conducting independent assessments of line and support activities and safety reviews.
- identify changes to the quality assurance program.
- initiate, trend and recommend solutions for deficiencies identified by NOS.

- maintain a suitably trained and qualified staff.
- monitoring day-to-day station activities.
- provide NOS management periodic reports on the status and adequacy of the QAP.
- quality verification inspections.
- promptly communicate significant issues to ROG NOS and appropriate site management.
- stop work or request any other actions to avoid unsafe plant conditions.

2.3.9. The Company uses a three-tiered approach to accomplish the oversight of safety which are:

- A collection of program elements for implementing and/or reviewing areas of quality of plant operations and nuclear safety. These elements include system performance monitoring, review of operating experience information, operability evaluations, and reviews of changes to technical specifications and final safety analysis reports that affect design bases. Specific guidance is contained in applicable procedures and programs.
- A NOS staff who assesses and performs quality verification inspection aspects of Company activities within the scope of the QATR relating to safety. This provides for an overview of activities affecting or potentially affecting safety.
- A NSRB which is an off-site committee that reports to and advises the President and Chief Nuclear Officer, Exelon Nuclear, of the results of independent oversight of plant operation relative to nuclear safety.
- In lieu of the collection of program elements for implementing and/or reviewing areas of quality of plant operations and nuclear safety as described above, the Independent On-site Safety Review Group (IOSRG) at Oyster Creek and Three Mile Island Nuclear Stations will perform the following:
  - IOSRG has no line responsibilities or line functions and is devoted solely to safety matters. It is independent of the plant staff and reports to the NOS Manager who reports to a ROG Director, NOS. The IOSRG will consist of a minimum of a manager and three full time engineers/ technical staff.
  - The IOSRG shall have access to the unit and unit records as necessary to perform its evaluations and assessments. Based on its reviews, the IOSRG shall provide recommendations to the management positions responsible for the areas reviewed. IOSRG reports of evaluations and assessments shall be transmitted to a ROG Director, NOS, the Site Vice President, and the management positions responsible for the areas reviewed.

2.4. Decommissioning Site Organization

Similar to the operating sites, the following positions are responsible for management oversight, directing, and implementing appropriate controls to maintain the site within the requirements and constraints applicable to a permanently shutdown station or unit (or those stations or units not under the control of an NRC approved decommissioning plan), and to ensure the safe storage of spent nuclear fuel.

2.4.1. Dresden Unit 1

The management position for Dresden Unit 1 has the day-to-day responsibility for decommissioning activities and for the operation and maintenance of structures and systems required for the safe storage of spent nuclear fuel. Activities of decommissioning work groups are managed and monitored to ensure that there is no adverse safety impact on the unit prior to execution. This position is also responsible for supporting the station in assuring that activities are performed within the constraints of the Decommissioning Technical Specifications (DTS) and in accordance with the QAP, as applicable.

2.4.2. Zion

The management position responsible for operations and engineering or Zion Station is responsible for engineering support and the operation of dedicated systems required for the safe storage of spent nuclear fuel. Activities of decommissioning work groups are managed and monitored to ensure that there is no adverse safety impact on the unit prior to execution. This position is also responsible for supporting the station in assuring that activities are performed within the constraints of the DTS and in accordance with the QAP, as applicable.

2.5. Responsibility

Each holder of position as identified in this Chapter, has the responsibility for the scope and effective implementation of the QAP and may delegate all or part of the activities of planning, establishing, and implementing the QAP to others, but retains the responsibility for the program's effectiveness.

The Company is responsible for ensuring that the applicable portion(s) of the QATR is properly documented, approved, and implemented before an activity within the scope of the QAP is undertaken by the Company or by others.

Personnel performing NOS assessment functions for the Company have the responsibility, authority, organizational freedom, and sufficient independence from cost and schedule to:

- assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.
- identify quality problems.

- initiate, recommend, or provide solutions to quality problems through designated channels.
- initiate stop work, order unit shutdown, or request any other actions deemed necessary to avoid unsafe plant conditions or a significant violation of the QAP
- verify implementation of solutions for significant conditions adverse to quality.

The Company may delegate certain phases of the work to non-company labor and contracted services, which act as the Company's agents in assigned areas. They shall work to a Company accepted quality program (or in accordance with the Company's program) under overall site direction and document their organization and any delegated responsibilities necessary to establish, execute, and verify their quality program. The Company may also assign the authority for certification and stamping in accordance with the ASME Code.

2.6. Authority

When the Company delegates responsibility for planning, establishing, or implementing any part of the overall QAP, sufficient authority to accomplish the assigned responsibilities is delegated. Regardless of delegation, the Company retains responsibility.

1. SCOPE

The purpose of this chapter is to define how the Company's QAP applies to those activities such as design, procurement, fabrication, installation, modification, maintenance, repair , refueling, operation, inspection, and tests related to systems, structures, and components. The QAP also applies to certain non-safety related structures, systems, components and activities to a degree consistent with their importance to safety. Policies, directives, procedures, guidelines, manuals, or instructions shall be reviewed, approved, distributed, and revised in accordance with administrative procedures.

2. REQUIREMENTS

2.1. General

The QAP comprises all those planned and systematic actions necessary to provide adequate confidence that structures, systems, and components will perform satisfactorily in service. Quality assurance includes quality verification, which comprises the examination of those physical characteristics of material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements. All persons and organizations involved in activities in support of the nuclear sites and governed by this program are responsible for implementing the requirements of this manual.

The QAP is based upon 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The requirements of 10CFR50.54, "Conditions of License," 10CFR50.55(a), "Codes and Standards," 10CFR50.59, "Changes, Test, and Experiments," 10CFR50 Appendix A, "General Design Criteria for Nuclear Power Plants," 10CFR50 Appendix R, "Fire Protection Programs for Nuclear Power Plants," are included in the basis for the QAP.

The requirements of 10CFR21, Reporting of Defects and Non-Compliance," 10CFR71, Subpart H, "Quality Assurance for Packaging and Transportation of Radioactive Material," and 10CFR72, Subpart G, "Quality Assurance for Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," are also included. The Company is committed to carrying out the provisions of various NRC regulatory guides and industry standards which further define Quality Assurance Program requirements (see attached Appendix C).

2.2. Supplier's Quality Assurance Program

The applicable Quality Assurance requirements of 10CFR50, Appendix B, as noted in Appendix C, are invoked on vendors, suppliers, or contractors through procurement document requirements.

2.3. Planning

Planning establishes the systematic, sequential progression of actions to meet the defined requirements. The Company documents these plans in appropriate communications, approvals, instructions, and procedures. Activities described in the QAP are accomplished under controlled conditions that include appropriate equipment, qualified personnel, suitable environment, and use of appropriate procedures.

2.4. Program Description

The Company's total program for providing administrative controls and quality assurance is incorporated in many diverse documents. The Company's nuclear document hierarchy describes the implementation of the QAP. Approved implementing procedures and instructions are written to the extent necessary to implement the quality requirements of 10CFR50 Appendix B. Line, staff, administrative, and quality oversight organizations issue and control these implementing procedures. All activities affecting quality are described in sufficient detail to assure quality.

2.5. Indoctrination & Training

Formal indoctrination and training programs for personnel performing or verifying activities within the scope of this Plan are established and maintained. A training organizational element is established and staffed with qualified instructors and is responsible for planning, scheduling, developing and providing training to Company personnel. The indoctrination and training programs are established by on-site and by off-site organizational units responsible for the performance or verification of activities within the scope of the QAP. Indoctrination, training, and qualification programs are established such that:

- personnel responsible for performing quality-affected activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.
- personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed.
- formal training and qualification programs documentation includes the objective, content of the program, attendees, and date of attendance.
- proficiency tests are given to those personnel performing and verifying activities affecting quality, and the acceptance criteria are developed to determine if individuals are properly trained and qualified.
- certificate of qualification clearly delineates the specific functions personnel are qualified to perform and the criteria used to qualify personnel in each function.
- proficiency of personnel performing and verifying activities affecting quality is maintained by re-training, re-examining, re-qualifying, and/or re-certifying as determined by management or program commitment.

2.6. Program Review

The effectiveness of the QAP and its implementation is periodically reviewed by various organizations at various levels. The results of these reviews are documented in reports to senior management for evaluation and corrective action is initiated as required. The effectiveness of the QAP is evaluated and reported by NOS through the monitoring, assessment, and inspection functions. Other organizational elements provide additional information/ evaluations as requested.

2.7. Quality Assurance Manual

This Quality Assurance Manual (QAM) contains the Company's QAP. The QAM is made available to NRC, Company personnel, the Authorized Nuclear Inspector, and other regulatory authorities. The Company submits revisions to the QAP document (as a topical report) to the NRC for acceptance.

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1. SCOPE

The purpose of this chapter is to establish the requirements and control measures for assuring design bases and regulatory requirements are correctly translated into design documents. The scope of design control covers all phases of engineering design, including: identification of design inputs (criteria and bases); identification and control of design interfaces; production of design documents, calculations and analyses; procurement related engineering and design verification.

2. REQUIREMENTS

2.1. General

The Company has overall responsibility for design and design control activities including, preparing, reviewing, approving, and verifying design documents related to the plant's structures, systems, and components within the scope of the QAP. Additionally, the Company is responsible for reactor core design analysis, core design specifications and design reviews, for nuclear fuel and in-core components.

Qualified personnel perform detailed design activities or review and control design work involving electrical, mechanical, structural, and instrumentation and control designs. Design activities are conducted to written procedures that include consideration of quality standards, quality assurance requirements, suitability of material parts, equipment, and processes, control of design interfaces, analytical or testing requirements, design basis, and configuration management.

2.2. Design Input

The Company has the responsibility to properly translate applicable safety analysis reports, regulatory requirements, ASME Code requirements, and design bases into specifications, drawings, procedures and instructions. The Company is responsible for electrical, mechanical, structural, instrumentation and control; nuclear engineering activities involved in nuclear station modifications, and also maintains a configuration management program.

Design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards shall be identified and documented. Their selection shall be reviewed and approved by the responsible design organization. The design input shall be specified and approved in a timely manner and be to the level of detail necessary to provide a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes. Changes from approved design inputs, including the reason for the changes shall be identified, approved, documented, and controlled.

2.3. Design Process

The Company is responsible for design changes, performs detailed design activities, and issues design documents in accordance with approved procedures. The responsible design organization shall prescribe and document design activities in a timely manner and to the level of detail necessary to permit verification that the design meets requirements.

Included in this scope of activities are considerations for field design engineering, fire hazards, human factors, physics, seismic, stress, compatibility of materials, application of special process, associated computer programs, thermal, hydraulic, ALARA and radiation factors, the safety analysis accident scenarios, and accessibility for in-service inspection, maintenance and repairs, and quality standards. Design documents shall be adequate to support facility design, construction, and operation. Selection of the appropriate quality standards shall be documented, reviewed and approved.

Reasons for changes from specified quality standards, shall be identified, documented, approved and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable industry experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

The final design output documents and approved changes thereto shall be relatable to the design input by documentation in sufficient detail to permit design verification. The final design shall identify assemblies and/or components that are part of the item being designed. If materials, parts, equipment, or processes are different from the published supplier information, these differences shall be documented.

Commercially standard (catalog items) materials, parts, or equipment, which have been previously approved for different applications, are reviewed for suitability in the design process.

2.4. Design Analyses

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review, understand the analysis, and verify the adequacy of the results without recourse to the originator. Calculations shall be identified for retrievability by subject including structure, system, component, originator, reviewer, and date or by other unique identifiers.

Computer programs shall be controlled to assure that changes are documented and approved. Verification shall be required for changes to previously verified computer programs including evaluation of the effects of these changes as specified below.

Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

- the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
- the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

2.5. Design Verification

Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following:

- performance of design reviews.
- use of alternate calculations.
- performance of qualification tests.

The results of design verification shall be documented including the identification of the verifier. Design verification shall be performed by competent individual(s) other than those who performed the original design but may be from the same organization. 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, did not establish the design inputs used in the design, or the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of design verification.

Verification shall be performed in a timely manner. Design verification, for the stage of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities provided sufficient data exists. Any unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

2.5.1. Extent of Design Verification

The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.

Where the design has been subjected to a verification process, the process need not be duplicated for identical designs. For each application the applicability of standardized or previously proven designs for design inputs shall be verified.

Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. The original design and associated verification shall be adequately documented and referenced in subsequent applications.

Design verification shall be required for changes to previously verified designs. This includes evaluation of the effects of those changes on the overall design and on any affected design analyses.

2.5.2. Design Reviews

Verification consists of a check of design adequacy by such methods as design reviews, use of alternate calculations or methods, or performance of verification or qualification testing. The method, or combination of methods, used to verify a design will be selected on a case-by-case basis

Acceptable verification methods include one or more of the following items:

- alternate calculations using alternate methods that verify the correctness of original calculations or analyses.
- critical design reviews providing assurance that the final design is correct and satisfactory.
- where design adequacy is to be verified by qualification tests, the tests are dentified.

2.6. Change Control

Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design.

These measures shall include assurance that the design analyses for the structure, system, or components are still valid. A 10CFR50.59/72.48 review is performed for changes to the facility.

Changes shall be approved by the same affected groups or organizations, which reviewed and approved the original design documents. In the case where the original organization is no longer responsible for design approval, then a new responsible design organization shall be designated. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

When a design change is approved, other than by revision to the affected design documents, measures shall be established to incorporate, where appropriate the change into these documents. Plant personnel will be made aware of design changes/modifications, which may affect the performance of their duties. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.7. Design Errors

The Company detects deficiencies or errors in design or in the design quality assurance program by:

- actual failure during operation.
- assessments.
- design verification measures.
- other means.
- personnel using the design documents.
- tests conducted.

2.8. Interface Control

Design interfaces shall be identified and controlled. The Company shall coordinate design efforts among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations. Controls shall be for the review, approval, release, distribution and revision of documents involving design interfaces. Design information transmitted across interfaces shall be documented and controlled.

2.9. Vendor Design Control

The Company reviews and accepts the specifications and drawings for electrical, mechanical, instrumentation, nuclear and structural material, equipment, and erection work, prepared by the Architect Engineer and NSSS Supplier. The purpose of these reviews is to verify inclusion of inspection, testing and acceptance criteria.

The Architect Engineer's evaluation of fabricator and erector's detailed designs, drawings, and work instructions are reviewed for reasonableness and completeness. Audits are conducted by the company for design review systems of architect engineers, nuclear fuel, and NSSS suppliers.

The Company assures that:

- personnel certifying ASME Section III design activities are qualified Registered Professional Engineers in accordance with ASME Section III, Appendix XXIII.
- architect engineers and NSSS suppliers maintain procedures to assure that their personnel certifying ASME Section III design activities are qualified Registered Professional Engineers in accordance with ASME Section III, Appendix XXIII.

The Company provides qualified personnel to review and approve the resolution of non-conformances relating to electrical, mechanical, instrumentation and structural portions of the plant and to evaluate discrepant modification test results for operating plants.

2.10. Modifications

The Company performs modifications that may affect the function of safety-related structures, systems, or components in a manner to assure quality at least equivalent to that specified in original design bases and requirements, materials specifications, and inspection requirements.

2.11. Documentation and Records

The Company notifies jurisdictional authorities of the location of ASME Code related permanent records. Design documentation and records which provide evidence that the design and design verification process were performed in accordance with the requirements of this chapter, shall be stored and maintained.

Documentation of design analyses shall include the following:

- statement of the objective of the analyses.
- list of design inputs and their sources.
- results of literature searches or other applicable background data.
- list of assumptions and indication of those that must be verified as the design proceeds.
- list of any computer calculation and the bases for its use.
- review and approval.

1. SCOPE

This Chapter identifies the requirements for preparation, review, approval, release, and retention of procurement documents.

2. REQUIREMENTS

2.1. General

The Company establishes measures for the preparation, review, and approval of procurement documents for those items and activities within the scope of the QATR. Procurement documents at all tiers include or reference the appropriate regulatory, technical, and quality requirements necessary to assure adequate quality. These requirements include reference to 10CFR21 when applicable.

2.2. Content of Procurement Documents

Procurement documents at all tiers include the following items as deemed necessary by the Company.

2.2.1. Scope of Work

Procurement documents describe the scope of the items or services to be furnished by a supplier. For those items that are important to plant safety, applicable requirements should be specified in the procurement document.

2.2.2. Technical Requirements

The Company establishes measures in controlled procedures to; specify technical requirements by reference to the appropriate specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished.

The procurement documents identify test, inspection and acceptance requirements as appropriate. These documents identify as appropriate special instructions and requirements for such activities as design, material and component identification, fabrication, special process controls, cleaning, erecting, packaging, handling, shipping, and extended storage.

2.2.3. Quality Assurance Program Requirements

Measures are established, in controlled procedures, to ensure the appropriate technical and quality requirements are established, by qualified personnel, for the material, equipment, and services purchased from vendors, suppliers, or contractors.

Any changes to these requirements require prior approval by the Company. Each vendor, supplier, or contractor has an acceptable quality assurance program, which is consistent with applicable regulatory requirements for the item or service.

The appropriate supply management groups maintain a controlled list of evaluated suppliers that are audited on a triennial basis. The evaluated list of such vendors, suppliers, and contractors is described in controlling procedures for the appropriate safety classification except for procurement from other licensees that has a NRC approved quality program.

Procurement documents require the vendors to incorporate quality assurance program requirements in sub-tier procurement documents and allow right of access to the vendors, sub-tier vendors, and contractors facilities and records for inspection or audit by the Company or designated representative.

2.2.4. Non-conformances

The Company procurement documents specify the requirements for reporting and approving the disposition of supplier non-conformances. "Use as is" or "Repair" requires approval of the supplier disposition by the appropriate Company representative.

2.2.5. Documentation Requirements

The procurement documents shall identify, at all tiers, the documentation required to be submitted for information, review, and approval including the time requirements for submittal. The Company procurement documents require the supplier to maintain specific quality assurance documents including retention times and disposition requirements.

2.2.6. Spare and Replacement Parts

The procurement documents require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies. These spare parts and replacement items are at least equivalent to the original design requirements or those specified by a properly reviewed and approved revision.

2.3. Procurement Document Review

Measures are established in controlled procedures to ensure the appropriate technical and quality requirements are established for the material, equipment, and services purchased from vendors, suppliers, or contractors prior to release for bid and contract award.

These documented reviews, including changes to the specification or purchase order, ensure the technical and quality requirements are correctly stated, inspectable, and controllable and have adequate acceptance and rejection criteria and are prepared, reviewed, and approved in accordance with QAP requirements.

Review of the exceptions or changes requested by the supplier shall be analyzed to ensure they do not change or impact the technical or quality requirements and are incorporated in to the procurement documents, prior to the supplier proceeding, using the same review and approval process as appropriate except for commercial terms and editorial changes.

Personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents shall perform reviews required by this chapter.

2.4. Procurement Records.

Records as required by the procurement documents or the QATR are retained in the Company's department files, vendor files, or both locations.

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1. SCOPE

Activities governed by the Company's QAP shall be performed as directed by documented instructions, procedures, and drawings appropriate for the activity. The requirements for the use of these procedures shall also be prescribed in writing. These instructions, procedures, and drawings shall include responsibilities and acceptance criteria as applicable or appropriate for the activity.

Those participating in any activity shall be aware of and use the proper and current revision of instructions, procedures, drawings, and engineering requirements for performing the activity. Procedures may include reference to vendor equipment manuals, design drawings and specifications, prerequisites, special precautions, and the delineation of work to be performed. Equipment Manuals and manufacturers instructions shall be readily available for use.

2. REQUIREMENTS

2.1. General

Operation, maintenance, or modification of equipment shall be preplanned and performed in accordance with written procedures that are appropriate to the circumstances and that conform to applicable codes, standards, specifications, and criteria. Documents identify and specify the content of records to be generated in conducting the activity. The establishment and execution of quality procedures shall be used by the station staff or those under their direction, for operating, maintenance, modifications, in-service inspection, refueling, and stores activities.

Temporary procedures may be issued to provide guidance in unusual situations that are not within the scope of the normal procedures. Temporary procedures shall be subject to review and approval, and shall include designation of the time period during which they may be used. In the event of an emergency not covered by an approved procedure, authorized personnel shall provide appropriate direction to minimize personnel injury and damage to the facility and to protect the health and safety of plant personnel and the general public.

2.2. Preparation and Review

Procedures shall be prepared, reviewed, approved, and used as prescribed in writing, and shall contain step by step instructions in the degree of detail necessary for qualified individuals to perform the required function or task. Where appropriate, these procedures will include checklists containing the necessary attributes to be observed or measured.

These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

The procedures will be independently reviewed and evaluated by other involved company organizations with interface responsibilities and the comments forwarded to the issuing department.

2.3. Procedures and Programs

Review and approval of site procedures are performed in accordance with technical specification requirements as delineated in the Technical Review or Station Qualified Review (SQR) programs.

2.3.1. Technical Review and Control

1. Procedures required by a station's Technical Specifications and other procedures which affect nuclear safety, as determined by the manager responsible for station operation, and changes thereto, other than editorial or typographical changes, shall be reviewed as follows prior to implementation, except as noted in item 5 (below).
   - Each procedure or procedure change shall be independently reviewed by a qualified individual knowledgeable in the area affected other than the individual who prepared the procedure or procedure change. This review shall include a determination of whether or not additional cross-disciplinary reviews are necessary. If deemed necessary, the reviews shall be performed by the qualified review personnel of the appropriate discipline(s).
   - Applicable Administrative Procedures recommended by Regulatory Guide 1.33 shall be submitted to the Plant Operations Review Committee (PORC) as applicable, for review prior to implementation. The PORC shall recommend approval or disapproval based on their review.
   - Review of procedures or procedure changes to those procedures, that describe the means for controlling or operating structure, systems, and/or components as described in the UFSAR, will include a review to determine if NRC review and approval is necessary prior to the implementation of the procedure activity. This review is based on the review of a written 10CFR50.59/72.48 review and evaluation prepared by qualified individual(s), or documentation that a 10CFR50.59/72.48 evaluation is not required. The PORC and the NSRB shall review and recommend approval of items requiring NRC review and approval prior to station approval for implementation. NRC approval shall also be obtained prior to station approval for implementation.

- Department head approval authority shall be as specified in station procedures.
- Written records of reviews performed in accordance with this specification shall be prepared and maintained.
- Editorial and typographical changes shall be made in accordance with station procedures.

2. Technical reviewers shall advise their supervisors and/or PORC on all matters related to nuclear safety that are identified during reviews. The reviewer shall be other than the originator. The reviewer shall determine if additional cross-disciplinary reviews are required to ensure all applicable technical disciplines are included. This review shall ensure technical accuracy, compliance with regulatory requirements, and shall verify the originator's determination of whether items reviewed constitutes a change to the Technical Specifications, Operating License, or if NRC review and approval is required prior to implementation.

3. Technical reviewers shall be qualified to perform technical reviews based on the individual's training, experience, and knowledge level. Technical reviewers, assigned the responsibility for reviewing 10CFR50.59/72.48 reviews and evaluations, shall receive training in this process. Technical reviewers shall be qualified to perform this function and meet the experience requirements per applicable standards. Personnel shall have expertise in one or more of the following disciplines as appropriate, for the subject or subjects being reviewed:

- chemistry
- instrumentation and controls
- mechanical and electrical systems
- nuclear power plant technology
- radiological controls
- reactor engineering
- reactor operations

4. Technical reviews shall be documented and records maintained.

5. Temporary Changes

Temporary changes to procedures required by 2.3.1.1 (above) may be made provided:

- the intent of the original procedure is not altered.
- the change is approved by two members of the plant management staff knowledgeable in the areas affected by the procedures, at least one of whom holds a Senior Reactor Operator's License on the unit affected.

- the change is documented, reviewed, and approved in accordance with 2.3.1 (above) within 14 days of implementation.

2.3.2. On-site Qualified Technical Review (Dresden Unit 1)

A Qualified Technical Reviewer shall conduct thorough reviews of the documents specified below. Persons performing these reviews shall be knowledgeable in the subject area being reviewed. Qualified technical reviews must be completed prior to implementation of proposed activities.

1. Qualified Technical Reviewers shall be individuals without direct responsibility for the document under review; these reviewers may be from the same functionally cognizant organization as the individual or group performing the original work.

2. Qualified Technical Reviewers shall have at least 5 years of professional experience and either a Bachelor's degree in Engineering or the Physical Sciences or shall have equivalent qualifications evaluated on a case by case basis and approved by the manager responsible for decommissioning activities. The appointment of Qualified Technical Reviewers shall be documented.

3. A Qualified Technical Reviewer shall independently review the following subjects:
   - Proposed changes to the license, technical specifications, or bases.
   - Proposed changes to the programs required by the Technical Specifications to verify that such changes do not involve a change to the Technical Specifications and will not require NRC review and approval as defined in 10CFR50.59/72.48.
   - 10CFR50.59 evaluations for changes in the facility as described in the De-fueled Safety Analysis Report (DSAR), changes in procedures as described in the DSAR, and tests or experiments not described in the DSAR to verify that such actions do not involve a change to the Technical Specifications or will not require NRC review and approval as defined in 10CFR50.59.

1. SCOPE

Measures shall be established to control and coordinate the classification, review, approval, issuance, revision, and change of documents that prescribe methods or provide the technical and/or quality requirements for activities and items within the scope of this program. These measures shall ensure that such documents are reviewed for adequacy, approved for release and use, and distributed to the location where the activity is performed

2. REQUIREMENTS

2.1. General

The Company document control process ensures that procedures are reviewed and approved before initial use. The Company has in place programmatic controls, which ensure that procedures are technically and administratively correct before use. These programmatic controls ensure that procedures are reviewed and revised as needed, when pertinent source material is changed, when the plant design is changed, or when deficiencies are identified and corrected. The following processes and programs support the programmatic controls that ensures the required reviews are accomplished:

- Commitment Management and Tracking Process.
- Integrated Reporting/Corrective Action Program.
- Operational Experience Feedback Program.
- Plant Modification Program.
- Procedure Feedback Process.
- Technical Specification and Updated Final Safety Analysis Report Revision Programs.
- Vendor Information Program.

2.2. Reviews

The company has also established provisions to ensure that the following reviews are conducted:

- inspection, identification of inspection personnel, and documentation of inspection results.
- maintenance, modification, and inspection procedures are reviewed by qualified personnel, knowledgeable in quality assurance disciplines.
- necessary inspection requirements, methods, and acceptance criteria have been identified.

2.3. Controlled Documents

Written document control procedures shall be established to provide for the control of approved documents. Documents that are controlled include, but are not limited to, the following items:

- as-built drawings.
- calibration procedures.
- computer codes and software.
- corrective action reports.
- design specifications.
- emergency operating procedures.
- engineering calculations.
- inspection and test reports.
- nonconformance reports.
- NOS procedures.
- operating procedures.
- purchase orders and related documents.
- safety analysis reports.
- supplier audit and surveillance procedures.
- technical specifications (station and Independent Spent Fuel Storage Installation)
- temporary and emergency procedure changes.
- topical reports.
- work instructions and procedures.

2.4. Control Measures

The Company document control process includes the following document control measures:

- coordinating and controlling interface documents.
- distributing documents approved for issuance in accordance with updated and current distribution lists.
- establishing document control procedures to assure that proper documents are accessible and are being used.
- establishing lists of documents controlled by organizations involved with activities affecting quality.
- establishing procedural requirements for the protection of safeguards information
- identifying and assuring that proper documents are used in performing activities affecting quality.

- identifying qualified individuals or organizations responsible for preparing, reviewing, approving and issuing documents, including revisions.
- recalling or identifying obsolete documents.

2.5. Document Changes

The Company document control process ensures changes to documents are reviewed and approved by the same organizations that performed the original review and approval, unless delegated to another responsible organization. The reviewing organization has access to pertinent background data or information upon which to base their approval. To avoid a possible omission of a required review, the Company document control process includes provisions to control minor changes.

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1. SCOPE

The Company establishes measures to assure the quality of purchased material, equipment and services conform to procurement document requirements for items contained within the QATR.

2. REQUIREMENTS

2.1. Supplier Selection

2.1.1. General

The Company establishes measures to assure that purchased material, equipment, and services conform to the procurement documents for safety related and ASME code specifications as appropriate. This assurance is accomplished by controlling both the selection of procurement sources and acceptance of the product at the source and/or upon receipt at the appropriate location.

The company procedures, which address the procurement process and receipt and storage of material and equipment, clearly define the responsibilities and interfaces between the line requisitioning organization, engineering, supply and quality assurance.

2.1.2. Methods

The Company establishes measures for evaluation and selection of procurement sources and must be completed prior to the award of contract. These measures include one or more of the following:

- evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use.
- supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
- supplier's technical and quality capability of meeting the applicable quality requirements of 10CFR50 Appendix B as determined by a direct evaluation of its facilities and personnel and the implementation of its quality assurance program.
- review and evaluation of audits, surveys, and inspections conducted by other utilities, or American Society of Mechanical Engineers (ASME).

The Company documents and files the results of these measures and maintains an evaluated list of suppliers.

2.2. Bid Evaluations

The Company reviews and evaluates bids and awards contracts using written procedures and documents the results. The Company designates individuals or organizations to review bids to assure that they conform to the procurement document requirements and the supplier has the appropriate technical ability, Quality Program, production capability, personnel, and acceptable past performance to supply the product or service. The Company obtains commitments to resolve unacceptable quality conditions identified as part of the bid evaluation before award of the contract and ensure exceptions and alternatives do not impact the technical or quality requirements.

2.3. Supplier In-Process Control

2.3.1. General

The Company establishes measures to interface with and to verify supplier performance. These measures include the following items:

- establishing an understanding between the Company and the supplier of the provisions and specifications contained in the procurement documents.
- establishing a method of document information exchange between the Company and the supplier.
- establishing the extent of source surveillance and inspection activities.
- identifying and processing necessary change information.
- requiring the supplier to identify planning techniques, tests, inspections, and processes to be used in fulfilling procurement document requirements.
- reviewing supplier documents that are generated or processed during activities fulfilling procurement requirements.

2.3.2. In-Process Control and Verification Planning

The Company and the supplier, establish as appropriate, notification points, including hold and witness points and incorporate into the appropriate documents based upon the complexity and scope of the item or service. When required by the procurement document or specification, surveillances and evaluations at the supplier's facility are conducted to verify continued compliance with the quality assurance requirements of the procurement documents.

Qualified individuals or its agents accomplish source inspections at the supplier's facility to verify that the procurement item or service is being supplied in accordance with the requirements of the procurement documents.

Such inspections, examinations or tests are accomplished in accordance with written procedures, plans, and/or checklists containing or referencing appropriate acceptance criteria. Upon acceptance by source verification, the Company furnishes documented evidence of acceptance to the receiving destination of the item, to the purchaser, and to the supplier.

2.3.3. Programmatic Verification

The Company or its agents verify the effectiveness of the supplier's quality program by survey, audit or surveillance. Verification is performed at intervals consistent with the importance to safety, complexity and quality of the product or services furnished. Activities are witnessed or observed and the results documented when source verification is performed.

The Company conducts audits per the requirements established in Chapter 18 or reviews audits performed by other license holders as defined in procedures. The results of these audits are used to support the maintenance of the list of evaluated suppliers. Verification activities are conducted as early as practicable so that subsequent activities do not prevent disclosure of deficiencies. The Company's verification activities do not relieve the supplier of its responsibility for quality verification.

2.3.4. Supplier and Verification of Supplier Performance Records

The Company establishes methods to control, handle and approve supplier documents. Suppliers submit their documents per procurement requirements. Acceptance criteria is used for the acquisition, processing, and record evaluation of technical inspection and test data.

The Company records activities to verify supplier conformance with the requirements of procurement documents. Source surveillances, procurement plans, inspections, audits, surveys, receiving inspections, non-conformance dispositions, waivers and corrective actions concerning supplier activities are documented. This documentation is used to determine the supplier's quality assurance program effectiveness.

2.3.5. Control of Procurement Changes

The Company documents changes to procurement documents involving technical or quality assurance matters. These changes are subjected to the same review and approval process as the original procurement document except for commercial terms and conditions and editorial changes.

2.4. Acceptance of Purchased Items and Services

2.4.1. General

Upon receipt the applicable materials, parts, and components are controlled. Qualified inspection personnel are responsible for inspecting, releasing, and maintaining the inspection status of purchased material and equipment. After receipt inspection, the purchased material is placed in a controlled storage area or issued for installation or further work.

2.4.2. Acceptance by Receiving Inspection

The Company uses approved procedures to accept purchased items and services. Acceptance of an item or service from a supplier includes certificate of conformance, source verification, receiving inspection or post installation testing at the plant location or a combination thereof. Items are inspected during receipt using approved procedures and checklists.

The Company does receiving inspections using procedures and inspection instructions to verify conformance to the specified requirements, using objective evidence to check such features as: complete documentation and visual inspection of: proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness. Items, which can not meet the purchase order requirements, will be segregated and controlled as defined in the applicable procedures.

The Company coordinates the review of supplier documentation with the receiving inspection when procurement documents require such documentation to be furnished prior to the receiving inspection. Source verification and audit activities are factored into the receipt inspection activities as appropriate.

2.4.3. Acceptance by Source Verification

The Company considers acceptance by source verification when the item or service is:

- vital to plant safety; or
- difficult to verify quality characteristics after delivery; or
- complex in design, manufacture, and test.

Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at pre-determined points. Upon acceptance by source verification, the Company furnishes documented evidence of acceptance to the receiving destination of the item, to the purchaser, and to the supplier.

2.4.4. Acceptance by Certificate of Conformance

The supplier's certificate of conformance attests the product or service provided is in accordance with the procurement documents is reviewed during source and/or receipt inspections to verify compliance. This document provides the purchase order number; codes, standards or other specifications required to be met in the purchase order. Requirements which cannot be met must be included with an explanation why and a means to resolve the non-conformances. A person who is responsible for quality assurance function attests to this certificate

The validity of a supplier's certificate of conformance is ascertained through any of the following methods source inspection, independent inspection agency, receipt inspections, surveillance, testing of hardware, quality assurance audits or surveillances at intervals commensurate with the suppliers past performance.

Inspection and test activities verify that the hardware performs in accordance with applicable technical requirements and serve to demonstrate that the hardware meets the requirements stated in a certificate of conformance.

The results of the source and/or receipt inspections, the acceptability of supplier furnished documentation, and the resulting determination of conformance or nonconformance is documented.

2.4.5. Acceptance by Post Installation Testing

When post-installation testing is used, the Company and the supplier mutually establish post-installation test requirements and acceptance documentation. Acceptance by this method is satisfactory when performed following the accomplishment of at least one preceding method and when:

- it is difficult to verify the quality characteristics of the item without it being installed and in use; or
- the item requires an integrated system checkout or test with other items to verify its quality characteristics; or
- the item cannot prove its ability to perform its intended function except when in use.

2.4.6. Acceptance of Services Only

In cases involving procurement of services only, the Company accepts the service by any of the following methods:

- technical verification of data produced.
- surveillance, audit, survey, or assessment of the activity.
- review of objective evidence for conformance to the procurement document requirements such as certifications, stress reports, etc.

In lieu of the above the Company performs a receiving inspection for items arriving back onsite that were sent offsite for repair, testing, or rework.

2.4.7. Commercial Grade Items

Where the safety related design utilizes commercial grade items, the following requirements are a permissible alternative for acceptance, to other requirements of this Chapter:

1. An approved design document identifies the commercial grade item. (An alternate commercial grade item may be applied, provided the cognizant design organization provided verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and its application.)

2. The Company performs source evaluation and selection, where determined necessary, based on complexity and importance to safety.
   - commercial grade dedication plans for use in a safety related applications state responsibility for 10CFR21 requirements.
   - the Company identifies commercial grade items in the purchase order by the supplier's published product description.

3. One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance:
   - acceptable supplier/item performance records.
   - commercial grade survey of the supplier.
   - source verification.
   - special test(s) or inspection(s) or both.

4. After receipt of a commercial grade item, the Company determines the following:
   - damage was not sustained during shipment.
   - documentation, as applicable to the item, was received and is acceptable.
   - inspection and/or testing are accomplished, as required by the purchaser, to assure conformance with the manufacturer's published requirements.
   - the item received was the item ordered.

2.5. Presence of Documentary Evidence

Documented evidence that material or equipment conforms to procurement requirements is present at the site before use or installation. This documentary evidence is traceable to the item and shall be retained at the nuclear power plant

site and shall be sufficient to identify the specific requirements such as codes, standards, or specifications met by the purchased material and equipment.

2.6. Spare or Replacement Items

Procedures control the procurement, storage and issuance of materials and components including spare and replacement parts. Procurement documents for these items identify the appropriate technical and quality related requirements. The Company purchases spare parts and replacement items, equipment and components to at least the original design requirements or those specified by a properly reviewed and approved revision.

Where the QA requirements of the original item cannot be determined, qualified individuals conduct an engineering evaluation to establish appropriate requirements and controls. This evaluation insures that interfaces, interchangeability, safety, fit and function are not adversely affected or are contrary to applicable regulatory or ASME Code requirements. The evaluators document their results.

Where the company procured the original item with no specifically identified quality assurance program requirements, or from an Original Equipment Manufacturer/Supplier (OEM/OES) who no longer is on a list of evaluated suppliers identical (like-for-like) items may be similarly procured from the OEM/OES through the use of procurement plans.

In such cases, the Company conducts a joint technical engineering and quality assurance documented evaluation to established requirements and controls to assure at least equivalent product performance. The evaluation shall assure that interfaces, interchangeability, safety, fit and function are not adversely affected or are not contrary to applicable regulatory or ASME Code requirements.

2.6.1. Procurement from Other Utilities

Purchases of safety related items can be made from other utilities who have had an NRC approved QA Program in effect at the time of their procurement and receipt and such utility has maintained a quality system program for storage, handling, and maintenance with documented traceability to the manufacturer of the items.

Certificates-of-Conformance to the above requirements and associated required documentation are provided.

2.6.2. Maintenance or Modification

The Company performs maintenance or modifications that may affect the function of safety related structures, systems, or components in a manner to assure quality at least equivalent to that specified in original design bases and requirements, materials specifications, and inspection requirements.

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1. SCOPE

Controls are established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner, which assures that identification is established and maintained.

2. REQUIREMENTS

2.1. General

The Company establishes measures for the identification and control of materials, parts and components, including partially fabricated assemblies, and assures that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items. Physical identification shall be used to the maximum extent possible.

Provisions are in place to maintain markings, which could be damaged during shipping or handling or deterioration due to environmental exposure. Provisions are also established to control nonconforming items and maintain parts, material, and equipment in storage traceable to quality assurance documents.

2.2. Traceability

Items within the scope of the QAP shall be identified, so that they can be traced to the appropriate documentation, which provides objective evidence that the technical and quality requirements are met.

Responsible organizations document and maintain identification and traceability of items from initial receipt, throughout fabrication, installation, and use of the items such as: subassemblies, components, equipment numbers, part numbers, serial number, heat treatment number, batch or lot numbers.

When installed material or equipment is removed for maintenance, repair, or modification, control measures are implemented to ensure proper identification and traceability is maintained. Before use or installation of an item, the installer verifies that identification has been maintained.

2.3. Identification Methods

Identification is on the item where practicable. Identification is clear, unambiguous and indelible. Identification does not affect the fit, function, quality, and service life of the item. If the item cannot be practicably marked, the Company uses records traceable to the item for identification.

If physical identification is either impractical or insufficient for proper control, the Company controls an item by physical separation, procedural control or other appropriate means.

2.4. Transfer of Markings

Prior to cutting or dividing material, each new piece shall be marked with the same traceability markings of the original piece to ensure that the traceability of the material is maintained Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. The Company independently verifies proper identification of each piece.

2.5. Limited Life Items

The Company identifies and controls items having limited life to preclude use of items whose shelf life or operating life has expired.

2.6. Stored Items

The Company uses procedures to assure proper control of identification for items in storage.

1. SCOPE

Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, shall be performed by qualified personnel, using qualified procedures, in accordance with specified requirements and are properly documented and evaluated. These requirements are defined in codes, standards, specifications, or special instructions. The quality of such processes is assured through reliance on operator skill and in-process control. Examples of special processes include, but are not limited to welding, heat treating, chemical cleaning, and non-destructive examination (NDE).

2. REQUIREMENTS

2.1. General

The Company organization directing work during repair, replacement, modification, or in-service inspection (ISI) activities is responsible for controlling special processes. Special process controls are assured through independent assessment and inspection activities.

2.2. Process Control

Instructions, procedures, drawings, checklists, or other appropriate means control processes. Process controls specify the prerequisite steps, processing details, conditions to be maintained during the process, equipment requirements, inspection and test requirements, acceptance criteria, and record requirements. Controlling includes:

- maintenance and retention of records.
- personnel qualification.
- procedure development and qualification.
- procedure implementation.
- qualification of equipment.

2.3. Special Processes

Measures shall be established and documented to assure that special processes are accomplished under controlled conditions in accordance with applicable codes, standards, applications criteria, regulatory requirements and commitments, and other special requirements including the use of qualified personnel and procedures. Special processes are controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means.

Special process controls specify the preparatory steps, processing details, conditions to be maintained during the process, equipment requirements, inspection and test requirements, acceptance criteria, and record requirements. Special process procedures are written and qualified in accordance with applicable requirements. Special process procedures are reviewed and approved as follows:

- coating and ASME Code concrete placement procedures are reviewed and approved by the appropriate Company organizations.
- Company heat treating, welding, brazing, and other non-NDE procedures are reviewed and approved by Engineering.
- Company NDE procedures are reviewed and approved by the appropriate Company Level III.
- contractor, subcontractor, Section III, XI, and other ISI-related NDE procedures are reviewed and approved by the Company NDE Level III.
- the responsible Company engineering organization reviews contractor and subcontractor special process procedures.

When permitted by applicable requirements, the Company may direct contractors or subcontractors to use Company special process procedures. The Company assures that qualification of Company, contractor, and subcontractor ASME Code NDE procedures is verified by the Authorized Inspection Agency (AIA). When there is a specific reason to question whether special process procedure requirements are being met, the Company, or the AIA may require re-evaluation of the procedure before work may proceed.

For special processes not covered by the existing codes or standards, or when the quality requirements of an item exceed the requirements of established codes or standards, the necessary qualifications of personnel, procedures and equipment shall be defined in the procedure.

2.4. Personnel Qualification

Company, contractor, and subcontractor personnel performing special processes are trained, tested, qualified, or certified in accordance with a procedure that meets applicable requirements. When permitted by applicable requirements, the Company may qualify and control contractor and subcontractor personnel.

The Company assures that qualification of Company, contractor, and subcontractor ASME Code NDE personnel is verified by the AIA. When there is a specific reason to question the ability of an individual performing special processes, the Company, or the AIA may require re-evaluation before that individual will be permitted to resume work. Individuals failing any retest will be removed from applicable operations pending re-qualification.

The appropriate NDE Level III is responsible for personnel and procedure development and qualification to ASME Code requirements for nondestructive examination. This position holder is qualified and certified in accordance with ASNT SNT-TC-1A / ASNT CP-189 and may designate qualified deputies for certification of personnel and procedures, and final Company authority of the interpretation of any NDE indication that has been recorded by a Level II Examiner or by a NDE contractor's Level III examiner.

Training and certification of personnel associated with nondestructive examination are carried out in accordance with the requirements of ASME NQA-1 and ASME Section XI. A Level III certified person administers all ASME Code examination activities.

2.5. Special Process Records

Special process records provide evidence that special processes were performed in accordance with approved procedures by qualified personnel. These records are retained by the Company or by the contractor or subcontractor as required by procurement documents. Records are maintained for currently qualified personnel, processes, and equipment for each special process.

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1. SCOPE

The Company plans and executes an inspection program to verify that activities affecting the quality of safety-related structures, systems, and components conform to documented requirements. For modification and non-routine maintenance activities, inspections are conducted in a manner similar (i.e. frequency, type and personnel performing such inspections) to those associated with construction phase activities. The independent inspections described in this Chapter are not intended to dilute or replace the clear responsibility of the first line supervisors for the quality of work performed under their supervision or personnel performing the activity.

2. REQUIREMENTS

2.1. General

The Company establishes controls for coordination and execution of inspection plans. Company quality verification organizations or other qualified organizations are responsible for implementation of established inspection plans. If an inspection plan includes inspections by personnel other than those in a quality verification organization, the inspection requirements, personnel qualification criteria, and inspector independence will be accepted by the responsible quality organization prior to implementation.

2.2. Inspection Plans

The Company prepares documented inspection plans. These inspection plans are applied when the activity is started. The inspection plans may be separate documents or an integral part of approved instructions, procedures or drawings. Related codes, standards, specifications and design documents are used to develop the inspection plans. Procedures used for documenting inspection plans are selectively reviewed, as appropriate, by NOS to assure that necessary verification points and inspection criteria are included. The plans identify:

- acceptance criteria.
- activities to be inspected.
- inspection characteristics.
- inspection techniques/equipment (including accuracy requirements).
- provisions for inspection and test status.
- provisions for the recording of inspection results.
- qualification requirements.
- responsible organizations.

2.3. Inspection Personnel and Qualification

A qualification program is established and documented to conform to applicable codes, standards, or licensing requirements. Qualifications and certifications are kept current.

Qualified personnel perform inspections. Inspectors with valid certifications perform inspections for acceptance. Inspectors are independent of those who perform or directly supervise the activity being inspected. On-the-Job training inspections shall be performed under the direct supervision of qualified personnel.

Second line supervisory personnel may conduct inspection of operating activities or other qualified personnel not assigned first line supervisory responsibility for the conduct of the work. Operating activities are defined as work functions associated with normal operations of the plant, routine maintenance, and certain technical services routinely assigned to the onsite operating organization.

2.4. Inspection Process

Inspections are performed using approved instructions, procedures, process sheets, travelers, or checklists and applicable drawings.

- Inspections are performed for each work or operating activity where necessary to verify quality. Where inspection sampling is used to verify the acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.
- Process monitoring may be used when inspection of processed material or products is impossible or impractical. When necessary, to ensure quality throughout the duration of the process, both inspection and process monitoring will be systematically used to verify conformance to requirements.
- When inspections must be performed before work can continue, hold points are established in appropriate documents. Consent to waive hold points are recorded prior to continuation of work. When inspection is desired, but not mandatory before work can continue, witness points are established. Completion of hold and witness points is documented.
- When acceptance criteria are not met, corrected areas are re-inspected. Changes to, or rework of, an item after inspection requires re-inspection of the affected areas. Such inspections are documented in the Corrective Action Program.
- A final evaluation is performed. Inspection results are reviewed to confirm that required inspections and quality records have been completed, identified non-conformances have been resolved and the item conforms to specified requirements. Engineering, Maintenance, Operations or Quality Verification approves final acceptance of the item.

- Inspection records are of sufficient detail to confirm completion and, as a minimum, identify:
  - authorized individual approving results.
  - date of inspection.
  - inspector/Data recorder.
  - item inspected.
  - M&TE used.
  - reference to action taken in connection with identified non-conformances.
  - results or acceptability.
  - type of observation.
- When the inspection activity is performed using a separate procedure, the procedure and its revision is recorded.

2.5. In-Service Inspections

A program for the required ISI/IST inspection of completed systems, structures and components shall be planned and executed by or for the organization responsible for the operation of the plant to assure that plant components perform satisfactorily under all operating conditions.

Inspection methods shall be established and executed to applicable codes, standards and regulations, including baseline examinations and subsequent periodic examinations, which continue through the life of the plant in accordance applicable technical specifications.

2.6. Independent Verification

Independent verifications are conducted by qualified personnel using approved procedures. Characteristics to be verified and methods to be employed shall be specified. Verification results and unacceptable conditions identified shall be documented. Verifications shall be performed by persons other than those who performed or directly supervised the work being verified. Personnel must have qualifications of greater than or equal to the activity being verified.

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1. SCOPE

A documented test program shall be established in accordance with applicable technical specifications, license conditions, and design documents to assure that all testing required demonstrating that the structures, systems, or components within the scope of this QAP will perform satisfactorily in service.

2. REQUIREMENTS

2.1. General

2.1.1. Testing Program

The Company establishes and controls a test program to assure that design and performance criteria have been satisfied and assures that testing does not adversely affect the safe operation of the plant. The test program includes, as appropriate, procedures to ensure those structures, systems, subsystems, and components will perform in service. Testing is conducted by appropriately trained and qualified personnel. The extent of testing shall be based on the complexity of the modification, replacement, or repair. The test program covers all required tests including:

- operational tests.
- production tests.
- prototype qualification tests.
- tests during design.
- tests during fabrication.
- the demonstration of satisfactory performance following plant maintenance and modifications or procedural changes.
- those tests required by plant maintenance or modifications.

2.1.2. Test Procedures

The program uses written test procedures which include the requirements and acceptance limits from applicable design documents. The Company reviews and approves test procedures and changes to test procedures, including changes that alter test sequence, in a similar manner to the original.

The organization responsible for the design of the item to be tested establishes the test requirements and acceptance criteria. Test requirements and acceptance criteria are based upon specified requirements contained in applicable design or other pertinent documents. Test requirements include specific characteristics to be tested.

The Company specifies specific test methods when they must be employed, uses written procedures or checklists, and documents the status of equipment both before and after testing.

The Company may use appropriate sections of related documents, such as ASTM methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria in lieu of specially prepared written test procedures. Such documents must include adequate instructions to assure the required quality of work. Test and inspection procedures contain:

- a description of objectives.
- acceptance criteria or limits contained in applicable design or other source documents, such as vendor's literature, engineering drawings or plant specifications that will be used to evaluate results.
- any special equipment or calibrations required to conduct the test or inspection.
- responsibilities.
- instructions or checklists used to verify or document that affected plant systems are arranged in their correct lineup and for restoring the system to the condition consistent with the normal operating status.
- limiting conditions.
- prerequisites for, or checks to be made prior to performing the tests or inspections including any special conditions to be used to simulate normal or abnormal operating conditions.
    - data documentation is in compliance with test procedures.
    - equipment to be tested is properly released for testing.
    - inspections and tests are done under suitable environmental conditions.
    - proper calibrated inspection and test instruments are used.
    - retention control of test data documentation is adequate.
- test or inspection requirements contained in applicable design documents.

Where tests and inspections are to be witnessed, the procedure identifies hold points or witness points in the testing sequence to permit witnessing. The procedure requires appropriate approval for the test to continue beyond the designated hold point.

1. Prerequisites

Prerequisites include the following, as applicable:

- appropriate test equipment.
- calibrated instrumentation in accordance with Chapter 12, "Control of Measuring and Test Equipment."
- condition of test equipment and the item to be tested.
- provisions for data acquisition.
- suitable environmental conditions.
- trained personnel.

Procedures ensure that prerequisite steps for equipment testing have been or will be performed. Such steps include:

- completion of necessary construction maintenance and modification activities.
- formal release for testing.
- measures to preserve equipment status.
- prior testing.
- safety precautions.

A detailed prescribed physical inspection of equipment components and facilities is performed to ensure readiness for operation. Typical inspection items include:

- calibration of instruments.
- cleanliness.
- lubrication.
- presence of safety devices.
- setting of limit switches.

2. Schedule

Schedules are provided to assure that all necessary tests are performed and properly evaluated on a timely basis. Testing is scheduled so that the safety of the plant is never dependent on the performance of an untested system.

3. Test Results and Records

Appropriate Company personnel evaluate test results to assure conformance with design and performance requirements. Inspection and test results are documented in a test report or data sheet. Each report identifies the following:

- acceptability of the test.
- actions taken to correct the deviations noted.
- any deviation of test results from acceptance criteria (nonconformance).
- as-found condition.

- as-left condition.
- completion date and other significant dates and times.
- data sheets completed during the tests.
- documents that provide acceptance criteria.
- identification of the conditions encountered which were not anticipated.
- identity of inspector or tester.
- item to which it applies.
- location where testing was performed or where test samples were taken.
- measuring and test equipment used.
- person evaluating test results.
- procedures or instructions followed in performing the task.
- test procedures.
- test results.

2.2. Instrumentation and Control

The Company tests instrumentation and control channels to assure that they are properly calibrated. In addition, specific tests are performed at critical levels such as "set points" in a manner simulating the approach toward the set point. These calibrations are made with the devices in their normal positions if the calibration is dependent upon location or attitude.

Testing determines that a proper response is obtained over the operating range of the device. It gives particular attention to verifying independence and dependence, as appropriate, of the elements of the systems. Calibration documentation includes indicating the date and identity of the person that performed the calibration.

The Company prepares and documents installation, inspection and test procedures and work instructions for instrumentation and electrical equipment. These documents are kept current and revised as necessary to assure that installation, inspections and tests are performed in accordance with latest information. They include as appropriate:

- approvals.
- data report forms.
- frequency of inspection or test.
- identification of test equipment and date for required re-calibration where required for interpretation of test results.
- inspection and test acceptance limits.
- inspection and test equipment required.
- inspection and test objectives.
- installation specifications.

- precautions to avoid component or system damage during testing or inspection.
- prerequisites.
- sequence of tests (if applicable).
- sequential actions to be performed.

2.3. Electrical Tests

Electrical tests include as appropriate:

- continuity tests, short circuit tests, polarity and rotational tests
- control system tests including indicating meters, recorders, transducers, targets and lamps, annunciators and alarms, controls and interlocks
- insulation resistance measurements as specified
- over potential (HIPOT) tests as specified. Overpotential tests conform to the applicable codes and standards. The manufacturer's recommendations are considered.
- voltage breakdown tests on liquid insulation

2.4. Mechanical Tests

The Company performs mechanical tests to ascertain that electric and/or instrumentation components or systems can withstand system pressure ratings. As a minimum, the Company applies such tests to pressure sensing and transmitting devices operating in steam, hydraulic, and vacuum systems and their hydraulic or pneumatic interconnecting piping or tubing and associated instruments.

Pressurized equipment that is part of electrical apparatus such as heat exchangers, circulating systems, actuating systems, and electric and instrumentation containment penetrations are likewise tested if site assembled or fabricated. Tests are conducted after the assembly is complete even though the components may have been tested previously. These tests are performed in accordance with the applicable codes and standards.

2.5. Physical and Chemical Tests

Physical and chemical tests, in accordance with the applicable codes, include, as appropriate:

- chemical analysis of fluids for oxygen or moisture content and purity.
- radiation sensitivity testing to confirm that radiation sensor and controlling devices is properly functioning.

2.6. Surveillance Tests

The Company's test program covers surveillance testing during the operational phase to provide assurances that failures or substandard performance do not remain undetected and that the required reliability of safety related systems is maintained.

2.7. Maintenance or Major Procedure Change

The Company performs tests following plant modification or significant changes in operating procedures to confirm that the modification or changes produce expected results. These tests also demonstrate that the change does not produce an unsafe operating condition.

1. SCOPE

Measures and responsibilities are established to assure tools, gauges, instruments, and other Measuring and Testing Equipment (M&TE) used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within specified limits. Measures shall also be established for the control of permanently installed instrument and control devices.

2. REQUIREMENTS

2.1. General

Exelon Power Labs is responsible for the governance of M&TE for Exelon plants. This includes the establishment of calibration practices, intervals, accuracy requirements, certification/de-certification, and equivalency decisions (except where accuracy is impactive non-conservatively), as well as the resolution of technical issues regarding M&TE calibration.

The ROG engineering organizations are responsible for decisions regarding the acceptability of changes to M&TE specifications where accuracies are less conservative than those currently established. The engineering organization performs M&TE equivalency calculations for these items to assure associated specifications are consistent with plant design, test procedures, and accuracy requirements (excluded are analytical chemistry and radiochemistry instruments).

The stations are responsible for the control and maintenance of calibrated M&TE for the station. The stations are also responsible for the control of station analytical chemistry instrumentation, radiochemistry instrumentation, and standard solutions.

2.2. Control

A control program specifies how M&TE are stored, handled, and used. As a minimum the following items are addressed:

- administrative controls (including equipment marking and traceability to calibration records).
- certification requirements.
- damaged or suspect M&TE.
- environmental restrictions.
- items not requiring certification.
- M&TE selection.
- out of tolerance resolution.

- personnel qualifications.
- repairs and maintenance.
- status and usage history.

2.3. Labeling

Equipment shall be suitably marked to indicate calibration status. Where neither labeling nor coding is practical, procedures shall provide for monitoring of records to ensure control.

2.4. Accuracy

Calibration of M&TE should be against reference standards that have an accuracy of at least four times the required accuracy of M&TE. Calibration of reference standards will be against hierarchical standards more accurate than the reference standards calibrated. When this is not possible, standards must have an accuracy that assures the M&TE is within the required tolerance, and that the basis for acceptance is documented and authorized by responsible management.

2.5. Traceability and Interval

M&TE is calibrated against and traceable to certified standards having valid relationships to nationally recognized standards. Where national standards do not exist, provisions are established to document the basis for calibration. Calibration intervals are established for all M&TE and the Company program specifies how this interval is established.

2.6. Certified M&TE

Certified M&TE is required where measurements with specific accuracy/tolerance requirements are delineated:

- calibration of other M&TE.
- environmental monitoring.
- safety-related and applicable ASME applications.
- technical Specification related applications (including balance of plant systems).
- verification of design parameters.

Certified M&TE is not required when measurements do not require specific accuracy or when commercial devices (such as rulers, tape measures, levels) provide adequate accuracy.

2.7. Corrective Actions

When M&TE is found to be out-of-tolerance, an evaluation is made of its previous uses to determine corrective action. Suspect equipment is identified and segregated to prevent inadvertent use.

2.8. Vendor Control

Vendors supplying calibration services are on the Company's approved suppliers list.

2.9. Commercial Devices

Control measures are not required for rulers, tape measures, levels, and other such commercial devices, if such equipment provides adequate accuracy.

2.10. Calibration Records

M&TE calibration records contain, as a minimum:

- as found/as left condition.
- calibration data.
- calibration procedure used.
- calibration results.
- equipment location.
- established accuracy.
- individual performing calibration.
- last calibration date.
- next calibration date.
- out of tolerance notification.
- repairs (if any).
- serial number.
- standards used.

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1. SCOPE

The Company establishes measures to control and specify special protective conditions in accordance with an item's design and procurement requirements, as necessary, to prevent damage or deterioration of materials, components, and systems during handling, packaging, preservation, storage, and shipping.

2. REQUIREMENTS

2.1. General

The Company uses written procedures or instructions for cleaning, packaging, shipping, storage, preservation, and to specify detailed requirements for access to storage areas, housekeeping, and removal of items from storage. Procedures include provisions for inspection, examination, testing and documentation. These procedures specify special protective conditions necessary to prevent damage, deterioration or loss before and after receipt of materials, equipment, special nuclear material, and radioactive wastes.

Procurement documents or the vendor's quality program specifies the establishment of controls, to assure through the use of shipping procedures to provide protection during loading and transit and inspections, that items are delivered in acceptable condition.

2.2. Special Equipment and Environments

When required, the Company:

- provides special equipment and special protective environments
- specifies special equipment (such as containers, shock absorbers and accelerometers)
- specifies special protective environments (such as inert gas atmosphere, specific moisture content levels and temperature levels)
- verifies the maintenance of special equipment and special protective environments

2.3. Classification of Items

Levels and methods of storage are classified to minimize the possibility of damage, deterioration, or contamination of items. This is based on the important physical characteristics and the importance to safety and reliability of the item. This classification considers the manufacturer's requirements.

The Company packages, ships, receives, stores, and handles items according to established manufacturers requirements or the Company's' prescribed level. When a package or assembly contains items of different levels, the Company classifies it to the highest level designated for any of the items contained.

2.4. Special Handling Tools and Equipment

The Company inspects and tests special handling tools and equipment using procedures at specified time intervals to verify adequate maintenance. The Company provides special handling procedures and instructions for items that are susceptible to handling damage. These procedures delineate acceptable techniques, necessary qualifications and precautions for maintenance and use. Operators of special handling and lifting equipment have experience or are trained in their usage.

2.5. Marking and Labeling

The Company establishes instructions for marking and labeling to identify, maintain, and preserve an item, including indication of the presence of special environments or the need for special controls.

Consumable materials such as chemicals, reagents, and lubricants maintained in storerooms and warehouses are controlled procedurally by an inventory control system, which includes provisions for identifying storage requirements and shelf lives by commodity, when applicable. Disposal of commodities whose shelf life has expired is addressed and controlled by procedures.

2.6. Storage

Periodic monitoring is performed to assure that storage areas are being maintained in accordance with applicable requirements. Access to storage areas shall be controlled and limited. Cleanliness and good housekeeping practices shall be enforced at all times in the storage areas. Fire protection measures commensurate with the type of storage area shall be provided and maintained .

1. SCOPE

Measures shall be established and documented to identify inspection, test, and operating status of structures, systems, and components in the scope of this QAP. Such measures shall provide means for assuring that required inspections and tests are performed and that the acceptability of items with regard to inspections and tests performed is known throughout procurement, installation, and operation in order to preclude inadvertent bypassing or altering the sequence of such inspections and tests.

2. REQUIREMENTS

2.1. General

The Company uses markings, tags, stamps, routing cards, labels, forms, inspection records, or other means to identify the operating status of plant equipment. This identification helps avoid inadvertent bypassing of the inspections and tests required prior to its use.

In cases where documentary evidence is not available to confirm that an item has passed required inspections and tests, that item shall be considered nonconforming. An operability determination for the nonconforming item with timeliness commensurate with the potential safety significance of the issue is performed. The operability determination is focused on whether the non-conforming item is capable of performing or supporting its specified functions of prevention or mitigation as described in the current licensing basis and will result in the determination of continued plant operation. If operability is assured based on this prompt determination, plant operation can continue while an appropriate corrective action program is implemented to restore qualification of the non-conforming item.

Control procedures describe the use of such tags, stamps, routing cards, labels, forms, inspection records, and other methods. The authority for application and removal of tags, markings, labels and stamps is specified. Tagging, labeling, color-coding, physical separation, or using an inventory system identifies acceptable or unacceptable items for installation.

The Company:

- clearly identifies and documents all temporary connections, such as jumpers and bypass lines, and temporary set points of control equipment to allow restoration before placing the item in service.
- conditionally releases items for installation pending subsequent correction of any non-conformances.
- indicates the date the item was placed in the acceptable or unacceptable installation status.

- maintains records, marks equipment to indicate calibration status, and identifies test equipment found out of calibration.

2.1.1. Procedures

The Company uses procedures for control of equipment to maintain personnel and reactor safety and to avoid unauthorized operation of equipment. These procedures require control measures such as locking or tagging to secure and identify equipment in a controlled status. The procedures require independent verifications, where appropriate, to ensure that necessary measures, such as equipment tagging, have been done correctly.

2.2. Operating Status

2.2.1. Release for Maintenance

Operating personnel, including a senior reactor operator, as applicable, may grant permission to release plant systems or equipment for maintenance or surveillance testing. Prior to granting permission, such operating personnel:

- verify that the equipment or system can be released.
- determine how long it may be out of service.
- determine what functional testing or redundant systems are required prior to and during the out-of-service period.

The Company documents such permission. The Company uses independent verification to the extent necessary to ensure that the proper system was removed from service. The Company considers the degraded protection available when one subsystem of a redundant safety system has been removed for maintenance or surveillance testing.

2.2.2. Preparation for Work

After permission has been granted to take the equipment out of service, measures provide for protection of equipment and workers. The Company clearly identifies the status of equipment and systems at any location where the equipment can be operated. The Company enforces strict control measures for such equipment. The operating staff can easily identify equipment, which is in other than normal conditions.

In addition to the requirements of the technical specifications, conditions to be considered in preparing equipment for maintenance or surveillance testing include, for example:

- electrical hazards.
- entry into closed vessels.
- establishment of a path for decay heat removal.
- handling hazardous materials.
- hazardous atmospheres and ALARA considerations.

- method of emergency core cooling.
- shutdown margin.
- temperature and pressure of the system.
- valves between work and hazardous materials.
- venting, draining, and flushing.

When entering a closed system, the Company prevents the entry of extraneous material and removes foreign material before re-closing the system. Appropriate personnel inform control room supervision of changes in equipment status, including temporary modifications, and the effects of such changes.

2.2.3. Temporary Modifications

The Company controls temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings with approved procedures. These procedures include requirements for the period of time when the temporary modification is in effect. They also include a requirement for:

- an independent verification by a second person of the proper installation or removal of the temporary modification, or
- a functional test which conclusively proves the proper installation or removal of the temporary modification.

The Company maintains a log or other documented evidence for the current status of such temporary modifications. The Company reviews temporary modifications periodically to assess their continued need and propriety.

2.2.4. Return to Service

When equipment is ready to be returned to service, operating personnel place the equipment in operation and verify and document its functional acceptability. The Company assures return to normal conditions using approved procedures, including:

- removal of electrical jumpers.
- removal of signals used during testing.
- returning valves, breakers, or switches to proper start-up or operating positions.
- assuring that all alarms, which are indicative of inoperative status, are cleared.

A second qualified person verifies proper alignment of equipment unless:

- all equipment, valves and switches involved in the activity can be proven to be in their correct alignment by functional testing without adversely affecting the safety of the plant, or
- such verification would result in significant radiation exposure.

The person who performs verifications (independent or concurrent) is qualified to perform such tasks. When placed into service, equipment receives additional surveillance during the run-in period. The on-duty supervisor responsible for the unit formally accepts equipment, which is returned to service.

1. SCOPE

Controls shall provide for identification, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations. Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.

2. REQUIREMENTS

2.1. General

Nonconforming items are processed in accordance with the corrective action program and / or documented procedures. The Company uses written procedures to identify and control items, services or activities that do not conform to requirements. These procedures address the:

- disposition of nonconforming items.
- documentation of identified nonconformances.
- identification of nonconforming items.
- notification of affected organizations.
- operability determination of the SSC with the identified nonconforming condition
- segregation of nonconforming items.

Implementation of these procedures prevents the inadvertent use, operation, or unauthorized installation of nonconforming items.

2.1.1. Supplier Nonconforming Items

The Company and its suppliers establish and document measures for the identification, control and disposition of items and services that do not meet procurement document requirements. These measures provide for:

- a review of nonconforming items.
- supplier notification to the Company of a nonconformance. These notifications include a supplier recommended disposition (e.g. "use - as - is" or "repair") and technical justification. The supplier submits nonconformances to the Company for approval if:
  - the supplier has violated a technical or material requirement, or
  - the supplier has violated a requirement in supplier documents, which have been approved by the Company, or
  - the supplier cannot correct the nonconformance by continuation of the original manufacturing process or by rework, or

- the item does not conform to the original procurement requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

- Company disposition of supplier recommendations.
- verification of disposition for nonconformances.
- maintenance of records for supplier nonconformances.

2.2. Identification

The Company identifies nonconforming items by marking, tagging, or other methods, which do not adversely affect the end use of the item. The identification is legible and easily recognizable.

2.3. Segregation

When practical, the Company segregates nonconforming items by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight or access limitations, other precautions are employed to preclude inadvertent use of a nonconforming item.

2.4. Disposition

2.4.1. Control

Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.

2.4.2. Evaluation

The Company has responsibility for resolution of nonconformances in accordance with written procedures. Where ASME Code requirements are involved, the Authorized Inspection Agency reviews and accepts or rejects the disposition and justification. Engineering provides technical justification and independent review of the disposition for the nonconformance. For items under a contractor's direct control, the Company may delegate to the contractor the authority to perform a technical evaluation of nonconformances, if the contractor has an acceptable procedure for handling nonconforming items. Where the Company delegates such authority, the contractor is responsible for establishing that:

- all actions fall within the requirements set by the Company.
- an accepted nonconformance meets the design intent.
- ASME Code items meet the requirements of the ASME Code.

– personnel performing the evaluation meet the requirements of section 2.4.3 below.

When a technical evaluation has not been delegated to a supplier, the Company makes a technical evaluation of all pertinent data relating to the nonconformity, including the cause, where known, and the corrective action either taken or planned to prevent recurrence per the corrective action program. The Company retains the responsibility for the satisfactory resolution of supplier nonconformances.

2.4.3. Personnel

Personnel having expertise in the pertinent discipline determine whether a nonconforming item may be accepted "as - is," may be repaired to an acceptable condition, or must be rejected. These personnel have adequate competence and knowledge necessary to make this evaluation and have access to pertinent background information.

2.4.4. Documentation

The Company identifies nonconforming items and documents their disposition (e.g. use - as - is, reject, repair, or rework). Each disposition is technically justified and traceable to each item. Appropriate documentation is retained.

Nonconformances to design requirements that are dispositioned as "use - as - is" or "repair" is subject to design control measures commensurate with those applied to the original design. The Company technically justifies dispositions designated "use - as - is," and "repair" to assure that the final condition of any nonconforming item meets applicable code requirements and will not adversely affect the safety, operability, or maintainability of the item, or of the component or system in which it is installed. The "as - built" records, if such records are required, reflect the accepted deviation.

If the nonconformance can be corrected after installation, the item may be released for installation on a conditional release basis. The Company documents the authority and technical justification for the conditional release of the item and makes it part of the documentation.

2.4.5. Repaired, Reworked, or Scrapped Items

The Company re-examines repaired or reworked items using procedures and the original acceptance criteria unless the nonconforming item's disposition has established alternate acceptance criteria. Items that have been corrected are re-inspected or re-tested as required by the approved disposition.

The area of inspection may be confined to the area of the nonconformance. When it has been determined that the corrected item is satisfactory, the status of the item is changed to "acceptable" and an appropriate entry is made in the documentation after acceptance is determined.

The Company scraps, discards or transfers to training usage a nonconforming item that cannot be corrected or accepted "as - is." Nonconforming items that are being used for training must be permanently identified and marked to prevent inadvertent or inappropriate use of the item.

1. SCOPE

This Chapter describes the Company program to identify and correct conditions adverse to quality.

2. REQUIREMENTS

2.1. General

The Company implements a Corrective Action Program to promptly identify and correct items or occurrences that are adverse to quality or might adversely affect the safe operation of a nuclear generating station. These items or occurrences are screened for reportability, operability, Part 21, etc. The Company makes a thorough investigation of occurrences and identifies corrective action to prevent recurrence of an event, as appropriate. Events may include reactor trips, failed equipment, personnel errors, and procedural infractions. Measures are taken to assure that the cause of any significant condition adverse to quality is determined and takes corrective action to prevent recurrence.

2.2. Conditions Adverse to Quality

Measures are established to assure that conditions adverse to quality are identified and corrected. Examples of conditions adverse to quality are provided in procedures. Examples include failures, malfunctions, adverse trends, deficiencies (including programmatic), deviations, defective material, design errors, equipment, and nonconformance to specified requirements.

An independent review body reviews violations, deviations and reportable events that require a report to the NRC in accordance with regulatory requirements and company procedures. This includes the review of results of any investigations made and the recommendations resulting from such investigations. These include items such as:

- events, as defined in applicable site technical specifications.
- significant operating abnormalities or deviations from normal or expected performance of plant safety-related structures, systems, or components.
- violations of applicable codes, regulations, orders, technical specifications, license requirements or internal procedures or instructions having safety significance.

2.2.1. Significant Conditions Adverse to Quality

In cases of significant conditions adverse to quality the cause of the condition is determined and documented, resolution determined and documented, and corrective action taken and documented to preclude recurrence.

1. Procurement

The Company uses procedures that include methods for the identification of conditions adverse to quality and for timely corrective action. The Company requires individual vendors and their contractors to include corrective action measures in their quality assurance programs. In cases of significant conditions adverse to quality that arise during the procurement process, the Company uses procedures to describe the method used to:

- identify and document deviations and non-conformances.
- review and evaluate the conditions to determine the cause, extent and measures needed to correct and prevent recurrence.
- report the conditions and corrective action to the appropriate levels of management.
- implement and maintain required corrective action.

2. Plant Hardware Malfunctions

The causes of malfunctions are determined, evaluated, and recorded, as appropriate. Experience with the malfunctioning equipment and similar components are reviewed and evaluated to determine if a replacement component of the same type can be expected to perform the function reliably. If evidence indicates that common components in safety-related systems have performed unsatisfactorily, corrective measures are planned prior to replacement or repair of all such components. Appropriate procedures are revised in a timely manner to prevent recurrence of equipment malfunction or abnormal operation.

3. Incorrect Design

When a significant design change is necessary because of an incorrect design, the Company reviews and modifies the design process and verification procedures, as appropriate. In cases of significant or recurring deficiencies (or errors), the Company follows written procedures to correct the deficiency (or error), determine the cause and make changes in the design process and the QAP to prevent similar types of deficiencies (or errors) from recurring.

2.3. Verification and Follow-up

The Company verifies completion of corrective actions for maintenance, repair, refueling, operation activities, completion of corrective action taken for assessment deficiencies (including programmatic), and performs assessments of site corrective action. The Company tracks and verifies completion of corrective action taken for independent assessment findings and approves the completion of corrective actions.

Trending and assessment results are evaluated to assure that corrective measures are implemented effectively and that actions to prevent recurrence are effective as appropriate. The Company also requires contractors and vendors to follow-up on corrective action commitments within their quality programs.

The Company regularly reviews and analyzes records to:

- assure that the causes of a nonconformance and the corrective action have been clearly described.
- assure that authorized Company personnel have evaluated the overall effect resulting from the use of nonconforming items.
- determine whether corrective measures will preclude recurrence.

2.4. Evaluation and Qualification

Personnel performing the evaluation function are responsible for considering the cause and the feasibility of corrective action to assure that the necessary quality of an item is not deteriorated. Where it is determined that the cause cannot be corrected immediately, the due date of corrective action will be determined during the review and evaluation. Evaluation may indicate the need for investigations to assure that corrective measures are considered complete and may also indicate that the nature of the deficient condition is minor and does not require corrective action.

Qualified personnel are responsible for determining the root cause(s) of an event and developing recommendations to preclude recurrence. These personnel report the results of their determination to appropriate station personnel and Company management.

2.5. Documentation and Reporting

The Company documents the identification of significant conditions adverse to quality, the cause of the condition, the corrective action taken, and reports these items to the appropriate levels of management, PORC, and the NSRB. If the identified issue is not an indication of a significant failure in any portion of the QAP, the Company does not require reporting to management.

Reports are made immediately if prompt corrective action is required. Formal reports are filed with the appropriate regulatory agency, when required. Reports of investigations include a detailed description of the occurrence, the findings of the investigation, and the recommended corrective measures. The Company notifies the rest of the nuclear industry of significant events with generic implications and its circumstances to help preclude a similar event occurring at another plant.

The Company keeps records to identify incidents (e.g., major damage, personal injury, major schedule delays.), non-conforming items, unfavorable conditions, programmatic deficiencies identified in assessment reports, significant equipment failures, and malfunctions that occur during station operation.

The Company tracks the completion of corrective actions for conditions adverse to quality and maintains records of their resolution. Parts or all of this system may be electronically monitored and electronic records may be used as the sole record of such a system.

1. SCOPE

The Company establishes and implements a program which defines requirements and responsibilities for identification, generation, collection, compilation, storage, maintenance, retention, and retrieval of records necessary to provide evidence of quality in design, fabrication, installation, inspection, testing, and operating activities.

2. REQUIREMENTS

2.1. Program

The records program provides for:

- administration.
- receipt and transmittal.
- storage and preservation.
- safekeeping and classification.
- retention and disposition.

2.2. Administration

Authority and responsibility for record control activities are delineated in procedures. Records are administered through a system, which includes an index of record type, retention period, and storage location. Distribution of records shall be controlled in accordance with written procedures. Measures are established for replacement, restoration, or substitution of lost or damaged records.

Records are legible, accurate, complete, identifiable, and retrievable. Records are considered valid and complete when dated and stamped, initialed, signed, or otherwise authenticated. Corrections, revisions, or supplements to completed records are reviewed and approved by an authorized individual in the originating organization. Such changes are dated and stamped, initialed, signed, or otherwise authenticated including the use of electronic approval and authorization.

Records may be stored in electronic media provided that the process for managing data is documented in procedures that comply with applicable regulations. Electronic records retention must be an integral component of the Corporate Records Management Program, approved by the management position responsible for Nuclear Generation records. The format used must be capable of producing legible, accurate, and complete documents during the required retention period. Electronic approval and authorization procedures are established to assure that only those persons authorized grant the required approvals.

2.3. Receipt and Transmittal

A system for receipt control of records is established. Receipt control is required for records transferred between Company locations, vendors and the Company, and from Company department files to final storage locations. Systems are established to transfer records between Company locations and between vendors and the Company. Records transferred from Company department files to a final storage location are also under such systems. The system includes inventory of transmitted records, receipt acknowledgment, and control of records during receipt.

2.4. Storage and Preservation

Record storage facilities are established and maintained in a manner that minimizes the risk of damage or destruction. Interim storage provisions shall be established to properly maintain and protect records until they are permanently transferred to record storage facilities for retention. Records may be kept by suppliers and maintained on an available basis for a specified period of time. Storage and Preservation systems provide for:

- assignment of responsibilities.
- attachment in binders, folders, or envelopes for storage in steel file cabinets or on shelving in containers.
- control and accountability of records removed.
- damage from natural disasters such as winds, floods, and fires.
- following manufacturer recommendations for special recording media.
- protection from environmental conditions such as high and low temperatures and humidity.
- protection from infestation of insects, mold, or rodents etc.
- special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media to prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity.

2.5. Safekeeping and Classification

Measures are established to prevent access to records by unauthorized personnel. These measures guard against theft and vandalism. Records are classified and retained in accordance with applicable regulations.

2.6. Retention and Disposition

Record retention periods are established to meet regulatory, UFSAR, and License requirements. The most stringent retention period is implemented when multiple requirements exist.

Record retention requirements for Limerick Generating Station are also defined in Technical Specifications. Records are dispositioned at the end of the prescribed retention period.

2.7. Plant Operating Records

2.7.1. Records and/or Logs, 5-Year Retention

Records and/or logs relative to the following items shall be kept in a manner convenient for review and shall be retained for at least 5 years. These items apply to Braidwood, Byron, Clinton, Dresden, LaSalle, Limerick, Peach Bottom (including the Independent Spent Fuel Storage Installation), and Quad Cities Stations unless otherwise noted:

- records of normal plant operation, including power levels and periods of operation at each power level.
- records and periodic checks, inspection and/or calibrations performed to verify that the surveillance requirements of the Technical Specifications (and Fire Protection Program at Clinton) are being met. All equipment failing to meet surveillance requirements and the corrective action taken shall be recorded.
- records of physics tests and other tests pertaining to nuclear safety. (Braidwood, Byron, Dresden, LaSalle, Peach Bottom, Quad Cities)
- records of changes to procedures required by a station's Technical Specifications and other procedures, which affect nuclear safety, as determined by the management position holder responsible for plant operation.
- shift manager/engineers' logs (Braidwood, Byron, Dresden, LaSalle, Quad Cities)
- records of principal maintenance activities, including inspection and repair, (and replacement for Braidwood, Byron, Limerick and Peach Bottom) regarding principal items of equipment pertaining to nuclear safety.
- by-product material inventory records and records of sealed source and fission detector leak tests and results (Braidwood, Byron, Clinton, Limerick, Peach Bottom and Zion).
- by-product material inventory records and source leak test results (Dresden, Clinton, and Quad Cities).
- records of changes made to the equipment or reviews of tests and experiments to comply with 10CFR50.59 (Dresden and Quad Cities).
- records of changes made to the procedures as required by Technical Specifications and the Operational Requirements Manual (Clinton).
- reportable events required by 10CFR50.73 and 10CFR72.216 as applicable (Clinton 10CFR50.73 only, Limerick and Peach Bottom).
- records of radioactive shipments (Limerick)

2.7.2. Lifetime Records

Lifetime records are those that are specified by applicable regulations, standards, codes, and licensing basis documents.

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1. SCOPE

A documented, comprehensive system of planned and periodic performance based assessments of the Company and its vendors are conducted to verify QAP compliance, adequacy, and effectiveness. Assessments are conducted in accordance with written procedures and to the requirements of ASME NQA-1 to evaluate the assessed organization and to assure completion of required corrective actions, commitments, or improvements and determine effectiveness in meeting program objectives. For internal assessments, the term "audit" and "assessment" are synonymous.

2. REQUIREMENTS

2.1. Assessments - General

2.1.1. Scheduling

Internal assessments shall be conducted on a performance driven frequency, not to exceed 24 months or at a frequency indicated in Appendix B, "Assessment Frequency," in accordance with the Company QAP and procedures. Planned and comprehensive performance based assessments are conducted to assure that safety related functions are fully evaluated. Internal assessments are performed to a schedule that includes required assessment areas and frequencies. The management position responsible for NOS, or designated staff member(s), approves them. Schedules are reviewed semi-annually and revised accordingly to assure that coverage is maintained current.

2.1.2. Preparation

A documented plan or an agenda identifies the assessment scope, requirements, assessment personnel, activities to be assessed, organizations to be notified, applicable documents, and schedule. An approved checklist or procedure for each scheduled assessment identifies the quality and technical elements of the area or items to be evaluated. Assessment plans, agendas, checklists, and procedures as applicable are prepared in advance under the direction of an Assessment Team Leader (ATL).

2.1.3. Personnel

Experienced and qualified personnel perform assessments and are familiar with written procedures, standards, and processes applicable to the area being assessed. Assessment personnel shall have sufficient authority and organizational freedom to make the assessment process meaningful and effective and shall not have direct responsibilities in the areas to be assessed. They shall have access to plant records necessary to fulfill the assessment function.

The ATL shall organize and direct the assessment and ensure the assessment team collectively has the required experience or training for the activities to be assessed. Technical specialists may supplement the assessment team to provide additional experience and competence.

2.1.4. Performance

Performance based assessments are conducted to assess specific activities, processes, and records on the basis of their impact and importance relative to safety, reliability, and functionality. Assessments can be focussed on areas most in need of improvement. Objective evidence shall be examined to the extent necessary to determine that a quality program is being effectively implemented.

Assessments are initiated early to assure effective quality assurance during design, procurement, manufacturing, construction, installation, inspection, testing, and operations. Additional unscheduled assessments may also be performed at various stages of activities, based on the nature and safety significance of the work being done; to verify continued adherence to and effectiveness of the quality systems.

2.1.5. Reporting and Follow-up

An assessment report includes the description of the assessment scope, identification of the assessment team and personnel contacted during assessment activities, a summary of results (including a statement on effectiveness of the QAP elements), and a description of each finding. The ATL shall sign the assessment report for which he or she is responsible.

Assessment results are documented and distributed to the management position of the assessing organization and to the appropriate managerial level of the organization having responsibility for the area or activity assessed. Deficiencies requiring prompt corrective action are reported immediately to the management of the assessed organization.

Findings and recommendations of each assessment shall be reported to appropriate site management and the management position responsible for NOS. All findings of noncompliance with NRC requirements, and any significant nuclear safety or quality issue, requiring escalated action, will be directed through the management position responsible for NOS to the President and CNO.

Responsible management shall take the necessary actions to correct findings identified in the assessment. They will identify the corrective action to be taken, actions that will prevent recurrence, and a schedule for implementing these actions.

Verification of the completion of scheduled corrective action commitments is performed to assure findings or adverse conditions are corrected. Follow-up action of previous deficient areas or adverse conditions (including re-assessment) is taken to verify that corrective action has been completed, is effective, implementation continues, and is properly documented, when indicated.

2.1.6. Records

Assessment results are documented and reports are generated and retained. Associated documentation is on file at the appropriate location. Personnel qualification records for assessment team members are established, maintained, and reviewed.

2.2. Vendor Assessments

Assessments, audits, or surveys of vendors and their sub-tier suppliers are performed to a pre-established schedule. The management position responsible for evaluation of suppliers, and/or the ATL, shall review and approve the assessment/audit/survey schedule and checklists, and sign reports. Schedules are reviewed semi-annually and revised accordingly to assure that suppliers are assessed, audited, or surveyed as required.

Assessment program requirements are imposed on suppliers by appropriate contract or procurement documents. The Company's active participation in nuclear industry assessments provides an alternative means to fulfilling its responsibility for examining suppliers activities.

2.3. Independent Management Assessment

A periodic assessment (not to exceed 24 months) of the status and adequacy of the QAP is performed by an independent organization to assure that assessments are being accomplished to program requirements. The management position responsible for NOS submits the results of this assessment to the President and CNO.

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1. SCOPE

It is the Company's policy to assure a high degree of availability and reliability for its nuclear plants while ensuring the health and safety of the public and its workers. Therefore, the Quality Assurance Program is applied in a graded manner to certain areas and activities that are not clearly defined as safety related. The Company calls this application Augmented Quality. Augmented Quality includes systems and components that are subject to the requirements of ASME Code Sections: I "Power Boilers," IV "Hot Water Heaters," and VIII "Non-fired Pressure Vessels" (see sub-section 2.7. below). This appendix applies to all sites unless otherwise noted below or in Appendices B through G.

2. REQUIREMENTS

The Company applies the following augmented quality requirements to certain systems, structures, components (SSC), and activities that are not safety related to a degree consistent with their importance to safety. Unless otherwise noted:

- routine audits are performed of the program's content and implementation.
- deficiencies are addressed in accordance with the corrective action program.
- program records of audits and reviews are maintained as required.

2.1. Health Physics and ALARA (As Low As Reasonably Achievable)

The Company develops, documents, and implements a radiation protection program sufficient to ensure compliance with the provisions of 10CFR20. The Company uses, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are as low as reasonably achievable.

2.2. Transport of Radioactive Waste

When the Company contracts with vendors to transport radioactive waste in NRC approved shipping packages, it meets the requirements of 10CFR71, Subpart H. The Company assures that this service is procured from an organization with a QA program and if applicable, includes a NRC licensed transport system. Loading, surveying, closure, placarding, and inspections are conducted in accordance with written procedures and instructions.

Transport casks and trailers are inspected before release in accordance with Department of Transportation (DOT) 49CFR.

Shipping manifests, including final radiation surveys, are completed and retained. Radioactive waste shipments not meeting the requirements for NRC approved packaging, shall meet the requirements of DOT 49CFR.

2.3. Services

The Company procures services from qualified suppliers. It is not necessary that these suppliers have an approved quality assurance program. Audits are conducted for these suppliers when it is necessary to assure the quality of the delivered services.

- meteorology.
- Offsite Dose Calculation Manual.
- radiological environmental monitoring.
- training.

2.4. Fire Protection

The Company's nuclear facilities shall have an established fire protection program for the protection of systems, structures and components performing a safety function. Engineering determines, in accordance with 10CFR50 "Appendix R," what fire protection systems and components protect SSCs performing a safety function. Engineering also establishes the requirements for the design, procurement, fabrication, installation and/or modification of such fire protection SSCs. Routine testing of fire protection systems assures reliability. All other fire protection equipment and supplies will be of commercial quality, acceptable to National Fire Protection Association (NFPA) specifications.

2.5. Station Blackout (Dresden and Quad Cities)

Dresden and Quad Cities stations procured and installed additional non-safety related equipment to achieve the redundancy required by 10CFR50.63. Replacement and consumable parts and supplies are classified non-safety related in accordance with original specifications and are procured as commercial items. Routine testing of Station Blackout (SBO) SSCs assures the necessary redundancy is maintained. SBO SSC reliability is monitored in accordance with the Station's Maintenance Rule program.

2.6. Augmented Quality Requirements for Dresden 1, Peach Bottom 1, and Zion

Dresden 1, Peach Bottom 1, and Zion 1 & 2 have ceased commercial operation and will ultimately be decommissioned. Staffing, qualification of personnel, and organization will be in accordance with the Dresden 1 and Zion De-fueled Technical Specifications (DTS) and De-fueled Safety Analysis Reports (DSAR), and the Peach Bottom 1 Updated Final Safety Analysis Report (UFSAR) and Technical Specifications.

Select SSCs at Zion are considered non-safety related but "Important-to-De-fueled-Condition (ITDC)" as defined in the DSAR. Procurement of parts and components will be in accordance with this non-safety related but ITDC classification.

Changes, tests, and experiments require the application of the design control measures that assure that applicable regulatory requirements, licensing and design bases, and codes and standards are correctly translated into specifications, procedures and instructions. These design control measures will include a review and evaluation in accordance with 10CFR50.59/72.48, except design verification. The originator's supervisor, providing the supervisor did not specify a singular design approach or rule out certain design considerations, may perform design verifications.

Except for inspections or examinations required for ASME repairs and replacements, station personnel may perform inspections provided they are experienced, task-qualified journeymen or supervisors who did not supervise the activity being inspected. Nuclear Oversight will monitor this activity through periodic overview.

Timeliness of corrective actions is prioritized commensurate with the safety significance. Sufficient records of maintenance and modification activities will be maintained to evaluate failures, perform root cause analysis, if applicable, and determine appropriate corrective actions and to meet the requirements of the applicable DSAR or Peach Bottom Unit 1 UFSAR. Audits are conducted of maintenance of shutdown facilities and decommissioning activities at least annually until the termination of license with the exception of Peach Bottom 1, which is conducted on a biennial frequency.

2.7. Repairs and Alterations

The requirements of ASME Code Sections II, V and IX shall be imposed as applicable for the repair or alteration job specific work scope.

2.7.1. State of Illinois

Welded repairs and all alterations to non-ISI boilers and pressure vessels, as described in Section 505.2500 of the Illinois Department of Nuclear Safety (IDNS) Boiler and Pressure Vessel Safety Rules, and the repair of pressure relief valves, as described in Section 505.2500(b) of the rules, are conducted in accordance with Section505.2500(a)(1)(A) of the rules.

Section 505.2500(a)(1)(A) requires that the Company apply an approved Quality Assurance (QA) Program to such repairs and alterations and describe how it is applied. The following describes the Company's application of these rules.

- The Company has a QA Program that is reviewed and accepted by the NRC. In addition, the QA Program is reviewed and accepted by an accredited Authorized Inspection Agency. Authorized Inspectors are present at each of the Company's plants while ASME Code work is in progress.
- Chapter 1 of this QA Program describes the authority and responsibilities of the organization. It also describes the retention of responsibility by the Company when repair and modification activities are subcontracted.

- Chapter 3 requires that design and changes to designs be defined, documented, and controlled.
- Chapter 5 requires that all work be accomplished in accordance with documented instructions and procedures and be subject to appropriate process controls. Specifically, the Company uses the Nuclear Work Request (NWR) to authorize, track, and control work in the plant. The NWR system includes provisions for specifying when work is ASME Code related and is not limited to any particular section of the ASME Code. It further provides for detailed instructions to accomplish the work. This includes the need for qualified inspectors, qualified welders, qualified procedures, special processes, required documentation, approved drawings, and post-maintenance/post-modification testing. NWRs marked as ASME Code work is offered to the Authorized Inspector for the insertion of hold and witness points.
- Chapters 4, 7, 8, and 13 address the procurement, receiving, handling, storage, disbursement, and marking of materials. Implementing procedures establish traceability of materials to the procurement and receiving processes and provide assurance that only ASME Code acceptable materials are utilized. Any specific requirements for heat traceability will be in accordance with the applicable sections of the ASME Code being used.
- Chapter 9 details the controls for special processes while Chapter 10 details those for inspection. This includes the requirement for the use of independent, qualified inspectors and examiners when required by the ASME Code, and invokes the Company's Special Processes and Procedures Manual (SPPM). The SPPM is also reviewed and accepted by the Authorized Inspection Agency.
- Chapters 6 and 17 require that documents and records be generated and maintained to satisfy the requirements of the ASME Code and the Jurisdiction.
- Chapter 18 provides for overview and audit of ASME Code activities.

Repairs and alterations performed as described above meet the requirements of the approved QA Program and meet the requirements of the IDNS B&PV rules; regardless of the safety classification of the boiler or pressure vessel or pressure relief valve being repaired.

2.8. Dry Cask Storage System

2.8.1. Peach Bottom Atomic Power Station (PBAPS)

Peach Bottom quality assurance program requirements are performed in accordance with TN-68, Safety Analysis Report. These requirements, although they do not use the guidance of NUREG/CR-6407 have been the methodology defined for quality assurance requirements and approved by the NRC. PBAPS "site important to safety related structures" use a similar approach for defining quality assurance requirements. These structures are defined in the PBAPS

Independent Spent Fuel Storage Installation (ISFSI) Final Safety Analysis Report.

2.8.2. Oyster Creek Nuclear Generating Station (OCNGS)

The OCNGS quality assurance program requirements are performed in accordance with NUH-003, Safety Analysis Report. These requirements, although they do not use the guidance of NUREG/CR-6407, have been the methodology defined for quality assurance requirements and approved by the NRC. OCNGS "site important to safety related structures" use a similar approach for defining quality assurance requirements. These structures are defined in the OCNGS ISFSI Final Safety Analysis Report.

2.8.3. Dresden Station

The ISFSI SSCs that are important to safety are categorized as Category A, B, or C in accordance with NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety." Per 10CFR72, Subpart G, the QATR applies to the ISFSI SSCs and activities consistent with their importance to safety as follows:

See Next Page.

Chapter	Title	Important to Safety SSCs Category		
		A	B	C
1	Organization (Roles and Responsibilities)	M	M	R
2	Quality Assurance Program (Subchapters 3.1, 3.4, 3.5, and 3.6)	M	M	NR
3	Design Control	M	M	R
4	Procurement Document Control	M	R	NR
5	Instructions, Procedures, and Drawings	M	M	R
6	Document Control	M	M	R
7	Control of Purchase Material, Equipment, and Services	M	R	R
8	Identification and Control of Materials, Parts, and Components	M	R	R
9	Control of Special Processes	M	M	R
10	Inspections	M	M	R
11	Test Control (Design, Fabrication, Installation, and Maintenance)	M	M	R
12	Control of Measuring, and Test Equipment	M	M	R
13	Handling, Storage, and Shipping	M	R	NR
14	Inspection, Test, and Operating Status	M	M	NR
15	Nonconforming Materials, Parts, or Components	M	M	R
16	Corrective Action	M	M	R
17	Quality Assurance Records	M	M	R
18	Audits	M	M	R

(M) Mandatory = Indicates the Appendix B QA Program shall be used.

(R) Recommended = Indicates application of the applicable quality assurance criterion may benefit the user. The Engineering organization shall determine the extent of application required for the SSCs in question.

(NR) Not Required = Indicates that little benefit has been identified or no regulatory basis has been found to require application of applicable QA criteria. Imprudent use of this criterion may add unnecessary burden.

Internal assessments shall be conducted on a performance driven frequency, not to exceed 24 months or at the frequencies indicated below, in accordance with the Company's QAP. Assessments shall include the following safety-related functions as applicable:

ASSESSMENT	FREQUENCY
a. The conformance of unit operation to provisions contained within the technical specifications and applicable license conditions.	24 Months
b. The adherence to procedures, training, and qualification of the station staff.	24 Months
c. The results of actions taken to correct deficiencies occurring in facility equipment, structures, systems, components, or method of operation that affect nuclear safety.	24 Months
d. The performance of activities required by the Quality Assurance Program to meet the criteria of Appendix B of 10CFR50.	24 Months
e. The fire protection programmatic controls including the implementing procedures (by qualified Nuclear Oversight personnel).	24 Months
f. The fire protection equipment and program implementation, including loss prevention, utilizing either a qualified offsite licensee fire protection engineer or an outside, independent fire protection consultant. An outside, independent fire protection consultant shall be used at least every second year.	24 Months
g. The Radiological Environmental Monitoring Program (REMP) and its results.	24 Months
h. The Offsite Dose Calculation Manual (ODCM) and implementing procedures.	24 Months

i. The Process Control Program (PCP) and implementing procedures for the solidification of radioactive wastes.	24 Months
j. The performance of activities required by the Company QAP for effluent and environmental monitoring.	24 Months
k. Randomly selected procedures to ensure that the programmatic control processes used to assure that procedures are technically and administratively correct prior to use are resulting in timely and accurate procedure revisions.	24 Months
l. The Security Plan and implementing procedures (Reference 10CFR50.54(p)(3)(ii) for lesser frequency requirements).	12 Months
m. The Emergency Plan and implementing procedures (Reference 10CFR50.54(t)(1)(ii) for lesser frequency requirements).	12 Months
n. NSRB activities at a frequency not to exceed 5-years.	60 Months
o. The conformance of Spent Fuel Storage Installation operation to provisions contained within the technical specifications and applicable license conditions and results of actions taken to correct deficiencies occurring in facility equipment, structures, systems, components, or methods of operation affecting nuclear safety (Dresden, Oyster Creek, and Peach Bottom only).	24 Months

1.1. Codes and Standards

The QAP takes into account the need for special controls, processes, test equipment, tools, and skills necessary to attain the required quality and the need for the verification of quality by inspection and test. The QAP complies with the quality requirements of the following codes and standards unless otherwise noted below or in sub-section 1.3.

- ANS 3.1 (1981), "Selection, Qualification, and Training of Personnel for Nuclear Power Plants."
- ANS 3.1(1978), "Selection and Training of Nuclear Power Plant Personnel."
- ANSI N101.4 (1972), "Test Methods for Applied Coatings."
- ANSI N18.1 (1971), "Standards for Selection and Training of Nuclear Power Plant Personnel."
- ANSI/ANS N18.7 (1976), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants."
- ANSI N18.7 (1972),"Administrative Controls for Nuclear Power Plants."
- ANSI/ANS 3.2 (1988), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants."
- ASME Boiler and Pressure Vessel Code Section III (NCA 4000), Division 1 and Division 2, 1992.
- ASME Boiler and Pressure Vessel Code Section XI, 1989 Edition. Exception: Section XI, Division 1, Appendix VIII "Performance Demonstration for Ultrasonic Examinations Systems" is in accordance with ASME BPV Section XI 1995 and 1996 Addenda.
- ASME NQA-1 (1994), "Quality Assurance Requirements for Nuclear Facility Applications, (Revision and Consolidation of ASME NQA-1-1989 and ASME NQA-2-1989 Editions)."
- AWS D1.1-80, "Structural Welding Code - Steel."
- IEEE Standard 323 (1974), "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations."

1.2. Regulatory Guides

The QAP also complies with the regulatory positions of the following Regulatory Guides because of compliance with the above list of codes, standards, and additional programmatic quality requirements unless otherwise noted below or in sub-section 1.3.

- 1.8 (Rev. 1-R), "Personnel Qualification and Training."
- 1.26 (Rev. 3), "Quality Group Classification and Standards for Nuclear Power Plants."
- 1.28 (Rev. 3), "Quality Assurance Program Requirements for Design and Construction."
- 1.29 (Rev. 3), "Seismic Design Classification."

- 1.30 (Rev. 0), "Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment."
- 1.31 (Rev. 3), "Control of Ferrite Content in Stainless Steel Weld Material" (Oyster Creek and Three Mile Island Only).
- 1.33 (Rev. 2), "Quality Assurance Program Requirements."
- 1.37 (Rev. 0), "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants."
- 1.38 (Rev. 2), "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants."
- 1.39 (Rev. 2), "Housekeeping Requirements for Water Cooled Nuclear Power Plants."
- 1.68 (Rev. 2), "Pre-Operational and Initial Start-Up Test Programs for Water Cooled Reactors."
- 1.94 (Rev. 1), "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Steel during the Construction Phase of Nuclear Power Plants."
- 1.116 (Rev. 0-R), "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems."
- 1.142 (Rev. 0), "Safety Related Concrete Structures for Nuclear Power Plants."
- 1.143 (Rev. 1), "Design Guidance for Radioactive Waste Management SSCs Installed in Light Water-Cooled Nuclear Power Plants."
- 4.15 (Rev. 1), "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment."

1.3. Site Specific Clarifications and Exceptions

1.3.1. Limerick (LGS) and Peach Bottom Atomic Power Station (PBAPS)

1. Regulatory Guide 1.28, Revision 3, August 1985, "Quality Assurance Program Requirements – Design and Construction". Endorses ANSI/ASME NQA-1-1983.

   LGS/PBAPS shall comply with Regulatory Guide 1.28, August 1985 and ANSI/ASME NQA-1-1994, except for the following alternatives.

   A. NQA-1, Supplement 2S-3, Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel, Sub-section 3.3, Audit Participation.

      NQA-1, Supplement 2S-3, Sub-section 3.3 (ANSI N45.2.23, Sub-section 2.3.4), Prospective Lead Auditors shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. This process is described in written procedures that provide for evaluation and documentation of the results of this

demonstration. A prospective Lead Auditor shall have participated in at least one nuclear oversight audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively implement the audit process and effectively lead audits, and having met the provisions of NQA-1, Supplement 2S-3, the individual may be certified as being qualified to lead audits. LGS/PBAPS was granted this alternative by NRC SER dated 6/26/97, to this requirement. (ANSI N45.2.23 section 2.3.4, "Audit Participation" was replaced by NQA-1-1994, Supplement 2S-3, Sub-section 3.3,"Audit Participation").

2. Regulatory Guide 1.30, August 1972, "Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electrical Equipment." Endorses ANSI N45.2.4-1972.

LGS/PBAPS shall comply with Regulatory Guide 1.30, August 1972, and ANSI N45.2.4-1972 (NQA-1, Part II, Subpart 2.4), except for the following alternatives.

A. ANSI N45.2.4, Section 1.1, Scope – An alternate to classification of Class I and IE electric power, instrumentation, and control equipment is to apply the requirements of this standard to LGS safety-related items (those instruments, equipment, and systems that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public).

B. ANSI N45.2.4, Section 3, Pre-construction Verification - Subsection (3) requires the checking of records of protective measures maintained during storage for conformance to storage requirements. ANSI N45.2.2-1978, Section 6.4, Control of Items in Storage, requires inspection and examination during the storage period. The responsibility for these inspections rests with Materials Management. Compliance with these requirements for checking of records is assured through the auditing and quality verification programs conducted NOS Department personnel along with the monitoring of Materials Management activities by Materials Management supervision.

C. ANSI N45.2.4, Section 7, Data Analysis and Evaluation - A program for processing, reviewing, and analyzing electrical equipment and instrumentation inspection and test data for acceptability is provided in the administrative procedures which govern the repair, maintenance, and testing of electrical equipment and instrumentation. Maintenance is controlled through the use of a work request form that has provisions for cognizant personnel sign-off after completion of the work. Functional testing and calibration procedures include provisions for review, analysis of data, and approval by signature of cognizant personnel.

D. ANSI N45.2.4, Section 6.2.1, Equipment Tests - Installed items requiring calibration are controlled through the preventive maintenance computer tracking system. Tags or labels are not affixed to the item to indicate calibration status.

E. ANSI N45.2, Section 9, Item 6, ANSI B31.7-1969, PBAPS follows USAS B31.1.0-1967 since PBAPS Units 2 and 3 were constructed to USAS B31.0.0-1967. (This item applies to PBAPS ONLY).

3. Regulatory Guide 1.33," Quality Assurance Program Requirements, (Operations)," endorses ANSI N18.7.

LGS shall comply with Regulatory Guide 1.33, Revision 2, February 1978, and ANSI N18.7-1976/ANS-3.2, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants"' during the operational phase except for the following clarifications or alternatives.

A. ANSI N18.7-1976/ANS-3.2, Section 5.2.2, Procedure Adherence - The term "supervisor in charge of the shift" means either the Shift Manager or Shift Supervisor.

B. ANSI N18.7-1976/ANS-3.2, Section 5.2.7.1, Maintenance Programs:

1. Emergency maintenance to safety-related equipment (work which must proceed immediately to correct a degraded condition) may be performed concurrent with procedure preparation and documentation of steps actually taken. Such maintenance may be performed with the authorization of designated personnel and subsequent procedure review by the PORC and/or SQR, per Technical Specification requirements.

2. The cause of repetitive malfunctions should be determined; however, it is not practical, and may not be possible, to determine the cause of every malfunction.

C. ANSI N18.7-1976/ANS-3.2, Section 5.2.10, "Housekeeping and Cleanliness Control".

1. Control measures to prevent contamination with foreign materials will be specified in administrative procedures and will include, as appropriate, access control.

2. Second paragraph, first and second sentences are taken to mean: "Where needed to prevent contamination...."

D. ANSI N18.7-1976/ANS-3.2, Section 5.2.13, "Procurement and Materials Control" - Item (1) - Administrative procedures shall specify the means for control of procurement of commercially "off-the-shelf" items. The administrative procedures shall describe the receipt inspection, storage, and handling prior to installation and operation.

Off-the-shelf (catalog) items are evaluated by qualified personnel for their intended use. The administrative procedures restrict the use of catalog items for only these evaluated applications. The purchase order shall require the vendor to notify the requisitioning organization of a change in an item described in the catalog.

E. ANSI N18.7-1976/ANS-3.2, Section 5.2.13.1, "Procurement Document Control," (second sentence) - QA Program requirements or alternate approved methods will be used to ensure quality. Examples of alternates for suppliers without QA programs include material analysis, sample testing, in-process inspection and monitoring, and design review by LGS/PBAPS.

F. ANSI N18.7-1976/ANS-3.2, Section 5.2.15, "Review, Approval and Control of Procedures" - The frequency of review of plant procedures is discussed in UFSAR Section 13.5, except for the following alternative.

1. Programmatic controls and processes described in UFSAR Section 13.5 are used to assure that procedures are current. These controls take the place of scheduled periodic reviews.

PBAPS shall comply with Regulatory Guide 1.33, November 1972, and ANSI N18.7-1972,"Administrative Controls for Nuclear Power Plants"' during the operational phase except for the following clarifications or alternatives.

G. The programmatic controls and processes found in QATR Chapter 6, Document Control section 2.1, General requirements are used to assure that procedures are current. These controls take the place of scheduled periodic reviews.

At least once every 2 years line organizations that have responsibility for procedures or procedure categories will perform self-assessments of the appropriate components that comprise the procedural development program in accordance with established guidelines. These self-assessments will provide a high degree of confidence maintaining procedures current. In addition, NOS will assess the programs and processes identified above as part of the NOS assessment function.

4. Regulatory Guide 1.37, March 1973, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants." Endorses ANSI N45.2.1-1973.

Decontamination and cleanup of radioactively contaminated systems and components are not included in the scope of this response.

LGS/PBAPS shall comply with Regulatory Guide 1.37, March 1973, and ANSI N45.2.1-1973 (NQA-1, Part II, Subpart 2.1) except for the following alternatives.

A. ANSI N45.2.1, Section 3.2, Water Quality Requirements - pH measurements are not required for conductivity values less than or equal to 1 micromho/cm. LGS/PBAPS utilized pH limits of 5.2 to 8.6 at 25 degrees centigrade, uncorrected for CO_2, and may apply conductivity measurements in place of total dissolved solids.

B. ANSI N45.2.1, Section 3.1.2, Class B - The flushing velocity may be as specified in other approved documents associated with the maintenance or modification, as well as procurement documents. . (This item applies to LGS ONLY).

5. Regulatory Guide 1.38, Revision 2, May 1977, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants." Endorses ANSI/ASME N45.2.2-1972.

LGS/PBAPS shall comply with Regulatory Guide 1.38, Revision 2, May 1977, and ANSI/ASME N45.2.2-1978 (NQA-1, Part II, Subpart 2.2), except for the following clarifications or alternatives.

A. ANSI/ASME N45.2.2, Section 2.7, Classification of Items – LGS/PBAPS does not classify items into the four (4) levels described in this standard. However, the specific guidance and recommendations which are appropriate to each class are applied to those items packaged, shipped, received, stored, and handled through the use of procedures, original specifications, instructions, and drawings, as applicable.

B. ANSI/ASME N45.2.2, Section 3, Packaging, and Section 4, Shipping – LGS/PBAPS utilizes the packaging and shipping requirements delineated in the original equipment specifications as part of our procurement requirements to suppliers or manufacturers. Those requirements and recommendations of Section 3 and 4 are included in the original specifications as appropriate for the item being procured. Receipt inspection activities are in accordance with Section 5 of this standard and are sufficient to identify packaging and shipping nonconformances.

C. ANSI/ASME N45.2.2, Section 6, Storage – LGS/PBAPS does not classify items into four (4) levels for storage purposes, as delineated in Section 6.1.2. Stored items are placed in limited access controlled areas, and are segregated with respect to the QA Class of the item(s). The specific guidance and recommendations which are appropriate to each class are applied to those items stored through the use of procedures, specifications, and manufacturers' recommendations and instructions.

D. ANSI/ASME N45.2.2, Section 6.4.2 (7), Care of Items - The rotating of certain electrical motors in storage, which must be energized to release an electrical brake, will be stored and maintained in

accordance with manufacturers' recommendations. Other motors, which can be rotated without energizing, will be maintained in accordance with the requirements of Section 6.4.2 (7) of the standard.

E. ANSI N45.2.2, Paragraph 6.4.2(5), Care of Items - Space Heaters will be energized on electrical equipment in storage based on the cost/benefit of repairing electrical equipment versus use of heaters. Predictive maintenance (insulation resistance checks) will be used to identify degraded insulation conditions on electrical equipment in storage where heaters are not utilized.

Additionally PBAPS has the following clarifications and alternatives.

F. ANSI N45.2.2, Paragraph 6.6, Storage Records - Written records shall be prepared that include such pertinent information as storage location, inspection results, and protection (care of items). Personnel access is controlled and limited to Stores Division personnel and visitors who are escorted by Stores Division personnel. (This item applies to PBAPS Only).

G. With regard to Paragraph 7.4, Inspections of Equipment and Rigging, load testing will be performed when feasible. (This item applies to PBAPS Only).

6. Regulatory Guide 1.39, Revision 2, September 1977, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants." Endorses ANSI N45.2.3-1973.

LGS/PBAPS shall comply with Regulatory Guide 1.39, September 1977, and ANSI N45.2.3-1973 (NQA-1, Part II, Subpart 2.3), except for the following alternatives.

A. ANSI N45.2.3, Section 2.1, Planning - Zone II requirements for clean gloves, shoe covers, and head coverings will be determined by health physics personnel under the radiation protection program and specific requirements listed on the Radiation Work Permit for entry in Zone II areas.

B. ANSI N45.2.3, Section 2.1, Planning - Material accountability for Zones II and III shall be controlled by procedural requirements, periodic inspections, and surveillance of areas for acceptable housekeeping practices. Implementing procedures for activities such as maintenance and modifications require housekeeping and cleanliness inspections of areas and equipment to eliminate foreign materials that may have a detrimental effect. Post maintenance or modification inspections for housekeeping and cleanliness shall be conducted and documented in accordance with administrative controls.

C. ANSI N45.2.3, Section 2.1, Planning - Personnel accountability for Zone III will be controlled as determined by the administrative controls for locked doors and radiation work permit requirements in lieu of specific access registers.

7. Regulatory Guide 1.94, Revision 1, April 1976, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structure Steel during the Construction Phase of Nuclear Power Plants." Endorses ANSI N45.2.5-1974.

LGS shall comply with Regulatory Guide 1.94, Revision 1, April 1976, and ANSI N45.2.5-1974 (NQA-1, Part II, Subpart 2.5), except for the following clarification.

A. ANSI N45.2.5-1974 will be implemented by LGS by initiating a procedure, prior to any work, that will assure satisfactory installation, inspection, and testing of structural concrete or structural steel.

PBAPS does not commit to this Regulatory Guide but shall comply with ANSI N45.2-1974 (NQA-1, Part II, Subpart 2.5), except for the following clarification.

B. ANSI N45.2.5-1974, exclusive of other documents referenced therein, will be implemented through alternate equivalent means prior to placement of any structural steel or concrete at PBAPS Units 2 and 3.

8. Regulatory Guide 1.116, Revision 0-R, May 1977, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems." Endorses ANSI N45.2.8-1975.

LGS/PBAPS shall comply with Regulatory Guide 1.116, Revision 0-R, May 1977, and ANSI N45.2.8-1975 (NQA-1, Part II, Subpart 2.8), except for the following alternative:

A. ANSI N45.2.8, Section 2.2, Procedures and Instructions – LGS UFSAR section 13.5 addresses compliance with ANSI N18.7-1976/ANS3.2 and Reg. Guide 1.33, PBAPS Technical Specifications require compliance with Reg. Guide 1.33, Appendix A along with PBAPS commitment to ANSI N18.7-1972. These commitments provide adequate controls for procedures and instructions addressed in this paragraph.

B. ANSI N45.2.8, Section 2.3, Results - LGS commitment to ANSI N18.7-1976/ANS3.2 and PBAPS commitment to ANSI N18.7-1972 provide adequate guidance for the documentation and review of results of inspection and tests.

C. ANSI N45.2.8, Section 3.4, Physical Condition – LGS/PBAPS responses to ANSI N45.2.1, N45.2.2, and N45.2.13 provide adequate guidance and control for the requirement that mechanical items are in

accordance with specified requirements and that the quality has been maintained.

9. Regulatory Guide 1.143, Revision 1, October 1979, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants."

LGS shall comply with Regulatory Guide 1.143, Revision 1, October 1979, for major modifications, subject to the exceptions and clarifications listed in LGS UFSAR Table 3.2-1, Note 18.

10. ASTM D3843-93, "Standard Practice for Quality Assurance for Protective Coatings applied to Nuclear Facilities."

LGS/PBAPS shall comply with ASTM D3843-93 for safety-related protective coating work in service level 1 areas during operation with the following additional clarification, exception, and requirement.

A. For coating formulations developed prior to issuance of ASTM D3843-93, service level 1 qualification based on ANSI N5.9 (Revised as ANSI N512-1974) and ANSI N101.2 remains valid.

B. Section 10.1, last sentence - instead of references to ANSI 45.2 and NQA-1, inspections will be documented for record purposes as required by 10CFR50, Appendix B, and by this QA program description.

C. Limitations on use of coatings and cleaning materials which contain elements which could contribute to corrosion, inter-granular cracking, or stress corrosion cracking of safety-related stainless steel will be followed as described in Section C.4 of regulatory Guide 1.54, June 1973.

11. Branch Technical Position (BTP) CMEB 9.5-1:

For modification work performed by the Nuclear Engineering Division during the operations phase, the Nuclear Engineering Division will maintain compliance with the requirements of CMEB 9.5-1 in accordance with Section 9.5.1.

12. ASME Boiler and Pressure Vessel Code Section III – The code year for the Section III B&PV Design Code is found in the applicable site UFSAR.

13. ASME Boiler and Pressure Vessel Code Section XI – The code year for the Section XI B&PV Inspection Code is found in the applicable site UFSAR.

1.3.2. Oyster Creek (OCNGS) and Three Mile Island (TMI) Stations

1. Regulatory Guide 1.30, August 1972, "Quality Assurance Requirements for the Installation, Inspection and Testing of Instrumentation and Electric Equipment."

   A. The Company shall comply with the Regulatory Position established in this Regulatory Guide in that QA programmatic/administrative requirements included therein shall apply to maintenance and modification activities even though such requirements were not in effect originally. Technical requirements associated with maintenance and modifications shall be the original technical requirements or better (e.g., code requirements, material properties, design margins, manufacturing processes, and inspection requirements).

   B. Sections 5.2 and 6.2 of ANSI N45.2.4 (NQA-1, Part II, Subpart 2.4) list tests which are to be conducted during the construction phase. In lieu of this, the Company utilizes its Engineering and/or Maintenance organizations to establish the need for specific tests or test procedures during the operational phase.

2. Regulatory Guide 1.33, Rev. 2, February 1978, "Quality Assurance Program Requirements (Operation)."

   The stations comply with the Regulatory Position of this Guide with the following clarifications:

   A. Paragraph 5.2.2 of ANSI N18.7-1976, titled "Procedure Adherence." In accordance with Section 6.8.3 of the OCNGS and TMI Technical Specifications, temporary changes shall be approved by two members of the Company's management staff qualified as a 50.59 Evaluator/Reviewer who meets the qualification criteria of Technical Specification 6.5.1.14 and knowledgeable in the area affected by the procedure. For changes, which may affect the operational status of facility systems or equipment, at least one of these individuals shall be a member of facility management or supervision holding a Senior Reactor Operator's License on the facility.

   B. Paragraph 5.2.15 of ANSI N18.7 - 1976, titled "Review, Approval and Control of Procedures." The third sentence of the third paragraph is interpreted to mean that applicable procedures shall be reviewed following a reportable incident such as an accident, an unexpected transient, significant operator error, or equipment malfunction.

3. Regulatory Guide 1.37, March 16, 1973, "Quality Assurance Requirements for Cleaning Fluids Systems and Associated Components of Water Cooled Nuclear Power Plants. "

The OCNGS and TMI QAP complies with the Regulatory Position of this Guide with the following clarifications:

A. Section 2.1 of ANSI N45.2.1-1973 (NQA-1, Part II, Subpart 2.1) states that required planning is frequently performed on a generic basis for application to many installations on one or more projects. This results in standard procedures or plans for installation and inspection and testing which meet the requirements of the Standard. Individual plans for each item or system are not normally prepared unless the work operations are unique. However, standard procedures or plans will be reviewed for applicability in each case. Installation plans or procedures are also limited in scope to those actions or activities, which are essential to maintain or achieve the required quality. This is consistent with Section 11, Paragraphs 2 and 3, of ANSI N45.2-1977, which provides for examination, measurement, or testing to assure quality or indirect control by monitoring of processing methods. However, final cleaning or flushing activities will be performed in accordance with procedures specific to the system.

B. Section 3.1.2.1 of ANSI N45.2.1-1973 (NQA-1, Part II, Subpart 2.1) states that surfaces shall be examined without magnification under a lighting level (background plus supplementary lighting) of at least 100 foot candles. The Company intends to permit the use of neutral 18% gray card with a 1/32" black line for determining acceptability of illumination in lieu of the 100 foot candles.

4. Regulatory Guide 1.38, Rev. 2, May 1977, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage and Handling of Items for Water Cooled Nuclear Power Plants."

The OCNGS and TMI QAP complies with the Regulatory Position of this Guide with the following modifications or clarifications to ANSI N45.2.2-1972 (NQA-1, Part II, Subpart 2.2):

A. Section 2.7, Classification of Items. The four-level classification system for storage of items will be followed, however, the designated classification level may not be explicitly identified on the item. The classification level will, however, be traceable through the procurement documents. Classification differing from Section 2.7 will be considered acceptable provided no degradation is assured; for example, electric motors designed for outside service may be stored in a level C area rather than a level B.

B. Section 3.2, Levels of Packaging. The four level classification system for packaging of items may not be explicitly used. Standard commercial grade packaging requirements may be specified for commercial grade items.

C. Section 3.6 concerns prevention of halogenated materials from contacting stainless steel or nickel alloy materials. The clarifications

applicable to Regulatory Guide 1.37, identified previously, also apply to this section of ANSI N45.2.2.

D. Section 3.7.1 Cleated, sheathed boxes will be used up to 1000 lbs. rather than 500 lbs. as specified. This type of box is safe for, and has been tested for, loads up to 1000 lbs. Other material standards (i.e., FED Spec. PPP-8-601) allow this. Special qualification testing shall be required for loads in excess of 1000 lbs.

E. Section 7.4 states that a system should be established to indicate acceptability of all equipment and rigging after each inspection, specify control of non-conforming lifting equipment, and supplement periodic inspections with special visual and nondestructive examinations and dynamic load tests. In lieu of this, the Company does perform dynamic load tests on new equipment, preventive maintenance on cranes, nondestructive examination of lifting hooks annually, and a visual inspection of lifting equipment prior to use.

F. Appendix A 3.4.2, Inert Gas Blankets. There may be cases involving large or complex shapes for which an inert or dry air purge flow is provided rather than static gas blanket in order to provide adequate protection due to difficulty of providing a leak proof barrier. In these cases a positive pressure purge flow may be utilized as an alternate to a leak proof barrier.

G. Appendix A.3.5.2, Tapes will meet a sulfur limit of 0.30% by weight instead of 0.10% as specified in A.3.5.2 (1)(a). This limit is reasonable based upon the chemical content of commercially available tapes. Tapes will be of a contrasting color rather than "Brightly Colored" as required by A.3.5.1 (3).

5. Regulatory Guide 1.39, Rev. 2, September 1977, "Housekeeping Requirements for Water Cooled Nuclear Power Plants." Endorses ANSI N45.2.3 – 1973.

The OCNGS and TMI QAP complies with this Guide with the following exception to ANSI N45.2.3-1973 (NQA-1, Part II, Subpart 2.3).

A. Sections 2.1 and 3.2, OCNGS will not utilize the five level zone designation system referenced in ANSI N45.2.3, but will utilize standard janitorial and work practices to maintain a level of cleanliness commensurate with company policy in the areas of housekeeping, plant and personnel safety, and fire protection. Cleanliness will be maintained consistent with the work being performed, so as to prevent the entry of foreign material into systems within the scope of this Plan. This will include, as a minimum, documented cleanliness inspections performed immediately prior to system closure. Control of personnel, tools, equipment, and supplies will be established when major portions of the reactor system are opened for inspection, maintenance or

repair. Additional housekeeping requirements will be implemented as required for control of radioactive contamination.

B. Section 3.2.3 discusses fire protection. Except for the quality assurance aspects of fire protection, no specific commitments are made in the QATR. As part of other activities, the Company has established positions or commitments relating to fire safety or protection.

6. Regulatory Guide 1.54, June 1973, "Quality Assurance Requirements for Protective Coatings Applied to Water Cooled Nuclear Power Plants."

The OCNGS and TMI QAP complies with this Guide with the following clarifications:

A. The Company will comply with the Regulatory Position established in this Regulatory Guide in that programmatic/administrative quality assurance requirements included therein shall apply to maintenance and modification activities, even though such requirements were not in effect originally. Technical requirements associated with maintenance and modifications (e.g., code requirements, material properties, design margins, manufacturing processes, and inspection requirements) shall be the original requirements or better.

B. The quality assurance program for protective coatings includes the planned and systematic actions necessary to provide adequate confidence that shop or field coating work for nuclear facilities will perform satisfactorily in service.

C. All protective coatings applied to surfaces within containment, except those noted in 3 below, are tested to demonstrate that they can withstand LOCA conditions. These tests are performed in accordance with Section 4 of ANSI N101.2, "Protective Coatings (Paints) for Light Water Nuclear Reactor Containment Facilities," under LOCA conditions, which equal or exceed those described in the FSAR.

D. The quality assurance program is applied to protective coatings consistent with the nature and scope of work specified in the Technical Specifications. The following elements are included:

1. Preparation of coatings specifications and procedures for generic coating materials/systems.

2. Review and evaluation of coating manufacturers' demonstration test data and quality assurance measures for control of manufacture, identification, and performance verification of applied coating systems.

3. Review and evaluation of supplier quality assurance measures to control storage and handling, surface preparation, application, touch-up, repair, curing and inspection of the coating systems.

4. Training and qualification of inspection personnel in coatings inspection requirements.

5. Supplier surveillance inspection.

E. The coatings qualification program and the associated quality assurance requirements are necessary only for coatings whose failure or failure mechanism would have a significant effect on safety.

F. Regulatory Guide 1.54 is not imposed for:

1. Surfaces to be insulated.

2. Surfaces "contained" within a cabinet or enclosure (for example, the interior surfaces of ducts).

3. Field repair on any Q-class coated item of less than 30 square inches surface area, such as; cut ends or otherwise damaged galvanizing; bolt heads, nuts, and miscellaneous fasteners; and damage resulting from spot, tack, or stud welding.

4. Field touch-up and repair of larger areas shall be in accordance with item A.

5. Small "production line" items such as small motors, hand wheels, electrical cabinets, control panels, loudspeakers, etc., where special painting requirements would be impracticable.

6. Stainless steel or galvanized surfaces.

7. Coating used for the banding of piping.

8. Strippable coatings used for cleanup.

G. Quality assurance documentation may not be similar to records and documents listed in Sections 7.4 through 7.8 of ANSI N101.4, but will be evaluated to assure that they provide at least the same degree of documentation as required by this standard.

7. Regulatory Guide 1.58, Rev. 1, September 1980, "Qualifications of Nuclear Power Plant Inspection, Examination, and Testing Personnel."

The OCNGS and TMI QAP complies with this Guide with the following clarifications:

A. Plant operation personnel may be utilized to perform the visual leakage examinations required by the edition of ASME Section XI and

related codes currently committed to for the conduct of in-service inspections. Such personnel shall be qualified consistent with these ASME Code requirements. The selection and qualification of such personnel shall be prescribed by a procedure(s), which is reviewed and concurred with by Quality Verification.

B. Not all personnel who review and approve inspection and testing procedures, evaluate the adequacy of activities to accomplish the inspection and test objectives, evaluate the adequacy of specific programs used to train and test inspection and test personnel, or certify Level III individuals in specific categories or classes, will be certified as meeting the Level III capability requirements of ANSI N45.2.6-1978 (NQA-1). Rather, these personnel will be determined by management to be fully qualified and competent to perform these functions through, evaluation of their education, experience and training. The basis for the determination will be documented.

8. NRC Regulatory Guide 1.94, Rev. 1, April 1976, "Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel during the Construction Phase of Nuclear Power Plants."

The OCNGS and TMI QAP complies with this Guide with the following clarifications:

A. Programmatic/administrative quality assurance requirements included in the Regulatory Guide shall apply to maintenance and modification activities even though such requirements were not in effect originally. Technical requirements associated with maintenance and modifications shall be the original requirements or better (e.g., code requirements, material properties, design margins, manufacturing processes, and inspection requirements).

B. Section 5.4 of ANSI N45.2.5-1974 specifies the frequency and method of calibration of automatic cut-off impact wrenches used to make up and inspect high strength bolted connections; and the frequency of calibration of hand held torque wrenches used to inspect high strength bolted connections. Section 5.2.6 of ANSI 18.7 as well as Chapter 12 of the QATR also specify controls for measuring and test equipment. Sections 5.2.16 of ANSI 18.7-1976, in conjunction with Chapter 12 of the QATR, shall be used in lieu of Section 5.4 of ANSI N45.2.5 to control the frequency of calibration of automatic cut-off impact wrenches and hand held torque wrenches used to make up and/or inspect high strength bolted connections. The method of calibration will be consistent with the manufacturer's recommendation(s).

9. Regulatory Guide 1.123, Rev. 1, July 1977, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants."

The OCNGS and TMI QAP complies with this Guide with the following clarifications:

A. Section 4.2.a of ANSI N45.2.13-1976 (NQA-1). When evaluation of a supplier is based solely on historical supplier data, these data will primarily include records that have been accumulated in connection with previous procurement actions. Data that includes experience of users of identical or similar products of the prospective supplier and product operating experience will be used if available.

B. Section 10.2.1, Verification of the Validity of Supplier Certificates and the Effectiveness of the Certification System, is as follows: The verification of the validity of supplier certificates and the effectiveness of the certification system are accomplished as an integral part of the total supplier control and product acceptance program, and no separate Company system exists that addresses itself solely to such verification. The degree of verification required will depend upon the type of item or service and their safety importance. The means of verification may include source witness/hold points, source audits, and document reviews; independent inspections at the time of material receipt; user tests on selected commodities, such as concrete components; and tests on selected components and systems after installation. All of these means verify whether or not a supplier has fulfilled procurement document requirements and whether or not a certification system is effective.

10. Regulatory Guide 1.142, October 1981, "Safety-Related Concrete Structures for Nuclear Power Plants (Other Than Reactor Vessels and Containments)."

A. The Company shall comply with the Regulatory Position established in this Regulatory Guide as augmented by ANSI N45.2.5 (NQA-1, Part II, Subpart 2.5), ANSI/ANS 6.4-1977, and ANSI/ACI 318-77 for the design and construction of new Safety Related or Augmented Quality structures, and additions to existing Safety Related or Augmented Quality structures. Inspectors will be qualified according to either ANSI N45.2.6 or Appendix VII of Section III, Division 2, of the ASME Boiler and Pressure Vessel Code.

11. Regulatory Guide 1.143, October 1979, "Design Guidance for Radioactive Waste Management Systems, Structures and Components Installed in Light-Water-Cooled Nuclear Power Plants."

Since OCNGS was originally designed and constructed to different classification criteria than those contained in this Guide; the Company will comply with the Regulatory Position of this Guide with the following clarifications:

A. For modifications to existing plant systems, items will be classified by Site Engineering according to the original design basis, or this Guide.

This classification will not degrade the safety of the system being modified.

B. Additions to existing plant systems will be designed and constructed to the same codes, standards, and technical requirements which were originally applied to the system to which the addition is to be made, or more recent versions of these codes, standards, and technical requirements. The addition will not degrade the safety of the system being added to.

C. For new construction, the latest applicable codes will be utilized, unless such utilization would result in hardship or unusual difficulty without providing an equivalent level of safety.

D. Hose may be used in lieu of pipe where the connections are temporary. The anticipated applications of hose would normally be (1) connections to contractor owned skid mounted radioactive waste processing equipment, (2) connections to a non-mounted, frequently-changed component such as a burial liner/HIC, or (3) connections to non-mounted pieces of radioactive waste processing or collection equipment which must be readily removable (e.g., items placed on equipment hatches). The pressure rating of such hoses and connections shall equal or exceed those of the systems or components to which they are connected.

1. Prior to use, the hoses shall be hydro-tested to the appropriate pressure for the system or component to which they will be connected. After installation, they will receive regular hydro-testing or in-service inspections.

2. A 50.59 evaluation is required to justify the use of such hose connections.

12. ASME Boiler and Pressure Vessel Code Section III – The code year for the Section III B&PV Design Code is found in the applicable site UFSAR.

13. ASME Boiler and Pressure Vessel Code Section XI – The code year for the Section XI B&PV Inspection Code is found in the applicable site UFSAR.

1.3.3. Clinton Power Station (CPS)

1. The CPS QAPD also includes the following sections of the Operations Requirements Manual (ORM) and the Updated Safety Analysis Report (USAR). The specific sections are as follows:

A. ORM Section 6.8.2, Procedures and Programs – Review and Approval

B. ORM Section 6.8.3, Procedures and Programs – Temporary Changes

C. ORM Section 6.10, Record Retention

D. USAR Section 13.4

E. USAR Table 3.2-1

2. Site specific clarifications and exceptions applicable to Clinton Power Station include:

A. ASME Boiler and Pressure Vessel Code Section III – The code year for the Section III B&PV Design Code is found in the CPS USAR.

B. ASME Boiler and Pressure Vessel Code Section XI – The code year for the Section XI B&PV Inspection Code is found in the CPS USAR.

C. ASME NQA-1 (1994), "Quality Requirements for Nuclear Facility Applications (Revision and Consolidation of ASME NQA-1-1989 and ASME NQA-2-1989 Editions)." CPS compliance with this Standard and Revision is contingent upon NRC approval.

D. AWS D.1.1: The code year utilized for AWS D.1.1 applications is found in the CPS USAR.

E. IEEE-Standard 323 (1974): CPS complies with the 1974 Standard with some code year differences, which are found in the CPS USAR.

F. CPS complies with ANS 3.1 (1978), "Selection, Qualification, and Training of Personnel for Nuclear Power Plants." (Member of the Independent Safety Engineering Group (ISEG) are qualified in accordance with ANS 3.1 (1981).) Specifics for compliance, exceptions and clarifications are found in the CPS USAR.

G. The CPS USAR Section 1.8, "Conformance to NRC Regulatory Guides", which provides the CPS project position for implementation of regulatory guides, includes additional clarifications and exceptions to the regulatory guides.

H. CPS complies with RG 1.8 (Proposed Rev 2), "Personnel Qualification and Training." (Also reference USAR Section 1.8.)

I. CPS complies with Regulatory Guide 1.33, Rev. 2 (February 1978); "Quality Assurance Program Requirements (Operation)." CPS complies with this guide and with the following additional exception:

1. ANSI N18.7-1976/ANS-3.2, Section 5.2.17 Inspections: During plant operations emergencies, inspections may be performed under the direction of the duty shift manager.

1. SCOPE

This Appendix consists of definitions for words or phrases found in the QAP and provides a common basis for understanding those words or phrases that may have a different meaning when used elsewhere. All words and phrases are subject to review and revision, as circumstances require. Site specific items are noted.

2. GLOSSARY OF TERMS

2.1. Approval

Approval as used herein means by signature or initialing and date by an authorized individual.

2.2. ASME Boiler and Pressure Vessel Code, Section I

Refers to ASME Section I, Power Boilers

2.3. ASME Boiler and Pressure Vessel Code, Section III, Division 1 and Division 2 for Concrete Containment

Refers to ASME Section III, Division 1 and Division 2 for Concrete Containment; ASME Section III; ASME Code; ASME; or Code.

2.4. ASME Boiler and Pressure Vessel Code, Section IV

Refers to ASME Section IV, Heating Boilers

2.5. ASME Boiler and Pressure Vessel Code, Section VIII

Refers to ASME Section VIII, Pressure Vessels

2.6. ASME Boiler and Pressure Vessel Code, Section XI

Refers to ASME Section XI, Rules for In-Service Inspection of Nuclear Power Plant Components.

2.7. Audit

A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. This term is synonymous with "assessment."

2.8. Audit Team Leader

An individual appointed to lead an Audit Team. The Audit Team Leader coordinates the preparation of the audit report.

2.9. Auditor

One qualified and authorized to examine quality assurance practices and verify whether requirements are being met.

2.10. Augmented D (CPS Only)

A term applied to those components within the Augmented D boundaries as defined in the engineering specifications. See K-2882, USAR Table 3.2.1, and Appendix C of this manual for scope of requirements and boundaries pertaining to Augmented D.

2.11. Authorized Inspector or AI or ANI

As used herein is meant to mean Authorized Nuclear Inspector. An Authorized Nuclear Inspector is an employee of an Authorized Inspection Agency who has qualifications for and has been properly accredited for Division 1 or Division 2.

2.12. Authorized Nuclear In-service Inspector or ANII

As used herein is meant to mean the Authorized Nuclear In-service Inspector. An ANII is an employee of an Authorized Inspection Agency who has qualifications for and has been properly accredited for ASME Section XI.

2.13. Balance of Plant

Generating station items and equipment not designed, furnished or installed as a part of the Nuclear Steam Supply System. Balance of Plant items include safety-related and ASME Code items, such as the containment as well as non safety-related and non-ASME Code items.

2.14. Basic Component

"Basic component", when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10CFR100.11 Chapter 1 (1-1-87), Part 21.

2.15. Bid Package

The total of drawings, specifications, codes, standards, quality and other requirements that describes the task on which a prospective contractor/supplier will bid.

2.16. Calibration

A method of assuring accuracy of gauges and instruments used for measuring and testing by comparing with recognized standards.

2.17. Certificate of Compliance

A written statement signed by a qualified person, attesting that the materials or items are in compliance with the purchasing documents.

2.18. Certified Personnel

Personnel who have passed a formal training program and a formal proficiency test for special processes such as welding, plating and nondestructive testing.

2.19. Certified Standards

Standards of measurement whose accuracy can be traced to standards at the National Institute of Standards and Technology or established standards.

2.20. Certified Material Test Report

A document attesting that material is in accordance with specified requirements including the actual results of all required chemical analyses, tests and examinations.

2.21. Change Order

A formal award to a vendor or contractor covering revision(s) to the original Purchase Order or Change Order, involving but not limited to quantity, technical requirements, quality assurance requirements or scope of work.

2.22. Change Order Requisition

A document describing revisions to be made to the original Purchase Order or subsequent Change Order and which is converted into a Change Order.

2.23. Characteristic

Any property or attribute of an item, process or service that is distinct, describable and measurable, as conforming or nonconforming to specified quality requirements. Quality characteristics are generally identified in specifications and drawings, which describe the item, process or service.

2.24. Code

See ASME Boiler and Pressure Vessel Code, Section III or Section XI, whichever is applicable.

2.25. code

A recognized standard for using or processing materials, or for the skill involved in use or processing.

2.26. Cognizant Engineer

The engineer assigned a specific task or area of responsibility in the design or testing of a component or system.

2.27. ComEd

Commonwealth Edison Company (an Exelon Company).

2.28. Company

Exelon Generation Company, LLC

2.29. Company Level III

Chief Level III (NDE) for the Company

2.30. Component

ASME Code items such as vessels, concrete containments, piping systems, pumps, valves, core support structures and storage tanks which will be combined with other components to form an assembly or installation of a nuclear power plant.

2.31. Component Identification Number

An identification number assigned (where appropriate) to an item for use throughout its lifetime.

2.32. Construction

Activities at the building site necessary to erect, inspect and accept a power generating station and its associated installation. This definition applies unless otherwise indicated.

- Construction (ASME Section III Div.1) comprises all activities relating to materials, design fabrication, examination, testing, inspection and certification required in the manufacture and installation of items.
- Construction (ASME Section III Div. 2) includes all those operations required to build the component and its parts in accordance with the

Design Drawings and Construction Specification which have been prepared by the Designer (AE).

2.33. Construction Tests

Those tests necessary to verify that the installation of each component of a system is complete and complies with the applicable specifications, standards, codes, drawings and engineering information.

2.34. Contract (including purchase order)

A binding agreement between two or more persons or companies.

2.35. Contractor

Any organization under contract for furnishing items or services. It includes the terms vendor, supplier, subcontractor, fabricator and sub-tier levels of these where appropriate. A "Code" contractor is a contractor holding a valid ASME Section III Certificate of Authorization.

2.36. Control Point

In a sequential operation, a checkpoint at which certain data are taken, inspections are made or approval is required.

2.37. Control Stamp

A stamp used to mark a unique identification of inspection or test status upon items, tags, labels, routing cards or records traceable to an item. Control stamp impressions learly identify the person who applied it such that traceability to their authorization is provided.

2.38. Corrective Action

Measures taken to rectify conditions adverse to quality, and, where necessary, to preclude repetition.

2.39. Department

When a responsibility is given to a department in this Manual it is meant that the department head has the responsibility.

2.40. Design Change

Any change in design that may affect functional requirements, operating conditions, safety-, regulatory-, reliability-, and ASME Code-related requirements, performance objectives, plant reliability or design life and would require that affected documentation be changed.

2.41. Design Controls

Methods for assuring that basic design requirements are formalized and translated into design documents with proper review to assure the scheduled release of a valid design.

2.42. Design Criteria

Statements of the form, function and interface requirements within well defined limitations.

2.43. Designer (Division 2)

As used in ASME Code Division 2 construction, the Designer (AE) is the organization responsible for the preparation and completion of the Design Report, design drawings, and construction specifications for applicable items.

2.44. Design Requirements

Documents that set the functional requirements, operating conditions, safety requirements, performance objectives, design margins and design life. Included are any special requirements for size, weight, ruggedness, materials, fabrications or constructions, testing, maintenance, operating environments, safety margins and derating factors.

2.45. Design Review

An analysis of design with respect to technical adequacy, interface control, inspectability, maintainability and conformance to applicable codes, standards, regulations and design criteria.

2.46. Design Specification

A document that sets the functional requirements; design requirements; environmental conditions, including radiation; ASME Code classification; definition of the boundaries; and material requirements. Sufficient detail shall be contained within the document to provide a complete basis for design.

For Section III ASME Code, Division I: A document prepared by the owner or owner's designee which provides a complete basis for construction in accordance with the ASME Code, Section III.

2.47. Desk Survey

An evaluation of a supplier's quality control capability made from documented procedures and records of past performance.

2.48. Destructive Test

A test to determine the properties of a material or the behavior of an item which results in the destruction of the sample or item.

2.49. Deviation

A non-conformance. Departure of a characteristic from specified requirements.

2.50. Discrepancy

A non-conformance.

2.51. Documentation

Any written or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results.

2.52. Drawing Manifest

A document for transmitting drawings released for construction to an engineering, construction and/or production organization.

2.53. Erector

An organization involved in assembling and building equipment or structures at the site.

2.54. Examination

Specific actions by qualified personnel using qualified procedures to verify that items and fabrication processes are in conformance with specified requirements. This term, when used in conjunction with qualification of personnel to perform quality-related activities shall mean a written examination.

2.55. Exelon Generation Company, LLC

A company consisting of AmerGen Energy Company, LLC (AmerGen), Commonwealth Edison (ComEd), and Philadelphia Electric Co (PECO).

2.56. Extended Quality Assurance Program (CPS Only)

The selected use of technical and management controls to improve the operational performance of equipment important to reliable station operation but not included in compliance based quality assurance programs.

2.57. Fabricator

An organization involved in the manufacture of equipment.

2.58. Fabricator (ASME Section III Div. 2)

The NPT Certificate holder

2.59. Final Safety Analysis Report (FSAR)

A finalization of the preliminary safety analysis report prepared for the Nuclear Regulatory Commission prior to issuance of an operating license.

2.60. First Level Design Review

A review conducted by the responsible project engineer within the design agency for a specific design discipline.

2.61. Flow Chart

A representation of the sequence of activities such as procurement, fabrication, processing, assembly, inspection and test, or the sequence of individual operations within one or more of those functions.

2.62. Hold Point

A designated stopping place during or following a specific activity at which inspection or examination is required before further work can be performed.

2.63. Incident

Occurrence of major damage, serious personal injury or significant schedule delay.

2.64. Independent Review

Review completed by personnel not having direct responsibility for the work functions under review regardless of whether they operate as a part of an organizational unit or as individual staff members.

2.65. In-service Inspection

A mandatory program of examinations, testing, inspections and control of repairs and replacements to ensure adequate safety in maintaining the nuclear power plant and to return the plant to service in a safe and expeditious manner.

2.66. Inspection

A phase of quality verification that, by means of examination, observation or measurement, determines the conformance of materials, supplies, components, parts, appurtenances, systems, processes or structures to predetermined quality requirements.

2.67. Inspection and Test Plan

A listing, with optimum sequencing, of all the inspections and tests required to be performed for a specific item, component, structure or service.

2.68. Interface

When two or more organizations have responsibilities for accomplishing an activity, the functional relationship that one organization has to the others in completing the activity is called an "interface" relation. One example of interface is when one organization must perform a step, which is a prerequisite to another organization accomplishing its function. Interface can also mean that several organizations accomplishing similar activities are under the coordination control of one organization.

2.69. Interface control

Consideration that components and structures are geometrically and functionally compatible and those materials are compatible with both process and environment.

2.70. Item

Any level of unit assembly, including structure, system, subsystem, subassembly, component, part or material. When ASME Code items are referenced, this means products constructed under a certificate of authorization and material.

2.71. Jurisdictional Boundaries

The physical limits of an ASME Code item, which are identified to determine the applicability of ASME Code rules for that item.

2.72. Lifetime Record

A record that meets one or more of the following criteria:

- those that would be of significant value in demonstrating capability for safe operation;
- those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;
- those that would be of significant value in understanding the cause of an accident or malfunction of an item;
- those that provide required baseline data for in-service inspections.

2.73. Like - for - Like Replacement

The replacement of an item with an item that is identical in all physical and performance characteristics.

2.74. Local Purchase Order

A purchase order initiated through the computer by a station for the purchase of only Company Stores Coded items.

2.75. Maintenance

Repair, rework, or replacement of a structure, system or component with equipment of the same design, i.e., meeting the same engineering requirements.

2.76. Maintenance/Modification Work Package

The complete set of documentation that enables the station to fabricate, examine, test and install ASME and safety related items. The work package consists of the work request, provisions for station traveler, document checklist and maintenance/modification procedures and supporting information such as, but not limited to, approved drawings, design specifications, and special process procedures.

2.77. Material

A substance or combination of substances forming components, parts, pieces and equipment. (Intended to include such things as machinery, castings, liquids, formed steel shapes, aggregates and cement.)

When ASME Code material is referenced (this refers to metallic materials) which are manufactured to a SA, SB, or SFA Specification or any other material specification permitted by Section III of the ASME Code. For Division 2, refers to metallic materials, as well as to nonmetallic materials, conforming to the specifications permitted in Section III of the ASME Code.

2.78. Material Supplier

An organization which supplies material produced and certified by Material Manufacturers, but does not perform any operations that affect the material except when agreed upon by the Certificate Holder who uses the material in ASME Code construction or when so authorized by a Quality System Certificate (Materials). The Material Supplier may perform and certify the results of tests, examinations, repairs, or treatments required by the material specification that were not performed by the Material Manufacturer.

2.79. Measuring and Test Equipment (M&TE)

Equipment used to quantitatively generate or measure physical or electrical parameters with a known degree of accuracy for the purpose of calibration, inspection, test, or repair of plant mechanical, electrical, or instrument control equipment.

2.80. Modification

A change to an item made necessary by, or resulting in, a change in design requirements (ASME - NCA 9000). A planned change in plant design or operation and accomplished in accordance with the requirements and limitation of applicable codes, standards, specifications, licenses and predetermined safety restrictions.

2.81. National Standards

Standards maintained at or issued by the National Institute of Standards and Technology (NIST) or other designated institutions, and the values for natural physical constants and conversion factors recommended by NIST.

2.82. Non-compliance

A failure to comply with a regulatory requirement

2.83. Nonconformance

A nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of a structure, system, or component (SSC) or activity unacceptable or indeterminate. Some examples of nonconforming conditions include the following:

- There is failure to conform to one or more applicable codes or standards specified in the UFSAR or procurement documents.
- As-built equipment, or as modified equipment, does not meet UFSAR descriptions or design bases.
- Requirements can not be substantiated with proper documentation.
- Physical defects.
- Test failures.
- Deviation from prescribed processing, inspection, or test procedures.

2.84. Nonpermanent Record

A record that is required to show evidence that an activity was performed in accordance with the applicable requirements but do not meet the criteria for a lifetime record.

2.85. NQA - 1 (ASME NQA - 1)

Quality Assurance Program Requirements for Nuclear Facilities. For ASME Section III activities, NQA - 1 is as modified by the ASME Code.

2.86. Nuclear Steam Supply System (NSSS)

That portion of the nuclear generating plant that provides steam from nuclear heat. It includes the reactor, its control systems, main coolant and steam generation systems, fuel handling equipment, emergency core cooling system and other safeguards, associated electrical equipment, instrumentation, spent fuel handling and radioactive waste disposal system.

2.87. Objective Evidence

Any statement of fact, information or record, either quantitative or qualitative, pertaining to the quality of an item or service based on observations, measurements or tests that can be verified.

2.88. Offsite Review

Offsite review is the offsite review and investigative function required by the Technical Specifications. Offsite review requirements are satisfied by the Nuclear Safety Review Boards for operating Units.

2.89. Onsite Review

Onsite review is the onsite review and investigative function required by the Technical Specifications. Onsite review requirements are satisfied by the Technical Review Program and the Plant Operations Review Committee at the operating plants.

2.90. Operable/Operability

A system, subsystem, train, component or device shall be operable or have operability when it is capable of performing its specified function(s) and when all necessary attendant instrumentation, controls, electrical power, cooling or seal water, lubrication or other auxiliary equipment that are required for the system, subsystem, train, component or device to perform its function(s) are also capable of performing their related support function(s). NOTE: Safe operation of the plant is determined by licensed operators.

2.91. Operational Tests

Tests that are performed during the operations of the plant to verify continued satisfactory performance of safety-related structures, systems and components.

2.92. Permanently Installed Instrument and Control Devices

The installed plant equipment including computer points used in determining acceptance criteria of Technical Specification surveillances (Category A Instruments for CPS).

2.93. Phased Replacement

Where several identical items are to be replaced with a new model, they are replaced a few at a time to allow monitoring of the new items.

2.94. Preliminary Safety Analysis Report (PSAR)

The initial detailed safety evaluation prepared for the U.S. Nuclear Regulatory Commission prior to issuance of the site construction permit. The PSAR delineates design, normal and emergency operation, potential accidents and predicted consequences of such accidents and the means proposed to prevent such accidents and/or reduce their consequences to acceptable levels.

2.95. Pre-Operational Testing

Preliminary testing prior to fuel loading and plant operation to assure that construction and installation are complete and to verify design and system functions.

2.96. Procedure

A controlled document that specifies or describes how an activity is to be performed. It may include methods to be employed, equipment or materials to be used, accept/reject criteria and sequence of operations.

2.97. Proprietary Designs

Designs engineered, produced and sold by manufacturers in accordance with their criteria and warranty.

2.98. Purchase Requisition

The basic document describing a material, component or service that is converted into a purchase order for procurements.

2.99. Quality Assurance

All those planned and systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service. For the ASME Code, Quality Assurance comprises all those planned and systematic actions necessary to provide adequate confidence that all items designed and constructed are in accordance with the applicable ASME Code.

2.100. Quality Assurance Program (QAP)

The Quality Assurance Program is the method for complying with the provisions of 10CFR50 Appendix B for nuclear power plant systems, structures, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The Quality

Assurance Program is defined in the Quality Assurance Topical Report and implementing procedures.

2.101. Quality Assurance Topical Report (QATR)

A NRC approved regulatory document that describes quality assurance program elements for the operational phase of nuclear power plants. This term is synonymous with Quality Assurance Program Description (QAPD), Operation Quality Assurance Program (OQAP), and Quality Assurance Manual (QAM).

2.102. Quality Control

See Quality Verification

2.103. Quality Receipt Inspection Report

A form utilized by station Quality Control to document technical receipt inspection of ASME Code and safety-related items received by the station.

2.104. Quality Related

Activities which influence quality of safety-related items or work related to those systems, structures and components as identified in the USAR, Table 3.2-1, including design, purchasing, fabricating, handling, shipping, storing, cleaning, preserving, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling or modifying.

2.105. Quality Verification

Those quality assurance examinations and actions that provide a means to control and measure the characteristics of an item, process or facility to determine or establish conformance to acceptance standards and specified requirements.

2.106. Receipt Inspection

An inspection which verifies that items are in satisfactory condition, that they match the purchase order requirements and that required documentation accurately reflects the item(s) received. Visual and physical inspection will be performed as necessary to determine the acceptability of the item(s).

2.107. Receiving Inspection Notice (RIN)

A form initiated by the station upon receipt of ASME Code or safety-related items to record inspection for damage, to record receipt of documentation and to notify station Quality Control that item(s) are available for technical receipt inspection.

2.108. Record

A completed document that:

- furnishes evidence of the quality of items or activities.
- furnishes evidence of compliance with regulations or requirements.
- is required by Technical Specifications.

Included are such related documents as drawings, specifications, procurement documents, procedures, operating logs, and reportable occurrences. Such documents may be originals or reproduced copies.

2.109. Registered Professional Engineer (RPE)

A person competent in the applicable field of design and qualified in accordance with the requirements of ASME Section III, Appendix XXIII.

2.110. Repair

The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirements. For ASME Section III items, repair is the process of physically restoring a nonconformance to a condition such that an item complies with ASME Code requirements.

2.111. Request for Bid

Invitation made to suppliers or contractors to bid on a specific task for materials, goods and services.

2.112. Request for Purchase

A generating station's document originated by foremen, supervisors or department heads that designates the required items and services and delineates the design specifications, applicable codes and standards, as well as, any special requirements. This document is the basis of initiating a Purchase Requisition.

2.113. Resolution (CPS Only)

The process by which a nonconforming item is corrected or determined to adequately perform its design function without adversely affecting safety. The resolution may contain controls or limitations that are to apply until the nonconformance is fully corrected.

2.114. Rework

The process by which a nonconforming item is made to conform to a prior specified requirement by completion, re-machining, and re-assembling using previously approved procedural requirements. (For ASME Section III, rework is same as repair.)

2.115. Safety-Related

Systems, structures and components, which are considered important to safety because they perform safety actions, required to avoid or mitigate the consequences of abnormal operation transients or accidents. In addition, design requirements are placed upon such equipment to assure the proper performance of safety actions, when required (Safety-related items are those designated Seismic Category 1, Safety Class 1, 2, 3, "Other" and Electrical Class 1E as identified in the CPS USAR, Section 3.2).

2.116. Second Level Design Review

Independent objective assessment of a design by qualified personnel who have no direct project responsibility for the design.

2.117. Seismic Classification

Plant structures, systems and components important to safety which are designed to withstand the effects of a safe shutdown earthquake and remain functional if they are necessary to assure:

- The integrity of the reactor coolant pressure boundary, or
- The capability to shutdown the reactor and maintain it in a safe condition, or
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the guideline exposures of 10CFR100.

(Plant structures, systems and components, including their foundations and supports, which are designed to remain functional in the event of an SSE are designated as Seismic Category 1 as indicated in Table 3.2-1 of the CPS USAR.)

2.118. Significant Conditions (adverse to quality)

Those violations, deficiencies or events, having safety significance, that are required to be reported in writing within 24 hours to the NRC; severe operating abnormalities or large deviations from expected plant performance of safety related structures, systems, or components; "events" as described in the plant Technical Specifications; pervasive breakdowns in the quality assurance program; recurring deficiencies or errors that cannot be dispositioned or brought into conformance by established corrective action systems; or violations of the ASME Code that cannot be readily brought into compliance.

2.119. Source Acceptance

Acceptance made at a vendor's plant prior to shipment of purchased items.

2.120. Source Inspection

Inspection carried out at a vendor's plant prior to shipment of purchased items.

2.121. Special Process

A process, the results of which are highly dependent on the control of the process or skill of the operator, or both.

2.122. Special Process Procedures Manual

A compilation of Company procedures governing nondestructive examination and special processes such as welding and heat-treating.

2.123. Specification

A concise set of requirements to be satisfied by a product, material or process. The set of requirements may, also, indicate the procedure by which one may determine if the given requirements are satisfied.

2.124. Start Up Tests

Tests that are performed after initial fuel loading and proceed through several power level plateaus to 100% power.

2.125. Stock Material

Material which is or may be used for conversion to an ASME SA, SB, or SFA Specification or allowable ASTM Specification. As used in this Program, Stock Material is that material that has not been produced in accordance with an NCA 3800 QA Program.

2.126. Stop Work

Collective term used to describe the following three levels of stopping work activities:

- The stopping of a single or specific work activity by NOS personnel.
- A hold imposed by a Department Head on a department or general work activity.
- A Stop Work Action initiated by the NOS Manager.

2.127. Surveillance

Examination of supplier's manufacturing, inspection and test operations and of records of work in progress. This activity is documented.

2.128. Survey

A documented evaluation of an organization's ability to perform activities as verified by a determination of the adequacy of the organization's quality program and by a review of the implementation of that program at the location of work.

2.130. System Safety Classifications (CPS Only)

Structures, systems and components are classified as Safety Class 1, Safety Class 2, Safety Class 3, Safety Class Other or Class 1E in accordance with the importance to Nuclear Safety. Equipment is assigned a specific safety class, recognizing that components within a system may be a differing safety importance. Definitions of various Safety Classes are:

2.130.1. Safety Class 1 (CPS Only)

Components of the reactor coolant pressure boundary or core support structure whose failure could cause a loss of reactor coolant at a rate in excess of the normal make-up system.

2.130.2. Safety Class 2 (CPS Only)

Structures, systems and components, other than service water systems, that are not Safety Class 1, but are necessary to accomplish the safety functions of:

1. Inserting negative reactivity to shut down the reactor,
2. Preventing rapid insertion of positive reactivity,
3. Maintaining core geometry appropriate to all plant process conditions,
4. Providing emergency core cooling,
5. Providing and maintaining containment,
6. Removing residual heat from the reactor and reactor core, or
7. Storing spent fuel.

2.130.3. Safety Class 3 (CPS Only)

Structures, systems and components that are not Safety Class 1 or Safety Class 2, but whose function is to process radioactive fluids and whose postulated failure would result in conservatively calculated offsite doses that exceed 0.5 rem to the whole body or its equivalent to any part of the body in accordance with Regulatory Guide 1.26.

2.130.4. Safety Class "Other" (CPS Only)

Structures, systems and components used in the power conversion or other portions of the facility which have no direct safety function, but which may be connected to or influenced by the equipment within the Safety Classes 1, 2 or 3.

2.130.5. Class 1E (CPS Only)

The safety classification of the electric equipment and systems that are essential to emergency reactor shutdown, containment isolation, reactor core cooling and containment and reactor heat removal or otherwise are essential in preventing significant release of radioactive material to the environment. (Structures, systems and component safety classifications and related Quality Assurance Program requirements classifications are summarized in Table 3.2-1 of the CPS USAR.)

2.131. Technical Review (nonconforming item)

A determination as to whether a nonconforming item will be accepted "as is", reworked, repaired to an acceptable condition or rejected.

2.132. Technical Specification

The design and performance criteria and operating limits and principles of an operating license to be observed during initial fuel loading, critical testing, start-up, power operations, refueling and maintenance operations.

2.133. Test

Determination of the physical and functional properties of an item by subjecting the item to a set of physical, chemical, environmental or operating conditions.

2.134. Test Plan

An outline, narrative description or flow diagram indicating the tests to be performed, the methods to be used and the points in the process where they are to be executed. It may be in the form of a test procedure.

2.135. Traceability

The ability to verify the history, location, or application of an item by means of recorded identification.

2.136. USAR

Abbreviation for the Updated Safety Analysis Report, which is the document submitted by the Company to the Nuclear Regulatory Commission in accordance with 10CFR50.71.

2.137. Use - As - Is

A disposition which may be imposed for a nonconformance when it can be established that the discrepancy will result in no adverse conditions to safety and that the item under consideration will continue to meet all engineering functional requirements including performance, maintainability, fit and safety.

2.138. Variation

A nonconformance. Departure of a characteristic from specified requirements.

2.139. Verification

The act of confirming, substantiating, assuring, and documenting that a task, element, or condition is implemented in conformance with the specified requirements. Two commonly used type of verification as are described as follows:

- Concurrent Verification is also known as "apart-in-action" because the verification is being done concurrently as the action is implemented. Concurrent Verification is accomplished when two individuals verify the actions concurrently and apart from each other as they perform the task. Concurrent verification should be used for any action that if performed incorrectly, could result in an immediate threat to personnel safety, nuclear safety, reliable plant operation, or for an activity that can't be verified after it's completed.
- Independent Verification is also known as "apart-in-time" because the verification occurs at some time after the action has been performed. An independent verification is performed at a later time by a second qualified individual who is not part of the initial job performance checking the actions previously performed by others. Independent verification may be used in cases were actions if done incorrectly, could significantly affect nuclear and personnel safety, regulatory or other issues important to safe and reliable plant operations, but would not result in immediate consequences.

2.140. Witness Points

In a sequential operation, a notification to the Company, or its authorized agent, that a phase of work is about to be reached, so that it may be witnessed at a specific time, or in process, to verify acceptable performance of the phase. Witness points may be established in the traveler, procedure or in the course of monitoring the work activity.

2.141. Work Instructions

Actions to be completed by personnel while they are performing specific tasks in areas such as material controls and identification and fabrication or installation of equipment.

2.142. Workmanship

That quality of an item expressing its skillful and artful manufacture, without apparent blemishes.

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1. SCOPE

Measures shall be established and documented to assure that the requirements of the Code of Federal Regulations, Title 10, Part 71, Title 10, Part 20, and Title 49, Parts 100 through 199, applicable to the packaging and transporting of radioactive wastes or materials are satisfied

2. REQUIREMENTS

2.1. General

It is the Company's to minimize the generation of radioactive waste, consistent with the ALARA concept to minimize personnel exposures and environmental contamination. The elements contained within this appendix apply to Three Mile Island, Oyster Creek, and Clinton Power Station

Part 20, requires that a quality control program be implemented to verify compliance with Title 10, Part 61.55 (Waste Classification) and Title 10, and Part 61.56 (Waste Characteristics). This Plan shall be implemented to the extent necessary to assure compliance with those Parts of Title 10, using a graded approach.

Subpart H to 10CFR71 identifies the quality assurance criteria applicable to the control of packaging to be utilized to ship radioactive wastes or materials. The portions of this Plan that relate to the criteria in Subpart H to 10CFR71 describe, to a large extent, the administrative controls and quality requirements to be applied in the control, packaging, and transportation of radioactive waste or material.

2.2. Three Mile Island/Oyster Creek

2.2.1. Procedures and administrative controls shall be developed and implemented to cover the following:

1. Processing of radioactive wastes, including the collection, handling and preparation for shipment of radioactive liquids and solids. These procedures shall be consistent with the ALARA program and shall clearly identify the administrative controls and organizational responsibilities.

2. Training and qualification of personnel operating radioactive waste processing equipment, health physics monitoring, packaging and shipping (which includes Waste Classification and establishment of Waste Characteristics) and other operations deemed appropriate by management.

3. The activities associated with the packaging of radioactive wastes or materials shall include the proper selection of the receptacles to be used for containing the waste materials, the selection of the shipping containers (structures used to contain and support the receptacle and its contents), establishment of Waste Characteristics, radiological control inspections of the packaging prior to release, proper markings on the outside of the package, and the preparation of shipping papers and certificates. The activities shall be in accordance with 10CFR20, 10CFR61, 10CFR71, and 49CFR.

4. Movement of radioactive wastes or materials within and outside the protected area to assure personnel protection at all times.

5. The shipment of radioactive wastes or materials from the Station shall be in accordance with the regulations of the U.S. Department of Transportation for the transportation of hazardous materials (49CFR) and of the NRC (10CFR71 and 10CFR20).

6. Design, fabrication, assembly, testing, and modification of packaging used for transportation of radioactive waste or material which exceed the limits specified by 10CFR71.10 shall not be performed by the Company. Such packaging shall be purchased from an outside supplier and shall comply with 10CFR71 and 49CFR. The Company shall review and accept designs of packaging purchased from an outside supplier.

7. The packaging used for transporting of radioactive waste or material, which does not exceed the limits specified in 10CFR71.10, whether purchased from an outside supplier or designed by the Company, shall meet 49CFR.

8. Minimization of the generation of radioactive wastes through training programs, prudent scheduling and use of equipment and personnel, and good housekeeping practices.

2.2.2. The carriers to be used for transporting of radioactive waste or material shall be selected on the basis of their experience, knowledge of DOT regulations, control and maintenance of their equipment and the selection and control of their drivers. The carrier is required to have or shall be supplied documented procedures covering acceptance of radioactive waste or material from a shipper, certification requirements, placarding, storage control, reporting of incidents and security. The Company shall review and accept carrier procedures specified by procurement documents covering the acceptance of radioactive waste or material for shipment.

2.2.3. Operations involving radioactive waste processing or radioactive material shall be controlled to minimize personnel exposures or environmental contamination, consistent with ALARA.

2.2.4. Operations procedures relating to radioactive waste or material shipping and packaging shall be reviewed by Quality Verification to establish any necessary inspection points.

2.3. Clinton Power Station

2.3.1. Radioactive Waste/Augmented "D" Systems.

QATR Chapters that are applicable to Radioactive Waste/Augmented "D" Systems are 1 through 7, 9 through 11, and 13 through 18. Chapters 8 and 12 do not apply.

1. Chapter 4 - Specification of quality assurance program requirements for suppliers of radioactive waste/augmented D materials, equipment and services shall be on a case-by-case basis. Commercial grade or off-the-shelf items may provide an acceptable level of quality based on the nature of the item. This determination shall be made by Engineering personnel prior to issuance of procurement documents.

2. Chapter 7 - Suppliers providing material, equipment and services for Radioactive Waste/Augmented D shall be subject to source evaluation and surveillance. The extent of imposition of these requirements shall be determined on a case-by-case basis by the design organization responsible for review and approval of the procurement specifications. Measures shall be established, and appropriate, for examination of products upon delivery.

3. Chapter 9 - Applicable to the qualification of welders and welding procedures (ASME Section IX) for Radioactive Waste systems. (Pressure boundaries only.)

4. Chapter 10 - Applicable only to inspection of those items and activities affecting Radioactive Waste/Augmented D systems within the quality assurance boundaries as specified in the USAR, Table 3.2-1, and further amplified by the appropriate design drawings.

2.3.2. Packaging and Transportation of Radioactive Material

QATR Chapters 1 through 18 are applicable to the packaging and transportation of radioactive material.

1. Chapter 3 - Applicable, design activities are not normally performed by CPS for radioactive material packaging, however, audits of suppliers establish that the design was accomplished under control of an NRC approved QA program.

2. Chapter 7 - Applicable, measures such as source surveillance and audits of records should be taken as appropriate to ensure that the design and fabrication of packaging were performed under the control of an NRC-approved QA program.

3. Chapter 9 - Applicable, special processes such as welding or nondestructive testing are not normally performed by CPS. However, if packaging requires major repairs necessitating use of special processes, e.g., welding or heat treating, measures shall be established to ensure that the special processes are controlled.

4. Chapter 10 - Applicable, visual inspections shall be performed upon receipt of packaging to ensure compliance with certificates of compliance.

5. Chapter 13 - Applicable, all conditions identified in a certificate of compliance when using packages shall be adhered to.

6. Chapter 16 - Applicable, measures are established for obtaining corrective actions from suppliers and for ensuring that follow-up is documented to verify that corrective actions were implemented and effective.

7. Chapter 17 - Applicable, records showing evidence of delivery of packages to a carrier and proof that all NRC and Department of Transportation (DOT) requirements have been satisfied shall also be retained.

8. Chapter 18 - Applicable, audits are performed on the supplier of packaging to ensure compliance with the certificate of compliance.

1. SCOPE

The Company establishes measures that provide a graded approach to quality at Oyster Creek and Three Mile Island Stations. The extent to which the requirements of this appendix and its associated implementing documents are applied to an item will be based upon the effect of a malfunction or failure of the item on nuclear safety or safe plant operations.

2. REQUIREMENTS

2.1. General

The quality requirements for items within the scope of this appendix shall be established using approved procedures. Quality requirements will be established by the responsible organizational element and subject to assessment by Nuclear Oversight.

The need for special controls, and surveillance or maintaining of processes, equipment and of operational activities will be applied consistent with:

- The design and fabrication complexity or uniqueness of the item.
- The degree to which functionality can be demonstrated by inspection or test.
- The quality history and degree of standardization of the item.

The extent to which the requirements of the QATR apply to activities will be based, as a minimum, on Operating License conditions and other plans previously submitted to the NRC for approval, other regulatory commitments as may have been made associated with activities, the text of this Plan, the unit's Technical Specifications, and Appendix C of the QATR.

Such other plans or regulatory commitments include, but are not limited to, those associated with emergency planning, physical plant security, safeguard contingency planning, radiological controls, radiological environmental controls, fire protection, in-service inspection, in-service testing, licensed operator qualification and re-qualification, process control, off-site dose calculation, Shift Technical Advisor training, environmental qualification of electrical equipment, security guard training and qualification, etc.

2.2. Quality Classification

The scope of the Company's QATR includes but is not limited to items and activities related to safe nuclear plant operation, protection of personnel, and protection of the public. To ensure consistency in identifying those items and activities within the scope of the QATR, a classification process has been developed and documented. This process relies on the use of the terms "Safety Related," "Augmented Quality," and "QATR Scope."

2.2.1. Nuclear Safety Related or Augmented Quality Items

1. Items within the scope of the QATR are designated as "Nuclear Safety Related" or "Augmented Quality." A quality classification process for Items has been developed. This classification process produces a Component Record List, which identifies the permanent plant structures, systems, and components that are within the scope of the QATR and their specific classification. New Items to which the QATR applies shall be added to the Component Record List subsequent to their installation. The classification of structures, systems, and components shall be subject to independent design review as part of the classification process.

2. Spare or replacement parts and materials are not necessarily classified the same as the component of which they are a part. Such parts and materials that perform or contribute to the performance of a Safety Related or Augmented Quality function are within the scope of the QATR and classified similar to the component of which it is a part. For procurement of spare or replacement parts which are of a different classification, the classification will be determined by Procurement Engineering. The determinations will be documented, retained, and subject to review and assessment.

3. The classification of items and consumable items (such as chemicals, radwaste liners, diesel fuel, etc.) and the technical and quality requirements will be specified, documented and approved as part of the procurement process.

4. The QATR may be applied to items, other than those designated as "Safety Related" or "Augmented Quality" as specified by Company management.

2.2.2. QATR Scope Activities

1. Activities within the scope of the QATR are designated as within "QATR Scope." Activities that are within the scope are those directly related to nuclear and radiological safety and protection of the public and are delineated below.

2. Support activities within the scope of the QATR are quality classification, operating experience assessment, design, maintenance of environmental and fire protection qualification, nuclear fuel management, procurement, fabrication, handling, shipping, storage, cleaning, erecting, installing, testing, repairing, training, welding, in-service inspection, heat treatment, document control, records management, access authorization and fitness-for-duty.

3. Operational activities within the scope of the QATR are normal, abnormal and emergency operation, chemistry control, core performance monitoring, shift technical advice, equipment control, surveillance testing, in-service testing, maintenance, housekeeping, fire protection, security,

radiological controls, radiological environmental monitoring, radwaste preparation for shipment, radwaste shipment, fuel handling/refueling, technical specification compliance, and emergency preparedness.

4. Assurance activities within the scope of the QATR are assessment (audit, document review, monitoring, survey, and surveillance), inspection, non-destructive examination, and safety review. Individuals who are not directly responsible for managing or performing the work or activity perform assurance activities. Nuclear Oversight personnel perform periodic assessments of the "assurance" activities performed by other organizational elements (e.g. NDE/ISI) to assure effectiveness and adequacy.

5. The above stated activities are controlled through the use of approved documents which are, as a minimum, consistent with the requirements of the QATR, the unit Operating License, specific Regulatory Guides to the extent listed and committed to in Appendix C of the QATR, the Final Safety Analysis Report, and other regulatory requirements and commitments.

6. A specific task associated with the above activities will be classified as within scope of the QATR depending upon:
   - Statements within the text and the Regulatory Guides identified in Appendix C of the QATR.
   - The relationship of the task to the safe operation of the nuclear plant.
   - The relationship of the task to the protection of personnel from the effects of radiation.
   - The relationship of the task to protection of the health and safety of the public.
   - The relationship of the task to regulatory requirements and commitments.
   - Other factors specified by Company management.

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1. SCOPE

10CFR50 Appendix B requires a quality assurance program be established in writing and executed for activities affecting the safety-related function of designated structures, systems and components to an extent consistent with their importance to safety.

2. REQUIREMENTS

2.1. Clinton Power Station (CPS)

The areas of Environmental, Fire Protection, and Security are specifically identified in Table 3.2-1 of the CPS USAR and/or highlighted in several Regulatory Guides that define and clarify its importance to the plant.

2.1.1. Environmental

QATR Chapters that are applicable to the Environmental area are 1, 2, 15, 16, and 18. Chapters 3, 9, and 10 do not apply.

1. Chapter 4 - Applicable to procurement of monitoring services to be performed by contractors providing services dealing with radiological data and to radionuclide reference standards used for calibration of radiation measurement systems.

2. Chapter 5 - Applicable to all activities related to carrying out the radiological monitoring program including: sample collection; packaging, shipment and receipt of samples for off-site analysis; procurement, maintenance, storage and use of radioactivity reference standards; calibration and checks of radiation and radioactivity measurement systems; and reduction, evaluation and reporting of data.

3. Chapter 6 - Applicable to procedures and instructions required by Chapter 5.

4. Chapter 7 - Applicable to radionuclide reference standards used for calibration of radiation measurement systems and to radiological monitoring activities (services) provided by contractors.

5. Chapter 8 - Applicable only to radiological sample collection, identification, packaging, shipping, receiving, storage and analysis.

6. Chapter 9 - Applicable to radioactivity measurements of samples, instrument backgrounds, replicate samples and analytical blanks; data reduction and verification; computer program documentation and verification.

7. Chapter 9 - Applicable to laboratory instruments for radiation and radioactivity measurement, continuous radiological effluent monitoring systems and flow-rate measuring devices associated with radiological effluent monitoring systems.

8. Chapter 13 - Applicable to radiological samples only.

9. Chapter 14 - Applicable to continuous radiological effluent monitoring systems equipment only.

10. Chapter 17 - Applicable to personnel training and qualification; field and in-plant collection of samples; continuous effluent monitoring; sample receipt and laboratory identification; sample preparation and radiochemical processing; radioactivity measurements of samples, instrument backgrounds and analytical blanks; data reduction and verification; instrument calibration and calibration standards; computer program documentation; audits; and corrective action.

2.1.2. Fire Protection

QATR Chapters that are applicable to the Fire Protection area are 1 through 7, 10, 11, and 14 through 18. Chapters 8, 9, 12 and 13 do not apply.

1. Chapter 4 - Applicable. Specification of quality assurance program requirements for suppliers of fire protection materials, equipment and services shall be on a case-by-case basis. Commercial grade or off-the-shelf items may provide an acceptable level of quality based on the nature of the item. This determination shall be made by Engineering personnel prior to issuance of procurement documents

2. Chapter 7 - Applicable. Suppliers providing material, equipment and services for fire protection shall be subject to source evaluation and surveillance. The extent of imposition of these requirements shall be determined on a case-by-case basis by the design organization responsible for review and approval of the procurement specifications. Measures shall be established, as appropriate, for examination of products upon delivery.

3. Chapter 10 - Applicable only to inspection of those items and activities affecting the fire protection system within the quality assurance boundaries as specified in the USAR, Table 3.2-1 and further amplified by the appropriate design drawings.

4. Chapter 17 - Applicable to documents designated as Quality Assurance Records generated in the implementation of the Fire Protection Program and consistent with the requirements identified in Chapter 10 above. Records are prepared and maintained to furnish evidence that the applicable criteria discussed herein are being met for activities affecting the Fire Protection Program.

5. Chapter 18 - Applicable. Audits shall be performed and documented to verify compliance with the Fire Protection Program, including design and procurement documents, instructions, procedures and drawings and inspection and test activities.

2.1.3. Security

QATR Chapters that are applicable to the Security area are 16 through 18. Chapters 1 through 15 do not apply.

1. Chapter 17 - Applicable to those records required by the CPS Physical Security Plan.

2. Chapter 18 - Applicable to the physical security of CPS and designated records.

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Attachment 2

Exelon Generation Company, LLC
AmerGen Energy Company, LLC

Quality Assurance Topical Report EGC-1A, Rev. 70

Reductions in Commitment for
Oyster Creek Generating Station
Docket Nos. 50-219 and 72-15

Summary of Proposed Changes for Oyster Creek Generating Station

The formation of Exelon Generation Company, LLC (Exelon) and AmerGen Energy Company, LLC (AmerGen), which are responsible for operation of multiple sites, makes it prudent to have a common and consistent set of quality assurance standards. The common Exelon/AmerGen Quality Assurance Topical Report (QATR), based on an update to the current NRC approved Quality Assurance Program described in Exelon QATR EGC-1A, Revision 69, will serve as the governing Quality Assurance Program for the nuclear facilities within the Exelon and AmerGen organizations. The Exelon/AmerGen QATR will allow efficiencies and flexibility in implementing quality assurance requirements, but will maintain sufficient control of activities affecting quality through administrative and programmatic controls.

The Exelon/AmerGen QATR was developed using guidance contained in NUREG-0800, "Standard Review Plan," Section 17.1, "Quality Assurance During Design and Construction Phases," and Section 17.2, "Quality Assurance During the Operations Phase," and, as permitted under the requirements of 10 CFR 50.54(a)(3)(ii), using quality assurance alternatives or exceptions approved by NRC Safety Evaluations for changes to other facility Quality Assurance Programs.

AmerGen's Oyster Creek Generating Station is adopting QATR EGC-1A in lieu of the currently docketed site-specific Quality Assurance Program as described in Operational Quality Assurance Plan (OQAP) 2000-PLN-7200.01. As a result of adopting the Exelon/AmerGen QATR, nine (9) of the proposed changes have been identified as requiring NRC review and approval as reductions in commitment pursuant to 10 CFR 50.54(a)(4) prior to implementation of the changes. The details and bases of the proposed changes are described below. The affected sections of OQAP 2000-PLN-7200.01 are provided in Enclosure 1 of this attachment. QATR EGC-1A, Revision 70, is provided in Attachment 1 to this letter.

Details and Bases of the Proposed Changes

Operational Quality Assurance Plan (OQAP) Section 1.6 (see Enclosure 1, Page 2 of 11)

The fifth paragraph, item "p" discusses a requirement for Nuclear Oversight (NOS) concurrence with closeout of nonconformances. NOS review and concurrence for nonconformance dispositions as well as verification of completion is being removed. This is considered a reduction in commitment. The Nuclear Oversight Continuous Assessment program does, however, require that the implementation of the Corrective Action Program be reviewed across functional areas on a quarterly basis. This is considered adequate to meet the intent of oversight of the nonconformance identification/resolution process and will not result in a reduction in the level of effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 1.8 (see Enclosure 1, Page 3 of 11)

The content of the first paragraph of Section 1.8 is contained in Exelon/AmerGen QATR Chapter 1, Section 2.3.2 with the exception of providing a selected review of plant operations and testing. This is a reduction in commitment. The OQAP Section 1.8 provides for the Director – Site Engineering to perform selected reviews of plant operations and testing procedures. Similar requirements are not addressed in the QATR. 10CFR50, Appendix B, and the QA Program Regulatory Guides and associated standards do not have a similar requirement. The requirement was added to the QA Plan in the early 1980's with the intent of providing engineering input into operationally oriented procedures. QATR Chapter 5 contains requirements for technical review and control of documents that provide specificity and far exceed the one line statement for engineering review of specified procedures.

Therefore, elimination of this specific requirement does not reduce the effectiveness of the QA Program to produce documents that are technically correct.

OQAP Section 2.5 (see Enclosure 1, Page 5 of 11)

The OQAP Section 2.5 describes that the plan is authorized by the Chief Nuclear Officer (CNO) and requires appropriate levels of management to implement the OQAP. Implementation responsibilities for the QATR are contained in the QATR, Policy and Applicability statements. Chapter 1, Section 2.2.2.2-7 of the QATR describes the plan authorization responsibility at the management position responsible for Nuclear Oversight (NOS), not at the CNO level as described in the OQAP. As written, this is considered to be a reduction in commitment. Approval is at the Management position at the highest level whose responsibilities are limited solely to the oversight of nuclear plant operations. This management position has the expertise, staff, and responsibility for the development, maintenance and implementation of the QA program. Adding the responsibility to approve the QATR and changes to it melds with his other QA program responsibilities. Moving the responsibility for approval of the OQAP to a position responsible for Nuclear Oversight does not reduce the responsibility of the CNO to ensure the safe and efficient operation of the site. Ultimate responsibility for all facets of site operation continues to rest with the CNO. The Management position responsible for Nuclear Oversight is a direct report to the CNO. This reporting relationship will ensure the CNO is advised of QA program changes. This reduction was evaluated to not be a reduction in effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 2.5.1 (see Enclosure 1, Page 6 of 11)

The content of Section 2.5.1 of the OQAP describes the approval and concurrence requirements of the OQAP. The QATR does not describe the concurrence requirements in detail, and the approval is by the management position responsible for Nuclear Oversight (Chapter 1, Section 2.2.2.2) as delegated by the Exelon Chief Nuclear Officer (CNO), not solely the CNO as required by the OQAP. This is considered to be a reduction in commitment. Approval by the Management responsible for Nuclear Oversight is addressed in the preceding paragraph. The elimination of concurrence detail was evaluated to be reduction in detail that is controlled by review and approval programs in addition to the authority and responsibilities as directed in QATR Chapter 1. QATR Chapters 5 and 6 detail the requirements for these programs. On this basis, the change was evaluated to not be a reduction in effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 2.5.4 (see Enclosure 1, Page 7 of 11)

The content of Section 2.5.4 of the OQAP describes the implementation of procedure changes within 60 days of an OQAP revision. This is not addressed implicitly in the QATR. As written, this is considered to be a reduction in commitment. The program for procedure controls includes all activities governed by the quality assurance program that are performed as directed by documented instructions, procedures and drawings appropriate for the activity. Also, there are programmatic controls that ensure that procedures are reviewed and revised as needed, when pertinent source material is changed. These requirements are included within the new standard QATR Chapter 5, "Instructions, Procedures and Drawings" and Chapter 6, "Document Control." The removal of this detailed requirement was evaluated to not reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 2.13 & 1.10.e (see Enclosure 1, Pages 4 and 8 of 11)

The content of Section 2.13 of the OQAP describing the Self-Assessment process is not addressed in the QATR. This is considered a reduction in commitment. Exelon programs such as 2000-ADM-

1291.03, "Self-Assessment Program", specifically address the self-assessment function. Functional responsibilities for NOS, as addressed in Chapter 1 Section 2.2.2.2, are to assess both the internal and management assessment programs. Evaluation of these processes is performed in accordance with the QATR as stated in Chapter 18, "Assessments," which requires that assessments of the Company and its vendors are conducted to verify QAP compliance, adequacy and effectiveness. These assessments are conducted in accordance with written procedures and to the requirements of NQA-1 to evaluate the assessed organization and to assure completion of required corrective actions, commitments, or improvements and determine effectiveness in meeting program objectives. These assessment program requirements are described within procedure requirements of NO-AA-200-001, "Nuclear Oversight Continuous Assessment Process." Included within this process is procedure NO-AA-200-001-1005, "Evaluating the Line Self-Assessment Process," as an element of completing the assessment process. Based on the process as described within QATR Chapter 18, "Assessments" and controlled by administrative procedures, deleting the detail of the self-assessment process from the QA plan was evaluated to be a reduction in commitment that does not reduce the effectiveness of the QA program to meet the requirements of 10 CFR 50, Appendix B.

The OQAP Section 1.10.e, third paragraph, provides for the Plant Manager assisting in the development of a comprehensive self assessment program. The QA Program provides for independent assessment of processes and programs that are required for the safe operation of the plant. Therefore, deletion of this feature from the QA Program description does not reduce the effectiveness of the QA Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 3.2.2.2.a (see Enclosure 1, Page 9 of 11)

The requirement that design descriptions and specifications for items, parts, and materials designated as safety related shall be marked as such is not addressed in the QATR. This is considered to be a reduction in commitment. The marking of documents is not required by 10CFR50, Appendix B. The document control requirements of 10CFR50, Appendix B, Criterion 6 continue to be fulfilled by the QATR Chapter 6 and Appendix C commitment to ASME NQA-1-1989 requirements. The marking of the document does not enhance the quality of the document. The QA program controls for development, use and control of the document is not impacted by this marking. This was evaluated to be a reduction in the level of detail but not in effectiveness of the QA program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 6.10.1 (see Enclosure 1, Page 10 of 11)

The OQAP Section 6.10.1 requirement for site Vice President approval prior to implementing modifications in areas or systems critical to safe operation while the plant is in operation is not specifically stated in the QATR. This is considered a reduction in commitment based on elimination of this level of detail provided. This is not a required element of 10CFR50, Appendix B. This reduction was evaluated to not be a reduction in effectiveness of the QA program based on the stated requirement that this individual remains responsible for overall plant safety as an organizational responsibility. This statement is contained in the QATR Chapter 1, Section 2.3. In addition, the QATR Chapter 1, Section 2.3.1 states that the plant manager is also responsible for assuring the safe, reliable and efficient operation of the plant within the constraints of applicable regulatory requirements, operating license, and the Quality Assurance Program.

OQAP Section 8.2.8 (see Enclosure 1, Page 11 of 11)

OQAP Section 8.2.8, third sentence is not specifically contained in the QATR. The OQAP requires that the results of all trending be reported to management. The QATR Chapter 16, Section 2.2.1, second and third paragraphs identify that trending will be done. Chapter 16, Section 2.5, first paragraph

identifies that significant conditions adverse to quality will be reported to appropriate levels of management. Therefore, if trending identifies an adverse trend which is determined to be significant, it will be reported to appropriate levels of management. This is considered a reduction in commitment in that all trending analysis will not require reporting to management; the focus will be on significant trends. While this is a reduction in commitment, this is designed to and is expected to result in more meaningful information being presented to management. Therefore, this will not reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

Conclusion

The proposed changes outlined above are considered to be reductions in Oyster Creek Generating Station Quality Assurance Program commitments. However, the proposed changes are acceptable because they were determined not to reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

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1.6 Mid-Atlantic ROG Director - Nuclear Oversight

The Mid-Atlantic ROG Director - Nuclear Oversight reports to the Vice President - Nuclear Oversight. The Mid-Atlantic ROG Director - Nuclear Oversight has the functional authority, independence and responsibility to assure the effective implementation of and compliance to the Quality Assurance Program. Consistent with this responsibility is the authority to render interpretations in writing on those activities to which this Plan applies and the extent to which the Plan applies to those activities. The Site Nuclear Oversight Manager assists the Mid Atlantic ROG Director, Nuclear Oversight by implementing day-to-day oversight of OCNGS. The Site Nuclear Oversight Manager reports directly to the Mid Atlantic ROG Director, Nuclear Oversight.

Additional responsibilities include providing recommendations or solutions to quality problems, and performing monitoring, assessments, audits, inspections, and independent oversight for all areas.

For on-site independent review issues, the Site Nuclear Oversight Manager and the Independent Onsite Safety Review Group (IOSRG) have the authority to directly report to and communicate with the Chief Nuclear Officer and the Vice President - Oyster Creek.

The Mid-Atlantic ROG Director - Nuclear Oversight reports directly to the Vice President - Nuclear Oversight on all Oyster Creek quality matters and has direct unencumbered access to the Chief Nuclear Officer with regard to activities affecting quality. This reporting relationship has been established to provide sufficient independence from the influence of costs and schedules to be able to effectively assure conformance to Quality Assurance Program requirements.

The Mid-Atlantic ROG Director - Nuclear Oversight has no duties or responsibilities unrelated to the responsibilities contained in this document that would prevent the required attention to quality assurance matters. The Mid-Atlantic ROG Director - Nuclear Oversight has the authority and responsibility to:

a. Develop and maintain the Oyster Creek Operational Quality Assurance Plan and Nuclear Oversight procedures required to assure that all Oyster Creek activities provide the required high degree of safety and reliability.

b. Assess, audit, monitor and inspect Oyster Creek activities to assure that they provide the required high degree of safety and reliability and are carried out consistent with all applicable laws, regulations, regulatory commitments, licenses, corporate policies and other requirements. Assessment schedules are developed and implemented to ensure all required areas are assessed.

c. Establish and conduct nuclear safety review and assessment activities which include those of the IOSRG and the Nuclear Safety Review Board (NSRB).

d. Identify and report nonconformances as they may exist. Initiate, recommend or provide solutions through designated channels. Verify implementation of resolutions as required.

e. Initiate stop work or unit shutdown recommendations when warranted by a safety concern and obtain unit shutdown with appropriate upper-management concurrence.

f. Provide for a review of selected documents which prescribe methods for activities and quality requirements for items within the scope of this Plan. Refer to Appendix B of this Plan.

g. Direct and manage Nuclear Oversight.

h. Provide a working interface and line of communication with other organizational elements and other appropriate industry groups for all program matters.

i. Provide indoctrination, certification, and/or training programs for Nuclear Oversight.

j. Assure Quality Assurance program indoctrination of appropriate personnel outside of Nuclear Oversight is provided.

k. Immediately notify the CNO, Vice President - Oyster Creek, and appropriate organizational elements directors and managers of any significant quality related problem or deficiency.

l. Perform assessments on a planned and periodic basis to comprehensively determine the effectiveness of the Quality Assurance Program and its implementation and detect adverse trends that may be present.

m. Issue periodic reports to the CNO, Vice President Nuclear Oversight, and the Vice President - Oyster Creek, and organizational elements directors and managers on the effectiveness of implementation of activities within the scope of this Plan.

n. Provide oversight of self-assessment activities to determine effectiveness of the program.

o. Review and concur with all procedures for reporting and controlling of non-conformance's for compliance with the requirements of this Plan.

p. Review, verify and concur with close-out of non-conformance's, when required.

q. Provide interpretations as necessary of this Plan to ensure proper implementation.

r. Provide and implement an inspection program (excluding Receipt Inspection and NDE) to ensure maintenance and modification activities are carried out consistent with this plan.

1.7 Director- Licensing

The Director - Licensing reports to the Vice President - Licensing and Regulatory Affairs. The Director - Licensing has the functional authority, independence and responsibility to assure the effective implementation of all applicable non-environmental laws, regulations, and licenses associated with the safe and reliable operation of the generating station. Consistent with this responsibility is the authority to render interpretations in writing on those licensing and regulatory activities to which this Plan applies and the extent to which the Plan applies to those activities.

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The Director - Licensing has the authority and responsibility to:

a. Provide, in coordination with the Oyster Creek Experience Assessment organization, the principal interface and control with all non-financial, regulatory agencies for AmerGen including NRC, appropriate state agencies, and supporting legal services. In addition, ensure preparation and coordination of responses to regulatory agencies, including NRC inspections and enforcement bulletins, circulars, notices and generic letters, and activities associated with INPO and NEI.

b. Provide for maintenance of the operating license for the Nuclear Plant.

c. Direct and manage the Licensing organizational element.

d. Provide a working interface and line of communication with other organizational elements and other appropriate industry and regulatory groups for all licensing and regulatory matters.

1.8 Director - Site Engineering

The Director - Site Engineering reports directly to the Vice President - Oyster Creek. The Director's Quality Assurance Plan responsibilities consist of providing the requisite engineering and technical support to: maintain the design basis of the nuclear plants; maintain the configuration control documents including development and maintenance of the Component Record List (CRL); provide nuclear fuel management; provide core performance monitoring; monitor and analyze the technical performance and reliability of systems and components; provide selective review of plant operations and testing procedures, and associated training; provide technical control and coordination of plant modifications as required by Section 6.10 of this Plan; and provide a weld program and a repair program.

Additional specific responsibilities associated with the above are:

a. Review of procurement documents to assure that quality requirements are correctly stated, inspectable and controllable; that there are adequate acceptance/rejection criteria; that source verification or receipt inspection is specified; that minimum documentation to be supplied is specified; and that the procurement documents have been processed in accordance with established requirements. (Section 5)

b. Ensuring programs are established and maintained for the special processes of welding, heat treating.

c. Performing a startup and test function to assure new or substantially modified plants, facilities and systems are tested in compliance with this Plan. (Section 6.4)

d. Establishing, implementing and maintaining document distribution and record retention programs and facilities.

e. Providing management direction and accountability for Information Technology (IT).

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1.9 Director - Training

The Director-Training reports directly to the Vice President-Oyster Creek. The Director's Quality Assurance Plan responsibilities consist of establishing and delivering training and education programs sufficient to assure safe, reliable and efficient operation, providing management direction and accountability for emergency preparedness.

1.10 Plant Manager

The Plant Manager reports directly to the Vice President - Oyster Creek. The Plant Manager's Quality Assurance Plan responsibilities consist of operating Oyster Creek in a safe, environmentally sound, reliable and efficient manner in accordance with company policies and all applicable laws, regulations licenses, technical requirements and procedures; providing and maintaining a qualified staff; staff and direct shift technical advisors; provide management accountability and direction for the following functions; plant operations, radwaste, plant chemistry, radiation protection and industrial safety.

The responsibilities of the Plant Manager include the authority to order the shutdown of the unit whenever the health and safety of the public are endangered or when, in his judgement, a shutdown is warranted.

Additional specific responsibilities associated with the above are:

a. Ensuring that programs are established and maintained for identification and control of equipment to avoid unauthorized use and to assure that operational equipment is in a ready status. These requirements shall include independent verifications to ensure proper implementation. (Section 6.9)

b. Ensuring that the appropriate requirements for controlling the inspection, test and operating status, including independent verification, are incorporated in the procedures used on all test and operation activities performed. (Section 6.7)

c. Ensuring that programs are established and maintained for minimizing the generation of radioactive waste and materials, the processing of radioactive waste and movement of radioactive materials. (Section 7)

d. Establishing, implementing and maintaining radiological controls and radiological environmental monitoring

e. Assist in the development of a comprehensive self assessment program.

f. Chairman for the Plant Operations Review Committee.

g. Providing management direction and accountability for the following functions; Physical Security Program; Safeguard Contingencies; Security Force Training and Qualification; Access Authorization Program; and Fitness-For-Duty Program.

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2.4.2 Level II - The activities at this level are primarily those of survey, surveillance, monitoring, and document review and are performed as deemed necessary by Nuclear Oversight and/or Nuclear Services. The level of surveillance or monitoring applied is consistent with the importance of the item to safety and the extent of administrative controls utilized for the Level I activity.

At this level, procedures and instructions are established and surveillance and/or monitoring records will be completed and maintained. Such surveillance/monitoring normally includes observation of tests and inspections, observation of selected operations, review of records, verifications of test reports, and direct inspection on a spot-check basis. The organizations performing this activity have the levels of authority, the lines of internal and external communication for management direction, and properly trained personnel for implementation of these activities.

2.4.3 Level III - The purpose of this level of activity is to assure, through a comprehensive program of review, assessment and audit, that all organizations conducting activities and/or tasks within the scope of this Plan are properly satisfying all the requirements of the Quality Assurance Program.

At this level, procedures and instructions are established, including the use of comprehensive checklists or detailed reports for documentation of the third-level activity.

For audits, the program requirements of ANSI N45.2.12 shall be satisfied. Lead auditors shall be utilized who are qualified to the requirements of ANSI N45.2.23. Additional technical support personnel, from areas with administrative reporting outside the function that is being audited, will be utilized as Audit Program Management deems necessary. The organization performing this audit activity has sufficient authority, independence and lines of internal and external communications to obtain the necessary access to management to conduct the review and audit, resolve any issues which may arise from the review and audit and secure additional technical support for the performance of audits as may be required.

2.5 Operational Quality Assurance Plan Control

This Plan is authorized by the CNO and requires that the appropriate levels of management, as designated herein, implement the Quality Assurance Program. This Plan is controlled to ensure that only the latest approved revision is implemented. This Plan is implemented through approved documents (refer to Section 3.0).

Appendix A provides a correlation of the sections of this Plan with the requirements of 10CFR50 Appendix B; 10CFR71, Subpart H; 10CFR72, Subpart G; ANSI N45.2; and ANSI N18.7.

2.5.1 Approval

This Plan shall be originated by the Mid-Atlantic ROG Director - Nuclear Oversight and be approved by the CNO with concurrence by the following:

Vice President - Oyster Creek
Vice President - Nuclear Oversight

2.5.2 Revisions

The Mid-Atlantic ROG Director -Nuclear Oversight is responsible for ensuring this Plan is modified and updated as needed. Proposed revisions to this Plan may be suggested by AmerGen personnel by submitting a written request to the Mid-Atlantic ROG Director-Nuclear Oversight.

The Mid-Atlantic ROG Director - Nuclear Oversight shall, for each revision to this Plan, determine whether the changes reduce the commitments in this Plan previously accepted by the NRC as required by 10CFR 50.54(a). The basis for this determination will be documented as part of the change package.

Revisions to this Plan that do not reduce commitments to the NRC shall be originated by the Mid-Atlantic ROG Director - Nuclear Oversight and approved by the CNO with the concurrence of the Vice President - Oyster Creek and the Vice President - Nuclear Oversight. The Cover Page containing the approval and concurrence signatures shall be retained. Revisions of this type do not require approval by the NRC prior to implementation, but must be submitted to the NRC with the FSAR updates in accordance with 10CFR50.71(e). The Document History page will be utilized to identify such changes.

Revisions of this Plan that reduce the commitments previously accepted by the NRC shall be submitted to the NRC. Such revisions shall be regarded as approved by the NRC upon receipt of a letter to this effect from the appropriate reviewing office or 60 days after submittal to the NRC, whichever comes first. The submittal of the revision to this Plan must include all pages affected by that change and must be accompanied by a transmittal letter identifying the change, the reason for the change, and the basis for concluding that the revision continues to satisfy 10CFR50, Appendix B and provides a suitable level of control. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items. A copy of this letter must be maintained as a facility record for three years. Revisions of this type shall be originated by the Mid-Atlantic ROG Director -Nuclear Oversight, approved by the CNO with the concurrence of the Vice President - Oyster Creek and the Vice President - Nuclear Oversight as indicated by their signatures on a revised Cover Page.

2.5.3 Distribution

Copies of the Operational Quality Assurance Plan may be distributed as "Controlled" or "Uncontrolled" in accordance with the requirements established in Section 3.

2.5.4 Effective Date of Implementation

Changes to this Plan shall be incorporated in the implementing documents within 60 days of the issuance date of the Plan unless an interim action plan is defined and approved by the Mid-Atlantic ROG Director -Nuclear Oversight. Implementing documents which do not require a substantive revision may be combined with a revision at a future date or at the next periodic review of the document. Examples of a non-substantive revision as used in this context include organizational titles, requirements which exceed the revised Plan requirements, or changes in reporting relationships not specified by Technical Specifications.

2.6 Quality Assurance Program Review

The effectiveness of the Quality Assurance Program and its implementation is periodically reviewed by various organizations at various levels and the results of these reviews are documented in reports to senior management for evaluation and corrective action as required. The effectiveness of the Quality Assurance Program is evaluated and reported by Nuclear Oversight through the monitoring, auditing and inspection functions. Other organizational elements provide additional information/ evaluations as requested.

In addition to the reviews and evaluation performed by Nuclear Oversight, the CNO shall, at least once per year, have an independent assessment of the Quality Assurance Program implementation performed to ensure that the Program is effective in ensuring that regulatory requirements and commitments; and AmerGen policies are met. This assessment may be performed utilizing a safety review group, an independent consultant, representatives of other utilities and/or his own staff. Any corrective action which may be deemed necessary as a result of these assessments shall be formally identified and tracked through resolution.

2.7 Indoctrination and Training

Formal indoctrination and training programs for personnel performing or verifying activities within the scope of this Plan are required to be established and maintained. A Training Organizational element is established and staffed and is responsible for planning, scheduling, developing and providing training to AmerGen personnel. The indoctrination and training programs are established by on-site and by off-site organizational units responsible for the performance or verification of activities within the scope of this Plan.

The proficiency of personnel shall be evaluated, and measures to maintain proficiency shall be implemented, either through retraining, reexamination and/or re-certification.

When certification is required, the certificate shall delineate the specific functions the individual is certified to be able to perform and the criteria used to certify the individual for those functions.

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2.12 Independent Safety Oversight

The first element of oversight of safety is the IOSRG. The IOSRG has no line responsibilities or line functions and is devoted solely to safety matters. It is independent of the plant staff and reports to the Nuclear Oversight Manager who reports to the Mid-Atlantic ROG Director -Nuclear Oversight. The IOSRG will consist of a minimum of a manager and three full time engineers/ technical staff.

The IOSRG shall have access to the unit and unit records as necessary to perform its evaluations and assessments. Based on its reviews, the IOSRG shall provide recommendations to the management positions responsible for the areas reviewed. IOSRG reports of evaluations and assessments shall be transmitted to the Mid-Atlantic ROG Director Nuclear Oversight, the Vice President - Oyster Creek and the management positions responsible for the areas reviewed.

The second element of oversight of safety is the Nuclear Oversight staff, who audit, monitor, assess and perform quality verification inspection aspects of AmerGen activities within the scope of this Plan or relating to safety. This provides for an overview of activities affecting or potentially affecting safety.

The third element of oversight of safety is the Nuclear Safety Review Board. This is a group of senior level individuals with diverse backgrounds and extensive nuclear experience. The Board reports to the Chairman Nuclear Safety Review Board and takes general direction from the CNO but has direct access to the AmerGen CEO. Its charter is broadly defined to encompass all matters potentially affecting nuclear safety (including management related aspects) so as to foresee potentially significant nuclear safety and radiation problems. Licensing provides staff support to the Nuclear Safety Review Board.

2.13 Self Assessment

Organizations responsible for performance of activities within the scope of this Plan may perform evaluations to assess their performance, seek opportunities for improvement or address known problems. Nuclear Oversight will typically review self-assessment activities conducted by other organizational elements as part of its independent assessments. Nuclear Oversight will not eliminate assessments required by this Plan as a result of organizational al self-assessment activities but may alter scope when self-assessment activities sufficiently address subject areas.

2.14 Employee Concerns Program

An Employee Concerns Program is provided by Nuclear Oversight. These individuals are accessible on a confidential basis, if desired, to anyone in the company having a nuclear or radiation safety concern that he or she considers is not being adequately addressed. These individuals are empowered to investigate such matters, identify any needed action and seek its resolution. The individual who raised the concern will be contacted with the result of the investigation.

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m. Procurement and Material Control Procedures and Instructions.

n. Radiological Control, Process Control, Radiological Environmental Monitoring, Radwaste Shipping and Chemistry Control Plans, Procedures, Instructions, Standards, and Specifications.

3.2.2.2 Procedures established for document control shall prescribe the following requirements:

a. Drawings, design descriptions and specifications for items, parts, and materials designated as Safety Related shall be marked as such.

b. Review and approval requirements for documents and their revisions shall be specified to ensure that adequate technical and quality requirements are incorporated prior to issue. Issuance requirements shall be specified to ensure adequate dissemination for use.

c. The organizations or positions responsible for reviewing, approving and issuing documents and their revision shall be specified.

d. Revisions shall be documented, approved, and issued prior to being implemented. Temporary changes shall be reviewed and approved consistent with Technical Specification requirements.

e. Revisions and changes shall be reviewed and approved by the same organizations that performed the original review and approval; or by organizations designated by the originating organizations, except for documents originated by organizations outside AmerGen. In this case, AmerGen may designate the review and approval organizations. Approved changes shall be promptly transmitted for incorporation into documents and obsolete or superseded documents shall be eliminated from use.

f. Document distribution shall be sufficient to assure that the documents are readily available to responsible personnel prior to commencement of work.

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6.10 Control of Construction, Maintenance (Preventive/Corrective) and Modifications Requirements

6.10.1 Construction, maintenance or modifications which have the potential to affect the functioning of structures, systems or components within the scope of this Plan shall be performed in a manner to ensure quality at least equivalent to that specified in the original design basis 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. Construction, maintenance or modification of equipment shall be pre-planned and performed in accordance with written procedures, instructions, or drawings appropriate to the circumstances which conform to applicable codes, standards, specifications, and criteria. In this regard, modification type work in areas and systems of the plant critical to the safe operation of the plant shall not be performed while the plant is operating without specific advance approval by the Vice President - Oyster Creek or designee.

6.10.2 Detailed step by step procedures are not required for all maintenance and modification work. The supervisor planning the job must consider the skills required to ensure proper completion of the work and identify the procedural requirements accordingly. Work such as replacing chart or drive speed gears, replacing fuses or tightening valve packing may not require written procedures.

Whereas, work involving inter-departmental coordination or risk of nuclear or personnel safety requires a higher level of administrative control, such as approved procedures and sign offs to properly coordinate, direct and document the activity.

6.10.3 Skills normally possessed by qualified maintenance personnel may not require detailed step-by-step delineation's in a written procedure, but are subject to general administrative procedural controls that govern or define the following areas:

a. Methods for obtaining permission and clearance from Operations personnel to work, and for logging such work.

b. Factors to be taken into account, including the necessity of maintaining occupational radiation exposure as low as reasonably achievable (ALARA).

c. Method for identification of what procedural coverage is necessary for the maintenance, construction or modification activity.

d. Considerations for system/equipment cleanliness control.

f. Disposition of nonconformance. The disposition shall be determined by the organization responsible for the nonconformance. Rework and scrap dispositions are made by the material user without engineering review; use-as-is and repair dispositions require concurrence and justification of cognizant engineering organizations. Quality Verification shall concur with all dispositions except those originated during receipt inspection. Receipt inspection hardware nonconformance dispositions shall be concurred with by Materials & Supply.

NOTE

The individual providing the disposition shall not sign for concurrence or verification of the disposition.

g. Notification to the affected organizations of the nonconformance.

h. Verification method, verification, and close out.

i. Record retention.

j. Required approval signatures on the disposition and the verification.

k. Evidence of review for Reportability to the NRC.

8.2.6 Reworked, repaired, and replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives as determined by Site Engineering and Quality Verification. (Note: Quality Verification is not required for hardware nonconformances found during receipt inspection.) All inspection, testing, rework, and repairs shall be controlled by approved procedures and the results documented.

8.2.7 Prior to the initiation of a preoperational test on a safety related item, all nonconformances shall be evaluated for significance or impact on further testing or operation and shall be dispositioned as appropriate. The evaluation/disposition shall be documented.

8.2.8 Nonconformance reports shall be periodically analyzed to detect adverse trends as may be present. Such analysis shall be based upon severity, number, frequency of nonconformances, the causes of the nonconformances and the timeliness of the reporting and resolution of nonconformances. The results of analyses shall be periodically reported to management for review and assessment. When significant conditions are identified, or when actions are required by upper management to correct problems, such as a generic problem identified by the trend analysis or repetitive failure to disposition nonconformances, these problems shall be elevated to upper levels of management for resolution.

Attachment 3

Exelon Generation Company, LLC
AmerGen Energy Company, LLC

Quality Assurance Topical Report EGC-1A, Rev. 70

Reduction in Commitment for
Peach Bottom Atomic Power Station
Docket Nos. 50-171, 50-277, 50-278 and 72-29

Summary of Proposed Change for Peach Bottom Atomic Power Station

The formation of Exelon Generation Company, LLC (Exelon) and AmerGen Energy Company, LLC (AmerGen), which are responsible for operation of multiple sites, makes it prudent to have a common and consistent set of quality assurance standards. The common Exelon/AmerGen Quality Assurance Topical Report (QATR), based on an update to the current NRC approved Quality Assurance Program described in Exelon QATR EGC-1A, Revision 69, will serve as the governing Quality Assurance Program for the nuclear facilities within the Exelon and AmerGen organizations. The Exelon/AmerGen QATR will allow efficiencies and flexibility in implementing quality assurance requirements, but will maintain sufficient control of activities affecting quality through administrative and programmatic controls.

The Exelon/AmerGen QATR was developed using guidance contained in NUREG-0800, "Standard Review Plan," Section 17.1, "Quality Assurance During Design and Construction Phases," and Section 17.2, "Quality Assurance During the Operations Phase," and, as permitted under the requirements of 10 CFR 50.54(a)(3)(ii), using quality assurance alternatives or exceptions approved by NRC Safety Evaluations for changes to other facility Quality Assurance Programs.

Exelon's Peach Bottom Atomic Power Station (PBAPS) is adopting QATR EGC-1A in lieu of the currently docketed site-specific Quality Assurance Program as described in Updated Final Safety Analysis Report (UFSAR), Appendix D.11. As a result of adopting the Exelon/AmerGen QATR, one (1) of the proposed changes has been identified as requiring NRC review and approval as a reduction in commitment pursuant to 10 CFR 50.54(a)(4) prior to implementation of the change. The details and basis of the proposed change is described below. The affected section of UFSAR, Appendix D.11, is provided in Enclosure 1 of this attachment. QATR EGC-1A, Revision 70, is provided in Attachment 1 to this letter.

Details and Basis of the Proposed Change

PBAPS UFSAR, Appendix D.11, Section 17.2.17.3.2 (see Enclosure 1, Page 1 of 1)

This section of the PBAPS Quality Assurance Program Description (QAPD) specifies a 10-year record retention period for NQA Assessment and Surveillances and Nuclear Oversight Continuous Assessment reports. The original record retention requirements were based on the guidance found in ANSI N45.2.9-1976 which did not, however, specify a 10-year retention period. This requirement was specific within the PBAPS QAPD. Exelon/AmerGen QATR, Chapter 17, defines Quality Assurance record retention requirements based on the guidance found in ASME/ANSI NQA-1, Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records." In accordance with this guidance, the above listed records are classified as "Nonpermanent Records" and the specific record retention requirements are delineated in records management procedures. This change to the record retention requirements from the existing criteria found in the PBAPS QAPD is considered a reduction in commitment. However, the record retention requirements detailed in the Exelon/AmerGen QATR do not reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

Conclusion

The proposed change outlined above is considered to be a reduction in a Peach Bottom Atomic Power Station Quality Assurance Program commitment. However, the proposed change is acceptable because it was determined not to reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

g. Deleted

h. Records of sealed source leak tests and results

i. Records of annual physical inventory of all source material of record

17.2.17.3.2 The following records shall be retained for at least 10 years.

a. Records of NQA assessments and surveillances and N.O. Continuous Assessment Reports

17.2.17.3.3 The following records shall be retained for the duration of the Facility Operating License and the Independent Spent Fuel Storage Installation License as applicable.

a. Records and drawing changes reflecting facility design modifications made to systems and equipment described in the UFSAR, and the Independent Spent Fuel Storage Installation 212 Report and SAR

b. Records of new and irradiated fuel inventory, fuel transfers, and assembly burnup histories

c. Records of facility radiation and contamination surveys

d. Records of radiation exposure for all individuals entering radiation control areas

e. Records of gaseous and liquid radioactive material released to the environs

f. Records of transient or operational cycles for those facility components designed for a limited number of transients or cycles

g. Records of training and qualification for current members of the plant staff

h. Records of in-service inspections performed pursuant to 10CFR50.55a

i. Records of Quality Assurance activities except as described in 17.2.17.1, 17.2.17.3.1, and 17.2.17.3.2 above

j. Records of reviews performed for changes made to procedures or equipment or reviews of tests

Attachment 4

Exelon Generation Company, LLC
AmerGen Energy Company, LLC

Quality Assurance Topical Report EGC-1A, Rev. 70

Reductions in Commitment for
Three Mile Island Nuclear Station, Unit 1
Docket No50-289

Summary of Proposed Changes for Three Mile Island, Unit 1

The formation of Exelon Generation Company, LLC (Exelon) and AmerGen Energy Company, LLC (AmerGen), which are responsible for operation of multiple sites, makes it prudent to have a common and consistent set of quality assurance standards. The common Exelon/AmerGen Quality Assurance Topical Report (QATR), based on an update to the current NRC approved Quality Assurance Program described in Exelon QATR EGC-1A, Revision 69, will serve as the governing Quality Assurance Program for the nuclear facilities within the Exelon and AmerGen organizations. The Exelon/AmerGen QATR will allow efficiencies and flexibility in implementing quality assurance requirements, but will maintain sufficient control of activities affecting quality through administrative and programmatic controls.

The Exelon/AmerGen QATR was developed using guidance contained in NUREG-0800, "Standard Review Plan," Section 17.1, "Quality Assurance During Design and Construction Phases," and Section 17.2, "Quality Assurance During the Operations Phase," and, as permitted under the requirements of 10 CFR 50.54(a)(3)(ii), using quality assurance alternatives or exceptions approved by NRC Safety Evaluations for changes to other facility Quality Assurance Programs.

AmerGen's Three Mile Island, Unit 1, is adopting QATR EGC-1A in lieu of the currently docketed site-specific Quality Assurance Program as described in Operational Quality Assurance Plan (OQAP) 1000-PLN-7200.01. As a result of adopting the Exelon/AmerGen QATR, nine (9) of the proposed changes have been identified as requiring NRC review and approval as reductions in commitment pursuant to 10 CFR 50.54(a)(4) prior to implementation of the changes. The details and bases of the proposed changes are described below. The affected sections of OQAP 1000-PLN-7200.01 are provided in Enclosure 1 of this attachment. QATR EGC-1A, Revision 70, is provided in Attachment 1 to this letter.

Details and Bases of the Proposed Changes

Operational Quality Assurance Plan (OQAP) Section 1.9 (see Enclosure 1, Page 3 of 10)

The fifth paragraph, item "p" discusses a requirement for Nuclear Oversight (NOS) concurrence with closeout of nonconformances. NOS review and concurrence for nonconformance dispositions as well as verification of completion is being removed. This is considered a reduction in commitment. The Nuclear Oversight Continuous Assessment program does, however, require that the implementation of the Corrective Action Program be reviewed across functional areas on a quarterly basis. This is considered adequate to meet the intent of oversight of the nonconformance identification/resolution process and will not result in a reduction in the level of effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 1.11 (see Enclosure 1, Page 4 of 10)

The content of the first paragraph of Section 1.11 is contained in Exelon/AmerGen QATR Chapter 1, Section 2.3.2 with the exception of providing a selected review of plant operations and testing. This is a reduction in commitment. The OQAP Section 1.11 provides for the Director – Site Engineering to perform selected reviews of plant operations and testing procedures. Similar requirements are not addressed in the QATR. 10CFR50, Appendix B, and the QA Program Regulatory Guides and associated standards do not have a similar requirement. The requirement was added to the QA Plan in the early 1980's with the intent of providing engineering input into operationally oriented procedures. QATR Chapter 5 contains requirements for technical review and control of documents that provide specificity and far exceed the one line statement for engineering review of specified procedures. Therefore, elimination of this specific requirement does not reduce the effectiveness of the QA Program to produce documents that are technically correct.

OQAP Section 2.5 (see Enclosure 1, Page 5 of 10)

The OQAP Section 2.5 describes that the plan is authorized by the Chief Nuclear Officer (CNO) and requires appropriate levels of management to implement the OQAP. Implementation responsibilities for the QATR are contained in the QATR, Policy and Applicability statements. Chapter 1, Section 2.2.2.2-7 of the QATR describes the plan authorization responsibility at the management position responsible for Nuclear Oversight (NOS), not at the CNO level as described in the OQAP. As written, this is considered to be a reduction in commitment. Approval is at the Management position at the highest level whose responsibilities are limited solely to the oversight of nuclear plant operations. This management position has the expertise, staff, and responsibility for the development, maintenance and implementation of the QA program. Adding the responsibility to approve the QATR and changes to it melds with his other QA program responsibilities. Moving the responsibility for approval of the OQAP to a position responsible for Nuclear Oversight does not reduce the responsibility of the CNO to ensure the safe and efficient operation of the site. Ultimate responsibility for all facets of site operation continues to rest with the CNO. The Management position responsible for Nuclear Oversight is a direct report to the CNO. This reporting relationship will ensure the CNO is advised of QA program changes. This reduction was evaluated to not be a reduction in effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 2.5.1 (see Enclosure 1, Page 5 of 10)

The content of Section 2.5.1 of the OQAP describes the approval and concurrence requirements of the OQAP. The QATR does not describe the concurrence requirements in detail, and the approval is by the management position responsible for Nuclear Oversight (Chapter 1, Section 2.2.2.2) as delegated by the Exelon Chief Nuclear Officer (CNO), not solely the CNO as required by the OQAP. This is considered to be a reduction in commitment. Approval by the Management responsible for Nuclear Oversight is addressed in the preceding paragraph. The elimination of concurrence detail was evaluated to be reduction in detail that is controlled by review and approval programs in addition to the authority and responsibilities as directed in QATR Chapter 1. QATR Chapters 5 and 6 detail the requirements for these programs. On this basis, the change was evaluated to not be a reduction in effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 2.5.4 (see Enclosure 1, Page 6 of 10)

The content of Section 2.5.4 of the OQAP describes the implementation of procedure changes within 60 days of an OQAP revision. This is not addressed implicitly in the QATR. As written, this is considered to be a reduction in commitment. The program for procedure controls includes all activities governed by the quality assurance program that are performed as directed by documented instructions, procedures and drawings appropriate for the activity. Also, there are programmatic controls that ensure that procedures are reviewed and revised as needed, when pertinent source material is changed. These requirements are included within the new standard QATR Chapter 5, "Instructions, Procedures and Drawings" and Chapter 6, "Document Control." The removal of this detailed requirement was evaluated to not reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 2.13 (see Enclosure 1, Page 7 of 10)

The content of Section 2.13 of the OQAP describing the Self-Assessment process is not addressed in the QATR. This is considered a reduction in commitment. Exelon programs such as 1000-ADM-1291.03, "Self-Assessment Procedure" for TMI, specifically address the self-assessment function. Functional responsibilities for NOS, as addressed in Chapter 1 Section 2.2.2.2, are to assess both the

internal and management assessment programs. Evaluation of these processes is performed in accordance with the QATR as stated in Chapter 18, "Assessments," which requires that assessments of the Company and its vendors are conducted to verify QAP compliance, adequacy and effectiveness. These assessments are conducted in accordance with written procedures and to the requirements of NQA-1 to evaluate the assessed organization and to assure completion of required corrective actions, commitments, or improvements and to determine effectiveness in meeting program objectives. These assessment program requirements are described within procedure requirements of NO-AA-200-001, "Nuclear Oversight Continuous Assessment Process." Included within this process is procedure NO-AA-200-001-1005, "Evaluating the Line Self-Assessment Process," as an element of completing the assessment process. Based on the process as described within QATR Chapter 18, "Assessments" and controlled by administrative procedures, deleting the detail of the self-assessment process from the QA plan was evaluated to be a reduction in commitment that does not reduce the effectiveness of the QA program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 3.2.2.2.a (see Enclosure 1, Page 8 of 10)

The requirement that design descriptions and specifications for items, parts, and materials designated as safety related shall be marked as such is not addressed in the QATR. This is considered to be a reduction in commitment. The marking of documents is not required by 10CFR50, Appendix B. The document control requirements of 10CFR50, Appendix B, Criterion 6 continue to be fulfilled by the QATR Chapter 6 and Appendix C commitment to ASME NQA-1-1989 requirements. The marking of the document does not enhance the quality of the document. The QA program controls for development, use and control of the document is not impacted by this marking. This was evaluated to be a reduction in the level of detail but not in effectiveness of the QA program to meet the requirements of 10 CFR 50, Appendix B.

OQAP Section 6.10.1 (see Enclosure 1, Page 9 of 10)

The OQAP Section 6.10.1 requirement for site Vice President approval prior to implementing modifications in areas or systems critical to safe operation while the plant is in operation is not specifically stated in the QATR. This is considered a reduction in commitment based on elimination of this level of detail provided. This is not a required element of 10CFR50, Appendix B. This reduction was evaluated to not be a reduction in effectiveness of the QA program based on the stated requirement that this individual remains responsible for overall plant safety as an organizational responsibility. This statement is contained in the QATR Chapter 1, Section 2.3. In addition, the QATR Chapter 1, Section 2.3.1 states that the plant manager is also responsible for assuring the safe, reliable and efficient operation of the plant within the constraints of applicable regulatory requirements, operating license, and the Quality Assurance Program.

OQAP Section 8.2.8 (see Enclosure 1, Page 10 of 10)

OQAP Section 8.2.8, third sentence is not specifically contained in the QATR. The OQAP requires that the results of all trending be reported to management. The QATR Chapter 16, Section 2.2.1, second and third paragraphs identify that trending will be done. Chapter 16, Section 2.5, first paragraph identifies that significant conditions adverse to quality will be reported to appropriate levels of management. Therefore, if trending identifies an adverse trend which is determined to be significant, it will be reported to appropriate levels of management. This is considered a reduction in commitment in that all trending analysis will not require reporting to management; the focus will be on significant trends. While this is a reduction in commitment, this is designed to and is expected to result in more meaningful information being presented to management. Therefore, this will not reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

Conclusion

The proposed changes outlined above are considered to be reductions in Three Mile Island, Unit 1, Quality Assurance Program commitments. However, the proposed changes are acceptable because they were determined not to reduce the effectiveness of the Quality Assurance Program to meet the requirements of 10 CFR 50, Appendix B.

1.3 ROG Senior Vice President

The ROG Senior Vice President reports to the Chief Executive Officer. This position is responsible for the overall leadership of the operations portion of TMI activities. This position provides for an additional level of executive management oversight regarding the operation of TMI. This position is also responsible for *maintenance / work control and for* supplying selected administrative and technical support to TMI.

1.4 Vice President - TMI - Unit 1

The Vice President - TMI reports to the ROG Senior Vice President. This position is responsible to operate, maintain, and refuel the generating station in a safe, reliable and efficient manner in accordance with corporate policies and all applicable laws, regulations, licenses and technical requirements. The Vice President - TMI - Unit 1 also has a direct reporting relationship to the AmerGen CEO for the purpose of AmerGen Company policy and business. The Vice President - TMI shall be responsible for TMI-1 operations and may, at any time, delegate his responsibilities in writing to the Plant Manager. He shall delegate the succession of his responsibilities in writing during his absence. The Vice President - TMI - Unit 1 is the senior AmerGen representative at the site, and as such, assures consistent implementation of policies and procedures at the plant and off-site facilities. The Operational Quality Assurance Plan responsibilities of the Vice President - TMI - Unit 1 consist of establishing, maintaining and delivering training and education programs sufficient to assure safe, reliable and efficient operation; establishing, implementing and maintaining radiological controls, radiological environmental monitoring, and emergency preparedness.

1.5 Senior Vice President - Nuclear Services

The Senior Vice - President Nuclear Services reports to the Chief Nuclear Officer. The Senior Vice - President Nuclear Services is responsible for nuclear fuels programs, Non-destructive examination, *generation support, outage services, training, security,* project management, engineering, and laboratory services.

1.6 Vice President – *Licensing & Regulatory Affairs*

The Vice President – *Licensing & Regulatory Affairs reports to the CEO. The Vice President – Licensing & Regulatory Affairs is responsible for the overall development and implementation of Licensing, Regulatory Affairs, and the Emergency Preparedness programs and services.*

1.7 Vice President – Business Operations

The Vice President – Business Operations reports to the CNO. The Vice President – Business Operations is responsible for information systems, and nuclear supply including the Contractor and Vendor Quality Assurance Program evaluation (as specified in Section 5 of this Plan), and the maintenance of an Evaluated Vendors List (EVL).

1.8 Vice President – Nuclear Oversight

The Vice President - Nuclear Oversight reports directly the Chief Nuclear Officer. The Vice President - Nuclear Oversight is responsible for the overall development and implementation of the AmerGen quality assurance program, and employee concern program. The Vice President - Nuclear Oversight also has the responsibility to keep management informed of conditions concerning quality. The Vice President Nuclear Oversight may delegate "Stop Work" authority to the Senior Vice President Nuclear Services for vendor related deficiencies. The Senior Vice President Nuclear Services has unencumbered access to the Vice President Nuclear Oversight for vendor/supplier corrective action escalation.

1.9 Director – Mid-Atlantic ROG Nuclear Oversight

The Director - Mid-Atlantic ROG Nuclear Oversight reports to the Vice President – Nuclear Oversight. The Director - Mid-Atlantic ROG Nuclear Oversight has the functional authority, independence and responsibility to assure the effective implementation of and compliance to the Quality Assurance Program. Consistent with this responsibility is the authority to render interpretations in writing on those activities to which this Plan applies and the extent to which the Plan applies to those activities. The Site Nuclear Oversight Manager assists the Director, Mid Atlantic ROG Nuclear Oversight by implementing day-to-day oversight of TMI. The Site Nuclear Oversight Manager reports directly to the Director, Mid Atlantic ROG Nuclear oversight.

Additional responsibilities include providing recommendations or solutions to quality problems, and performing assessments, inspections, and independent oversight for all areas.

For on-site independent review issues, the Nuclear Oversight Manager and the Independent Onsite Safety Review Group (IOSRG) have the authority to directly report to and communicate with the Chief Nuclear Officer and the Vice President - TMI - Unit 1.

The Director - Mid-Atlantic ROG Nuclear Oversight reports directly to the Vice President - Nuclear Oversight and has unencumbered access to Chief Nuclear Officer on all TMI - Unit 1 quality matters and has direct unencumbered access to the Vice President - TMI - Unit 1 with regard to activities affecting quality. This reporting relationship has been established to provide sufficient independence from the influence of costs and schedules to be able to effectively assure conformance to Quality Assurance Program requirements.

The Director - Mid-Atlantic ROG Nuclear Oversight has no duties or responsibilities unrelated to the responsibilities contained in this document that would prevent the required attention to quality assurance matters. The Director - Mid-Atlantic ROG Nuclear Oversight has the authority and responsibility to:

a. Develop and administer the maintenance of the TMI -Unit 1 Operational Quality Assurance Plan and Nuclear Oversight procedures required to assure that all TMI - Unit 1 activities provide the required high degree of safety and reliability.

b. Assess and inspection of TMI - Unit 1 activities to assure that they provide the required high degree of safety and reliability and are carried out consistent with all applicable laws, regulations, regulatory commitments, licenses, corporate policies and other requirements. Assessment schedules are developed and implemented to ensure all required areas are assessed.

c. Establish and conduct nuclear safety review and assessment activities which include those of the IOSRG and the Nuclear Safety Review Board (NSRB).

d. Identify and report nonconformances as they may exist. Initiate, recommend or provide solutions through designated channels. Verify implementation of resolutions as required.

e. Initiate stop work or unit shutdown recommendations when warranted by a safety concern and obtain unit shutdown with appropriate upper-management concurrence.

f. Provide for a review of selected documents which prescribe methods for activities and quality requirements for items within the scope of this Plan. Refer to Appendix B of this Plan.

g. Direct and manage Nuclear Oversight.

h. Provide a working interface and line of communication with other organizational elements and other appropriate industry groups for all program matters.

i. Provide indoctrination, certification, and/or training programs for Nuclear Oversight.

j. Assure Quality Assurance program indoctrination of appropriate personnel outside of Nuclear Oversight is provided.

k. Immediately notify the CNO, CEO, Senior Vice President MA ROG, Vice President - Nuclear Oversight, and the Vice President - TMI – Unit 1, and appropriate organizational elements directors and managers of any significant quality related problem or deficiency.

l. Perform assessments on a planned and periodic basis to comprehensively determine the effectiveness of the Quality Assurance Program and its implementation; and, detect adverse trends that may be present.

m. Issue periodic reports to the CNO, CEO, Senior Vice President MA ROG, Vice President - Nuclear Oversight, and the Vice President - TMI - Unit 1, and organizational elements directors and managers on the effectiveness of implementation of activities within the scope of this Plan.

n. Provide oversight of self-assessment activities to determine effectiveness of the program.

o. Review and concur with all procedures for reporting and controlling of non-conformance's for compliance with the requirements of this Plan.

p. Review, verify and concur with close-out of non-conformance's, when required.

q. Provide interpretations as necessary of this Plan to ensure proper implementation.

r. Provide and implement an inspection program (excluding Receipt Inspection and NDE) to ensure maintenance and modification activities are carried out consistent with this plan.

1.*10* MA ROG Director - Licensing

The MA ROG Director – Licensing reports through the Senior Vice President – *Licensing & Regulatory Affairs* management. The MA ROG Director - Licensing has the functional authority, independence and responsibility to assure the effective implementation of all applicable non-environmental laws, regulations, and licenses associated with the safe and reliable operation of the generating station. Consistent with this responsibility is the authority to render interpretations in writing on those licensing and regulatory activities to which this Plan applies and the extent to which the Plan applies to those activities.

The MA ROG Director - Licensing has the authority and responsibility to:

a. Provide in coordination with the TMI - Unit 1 Regulatory Assurance organization principal interface and control with all non-financial, regulatory agencies for AmerGen including NRC, appropriate state agencies, and supporting legal services. In addition, ensure preparation and coordination of responses to regulatory agencies, including NRC inspections and enforcement bulletins, circulars, notices and generic letters, and activities associated with INPO and NEI.

b. Provide for maintenance of the operating license for the Nuclear Plant.

c. Direct and manage the Licensing organizational element.

d. Provide a working interface and line of communication with other organizational elements and other appropriate industry and regulatory groups for all licensing and regulatory matters.

1.*11* Director - Site Engineering

The Director - Site Engineering reports directly to the Vice President - TMI - Unit 1. The Director's Quality Assurance Plan responsibilities consist of providing the requisite engineering and technical support to:

maintain the design basis of the nuclear plants; maintain the configuration control documents including development and maintenance of the Component Record List (CRL); conduct operating experience assessment; provide nuclear fuel management; provide core performance monitoring; monitor and analyze the technical performance and reliability of systems and components; provide selective review of plant operations and testing procedures, and associated training; provide technical control and coordination of plant modifications as required by Section 6.10 of this Plan; coordinate and implement In-Service Inspection services; and provide a weld program and a repair program, provide management direction and accountability for information technology.

Additional specific responsibilities associated with the above are:

a. Ensuring programs are established and maintained for the special processes of welding, heat treating, and nondestructive examination. (Section 6.3)

b. Performing a startup and test function to assure new or substantially modified plants, facilities and systems are tested in compliance with this Plan. (Section 6.4)

c. Establishing, implementing and maintaining document distribution and record retention programs and facilities.

d. Ensuring that nonconformances are reported and corrected for all activities within the scope of this Plan. Items such as failures, malfunctions and deficiencies are handled in a manner consistent with their importance to nuclear safety and reviewed in accordance with appropriate procedures and the applicable Technical Specification. (Section 6.7 & 8)

1.12 Director - Training

The Director -Training reports directly to the Vice President -TMI - Unit 1. The Director's Quality Assurance Plan responsibilities consist of establishing and delivering training and education programs sufficient to assure safe, reliable and efficient operation.

1.13 Plant Manager

The Plant Manager reports directly to the Vice President -TMI - Unit 1. The Plant Manager's Quality Assurance Plan responsibilities consist of operating TMI - Unit 1 in a safe, environmentally sound, reliable and efficient manner in accordance with company policies and all applicable laws, regulations licenses, technical requirements and procedures; providing and maintaining a qualified staff; fitness-for-duty testing plans and procedures; staff and direct shift technical advisors; provide management accountability and direction for the following functions; plant operations, radwaste, plant chemistry, radiation protection, site security and industrial safety.

The responsibilities of the Plant Manager include the authority to order the shutdown of the unit whenever the health and safety of the public are endangered or when, in his judgement, a shutdown is warranted.

Additional specific responsibilities associated with the above are:

a. Ensuring that programs are established and maintained for identification and control of equipment to avoid unauthorized use and to assure that operational equipment is in a ready status. These requirements shall include independent verifications to ensure proper implementation. (Section 6.9)

b. Ensuring that the appropriate requirements for controlling the inspection, test and operating status, including independent verification, are incorporated in the procedures used on all test and operation activities performed. (Section 6.7)

Section 6.2 and Appendix C). Checklists, weld history records, travelers, reports, etc., are typically used for documenting the results of the activity and for providing a record of the performance of the activity.

2.4.2 Level II - The activities at this level are primarily those of survey, surveillance, and document review and are performed as deemed necessary by Nuclear Oversight and/or Nuclear Services. The level of surveillance applied is consistent with the importance of the item to safety and the extent of administrative controls utilized for the Level I activity.

At this level, procedures and instructions are established and surveillance records will be completed and maintained. Such surveillance normally includes observation of tests and inspections, observation of selected operations, review of records, verifications of test reports, and direct inspection on a spot-check basis. The organizations performing this activity have the levels of authority, the lines of internal and external communication for management direction, and properly trained personnel for implementation of these activities.

2.4.3 Level III - The purpose of this level of activity is to assure, through a comprehensive program of review and assessment, that all organizations conducting activities and/or tasks within the scope of this Plan are properly satisfying all the requirements of the Quality Assurance Program.

At this level, procedures and instructions are established, including the use of comprehensive checklists or detailed reports for documentation of the third-level activity.

For assessments, the program requirements of ANSI N45.2.12 shall be satisfied. Assessment Team Leaders shall be utilized who are qualified to the requirements of ANSI N45.2.23. Additional technical support personnel, from areas with administrative reporting outside the function that is being assessed, will be utilized as Nuclear Oversight Management deems necessary. The organization performing this assessment activity has sufficient authority, independence and lines of internal and external communications to obtain the necessary access to management to conduct the review and assessment, resolve any issues which may arise from the review and assessment and secure additional technical support for the performance of assessments as may be required.

2.5 Operational Quality Assurance Plan Control

This Plan is authorized by the CNO and requires that the appropriate levels of management, as designated herein, implement the Quality Assurance Program. This Plan is controlled to ensure that only the latest approved revision is implemented. This Plan is implemented through approved documents (refer to Section 3.0).

Appendix A provides a correlation of the sections of this Plan with the requirements of 10CFR50 Appendix B; 10CFR71, Subpart H; ANSI N45.2; and ANSI N18.7.

2.5.1 Approval

This Plan shall be originated by the Director - Mid-Atlantic ROG Nuclear Oversight and be approved by the CNO with concurrence by the following:

Vice President - TMI - Unit 1
50.59 Screener / Evaluator / Reviewer
Vice President – Nuclear Oversight

2.5.2 Revisions

The Director - Mid-Atlantic ROG Nuclear Oversight is responsible for ensuring this Plan is modified and updated as needed. Proposed revisions to this Plan may be suggested by AmerGen personnel by submitting a written request to the Director - Mid-Atlantic ROG Nuclear Oversight.

The Director - Mid-Atlantic ROG Nuclear Oversight shall, for each revision to this Plan, determine whether the changes reduce the commitments in this Plan previously accepted by the NRC.

Revisions to this Plan that do not reduce commitments to the NRC shall be originated by the Director - Mid-Atlantic ROG Nuclear Oversight and approved by the CNO with the concurrence of the Vice President - TMI - Unit 1, Vice President - Nuclear Oversight and the Required Technical Reviewer. Documentation containing the approval and concurrence signatures of the CNO, the Vice President - TMI - Unit 1, Vice President - Nuclear Oversight and the Required Technical Reviewer shall be retained. Revisions of this type do not require approval by the NRC prior to implementation, but must be submitted to the NRC at least annually. The Document History page will be utilized to identify such changes.

Revisions of this Plan that reduce the commitments previously accepted by the NRC shall be submitted to the NRC. Such revisions shall be regarded as approved by the NRC upon receipt of a letter to this effect from the appropriate reviewing office or 60 days after submittal to the NRC, whichever comes first. The submittal of the revision to this Plan must include all pages affected by that change and must be accompanied by a transmittal letter identifying the change, the reason for the change, and the basis for concluding that the revision continues to satisfy 10CFR50, Appendix B and provides a suitable level of control. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items. A copy of this letter must be maintained as a facility record for three years. Revisions of this type shall be originated by the Director - Mid-Atlantic ROG Nuclear Oversight, approved by the CNO with the concurrence of the Vice President - TMI - Unit 1, Vice President - Nuclear Oversight and the Required Technical Reviewer as indicated by their signatures.

2.5.3 Distribution

Copies of the Operational Quality Assurance Plan may be distributed as "Controlled" or "Uncontrolled" in accordance with the requirements established in Section 3.

2.5.4 Effective Date of Implementation

Changes to this Plan shall be incorporated in the implementing documents within 60 days of the issuance date of the Plan unless an interim action plan is defined and approved by the Director - Mid-Atlantic ROG Nuclear Oversight. Implementing documents which do not require a substantive revision may be combined with a revision at a future date or at the next periodic review of the document. Examples of a non-substantive revision as used in this context include organizational titles, requirements which exceed the revised Plan requirements, or changes in reporting relationships not specified by Technical Specifications.

2.6 Quality Assurance Program Review

The effectiveness of the Quality Assurance Program and its implementation is periodically reviewed by various organizations at various levels and the results of these reviews are documented in reports to senior management for evaluation and corrective action as required. The effectiveness of the Quality Assurance Program is evaluated and reported by Nuclear Oversight through the assessment and inspection functions. Other organizational elements provide additional information/ evaluations as requested.

2.12 Independent Safety Oversight

The first element of oversight of safety is the IOSRG. The IOSRG has no line responsibilities or line functions and is devoted solely to safety matters. It is independent of the plant staff and reports to the Nuclear Oversight Manager who reports to the Director - Mid-Atlantic ROG Nuclear Oversight. The IOSRG will consist of a minimum of a manager and three full time engineers / technical staff.

The IOSRG shall have access to the unit and unit records as necessary to perform its evaluations and assessments. Based on its reviews, the IOSRG shall provide recommendations to the management positions responsible for the areas reviewed. IOSRG reports of evaluations and assessments shall be transmitted to the Director - Mid-Atlantic ROG Nuclear Oversight and the management positions responsible for the areas reviewed.

The second element of oversight of safety is the Nuclear Oversight staff, who assess and perform quality verification inspection aspects of AmerGen activities within the scope of this Plan or relating to safety. This provides for an overview of activities affecting or potentially affecting safety.

The third element of oversight of safety is the Nuclear Safety Review Board. This is a group of senior level individuals with diverse backgrounds and extensive nuclear experience. The Board reports to the Chairman Nuclear Safety Review Board and takes general direction from the CEO/CNO but has direct access to the AmerGen Management Committee. Its charter is broadly defined to encompass all matters potentially affecting nuclear safety (including management related aspects) so as to foresee potentially significant nuclear safety and radiation problems. Licensing provides staff support to the Nuclear Safety Review Board.

2.13 Self Assessment

Organizations responsible for performance of activities within the scope of this Plan may perform evaluations to assess their performance, seek opportunities for improvement or address known problems. Nuclear Oversight will typically review self-assessment activities conducted by other organizational elements as part of its independent assessments. Nuclear Oversight will not eliminate assessments required by this Plan as a result of organizational self-assessment activities but may alter scope when self-assessment activities sufficiently address subject areas.

2.14 Employee Concerns Program

An Employee Concerns Program is provided by Nuclear Oversight. The responsible individual is accessible on a confidential basis, if desired, to anyone in the company having a nuclear or radiation safety concern that he or she considers is not being adequately addressed. This individual is empowered to investigate such matters, identify any needed action and seek its resolution. The individual who raised the concern will be contacted with the result of the investigation.

3.0 CONTROL OF DOCUMENTS AND RECORDS

3.1 Plans, Procedures, Instructions, Drawings, Specifications

3.1.1 General

Activities which are within the scope of this Plan shall be prescribed by approved documents of a type appropriate to the circumstances. These documents shall be complied with in the performance of the activity or changed prior to proceeding with the activity. These documents typically include but are not limited to those termed plans, procedures, instructions, directives, drawings and specifications. All personnel shall be indoctrinated in the use or content of such documents prior to commencement of the activity.

n. Radiological Control, Process Control, Radiological Environmental Monitoring, Radwaste Shipping and Chemistry Control Plans, Procedures, Instructions, Standards, and Specifications.

3.2.2.2 Procedures established for document control shall prescribe the following requirements:

a. Design descriptions and specifications for items, parts, and materials designated as safety related shall be marked as such.

b. Documents which prescribe how to perform activities within the scope of this Plan shall be marked as within "QA Plan Scope". These documents typically will be those termed plans, procedures, instructions, and directives.

c. Review and approval requirements for documents and their revisions shall be specified to ensure that adequate technical and quality requirements are incorporated prior to issue. Issuance requirements shall be specified to ensure adequate dissemination for use.

d. The organizations or positions responsible for reviewing, approving and issuing documents and their revision shall be specified.

e. Revisions shall be documented, approved, and issued prior to being implemented. Temporary changes shall be reviewed and approved consistent with Technical Specification requirements.

f. Revisions and changes shall be reviewed and approved by the same organizations that performed the original review and approval; or by organizations designated by the originating organizations, except for documents originated by organizations outside AmerGen. In this case, AmerGen may designate the review and approval organizations. Approved changes shall be promptly transmitted for incorporation into documents and obsolete or superseded documents shall be eliminated from use.

g. Document distribution shall be sufficient to assure that the documents are readily available to responsible personnel prior to commencement of work.

h. The user of approved documents is responsible for assuring that the latest issue of the document is being used to perform work, thus assuring that voided, superseded or obsolete documents are not used. Master lists or indices which identify current revision status of approved documents will be maintained to assist users. In addition to master lists or indices, documents may be stamped "Controlled Copy". Holders of controlled documents or master lists are responsible for maintaining their assigned copies in a current status. Documents distributed and stamped as information only will not be considered to be current, and, as such, will not be used in performing an activity within the scope of this Plan.

i. In the special case of documents containing information pertaining to plant security, provisions shall be made to prohibit unauthorized disclosure of certain safeguards information. These provisions shall include identification of the documents, restrictions on their distribution, and storage in locked security storage containers.

6.10 Control of Construction, Maintenance (Preventive/Corrective) and Modifications Requirements

6.10.1 Construction, maintenance or modifications which have the potential to affect the functioning of structures, systems or components within the scope of this Plan shall be performed in a manner to ensure quality at least equivalent to that specified in the original design basis 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. Construction, maintenance or modification of equipment shall be pre-planned and performed in accordance with written procedures, instructions or drawings appropriate to the circumstances which conform to applicable codes, standards, specifications, and criteria. In this regard, modification type work in areas and systems of the plant critical to the safe operation of the plant shall not be performed while the plant is operating without specific advance approval by the Vice President - TMI - Unit 1 or designee.

6.10.2 Detailed step by step procedures are not required for all maintenance and modification work. The supervisor planning the job must consider the skills required to ensure proper completion of the work and identify the procedural requirements accordingly. Work such as replacing chart or drive speed gears, replacing fuses or tightening valve packing may not require written procedures.

Whereas, work involving inter-departmental coordination or risk of nuclear or personnel safety requires a higher level of administrative control, such as approved procedures and sign offs to properly coordinate, direct and document the activity.

6.10.3 Skills normally possessed by qualified maintenance personnel may not require detailed step-by-step delineations in a written procedure, but are subject to general administrative procedural controls that govern or define the following areas:

a. Methods for obtaining permission and clearance from Operations personnel to work, and for logging such work.

b. Factors to be taken into account, including the necessity of maintaining occupational radiation exposure as low as reasonably achievable (ALARA).

c. Method for identification of what procedural coverage is necessary for the maintenance, construction or modification activity.

d. Considerations for system/equipment cleanliness control.

e. Method for identification of post maintenance, construction or modification testing, including system/equipment functional capability to meet operational requirements in all respects.

f. Method for ensuring that maintenance, construction or modification activities, performed either on-site or off-site, are properly reviewed.

g. Considerations for other activities already taking place in the general area.

6.10.4 Means (for example, inspections, measurements, tests, welding, heat treatment, cleaning, nondestructive examination and worker qualifications in accordance with applicable codes and standards) for assuring quality of maintenance, modifications or construction activities, and measures to document the performance thereof, shall be established. Measures shall be established and documented to identify the inspection and test status of items to be used in maintenance, modification, or construction activities. Quality Verification shall review selected

h. Verification method, verification, and close out.

i. Record retention.

j. Required approval signatures on the disposition and the verification.

k. Evidence of review for Reportability to the NRC.

8.2.6 Reworked, repaired, and replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives as determined by Site Engineering and Quality Verification. (Note: Quality Verification is not required for hardware nonconformances found during receipt inspection.) All inspection, testing, rework, and repairs shall be controlled by approved procedures and the results documented.

8.2.7 Prior to the initiation of a preoperational test on a safety related item, all nonconformances shall be evaluated for significance or impact on further testing or operation and shall be dispositioned as appropriate. The evaluation/disposition shall be documented.

8.2.8 Nonconformance reports and those deficiencies addressed in 8.I.3 shall be periodically analyzed to detect adverse trends as may be present. Such analysis shall be based upon severity, number, frequency of nonconformances, the causes of the nonconformances and the timeliness of the reporting and resolution of nonconformances. The results of analyses shall be periodically reported to management for review and assessment. When significant conditions are identified, or when actions are required by upper management to correct problems, such as a generic problem identified by the trend analysis or repetitive failure to disposition nonconformances, these problems shall be elevated to upper levels of management for resolution.

9.0 ASSESSMENT

9.1 General

A program of assessment shall be conducted by Nuclear Oversight (internal) and Nuclear Services (external). The assessment program shall combine elements of survey, surveillance, assessment and document review to assess the adequacy of performance for activities within the scope of this Plan. Attributes such as accomplishment of objectives; ability to meet management expectations; and compliance to procedures, policies and plans shall be considered when planning and performing assessment activities. Nuclear Oversight personnel shall not have any direct responsibility for managing or performing activities being assessed. Nuclear Oversight personnel shall meet applicable qualification standards when required.

Assurance activities performed by other organizations (e.g. Receipt Inspection) shall be periodically evaluated to assure compliance to this Plan and applicable procedures. Assessed organizations shall provide sufficient support to assure the accuracy of assessment results, timely review and response to nonconformances, and effective evaluation of root cause and actions to prevent recurrence of significant conditions adverse to quality.

A comprehensive and documented assessment system shall be established, implemented and maintained to ensure that:

a. Plans, procedures and instructions define sufficient organizational responsibilities, prescribe methods and provide results consistent with Operating License requirements, other regulatory requirements and commitments, technical requirements, contractual requirements, and this Plan.

Attachment 5

Exelon Generation Company, LLC
AmerGen Energy Company, LLC

Quality Assurance Topical Report EGC-1A, Rev. 70

NQA-1-1983-1a Versus NQA-1-1994
Side-by-Side Analysis of Requirement Equivalency

ANSI/ASME NQA-1

Quality Assurance Program Requirements for Nuclear Facilities

History

ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Facilities," the quality standard endorsed by Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3, was divided into multiple sections and even different documents. The 1994 edition of NQA-1 consolidated these standards into a single document that combined the basic requirements and supplements into a single requirement section in Part I. The criteria that were previously in ASME NQA-2-1989, "Quality Assurance Requirements for Nuclear Facility Applications," were placed in Part II. The non-mandatory guidance that was in the Appendices has been relocated to Part III, and future positions and applications matrices will be included in Section IV. The improved structure in the 1994 edition of NQA-1 provides a better separation between requirements and guidance.

Currently, within Exelon Generation Company, LLC (Exelon), Braidwood Station, Byron Station, Dresden Nuclear Power Station, LaSalle County Station, and Quad Cities Nuclear Station are committed to the 1989 version of NQA-1 & 2 which was approved by Regional NRC Management in conjunction with maintenance of the ASME N-Stamp Program. These stations have 10 plus years of experience in the use of NQA-1 & 2 as the baseline quality assurance standards of the Quality Assurance Program. NQA-1 was chosen as the quality standard that will define the new common Exelon/AmerGen Energy Company, LLC (AmerGen), Quality Assurance Program, which will now also encompass Clinton Power Station, Limerick Generating Station, Oyster Creek Generating Station, Peach Bottom Atomic Power Station and Three Mile Island Nuclear Station. The common Exelon/AmerGen Quality Assurance Program proposes the use of the 1994 version of NQA-1. The NRC previously approved the use of ASME NQA-1-1994 as the quality standard for a nuclear fuels vendor, although not a nuclear facility licensee, to effectively implement the requirements of 10 CFR 50, Appendix B. A comparison of the quality standards delineated in NQA-1-1983 versus NQA-1-1994 is provided below.

Document Structure

The side-by-side comparisons are divided by the Basic 18 criteria requirements that correspond to 10 CFR 50, Appendix B, and the published NQA editions. Each side-by-side comparison is further divided in to three columns. From left to right these columns are as follows:

1. NQA-1-1983-1a: This is the edition of NQA endorsed by the NRC in Regulatory Guide 1.28, Revision 3. It is included as a base reference for the comparison with the NQA-1-1994 edition.

2. NQA-1-1994: This edition represents the culmination of changes from the NQA-1 & 2, 1989 editions, plus addendum 1a-1989, 1b-1991, and 1c-1992.

3. Comments: This column is used to explain differences between the 1983 edition and the 1994 edition.

Conclusion

Based on the attached comparison, the requirements contained in NQA-1-1983, as endorsed by Regulatory Guide 1.28, Revision 3, are equivalent to those found in NQA-1-1994. The 1989 version of NQA-1, committed to by the Exelon Nuclear Mid-West Regional Operating Group (MWROG) plants described above, is contained within NQA-1-1994 which allows a more rapid response to varied applications of NQA provisions or measures. This conclusion is based on the attached comparison of the basic requirements of the current NRC endorsed NQA-1-1983 to those of NQA-1-1994, which incorporates NQA-1& 2-1989.

BASIC REQUIREMENT 1 ORGANIZATION	BASIC REQUIREMENT 1 ORGANIZATION	COMMENTS
The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.	The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented.	
Persons or organizations responsible for assuring that an appropriate quality assurance program is established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to	Persons or organizations responsible for assuring that an appropriate quality assurance program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:	
(1) identify quality problems;	*(a)* identify quality problems;	
(2) initiate, recommend, or provide solutions to quality problems through designated channels;	*(b)* initiate, recommend, or provide solutions to quality problems through designated channels;	
(3) verify implementation of solutions; and	*(c)* verify implementation of solutions; and	
(4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.	*(d)* assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.	
SUPPLEMENT 1S-1 SUPPLEMENTARY REQUIREMENTS FOR ORGANIZATION	**SUPPLEMENT 1S-1 Supplementary Requirements for Organization**	
1 GENERAL	**1 GENERAL**	
This Supplement provides amplified requirements for organization. It supplements the requirements of Basic Requirement 1 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	This Supplement provides amplified requirements for organization. It supplements the requirements of Basic Requirement 1 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
2 RESPONSIBILITY	**2 RESPONSIBILITY**	
2.1 Purpose	**2.1 Purpose**	

BASIC REQUIREMENT 1 ORGANIZATION	BASIC REQUIREMENT 1 ORGANIZATION	COMMENTS
The organizational structure and the responsibility assignments shall be such that:	The organizational structure and the responsibility assignments shall be such that:	
(*a*) quality is achieved and maintained by those who have been assigned responsibility for performing work; and (*b*) quality achievement is verified by persons or organizations not directly responsible for performing the work.	*(a)* quality is achieved and maintained by those who have been assigned responsibility for performing work; and *(b)* quality achievement is verified by persons or organizations not directly responsible for performing the work.	
2.2 Delegation of Work	**2.2 Delegation of Work**	
The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefore.	The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility therefore.	
2.3 Nonconforming Items	**2.3 Nonconforming Items**	
Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing.	Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items shall be designated in writing.	
3 MULTIPLE ORGANIZATIONS	**3 MULTIPLE ORGANIZATIONS**	
3.1 Responsibility	**3.1 Responsibility**	
Where more than one organization is involved in the execution of activities covered by this Standard, the responsibility and authority of each organization shall be clearly established and documented.	Where more than one organization is involved in the execution of activities covered by this Part (Part I), the responsibility and authority of each organization shall be clearly established and documented.	
3.2 Interface Control	**3.2 Interface Control**	
3.2.1 The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	**3.2.1** The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	
3.2.2 Interface responsibilities shall be defined and documented.	**3.2.2** Interface responsibilities shall be defined and documented.	

BASIC REQUIREMENT 2 QUALITY ASSURANCE PROGRAM	BASIC REQUIREMENT 2 Quality Assurance Program	COMMENTS
A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Standard, or portions thereof. The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality.	A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality.	
The program shall provide control over activities affecting quality to an extent consistent with their importance.	The program shall provide control over activities affecting quality to an extent consistent with their importance.	
The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions.	The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions.	
Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.	Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.	
The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality. The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.	The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality. The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.	
Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation. **SUPPLEMENT 2S-1** **Supplementary Requirements for the Qualification Of Inspection and Test Personnel**	Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation. **SUPPLEMENT 2S-1** **Supplementary Requirements for the Qualification Of Inspection and Test Personnel**	
1 GENERAL	**1 GENERAL**	

BASIC REQUIREMENT 2 QUALITY ASSURANCE PROGRAM	BASIC REQUIREMENT 2 Quality Assurance Program	COMMENTS
This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination.	This Supplement provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. It supplements the requirements of Basic Requirement 2 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I). The requirements of this Supplement do not apply to the qualification of personnel for performance of nondestructive examination.	
2 CERTIFICATION	**2 CERTIFICATION**	
2.1 Qualification Requirements	**2.1 Qualification Requirements**	
The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel.	The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel.	
Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities.	Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel, and for the assurance that only those personnel who meet the requirements of this Supplement are permitted to perform inspection and test activities.	
When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Standard may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.	When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this Part (Part I) may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.	
2.2 Personnel Selection	**2.2 Personnel Selection**	
Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities	Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.	
2.3 Indoctrination	**2.3 Indoctrination**	
Provisions shall be made for the indoctrination of personnel as to the	Provisions shall be made for the indoctrination of personnel as to the	

BASIC REQUIREMENT 2 QUALITY ASSURANCE PROGRAM	BASIC REQUIREMENT 2 Quality Assurance Program	COMMENTS
technical objectives and requirements of the applicable codes and standards and the quality assurance program elements that are to be employed.	technical objectives and requirements of the applicable codes and standards, and the quality assurance program elements that are to be employed.	
2.4 Training The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests.	**2.4 Training** The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall also be included in the program, with emphasis on first-hand experience gained through actual performance of inspections and tests.	
2.5 Determination of Initial Capability The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate?s education, experience, training, and either test results or capability demonstration.	**2.5 Determination of Initial Capability** The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's education, experience, training, and either test results or capability demonstration.	
2.6 Evaluation of Performance The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. Reevaluation shall be by evidence of continued satisfactory performance or re-determination of capability in accordance with the requirements of 2.5 above. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of one year shall be reevaluated by a re-determination of required capability in accordance with the requirements of 2.5 above.	**2.6 Evaluation of Performance** The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or re-determination of capability in accordance with the requirements of para. 2.5 above. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in his qualified area for a period of 1 year shall be reevaluated by a re-determination of required capability in accordance with the requirements of para. 2.5 above.	
2.7 Certificate of Qualification The qualification of personnel shall be certified in writing in an appropriate form, including the following information:	**2.7 Certificate of Qualification** The qualification of personnel shall be certified in writing in an appropriate form, including the following information:	

BASIC REQUIREMENT 2 QUALITY ASSURANCE PROGRAM	BASIC REQUIREMENT 2 Quality Assurance Program	COMMENTS
(*a*) employer?s name; (*b*) identification of person being certified; (*c*) activities certified to perform; (*d*) basis used for certification, which includes such factors as: (*1*) education, experience, and training (*2*) test results, where applicable (*3*) results of capability demonstration (*e*) results of periodic evaluation; (*f*) results of physical examinations, when required; (*g*) signature of employer?s designated representative who is responsible for such certification; (*h*) date of certification and date of certification expiration. **2.8 Physical** The responsible Organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. **3 RECORDS** **3.1 Record Files** Records of personnel qualification shall be established and maintained by the employer. **SUPPLEMENT 2S-2** **SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL** **1 GENERAL** This Supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), and leak testing (LT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with	(*a*) employer's name; (*b*) identification of person being certified; (*c*) activities certified to perform; (*d*) basis used for certification, which includes such factors as: (*1*) education, experience, indoctrination, and training (*2*) test results, where applicable (*3*) results of capability demonstration (*e*) results of periodic evaluation; (*f*) results of physical examinations, when required; (*g*) signature of employer's designated representative who is responsible for such certification; (*h*) date of certification and date of certification expiration. **2.8 Physical** The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. **3 RECORDS** **3.1 Record Files** Records of personnel qualification shall be established and maintained by the employer. <u>These records shall include the information required by para. 2.7 above.</u> **SUPPLEMENT 2S-2** **Supplementary Requirements for the Qualification of Nondestructive Examination Personnel** **1 GENERAL** This Supplement provides amplified requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), eddy current (ET), neutron radiographic (NRT), leak testing (LT), acoustic emission (AE), and visual testing (VT) [hereinafter referred to as nondestructive examination (NDE)] to verify conformance to specified requirements. It supplements the requirements of Basic Requirement 2 of this Part (Part I) and shall be used in conjunction with	No impact from added detail

BASIC REQUIREMENT 2 QUALITY ASSURANCE PROGRAM	BASIC REQUIREMENT 2 Quality Assurance Program	COMMENTS
that Basic Requirement when and to the extent specified by the organization invoking this Standard.	that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
2 CERTIFICATION	**2 CERTIFICATION**	
2.1 Applicable Documents	**2.1 Applicable Documents**	
The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1975 Edition, and its applicable supplements shall apply as requirements to NDE Personnel covered by this Supplement.	The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, December 1980 Edition, and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement.	Aligns with ASME Code
2.2 Program	**2.2 Program**	
The responsible organization shall establish written procedures for the control and administration of NED personnel training, examination, and certification.	The responsible organization shall establish written procedures for the control and administration of NDE personnel training, examination, and certification.	
2.3 Records	**2.3 Records**	
Records of personnel qualification shall be established and maintained by the employer.	Records of personnel qualification shall be established and maintained by the employer.	
SUPPLEMENT 2S-3 SUPPLEMENTARY REQUIREMENTS FOR THE QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL	**SUPPLEMENT 2S-3 Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel**	
1 GENERAL	**1 GENERAL**	
This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a *Lead Auditor*, who organizes and directs audits, reports audit findings, and evaluates corrective action. This Supplement also provides amplified requirements for the qualified individuals, henceforth referred to as *Auditors*, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training.	This Supplement provides amplified requirements for the qualification of an audit team leader, henceforth identified as a *Lead Auditor*, who organizes and directs audits, reports audit findings, and evaluates corrective action. This Supplement also provides amplified requirements for the qualifications of individuals, henceforth referred to as *Auditors*, who participate in an audit, such as technical specialists, management representatives, and auditors-in-training.	
It supplements the requirements of Basic Requirement 2 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	It supplements the requirements of Basic Requirement 2 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
2 QUALIFICATION OF AUDITORS	**2 QUALIFICATION OF AUDITORS**	
2.1 Responsibility of Auditing Organization	**2.1 Responsibility of Auditing Organization**	

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The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below: (*a*) orientation to provide a working knowledge and understanding of this Standard and the auditing organization?s procedures for implementing audits and reporting results: (*b*) training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings. (*c*) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits. **3 QUALIFICATION OF LEAD AUDITORS** An individual shall meet the requirements of 3.1 through 3.4 below prior to being designated a Lead Auditor. **3.1 Communication Skills** The prospective Lead Auditor shall have the capability to communicate	The responsible auditing organization shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below: *(a)* orientation to provide a working knowledge and understanding of this Part (Part I) and the auditing organization's procedures for implementing audits and reporting results: *(b)* training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings. *(c)* on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits. **3 QUALIFICATION OF LEAD AUDITORS** An individual shall meet the requirements of paras. 3.1 through 3.4 below prior to being designated a Lead Auditor. **3.1 Communication Skills** The prospective Lead Auditor shall have the capability to communicate	

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effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor?s employer.	effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.	
3.2 Training Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.	**3.2 Training** Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor.	
3.2.1 Knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.	**3.2.1** Knowledge and understanding of this Part (Part I) and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.	
3.2.2 General structure of quality assurance programs as a whole and applicable elements as defined in this Standard.	**3.2.2** General structure of quality assurance programs as a whole and applicable elements as defined in this Part (Part I).	
3.2.3 Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.	**3.2.3** Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.	
3.2.4 Audit planning in the quality-related functions for the following activities: design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, and safety aspects of the nuclear facility.	**3.2.4** Audit planning in the quality-related functions for the following activities: siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning of nuclear facilities or associated components, and safety aspects of the nuclear facility.	
3.2.5 On-the-job training to include applicable elements of the audit program.	**3.2.5** On-the-job training to include applicable elements of the audit program.	
3.3 Audit Participation The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.	**3.3 Audit Participation** The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.	
3.4 Examination The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in 3.2 above.	**3.4 Examination** The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in para. 3.2 above.	

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The test may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement.	The examination may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be in accordance with Section 5 of this Supplement.	
4 MAINTENANCE OF QUALIFICATION	**4 MAINTENANCE OF QUALIFICATION**	
4.1 Maintenance of Proficiency Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; and participation in training program(s).	**4.1 Maintenance of Proficiency** Lead Auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training program(s).	
Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.	Based on annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.	
4.2 Requalification Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of 3.2 above, reexamination in accordance with 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit.	**4.2 Requalification** Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para. 3.2 above, reexamination in accordance with para. 3.4 above, and participation as an Auditor in at least one nuclear quality assurance audit.	
5 ADMINISTRATION	**5 ADMINISTRATION**	
5.1 Organization Responsibility Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.	**5.1 Organizational Responsibility** Training of auditors shall be the responsibility of the employer. The responsible auditing organization shall select and assign personnel who are independent of any direct responsibility for performance of the activities which they will audit. The Lead Auditor shall, prior to commencing the audit, concur that assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.	
5.2 Qualification Examination The development and administration of the examination for a Lead Auditor required by 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility for	**5.2 Qualification Examination** The development and administration of the examination for a Lead Auditor required by para. 3.4 above is the responsibility of the employer. The employer may delegate this activity to an independent certifying agency, but shall retain responsibility	

BASIC REQUIREMENT 2 QUALITY ASSURANCE PROGRAM	BASIC REQUIREMENT 2 Quality Assurance Program	COMMENTS
conformance of the examination and its administration to this Standard. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of Section 6 below. **6 RECORDS** **6.1 General** Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. **6.2 Certification of Qualification** Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following: (*a*) employer?s name; (*b*) Lead Auditor?s name; (*c*) date of certification or recertification; (*d*) basis of qualification (i.e., education, experience, communication skills, training, examination, etc.); (*e*) signature of employer?s designated representative who is responsible for such certification. **6.3 Updating of Lead Auditors? Records** Records for each Lead Auditor shall be maintained and updated annually.	for conformance of the examination and its administration to this Part (Part I). Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of Section 6 below. **6 RECORDS** **6.1 General** Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained by the employer. **6.2 Certification of Qualification** Each Lead Auditor shall be certified by his employer as being qualified to lead audits. This certification shall, as a minimum, document the following: *(a)* employer's name: *(b)* Lead Auditor's name; *(c)* date of certification or recertification; *(d)* basis of qualification (i.e., education, experience, communication skills, training, examination, etc.); *(e)* signature of employer's designated representative who is responsible for such certification. **6.3 Updating of Lead Auditors' Records** Records for each Lead Auditor shall be maintained and updated annually. **SUPPLEMENT 2S-4** **Supplementary Requirements for Personnel Indoctrination and Training** **1 GENERAL** This Supplement provides amplified requirements for the indoctrination and training of personnel performing or managing activities affecting quality. It supplements the requirements of Basic Requirement 2 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I). **2 APPLICABILITY** This Supplement applies to personnel performing or managing activities affecting quality. Personnel to be indoctrinated or trained	Supplemental Guidance for QC personnel and others engaged in verifying quality.

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	shall be identified. The extent of indoctrination and training shall be commensurate with the following: *(a)* the scope, complexity, and nature of the activity; and *(b)* the education, experience, and proficiency of the person. Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning. **3 INDOCTRINATION** Personnel shall be indoctrinated in the following subjects as they relate to a particular function: *(a)* general criteria, including applicable codes, standards, and company procedures; *(b)* applicable quality assurance program elements; and *(c)* job responsibilities and authority. **4 TRAINING** Training shall be provided, if needed, to: *(a)* achieve initial proficiency; *(b)* maintain proficiency; and *(c)* adapt to changes in technology, methods, or job responsibilities. **5 RECORDS** Records of the implementation of indoctrination and training may take the form of: *(a)* attendance sheets; *(b)* training logs; or *(c)* personnel training records.	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design. **SUPPLEMENT 3S-1** **SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL** **1 GENERAL** This Supplement provides amplified requirements for design control. It supplements the requirements of Basic Requirement 3 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 DESIGN INPUT** Applicable design inputs such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled. **3 DESIGN PROCESS** The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit	The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design. **SUPPLEMENT 3S-1** **SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL** **1 GENERAL** This Supplement provides amplified requirements for design control. It supplements the requirements of Basic Requirement 3 of this Part and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part. **2 DESIGN INPUT** Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, approved, documented, and controlled. **3 DESIGN PROCESS** The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
verification that the design meets requirements.	verification that the design meets requirements.	
	Design documents shall be adequate to support facility design, construction, and operation.	Clarifies documentation requirements for what is a design document.
Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall: (a) be relatable to the design input by documentation in sufficient detail to permit design verification; and	Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Changes from specified quality standards, including the reasons for the changes, shall be identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) shall: **4** be relatable to the design input by documentation in sufficient detail to permit design verification; and	
(b) identify assemblies and/or components that are part of the item being designed. When such an assembly or component Part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier?s published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.	*(b)* identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier?s published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.	
3.1 Design Analyses Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the	**3.1 Design Analyses** Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date: or by other data such that the calculations are retrievable. (a) computer programs may be utilized for design analysis without individual verification of the program for each application provided:	subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable. *(a)* Computer programs may be utilized for design analysis without individual verification of the program for each application provided:	
(1) the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and (2) the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.	*(1)* the computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and *(2)* the encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.	
Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.	Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on (1) and (2) above.	
(b) Documentation of design analyses shall include (1) through (6) below: (1) definition of the objective of the analyses; (2) definition of design inputs and their sources; (3) results of literature searches or other applicable background data: (4) identification of assumptions and indication of those that must be verified as the design proceeds: (5) identification of any computer calculation, including computer type, computer program (i.e., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem:	*(b)* Documentation of design analyses shall include (1) through (6) below: *(1)* definition of the objective of the analyses; *(2)* definition of design inputs and their sources; *(3)* results of literature searches or other applicable background data; *(4)* identification of assumptions and indication of those that must be verified as the design proceeds; *(5)* identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem;	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
(6) review and approval	*(6)* review and approval.	
4 DESIGN VERIFICATION	**4 DESIGN VERIFICATION**	
Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests.	Design control measures shall be applied to verify the adequacy of design, such as by one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests.	
	Verification of computer programs shall include appropriate testing.	Additional detail to cover computer programs used in design.
The responsible design organization shall identify and document the particular design verification method(s) used.	The responsible design organization shall identify and document the particular design verification method(s) used.	
The results of design verification shall be clearly documented with the identification of the verifier clearly indicated.	The results of design verification shall be clearly documented with the identification of the verifier clearly indicated.	
Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization.	Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization.	
This verification may be performed by the originator?s supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification.	This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification.	
Cursory supervisory reviews do not satisfy the intent of this Standard.	Cursory supervisory reviews do not satisfy the intent of this Part.	
Verification shall be performed in a timely manner.	Verification shall be performed in a timely manner.	
Design verification for the level of design Activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist.	Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities except in those cases where this timing cannot be met, such as when insufficient data exist.	
In those cases, the unverified portion of the design shall be identified and controlled.	In those cases, the unverified portion of the design shall be identified and controlled.	
In all cases, the design verification shall be completed prior to relying upon the component, system, or structure to perform its function.	In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.	
4.1 Extent of Design Verification	**4.1 Extent of Design Verification**	
The extent of the design verification required is a function of the importance	The extent of the design verification required is a function of the importance	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.	to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.	
Where the design has been subjected to a verification process in accordance with this Standard, the verification process need not be duplicated for identical designs.	Where the design has been subjected to a verification process in accordance with this Part, the verification process need not be duplicated for identical designs.	
However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.	However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.	
Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered.	Known problems affecting the standard or previously proven designs and their effects on other features shall be considered.	
The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.	The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.	
Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design.	Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design <u>and on any design analyses upon which the design is based that are affected by the change to previously verified design.</u>	Added to clarify need to recheck all previous uses of a design analysis.
4.2 Methods	**4.2 Methods**	
Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.	Acceptable verification methods include, but are not limited to, any one or a combination of the following: design reviews, alternate calculations, and qualification testing.	
4.2.1 Design Reviews	**4.2.1 Design Reviews.**	
These are critical reviews to provide assurance that the final design is correct and satisfactory.	These are critical reviews to provide assurance that the final design is correct and satisfactory.	
Where applicable, (a) through (f) below shall be addressed.	Where applicable, (a) through (f) below shall be addressed.	
(a) Were the design inputs correctly selected?	*(a)* Were the design inputs correctly selected?	
(b) Are assumptions necessary to perform the design activity adequately described and reasonable?	*(b)* Are assumptions necessary to perform the design activity adequately described and reasonable?	
Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are	Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
completed? © Was an appropriate design method used? (d) Were the design inputs correctly incorporated into the design? (e) Is the design output reasonable compared to design inputs? (f) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions? **4.2.2 Alternate Calculations** These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed. **4.2.3 Qualification Tests** Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified.	completed? © Was an appropriate design method used? *(d)* Were the design inputs correctly incorporated into the design? *(e)* Is the design output reasonable compared to design inputs? *(f)* Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions? **4.2.2 Alternate Calculations** These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed. **4.2.3 Qualification Tests** Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified.	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.	The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.	
5 CHANGE CONTROL	**5 CHANGE CONTROL**	
Changes to final designs, including field changes, shall be justified and subjected to design control measures commensurate with those applied to the original design and approved by the same affected groups or organizations which reviewed and approved the original design documents: except where an organization which originally was responsible for approving a particular design document is no longer responsible for approving a particular design document is no longer responsible, then the owner or his designee shall designate a new responsible organization which could be the Owner?s engineering organization.	Changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair shall be justified and subject to design control measures commensurate with those applied to the original design.	Removed ambiguity as to who must be responsible by splitting up paragraph – no impact from change.
	These measures shall include assurance that the design analyses for the structure, system, or component are still valid.	
	Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the Owner or his designee shall designate a new responsible organization which could be the Owner's engineering organization.	No substantive changes.
The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	
	When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.	Further defined responsibility for incorporation of design changes.
Where a significant design change is necessary because of an incorrect design , the design process and verification procedure shall be reviewed and modified as necessary.	Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.	
6 INTERFACE CONTROL	**6 INTERFACE CONTROL**	

BASIC REQUIREMENT 3 DESIGN CONTROL	BASIC REQUIREMENT 3 DESIGN CONTROL	COMMENTS
Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	
Design information transmitted across interfaces shall be documented and controlled.	Design information transmitted across interfaces shall be documented and controlled.	
	Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval	Added detail – no impact
Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.	Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.	
7 DOCUMENTATION AND RECORDS	**7 DOCUMENTATION AND RECORDS**	
Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Standard, shall be collected, stored, and maintained in accordance with documentation procedures. The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of Design inputs that support the final design.	Design documentation and records, which provide evidence that the design and design verification processes were performed in accordance with the requirements of this Part (Part 1), shall be collected, stored, and maintained in accordance with documented procedures. The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.	

BASIC REQUIREMENT 4 PROCUREMENT DOCUMENT CONTROL	BASIC REQUIREMENT 4 PROCUREMENT DOCUMENT CONTROL	COMMENTS
Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services.	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 quality assurance program consistent with the applicable requirements of this Standard.	To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Part (Part1).	
SUPPLEMENT 4S-1 SUPPLEMENTARY REQUIREMENTS FOR PROCUREMENT DOCUMENT CONTROL **1 GENERAL** This Supplement provides amplified requirements for procurement document control. It supplements the requirements of Basic Requirement 4 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	**SUPPLEMENT 4S-1 SUPPLEMENTARY REQUIREMENTS FOR PROCUREMENT DOCUMENT CONTROL** **1 GENERAL** This Supplement provides amplified requirements for procurement document control. It supplements the requirements of Basic Requirement 4 of this Part (Part1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part1).	
2 CONTENT OF THE PROCUREMENT DOCUMENTS Procurement documents issued at all tiers of procurement shall include provision for the following, as deemed necessary by the Purchaser.	**2 CONTENT OF THE PROCUREMENT DOCUMENTS** Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the Purchaser.	
2.1 Scope of Work A statement of the scope of the work to be performed by the Supplier shall be in the procurement documents.	**2.1 Scope of Work** A statement of the scope of the work to be performed by the Supplier shall be in the procurement documents.	
2.2 Technical Requirements Technical requirements shall be specified in the procurement documents.	**2.2 Technical Requirements** Technical requirements shall be specified in the procurement documents.	
Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items of services to be furnished.	Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished.	
The procurement documents shall provide for identification of test, inspection, and acceptance	The procurement documents shall provide for identification of test, inspection, and acceptance	

BASIC REQUIREMENT 4 PROCUREMENT DOCUMENT CONTROL	BASIC REQUIREMENT 4 PROCUREMENT DOCUMENT CONTROL	COMMENTS
requirements of the Purchaser for monitoring and evaluating the Supplier's performance.	requirements of the Purchaser for monitoring and evaluating the Supplier's performance.	
2.3 Quality Assurance Program Requirements Procurement documents shall require that the supplier have a documented quality assurance program that implements portions or all of the requirements of this Standard.	**2.3 Quality Assurance Program Requirements** Procurement documents shall require that the Supplier have a documented quality assurance program that implements portions or all of the requirements of this Part (Part1).	
The extent of the program required shall depend upon the type and use of the item or service being procured.	The extent of the program required shall depend upon the type and use of the item or service being procured.	
The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.	The procurement documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.	
2.4 Right of Access At each tier of a procurement, the procurement documents shall provide for access to the Supplier?s plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser.	**2.4 Right of Access** At each tier of a procurement, the procurement documents shall provide for access to the Supplier's plant facilities and records for inspection or audit by the Purchaser, his designated representative, and/or other parties authorized by the Purchaser.	
2.5 Documentation Requirements The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser.	**2.5 Documentation Requirements** The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser.	
The time of submittal shall also be established.	The time of submittal shall also be established.	
When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.	When the Purchaser requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.	
2.6 Nonconformances	**2.6 Nonconformances**	
The procurement documents shall include Purchaser?s requirements for reporting and approving disposition of nonconformance.	The procurement documents shall include Purchaser's requirements for reporting and approving disposition of nonconformances.	
2.7 Spare and Replacement Parts The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate	**2.7 Spare and Replacement Parts** The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate	

BASIC REQUIREMENT 4 PROCUREMENT DOCUMENT CONTROL	BASIC REQUIREMENT 4 PROCUREMENT DOCUMENT CONTROL	COMMENTS
delineation of the technical and quality assurance related data required for ordering these parts or assemblies.	delineation of the technical and quality assurance related data required for ordering these parts or assemblies.	
3 PROCUREMENT DOCUMENT REVIEW A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: (a) appropriate requirements specified in Section 2 of this Supplement; (b) determination of any additional or modified design criteria; (c) analysis of exceptions of changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished. Reviews required by this Section 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.	**3 PROCUREMENT DOCUMENT REVIEW** A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluations or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: *(a)* appropriate requirements specified in Section 2 of this Supplement; *(b)* determination of any additional or modified design criteria, *(c)* analysis of exceptions or changes requested or specified by the Supplier and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished. Reviews required by this Section 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 PROCUREMENT DOCUMENT CHANGES Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.	**4 PROCUREMENT DOCUMENT CHANGES** Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.	

BASIC REQUIREMENT 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS	BASIC REQUIREMENT 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS	COMMENTS
Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.	Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.	

BASIC REQUIREMENT 6 DOCUMENT CONTROL	BASIC REQUIREMENT 6 DOCUMENT CONTROL	COMMENTS
The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed.	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed.	
Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.	Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.	
SUPPLEMENT 6S-1 SUPPLEMENTARY REQUIREMENTS FOR DOCUMENT CONTROL	**SUPPLEMENT 6S-1 Supplementary Requirements For Document Control**	
1 GENERAL	**1 GENERAL**	
This Supplement provides amplified requirements for a document control system.	This Supplement provides amplified requirements for a document control system.	
It supplements the requirements of Basic Requirement 6 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	It supplements the requirements of Basic Requirement 6 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
	The documents which shall be controlled in accordance with this Supplement are only those documents which specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings.	Added language to bound and limit what falls under document control.
	The term *document control* used throughout this Supplement is defined as the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.	Added language to bound and limit what falls under document control.
2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE	**2 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE**	
Documents shall be controlled to assure that correct and applicable documents are available at the location where they are to be used.		When used in conjunction with preceding paragraph – no impact.
The controls shall be documented.. Document controls shall provide for (a) through (c) below:	The control system shall be documented and shall provide for (a) through (c) below:	
(a) identification of documents to be controlled	(a) identification of documents to be controlled and their specified distribution;	
(b) identification of assignment of	(b) identification of assignment of	

BASIC REQUIREMENT 6 DOCUMENT CONTROL	BASIC REQUIREMENT 6 DOCUMENT CONTROL	COMMENTS
responsibility for preparing, reviewing, approving, and issuing documents (c) review of documents for adequacy, completeness, and correctness prior to approval and issuance	responsibility for preparing, reviewing, approving, and issuing documents; (c) review of documents for adequacy, completeness, and correctness prior to approval and issuance.	
3. DOCUMENT CHANGES	**3 DOCUMENT CHANGES**	
3.1 Major Changes Changes to documents, other than those defined as minor changes in 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.	**3.1 Major Changes** Changes to documents, other than those defined as minor changes in para. 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.	
The reviewing organization shall have access to pertinent background data or information upon which to base their approval.	The reviewing organization shall have access to pertinent background data or information upon which to base their approval.	
3.2 Minor Changes	**3.2 Minor Changes**	
Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.	Minor changes to documents, such as inconsequential editorial corrections, shall 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 decision shall be clearly delineated.	To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.	

BASIC REQUIREMENT 7 CONTROL OF PURCHASED ITEMS AND SERVICES	BASIC REQUIREMENT 7 CONTROL OF PURCHASED ITEMS AND SERVICES	COMMENTS
The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.	The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.	
SUPPLEMENT 7S-1 SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PURCHASED ITEMS AND SERVICES **1 GENERAL** This supplement provides amplified requirements for control of purchased items and services. It supplements the requirements of Basic Requirement 7 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. This Supplement includes requirements for source selection, bid evaluation, Supplier performance evaluation, and verification of conformance.	**SUPPLEMENT 7S SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PURCHASED ITEMS AND SERVICES** **1 GENERAL** This Supplement provides amplified requirements for control of purchased items and services. It supplements the requirements of Basic Requirement 7 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1). This Supplement includes requirements for source selection, bid evaluation, Supplier performance evaluation, and verification of conformance.	
2 PROCUREMENT PLANNING Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. Planning shall determine the following: (a) what is to be accomplished; (b) who is to accomplish it; (c) how it is to be accomplished; (d) when it is to be accomplished. Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled , to assure interface compatibility and a uniform approach to the procurement process.	**2 PROCUREMENT PLANNING** Procurement activities shall be planned and documented to assure a systematic approach to the procurement process. Procurement planning shall result in the documented identification of procurement methods and organizational responsibilities. Planning shall determine the following: *(a)* what is to be accomplished; *(b)* who is to accomplish it; *(c)* how it is to be accomplished; *(d)* when it is to be accomplished. Planning shall be accomplished as early as practicable, and no later than at the start of those procurement activities which are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.	

BASIC REQUIREMENT 8 IDENTIFICATION AND CONTROL OF ITEMS	BASIC REQUIREMENT 8 IDENTIFICATION AND CONTROL OF ITEMS	COMMENTS
Controls shall be established to assure that only correct and accepted items are used or installed.	Controls shall be established to assure that only correct and accepted items are used or installed.	
Identification shall be maintained either on the items or in documents traceable to the items.	Identification shall be maintained on the items or in documents traceable to the items, or in a manner which assures that identification is established and maintained.	Allows for alternatives to marking or tagging on the item itself
SUPPLEMENT 8S-1 SUPPLEMENTARY REQUIREMENTS FOR IDENTIFICATION AND CONTROL OF ITEMS	**SUPPLEMENT 8S-1 SUPPLEMENTARY REQUIREMENTS FOR IDENTIFICATION AND CONTROL OF ITEMS**	
1 GENERAL	**1 GENERAL**	
This Supplement provides amplified requirements for identification and control of items. It supplements the requirements of Basic Requirement 8 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	This Supplement provides amplified requirements for identification and control of items. It supplements the requirements of Basic Requirement 8 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
2. IDENTIFICATION METHODS **2.1 Item Identification** Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items up to and including installation and use.	**2 IDENTIFICATION METHODS** **2.1 Item Identification** Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of the items up to and including installation and use.	
This identification shall relate an item to an applicable design or other pertinent specifying document.	This identification shall relate an item to an applicable design or other pertinent specifying document.	
2.2 Physical Identification Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.	**2.2 Physical Identification** Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.	
2.3 Markings	**2.3 Markings**	

BASIC REQUIREMENT 8 IDENTIFICATION AND CONTROL OF ITEMS	BASIC REQUIREMENT 8 IDENTIFICATION AND CONTROL OF ITEMS	COMMENTS
Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when sub-divided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. **3 SPECIFIC REQUIREMENTS** **3.1 Identification and Tracebility of Items** When specified by codes, standards, or specifications that include specific identification or tractability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records) the program shall be designed to provide such identification and traceability control. **3.2 Limited Life Items** Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired. **3.3 Maintaining Identification of Stored Items** Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as: (1) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; (2) protection of identifications on items subject to excessive deterioration due to environmental exposure; (3) provisions for updating existing plant records.	Identification markings, when used, shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. **3 SPECIFIC REQUIREMENTS** **3.1 Identification and Traceability of Items** When specified by codes, standards, or specifications that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall be designed to provide such identification and traceability control. **3.2 Limited Life Items** Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired. **3.3 Maintaining Identification of Stored Items** Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as: *(a)* provisions for maintenance or replacement of markings and identification records due to damage during handling or aging; *(b)* protection of identifications on items subject to excessive deterioration due to environmental exposure; *(c)* provisions for updating existing plant records.	

BASIC REQUIREMENT 9 CONTROL OF PROCESSES	BASIC REQUIREMENT 9 CONTROL OF PROCESSES	COMMENTS
Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.	Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.	
SUPPLEMENT 9S-1 SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PROCESSES **1 GENERAL** This Supplement provides amplified requirements for control of processes. If supplements the requirements of Basic Requirement 9 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 PROCESS CONTROL** Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained. **3 SPECIAL PROCESSES** Each special process shall be performed in accordance with appropriate instructions which include or reference procedure, personnel, and equipment qualification requirements. **3.1 Responsibility** It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes. 3.1.1 Qualification of personnel, procedures, and equipment shall comply with specified requirements. 3.1.2 Conditions necessary for accomplishment of the process shall be included in procedures or instructions. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements. **3.2 Acceptance Criteria**	**SUPPLEMENT 9S-1 SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF PROCESSES** **1 GENERAL** This Supplement provides amplified requirements for control of processes. It supplements the requirements of Basic Requirement 9 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1). **2 PROCESS CONTROL** Processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These means shall assure that process parameters are controlled and that specified environmental conditions are maintained. **3 SPECIAL PROCESSES** Each special process shall be performed in accordance with appropriate instructions which include or reference procedure, personnel, and equipment qualification requirements. **3.1 Responsibility** It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes. **3.1.1** Qualification of personnel, procedures, and equipment shall comply with specified requirements. **3.1.2** Conditions necessary for accomplishment of the process shall be included in procedures or instructions. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements. **3.2 Acceptance Criteria**	

BASIC REQUIREMENT 9 CONTROL OF PROCESSES	BASIC REQUIREMENT 9 CONTROL OF PROCESSES	COMMENTS
The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions. **3.3 Records** Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process. **3.4 Special Requirement** For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.	The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions. **3.3 Records** Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process **3.4 Special Requirements** For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.	

BASIC REQUIREMENT 10 INSPECTION	BASIC REQUIREMENT 10 INSPECTION	COMMENTS
Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed.	Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed.	
Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented.	Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented.	
Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.	Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.	
SUPPLEMENT 10S-1 SUPPLEMENTARY REQUIREMENTS FOR INSPECTION **1 GENERAL** This Supplement provides amplified requirements for inspection of items and activities. It supplements the requirements of Basic Requirement 10 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	**SUPPLEMENT 1OS-1 SUPPLEMENTARY REQUIREMENTS FOR INSPECTION** **1 GENERAL** This Supplement provides amplified requirements for inspection of items and activities. It supplements the requirements of Basic Requirement 10 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
	2 INSPECTION REQUIREMENTS Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.	Adds necessary detail for where to obtain inspection criteria
	Inspection activities shall be documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means.	Adds necessary detail that inspections need to be documented.
2. PERSONNEL **2.1 Report Independence** Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.	**3 PERSONNEL** **3.1 Reporting Independence** Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.	
2.2 Qualification Inspection 1a-83 Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.	**3.2 Qualification** Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task.	

BASIC REQUIREMENT 10 INSPECTION	BASIC REQUIREMENT 10 INSPECTION	COMMENTS
Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved. 1a-83	Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.	
3 INSPECTION HOLD POINTS If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents.	**4 INSPECTION HOLD POINTS** If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents.	
Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.	Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.	
4 INSPECTION PLANNING **4.1 Planning** Planning for inspection activities shall be accomplished and documented.	**5 INSPECTION PLANNING** **5.1 Planning** Planning for inspection activities shall be accomplished and documented.	
The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.	The documentation shall identify characteristics, methods, and acceptance criteria, and shall provide for recording objective evidence of inspection results.	
4.2 Sampling Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.	**5.2 Sampling** Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices.	
5 IN-PROCESS INSPECTION **5.1 Inspection** Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality.	**6 IN-PROCESS INSPECTION** **6.1 Inspection** Inspection of items in-process or under construction shall be performed for work activities where necessary to verify quality.	
If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.	If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.	
Both inspection and process monitoring shall be provided when control is inadequate without both.	Both inspection and process monitoring shall be provided when control is inadequate without both.	
5.2 Combined Inspection and Monitoring	**6.2 Combined Inspection and Monitoring**	

BASIC REQUIREMENT 10 INSPECTION	BASIC REQUIREMENT 10 INSPECTION	COMMENTS
5.2.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.	6.2.1 A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.	
5.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.	6.2.2 Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.	
6 FINAL INSPECTIONS	**7 FINAL INSPECTIONS**	
6.1 Resolution of Nonconformances	**7.1 Resolution of Nonconformances**	
Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections.	Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections.	
The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.	The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.	
6.2 Inspection Requirements	**7.2 Inspection Requirements**	
Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformances of the item to specified requirements.	Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformances of the item to specified requirements.	
Quality records shall be examined for adequacy and completeness if not previously so examined.	Quality records shall be examined for adequacy and completeness if not previously so examined.	
6.3 Acceptance	**7.3 Acceptance**	
The acceptance of the item shall be documented and approved by authorized personnel.	The acceptance of the item shall be documented and approved by authorized personnel.	
6.4 Modifications, Repairs, or Replacements	**7.4 Modifications, Repairs, or Replacements**	
Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.	Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.	
7 INSERVICE INSPECTION	**8 INSERVICE INSPECTION**	
7.1 Planning and Performance	**8.1 Planning and Performance**	
Required in-service inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.	Required in-service inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for operation.	

BASIC REQUIREMENT 10 INSPECTION	BASIC REQUIREMENT 10 INSPECTION	COMMENTS
7.2 Methods Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.	**8.2 Methods** Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.	
8 RECORDS Records shall, as a minimum, identify (a) through (f) below: (a) item inspected (b) date of inspection (c) inspector (d) type of observation (e) results or acceptability (f) reference to information on action taken in connection with nonconformances	**9 RECORDS** Records shall, as a minimum, identify (a) through below: (a) item inspected (b) date of inspection (c) inspector (d) type of observation (e) results or acceptability (f) reference to information on action taken in connection with nonconformances	

BASIC REQUIREMENT 11 TEST CONTROL	BASIC REQUIREMENT 11 TEST CONTROL	COMMENTS
BASIC REQUIREMENT Tests required to verify conformance of an item to specified requirements and to demonstrate that items will perform satisfactorily in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated.	**BASIC REQUIREMENT** Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated. <u>Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.</u>	Added additional requirement for test of computer software; already addressed in NQA-1-1989 Supplement 11S-1 Added to allow for R&D and other users such as Yucca Mtn. No impact on LWR operators.
SUPPLEMENT 11 S-1 **SUPPLEMENTARY REQUIREMENTS FOR TEST CONTROL** **1. GENERAL** This Supplement provides amplified requirements for test control. It supplements the requirements of Basic Requirement 11 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 TEST REQUIREMENTS** Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents. **3 TEST PROCEDURES**	**SUPPLEMENT 11S-1** **SUPPLEMENTARY REQUIREMENTS FOR TEST CONTROL** **1 GENERAL** This Supplement provides amplified requirements for test control. It supplements the requirements of Basic Requirement 11 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1). **2 TEST REQUIREMENTS** Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents. **3 TEST PROCEDURES**	

BASIC REQUIREMENT 11 TEST CONTROL	BASIC REQUIREMENT 11 TEST CONTROL	COMMENTS
Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.	Tests procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained. Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition.	
In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.	In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to assure the required quality of work.	
4 TEST RESULTS Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied.	**4 TEST RESULTS** Test results shall be documented and evaluated by a responsible authority to assure that test requirements have been satisfied.	
5 TEST RECORDS Test records shall, as a minimum, identify (a) through (g) below: (a) item tested	**5 TEST RECORDS** Test records shall, as a minimum, identify (a) through (g) below: **12** item tested	
(b) date of test I tester or data recorder (d) type of observation (e) results and acceptability (f) action taken in connection with any deviations noted (g) person evaluating test results	*(b)* date of test *I* tester or data recorder *(d)* type of observation *(e)* results and acceptability *(f)* action taken in connection with any deviations noted (g) person evaluating test results	
	SUPPLEMENT 11S—2 SUPPLEMENTARY REQUIREMENTS FOR COMPUTER PROGRAM TESTING **1 GENERAL**	Added language that became NQA Part 2.7 on requirements for QA for Computers and Software.

BASIC REQUIREMENT 11 TEST CONTROL	BASIC REQUIREMENT 11 TEST CONTROL	COMMENTS
	This Supplement provides amplified requirements for testing of computer programs and associated computer systems. It supplements the requirements of Basic Requirement 11 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1). **2 TEST REQUIREMENTS** Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests including (as appropriate) verification tests, hardware integration tests, and in-use tests shall be controlled. Test requirements and acceptance criteria shall be based upon applicable design or other pertinent technical documents. **2.1 Verification Tests** Verification tests shall demonstrate the capability of the computer program to produce valid results for test problems encompassing the range of permitted usage defined by the program documentation. Acceptable test problem solutions are as follows: *(a)* hand calculations; *(b)* calculations using comparable proven programs; or *I* empirical data and information from technical literature. For programs used for operational control, testing shall demonstrate required performance over the range of operation of the controlled function or process. Depending on the complexity of the computer program being tested, testing may range from a single test of the completed computer program to a series of tests performed at various stages of computer program development to verify correct translation between stages and proper working of individual modules, followed by an overall computer program test.	

BASIC REQUIREMENT 11 TEST CONTROL	BASIC REQUIREMENT 11 TEST CONTROL	COMMENTS
	Regardless of the number of stages of testing performed, verification testing shall be sufficient to establish that test requirements are satisfied and that the computer program produces a valid result for its intended function. **2.2 In-Use Tests** Test problems shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. Test problems shall be run whenever the computer program is installed on a different computer, or when significant hardware or operating system configuration changes are made. Periodic in-use manual or automatic self-check routines shall be prescribed and performed for those applications where computer failures or drift can affect required performance. **3 TEST PROCEDURES** 200 COMPUTER PROGRAM TEST PROCEDURES Test procedures or plans shall specify the following, as applicable: *(a)* required tests and test sequence *(b)* required ranges of input parameters *I* identification of the stages at which testing is required *(d)* criteria for establishing test cases *(e)* requirements for testing logic branches *(f)* requirements for hardware integration *(g)* anticipated output values *(h)* acceptance criteria *(i)* reports, records, standard formatting, and conventions. **4 TEST RESULTS**	

BASIC REQUIREMENT 11 TEST CONTROL	BASIC REQUIREMENT 11 TEST CONTROL	COMMENTS
	Test results shall be documented. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied. **5 TEST RECORDS** *(a)* Verification test records shall identify (1) through (10) below. *(1)* computer program tested *(2)* computer hardware used *(3)* test equipment and calibrations, where applicable *(4)* date of test *(5)* tester or data recorder *(6)* simulation models used, where applicable *(7)* test problems *(8)* results and acceptability *(9)* action taken in connection with any deviations noted *(10)* person evaluating test results. *(b)* in-use test results shall identify (1) through (6) below: *(1)* computer program tested *(2)* computer hardware used *(3)* test equipment and calibrations, where applicable *(4)* date of test *(5)* tester or data recorder *(6)* acceptability.	

BASIC REQUIREMENT 12 CONTROL OF MEASURING AND TEST EQUIPMENT	BASIC REQUIREMENT 12 CONTROL OF MEASURING AND TEST EQUIPMENT	COMMENTS
Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.	
SUPPLEMENT 12S-1 SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF MEASURING AND TEST EQUIPMENT **1 GENERAL** This Supplement provides amplified requirements for control of measuring and test equipment. It supplements the requirements of Basic Requirement 12 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	**SUPPLEMENT 12S-1 SUPPLEMENTARY REQUIREMENTS FOR CONTROL OF MEASURING AND TEST EQUIPMENT** **1 GENERAL** This Supplement provides amplified requirements for control of measuring and test equipment. It supplements the requirements of Basic Requirement 12 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1).	
2 SELECTION Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.	**2 SELECTION** Selection of measuring and test equipment shall be controlled to assure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.	
3 CALIBRATION AND CONTROL **3.1 Calibration** Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.	**3 CALIBRATION AND CONTROL** **3.1 Calibration** *Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards.* If no nationally recognized standards exist, the bases for calibration shall be documented.	
3.2 Control The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.	**3.2 Control** The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.	

BASIC REQUIREMENT 12 CONTROL OF MEASURING AND TEST EQUIPMENT	BASIC REQUIREMENT 12 CONTROL OF MEASURING AND TEST EQUIPMENT	COMMENTS
When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect. **3.3 Commercial Devices** Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy. **4 HANDLING AND STORAGE** Measuring and test equipment shall be properly handled and stored to maintain accuracy. **5 RECORDS** Records shall be maintained and equipment shall be suitably marked to indicate calibration status.	When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect. **3.3 Commercial Devices** Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy. **4 HANDLING AND STORAGE** Measuring and test equipment shall be properly handled and stored to maintain accuracy. **5 RECORDS** Records shall be maintained and equipment shall be suitably marked to indicate calibration status.	

BASIC REQUIREMENT 13 HANDLING, STORAGE, AND SHIPPING	BASIC REQUIREMENT 13 HANDLING, STORAGE, AND SHIPPING	COMMENTS
Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.	Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.	
SUPPLEMENT 13S-1 SUPPLEMENTARY REQUIREMENTS FOR HANDLING, STORAGE, AND SHIPPING **1 GENERAL** This Supplement provides amplified requirements for handling, storage, and shipping. It supplements the requirements of Basic Requirement 13 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. **2 INSTRUCTION** Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.	**SUPPLEMENT 13S-1 SUPPLEMENTARY REQUIREMENTS FOR HANDLING, STORAGE, AND SHIPPING** **1 GENERAL** This Supplement provides amplified requirements for handling, storage, and shipping. It supplements the requirements of Basic Requirement 13 of this Part (Part 1) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part 1). **2 INSTRUCTION** Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.	
3 REQUIREMENTS **3.1 General** When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.	**3 REQUIREMENTS** **3.1 General** When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.	
3.2 Procedures When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.	**3.2 Procedures** When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.	
3.3 Tools and Equipment Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling.	**3.3 Tools and Equipment** Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling.	

BASIC REQUIREMENT 13 HANDLING, STORAGE, AND SHIPPING	BASIC REQUIREMENT 13 HANDLING, STORAGE, AND SHIPPING	COMMENTS
Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained. **3.4 Operators** Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment. **4 MARKING** Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.	Special handling tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained. **3.4 Operators** Operators of special handling and lifting equipment shall be experienced or trained in use of the equipment. **4 MARKING** Instructions for marking and labeling for packaging, shipment, handling, and storage of items shall be established as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.	

BASIC REQUIREMENT 14 INSPECTION, TEST, AND OPERATING STATUS	BASIC REQUIREMENT 14 INSPECTION, TEST, AND OPERATING STATUS	COMMENTS
The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.	The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.	
Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.	Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.	
The authority for application and removal of tags, markings, labels, and stamps shall be specified.	The authority for application and removal of tags, markings, labels, and stamps shall be specified.	
Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.	Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.	

BASIC REQUIREMENT 15 CONTROL OF NONCONFORMING ITEMS	BASIC REQUIREMENT 15 CONTROL OF NONCONFORMING ITEMS	COMMENTS
Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.	Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.	
Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.	Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.	
SUPPLEMENT 15S-1 SUPPLEMENTARY REQUIREMENTS FOR THE CONTROL OF NONCONFORMING ITEMS	**SUPPLEMENT 15S-1 SUPPLEMENTARY REQUIREMENTS FOR THE CONTROL OF NONCONFORMING ITEMS**	
1 GENERAL	**1 GENERAL**	
This Supplement provides amplified requirements for the control of nonconforming items.	This Supplement provides amplified requirements for the control of nonconforming items.	
It supplements the requirements of Basic Requirement 15 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard.	It supplements the requirements of Basic Requirement 15 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
2 IDENTIFICATION	**2 IDENTIFICATION**	
(a) Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item.	(a) Identification of nonconforming items shall be by marking, tagging, or other methods which shall not adversely affect the end use of the item.	
The identification shall be legible and easily recognizable.	The identification shall be legible and easily recognizable.	
(b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.	(b) If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.	
3 SEGREGATION	**3 SEGREGATION**	
(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.	**16** Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.	
(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.	(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.	
4 DISPOSITION	**4 DISPOSITION**	
4.1 Control	**4.1 Control**	

BASIC REQUIREMENT 15 CONTROL OF NONCONFORMING ITEMS	BASIC REQUIREMENT 15 CONTROL OF NONCONFORMING ITEMS	COMMENTS
Nonconforming characteristics shall be reviewed and recommended dispositions of non conforming items shall be proposed and approved in accordance with documented procedures.	Nonconforming characteristics shall be reviewed and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures.	
Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel.	Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending an evaluation and an approved disposition by authorized personnel	
4.2 Responsibility and Authority The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.	**4.2 Responsibility and Authority** The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined.	
4.3 Personnel Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.	**4.3 Personnel** Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.	
4.4 Final Disposition The final disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.	**4.4 Disposition** The disposition, such as use-as-is, reject, repair, or rework, of nonconforming items shall be identified and documented.	
4.5 Technical Justification Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented.	Technical justification for the acceptability of a nonconforming item, dispositioned repair, or use-as-is shall be documented.	
	Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.	Added detail that restates basic requirement – no impact.
The as-built records, if such records are required, shall reflect the accepted deviation.	The as-built records, if such records are required, shall reflect the accepted deviation.	
4.6 Repaired or Reworked Items Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.	**4.5 Repaired or Reworked Items** Repaired or reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.	

BASIC REQUREMENT 16 CORRECTIVE ACTION	BASIC REQUIREMENT 16 CORRECTIVE ACTION	COMMENTS
Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.	Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.	Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.	
SUPPLEMENT 17S-1 **SUPPLEMENTARY REQUIREMENTS FOR QUALITY ASSURANCE RECORDS** **1 GENERAL** This Supplement provides amplified requirements for quality assurance records. It supplements the requirements of Basic Requirement 17 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard. The requirements of this Supplement apply to quality assurance records which have been completed. The term *records*, used throughout this Supplement, is to be interpreted as *Quality Assurance Records*. **2 RECORDS ADMINISTRATION** **2.1 Records System** A records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. **2.2 Generation of Records** The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the Owner.	**SUPPLEMENT 17S-1** **Supplementary Requirements for Quality Assurance Records** **1 GENERAL** This Supplement provides amplified requirements for quality assurance records. It supplements the requirements of Basic Requirement 17 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I). The requirements of this Supplement apply to quality assurance records which have been completed. The term *records*, used throughout this Supplement, is to be interpreted as *Quality Assurance Records*. **2 RECORDS ADMINISTRATION** **2.1 Records System** A records system(s) shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the general requirements of this Supplement. The records system(s) shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. **2.2 Generation of Records** The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents shall specify the records to be generated, supplied, or maintained by or for the Owner.	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished.	Documents that are designated to become records shall be legible, accurate, and completed appropriate to the work accomplished.	
2.3 Record Validation	**2.3 Record Validation**	
Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.	Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.	
This authentication may take the form of a statement by the responsible individual or organization.	This authentication may take the form of a statement by the responsible individual or organization.	
Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.	Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.	
The records may be originals or reproduced copies.	These records may be originals or reproduced copies.	
2.4 Index	**2.4 Index**	
The records shall be indexed. The indexing system(s) shall include, as a minimum, record retention times and the location of the record within the record system.	The records shall be indexed. The indexing system(s) shall include, as a minimum, record retention times and the location of the record within the record system.	
2.5 Distribution	**2.5 Distribution**	
The records shall be distributed, handled, and controlled in accordance with written procedures.	The records shall be distributed, handled, and controlled in accordance with written procedures.	
2.6 Identification	**2.6 Identification**	
Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.	Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item(s) or activity(ies) to which it applies.	
2.7 Classification	**2.7 Classification**	
Records shall be classified as *Lifetime* or *Nonpermanent* by the Owner, or his agent when authorized, in accordance with the criteria in 2.7.1 and 2.7.2 below.	Records shall be classified as *Lifetime* or *Nonpermanent* by the Owner, or his agent when authorized, in accordance with the criteria given in paras. 2.7.1 and 2.7.2 below.	
2.7.1 Lifetime Records.	**2.7.1 Lifetime Records.**	
Lifetime records are those that meet one or more of the following criteria:	Lifetime records are those that meet one or more of the following criteria:	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
those which would be of significant value in demonstrating capability for safe operation;	*(a)* those which would be of significant value in demonstrating capability for safe operation;	
those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;	*(b)* those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;	
those which would be significant value in determining the cause of an accident or malfunction of an item;	*(c)* those which would be of significant value in determining the cause of an accident or malfunction of an item;	
those which provide required baseline data for in-service inspections.	*(d)* those which provide required baseline data for in-service inspections.	
Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.	Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.	
2.7.2 Nonpermanent Records.	**2.7.2 Nonpermanent Records.**	
Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.	Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.	
2.8 Retention of Records Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing.	**2.8 Retention of Records** Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing.	
2.9 Corrected Information in Records Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.	**2.9 Corrected Information in Records** Records may be corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction shall include the date and the identification of the person authorized to issue such correction.	
3 RECEIPT **3.1 Responsibility** The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.	**3 RECEIPT** **3.1 Responsibility** The individual or organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession.	
3.2 Receipt Control	**3.2 Receipt Control**	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records.	Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records.	
The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.	The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.	
As a minimum, a receipt control system shall include the following:	As a minimum, a receipt control system shall include the following:	
(*a*) a method for designating the required records; (*b*) a method for identifying records received; (*c*) procedures for receipt and inspection of incoming records.	*(a)* a method for designating the required records; *(b)* a method for identifying records received; *(c)* procedures for receipt and inspection of incoming records; *(d)* a method for submittal of completed records to the storage facility without unnecessary delay.	Added detail that implies timeliness of document turnover to archives.
3.3 Status Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.	**3.3 Status** Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.	
4 STORAGE, PRESERVATION, AND SAFEKEEPING **4.1 Storage**	**4 STORAGE, PRESERVATION, AND SAFEKEEPING** **4.1 Storage**	
The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.	The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies.	
Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure.	Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure.	
This procedure shall include, as a minimum, (a) through (g) below:	This procedure shall include, as a minimum, (a) through (g) below:	
a description of the storage facility; (*b*) the filing system to be used; (*c*) a method for verifying that the records received are in agreement with the transmittal document and that the records are legible; (*d*) a method of verifying that the records are those designated (see 3.2 above);	*(a)* a description of the storage facility; *(b)* the filing system to be used; *(c)* a method for verifying that the records received are in agreement with the transmittal document and that the records are legible; *(d)* a method of verifying that the records are those designated (see para. 3.2 above);	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
(*e*) the rules governing access to and control of the files; (*f*) a method for maintaining control of and accountability for records removed from the storage facility; (*g*) a method for filing supplemental information (see 2.9 above) and disposing of superseded records.	*(e)* the rules governing access to and control of the files; *(f)* a method for maintaining control of and accountability for records removed from the storage facility; *(g)* a method for filing supplemental information (see para. 2.9 above) and disposing of superseded records.	
4.2 Preservation Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records the requirements of (a) through (c) below shall apply.	**4.2 Preservation** Records shall be stored in a manner approved by the organization or organizations responsible for storage. In order to preclude deterioration of the records, the requirements of (a) through (c) below shall apply.	
(*a*) Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure. (*b*) Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.	*(a)* Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure. *(b)* Records shall be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. *(c)* Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.	
4.3 Safekeeping Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.	**4.3 Safekeeping** Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.	
4.4 Facility Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: (*a*) natural disasters such as winds, floods, or fires;	**4.4 Storage Facilities** Records shall be stored in facilities constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: *(a)* natural disasters such as winds, floods, or fires;	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
(*b*) environmental conditions such as high and low temperatures and humidity; (*c*) infestation of insects, mold, or rodents. There are two satisfactory methods of providing storage facilities, single or dual. **4.4.1 Single Facility.** Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below: (*a*) reinforced concrete, concrete block, masonry, or equal construction; floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included. (*c*) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating; (*d*) sealant applied over walls as a moisture or condensation barrier; (*e*) surface sealant on floor providing a hard wear surface to minimize concrete dusting; (*f*) foundation sealant and provisions for drainage; (*g*) forced air circulation with filter system; (*h*) fire protection system; (*i*) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/ humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating. The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing. If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria. **4.4.2 Alternate Single Facilities.** The following are acceptable alternatives to the criteria of 4.4.1 above for a single facility:	(*b*) environmental conditions such as high and low temperatures and humidity; (*c*) infestation of insects, mold, or rodents. There are two satisfactory methods of providing storage facilities, single or dual. **4.4.1 Single Storage Facility.** Design and construction of a single record storage facility shall meet the criteria of (a) through (i) below: (*a*) reinforced concrete, concrete block, masonry, or equal construction; (*b*) floor and roof with drainage control; If a floor drain is provided, a check (*c*) doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hr fire rating; (*d*) sealant applied over walls as a moisture or condensation barrier; (*e*) surface sealant on floor providing a hard wear surface to minimize concrete dusting; (*f*) foundation sealant and provisions for drainage; (*g*) forced air circulation with filter system; (*h*) fire protection system; (*i*) only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hr fire protection rating. The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing. If the storage facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria. **4.4.2 Alternate Single Storage Facility.** The following are acceptable alternatives to the criteria of para. 4.4.1 above for a single storage facility:	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
(*a*) 2 hr fire rated vault meeting NFPA 232-1975[1]; (*b*) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232- 1975[1]; or (*c*) 2 hr fire rated file room meeting the requirements of NFPA 232-1975[1] with the following additional provisions: (*1*) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station; (*2*) records storage in fully enclosed metal cabinets; (*3*) adequate access and aisle ways; (*4*) prohibition in the room of work not directly associated with record storage or retrieval; (*5*) prohibition in the room of smoking, eating, or drinking; (*6*) 2 hr fire rated dampers or doors in all boundary penetrations.	(*a*) 2 hr fire rated vault meeting NFPA 232-1986 or NFPA 232AM-1986 or both;[1] (*b*) 2 hr fire rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both;[1] or (*c*) 2 hr fire rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both[1] with the following additional provisions: (*1*) early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station; (*2*) records storage in fully enclosed metal cabinets; (*3*) adequate access and aisle ways; (*4*) prohibition in the room of work not directly associated with record storage or retrieval; (*5*) prohibition in the room of smoking, eating, or drinking; (*6*) 2 hr fire rated dampers or doors in all boundary penetrations.	
	4.4.3 Temporary Storage. When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1 hr fire rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying 1 hr fire protection or be certified by a person competent in the technical field of fire protection.	Added flexibility to allow temporary storage when archiving immediately is not practical.
4.4.3 Dual Facilities. If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either 4.4.1 or 4.4.2 above, but shall meet the other requirements of this Standard.	**4.4.4 Dual Storage Facilities.** If dual storage facilities for each record are provided, the storage facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each storage facility is not required to satisfy the requirements of para. 4.4.1, para. 4.4.2 or para. 4.4.3 above, but shall meet the other requirements of this Part (Part I).	
5 RETRIEVAL Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained designating those personnel who shall have access to the files.	**5 RETRIEVAL** Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained designating those personnel who shall have access to the files.	

BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	BASIC REQUIREMENT 17 QUALITY ASSURANCE RECORDS	COMMENTS
Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner. **6 DISPOSITION** Records accumulated at various locations, prior to transfer, shall be made accessible to the Owner directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Standard. Various regulatory agencies have requirements concerning records that are within the scope of this Standard. The most stringent requirements shall be used in determining the final disposition. The Supplier?s nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied: *(a)* items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed; *(b)* regulatory requirements are satisfied; *(c)* operational status permits; *(d)* warranty consideration is satisfied; *(e)* Purchaser?s requirements are satisfied.	Records maintained by a Supplier at his facility or other location shall be accessible to the Purchaser or his designated alternate, e.g., the Owner. **6 DISPOSITION** Records accumulated at various locations, prior to transfer, shall be made accessible to the Owner directly or through the procuring organization. The custodian shall inventory the submittals, acknowledge receipt, and process these records in accordance with this Part (Part I). Various regulatory agencies have requirements concerning records that are within the scope of this Part (Part I). The most stringent requirements shall be used in determining the final disposition. The Supplier's nonpermanent records shall not be disposed of until the applicable conditions listed in (a) through (e) below are satisfied: *(a)* items are released for shipment, a Code Data Report is signed, or a Code Symbol Stamp is affixed; *b)* regulatory requirements are satisfied; *(c)* operational status permits; *(d)* warranty consideration is satisfied; *(e)* Purchaser's requirements are satisfied.	

BASIC REQUIREMENT 18 AUDITS	BASIC REQUIREMENT 18 AUDITS	COMMENTS
Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness.	Planned and scheduled audits shall be performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness.	
These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited	These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.	
Audit results shall be documented and reported to and reviewed by responsible management.	Audit results shall be documented and reported to and reviewed by responsible management.	
Follow-up action shall be taken where indicated.Follow-up action shall be taken where indicated.Follow-up action shall be taken where indicated.	Follow-up action shall be taken where indicated.Follow-up action shall be taken where indicated.Follow-up action shall be taken where indicated.	
SUPPLEMENT 18S-1 SUPPLEMENTARY REQUIREMENTS FOR AUDITS	**SUPPLEMENT 18S-1 SUPPLEMENTARY REQUIREMENTS FOR AUDITS**	
1 GENERAL	**1 GENERAL**	
This Supplement provides amplified requirements for quality assurance audits. It supplements the audit requirements of Basic Requirement 18 of this Standard and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Standard	This Supplement provides amplified requirements for quality assurance audits. It supplements the audit requirements of Basic Requirement 18 of this Part (Part I) and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part (Part I).	
SCHEDULING	**2 SCHEDULING**	
Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities.	Internal or external quality assurance audits, or both, shall be scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities.	
Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current.	Audits shall be scheduled at a frequency commensurate with the status and importance of the activity. The audit schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained current.	
Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.	Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.	
3 PREPARATION	**3 PREPARATION**	
3.1 Audit Plan	**3.1 Audit Plan**	

BASIC REQUIREMENT 18 AUDITS	BASIC REQUIREMENT 18 AUDITS	COMMENTS
The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. **3.2 Personnel** The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. **3.3 Selection of Audit Team** An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit. **4 PERFORMANCE** Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements.	The auditing organization shall develop and document an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. **3.2 Personnel** The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activities which they will audit. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. **3.3 Selection of Audit Team** An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates responses. The audit team leader shall ensure that the audit team is prepared prior to initiation of the audit. **4 PERFORMANCE** Audits shall be performed in accordance with written procedures or checklists. Auditing shall begin as early in the life of the activity as practical and shall be continued at intervals consistent with the schedule for accomplishing the activity. Elements that have been selected for audit shall be evaluated against specified requirements.	

BASIC REQUIREMENT 18 AUDITS	BASIC REQUIREMENT 18 AUDITS	COMMENTS
Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. **5 REPORTING** The audit report shall be signed by the audit team leader and issued and shall include the following information, as appropriate: (a) description of the audit scope (b) identification of the auditors (c) identification of persons contacted during audit activities (d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited (e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization **6 RESPONSE** Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization. **7 FOLLOW-UP ACTION** Follow-up action shall be taken to verify that corrective action is accomplished as scheduled. **8 RECORDS** Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.	Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. **5 REPORTING** The audit report shall be signed by the audit team leader and issued, and it shall include the following information, as appropriate: (a) description of the audit scope; (b) identification of the auditors; (c) identification of persons contacted during audit activities; (d) summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited; (e) description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization. **6 RESPONSE** Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence, and notify the appropriate organization in writing of action taken or planned. The adequacy of audit responses shall be evaluated by or for the auditing organization. **7 FOLLOWUP ACTION** Follow-up action shall be taken to verify that corrective action is accomplished as scheduled. **8 RECORDS** Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.	