Exelon Generation®

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10 CFR 50.54(a)(3)
10 CFR 71.106(b)

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RA-20-001
TMI-20-001
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February 10, 2020

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

Braidwood Station, Units 1 and 2
Renewed Facility Operating License Nos. NPF-72 and NPF-77
NRC Docket Nos. STN 50-456, STN 50-457, 71-0008, and 72-0073

Byron Station, Units 1 and 2
Renewed Facility Operating License Nos. NPF-37 and NPF-66
NRC Docket Nos. STN 50-454, STN 50-455, 71-0008, and 72-0068

Calvert Cliffs Nuclear Power Plant, Units 1 and 2
Renewed Facility Operating License Nos. DPR-53 and DPR-69
NRC Docket Nos. 50-317, 50-318, 71-0008, and 72-0008

Clinton Power Station, Unit 1
Facility Operating License No. NPF-62
NRC Docket No. 50-461 , 71-0008, and 72-1046

Dresden Nuclear Power Station, Units 1, 2 and 3
Facility Operating License No. DPR-2
Renewed Facility Operating License Nos. DPR-19 and DPR-25
NRC Docket Nos. 50-10, 50-237, 50-249, 71-0008, and 72-0037

James A. FitzPatrick Nuclear Power Plant
Renewed Facility Operating License No. DPR-59
NRC Docket Nos. 50-333, 71-0008, and 72-0012

LaSalle County Station, Units 1 and 2
Renewed Facility Operating License Nos. NPF-11 and NPF-18
NRC Docket Nos. 50-373, 50-374, 71-0008, and 72-0070

Limerick Generating Station, Units 1 and 2
Renewed Facility Operating License Nos. NPF-39 and NPF-85
NRC Docket Nos. 50-352, 50-353, 71-0008, and 72-0065

Nine Mile Point Nuclear Station, Units 1 and 2
Renewed Facility Operating License Nos. DPR-63 and NPF-69
NRC Docket Nos. 50-220, 50-410, 71-0008, and 72-1036

Peach Bottom Atomic Power Station, Units 1, 2 and 3
Facility Operating License No. DPR-12
Renewed Facility Operating License Nos. DPR-44 and DPR-56
NRC Docket Nos. 50-171, 50-277, 50-278, 71-0008, and 72-0029

Quad Cities Nuclear Power Station, Units 1 and 2
Renewed Facility Operating License Nos. DPR-29 and DPR-30
NRC Docket Nos. 50-254, 50-265, 71-0008, and 72-0053

R.E. Ginna Nuclear Power Plant
Renewed Facility Operating License No. DPR-18
NRC Docket No. 50-244, 71-0008, and 72-0067

Three Mile Island Nuclear Station, Unit 1
Renewed Facility Operating License No. DPR-50
NRC Docket No. 50-289 and 71-0008

Subject: Summary of Changes to Exelon Generation Company, LLC, Quality Assurance Topical Report, NO-AA-10, and Decommissioning Quality Assurance Program, NO-DC-10

Reference: 1. Letter from D. Helker, Exelon Generation Company, LLC, to U.S. Nuclear Regulatory Commission, " Summary of Changes to Exelon Generation Company, LLC, Quality Assurance Topical Report, NO-AA-10, and Decommissioning Quality Assurance Program, NO-DC-10," dated February 8, 2019 (ADAMS Accession No. ML19039A007)

In accordance with the requirements of 10 CFR 50.54(a)(3) and 10 CFR 71.106(b), Exelon Generation Company, LLC (Exelon) is submitting a summary of changes to the Exelon Quality Assurance Topical Report (QATR), NO-AA-10, and the Exelon Decommissioning Quality Assurance Program (DQAP), NO-DC-10, that did not reduce commitments in the quality assurance program description, and therefore, did not require NRC approval prior to implementation. There were no changes to the QATR or DQAP that required NRC approval prior to implementation.

Since the previous quality assurance program description summary of changes submitted on February 8, 2019 (Reference 1), there have been no revisions to the QATR. Revision 94 is the current version of the QATR in use and was effective on September 19, 2018.

Since the previous quality assurance program description summary of changes submitted on February 8, 2019 (Reference 1), DQAP Revision 1 has been implemented in accordance with the requirements of 10 CFR 50.54(a)(3) and 10 CFR 71.106(b). Revision 1 is the current version of the DQAP in use and was effective on September 10, 2019.

The summary of the changes for Revision 1 of the DQAP is provided in Attachment 1 of this letter. Attachment 2 of this letter provides a copy of Revision 1 of the DQAP for information purposes only.

If you have any questions or require additional information, please contact Glenn Stewart, Licensing and Regulatory Affairs, at 610-765-5529.

Respectfully,

Shannon Rafferty-Czincila
Director, Licensing
Exelon Generation Company, LLC

Attachments: 1 - DQAP NO-DC-10, Revision 1 - Summary of Changes
2 - DQAP NO-DC-10, Revision 1 (Information Only)

cc: (w/ Attachments)
Regional Administrator - NRC Region I
Regional Administrator - NRC Region III
NRC Senior Resident Inspector - Braidwood Station
NRC Senior Resident Inspector - Byron Station
NRC Senior Resident Inspector - Calvert Cliffs Nuclear Power Plant
NRC Senior Resident Inspector - Clinton Power Station
NRC Senior Resident Inspector - Dresden Nuclear Power Station
NRC Senior Resident Inspector - James A. FitzPatrick Nuclear Power Plant
NRC Senior Resident Inspector - LaSalle County Station
NRC Senior Resident Inspector - Limerick Generating Station
NRC Senior Resident Inspector - Nine Mile Point Nuclear Station
NRC Senior Resident Inspector - Peach Bottom Atomic Power Station
NRC Senior Resident Inspector - Quad Cities Nuclear Power Station
NRC Senior Resident Inspector - R. E. Ginna Nuclear Power Plant
NRC Decommissioning Inspector - Three Mile Island Nuclear Station, Unit 1

NRC Project Manager, NRR - Braidwood Station
NRC Project Manager, NRR - Byron Station
NRC Project Manager, NRR - Calvert Cliffs Nuclear Power Plant
NRC Project Manager, NRR - Clinton Power Station
NRC Project Manager, NRR - Dresden Nuclear Power Station
NRC Project Manager, NRR - James A. FitzPatrick Nuclear Power Plant
NRC Project Manager, NRR - LaSalle County Station
NRC Project Manager, NRR - Limerick Generating Station
NRC Project Manager, NRR - Nine Mile Point Nuclear Station
NRC Project Manager, NRR - Peach Bottom Atomic Power Station
NRC Project Manager, NRR - Quad Cities Nuclear Power Station
NRC Project Manager, NRR - R. E. Ginna Nuclear Power Plant
NRC Project Manager, NRR - Three Mile Island Nuclear Station, Unit 1
Decommissioning Branch Chief, NRC Region III
Illinois Emergency Management Agency - Division of Nuclear Safety
Director, Bureau of Radiation Protection, PA Department of Environmental Protection
Chairman, Board of County Commissioners of Dauphin County, PA
Chairman, Board of Supervisors of Londonderry Township, PA
D. A. Tancabel, State of Maryland
A. L. Peterson, NYSERDA
S. T. Moore, Mid-American Energy

ATTACHMENT 1

EXELON GENERATION COMPANY, LLC

DECOMMISSIONING QUALITY ASSURANCE PROGRAM, NO-DC-10 REVISION 1

SUMMARY OF CHANGES

Revision 1 effective date of September 10, 2019

The Decommissioning Quality Assurance Program (DQAP) has been revised to:

- Remove Oyster Creek Site Specific Administrative Requirements from Appendix E.
- Add Three Mile Island Unit 1 Site Specific Administrative Requirements to Appendix E.

No changes required NRC approval prior to implementation. All changes have been reviewed in accordance with 10CFR50.54(a) and did not reduce Exelon's commitments previously approved by the NRC.

The specific changes are described below.

Table of Contents

- Changed the DQAP Table of Contents by removing Oyster Creek Site Specific Administrative Requirements from Appendix E and replacing it with Three Mile Island (Unit 1) Site Specific Administrative Requirements.

Appendix D

- Added the following:

D.6. Independent Spent Fuel Storage Installation (ISFSI) SSC

D.6.1. ISFSI quality assurance program requirements are performed in accordance with the applicable 10 CFR 72.212 report which invokes the portions of the NRC approved 10 CFR 50 Appendix B quality assurance program as described in this DQAP, commensurate with the safety classification of the component and quality requirements specified in the cask vendor Final Safety Analysis Report (FSAR) or site-specific license.

Appendix E

- Removed Oyster Creek Site Specific Administrative Requirements from Appendix E, Sections E.1 through E.3
- Added Three Mile Island (Unit 1) Site Specific Administrative Requirements to Appendix E, Sections E.1 through E.3 as follows:

E.1. Regulatory Guide 1.33

E.1.1. Written procedures applicable to safe storage of nuclear fuel recommended in Appendix A of Regulatory Guide 1.33, shall be established, implemented, and maintained. (ref. TMI DC Technical Specification Section 6.8.1 Procedures and Programs).

E.2. Records Retention

E.2.1 The following records shall be retained for at least five years:

- Records and logs of activities related to the safe storage of irradiated fuel.

- Records and logs of principle maintenance activities, including inspection, repairs, substitution, or replacement of principal items of equipment related to safe storage of irradiated fuel.
- All REPORTABLE EVENTS.
- Records of periodic checks, tests and calibrations.
- Changes to the procedures required by the Technical Specification 6.8.1.
- Test results, in units of microcuries, for leak tests performed on licensed seal sources on record.
- Records of annual physical inventory verifying accountability of licensed sources on record.

E.2.2. The following records shall be retained for the duration of the Facility Operating License:

- Records and drawing changes reflecting facility design modification made to systems and equipment needed for the safe storage of irradiated fuel as described in the Safety Analysis Report.
- Records of irradiated fuel inventory, fuel transfers and assembly burnup histories.
- Routine unit radiation surveys and monitoring records.
- Records of doses received by all individuals for whom monitoring was required.
- Records of radioactive liquids and gaseous wastes released to the environment, and records of environmental monitoring surveys.
- Records of training and qualification for current members of the unit staff.
- Records of reviews performed for changes made to procedures or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59.
- Records of analyses required by the radiological environmental monitoring program.
- Records of solid radioactive shipments.
- Records of reviews performed for changes made to the Offsite dose Calculation Manual and the Process Control Plan.

E.3. <u>Facility Staff Qualifications</u>

E.3.1 Each member of the facility staff shall meet or exceed the minimum qualifications of ANSI/ANS 3.1 of 1978 for comparable positions unless otherwise noted in the Technical Specifications. Individuals who do not meet ANSI/ANS 3.1 of 1978, Section 4.5, are not considered technicians or maintenance personnel for purposes of determining qualifications but are permitted to perform work for which qualification has been demonstrated.

E.3.2 The management position responsible for radiological controls shall meet or exceed the qualifications of Regulatory Guide 1.8 of 1977. Each radiological control technician/supervisor shall meet or exceed the qualifications of ANSI-N

18.1-1971, paragraph 4.5.2/4.3.2, or be formally qualified through an NRC approved TMI-I Radiation Controls training program. All radiological controls technicians will be qualified through training and examination in each area or specific task related to their radiological controls' functions prior to their performance of those tasks.

ATTACHMENT 2

EXELON GENERATION COMPANY, LLC

DECOMMISSIONING QUALITY ASSURANCE PROGRAM, NO-DC-10
REVISION 1

Exelon Generation Company, LLC

DECOMMISSIONING QUALITY ASSURANCE PROGRAM (DQAP)

NO-DC-10

Revision 1

Exelon Nuclear

Corporate Headquarters

4300 Winfield Road
Warrenville, IL 60555

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Decommissioning Quality Assurance Program (NO-DC-10) - Revision 1 Transmittal and Summary of Changes

To: All Site Document Control Centers

These changes are effective September 10, 2019, with a site and corporate implementation no later than November 8, 2019.

The Decommissioning Quality Assurance Plan (DQAP) has been revised as follows:

- Oyster Creek site specific information was removed from Appendix E.
- Three Mile Island Unit 1 site specific information was added to Appendix E.

This DQAP has been reviewed in accordance with 10CFR50.54 (a) and did not reduce Exelon's commitments previously approved by the NRC. (Ref. AT 4182346-10 for supporting 50.54(a) evaluations). This revision to the DQAP will be submitted to the NRC for post implementation review as tracked by Action Tracking Number 4182346-10-03.

Personnel engaged in activities covered by the DQAP are required to review the chapters and appendices. Affected procedures should be changed and training provided as needed to ensure compliance with the requirements.

Prepared By: _____ 8/19/19
Mike Porter / Date
Nuclear Oversight Quality Assurance Specialist

Approved BY: _____ 8/19/2019
Rob Radulovich / Date
Nuclear Oversight Audit and Programs Director

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Policy Statement

The Decommissioning Quality Assurance Program (DQAP), NO-DC-10, is the highest tiered document that assigns major functional responsibilities for decommissioning facilities owned and operated by Exelon Generation Company, LLC (Company).

Implementing documents assign more specific responsibilities and define the organizational interfaces involved in conducting safety-related and important to safety activities within the scope of this DQAP. 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 Program relies on those who manage, perform, and support the performance of activities within the scope of the DQAP. Assurance of this attainment relies on those who have no direct responsibility for performing the activity.

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

1. ORGANIZATION

The Company is responsible for the establishment and execution of the DQAP at sites that have submitted a Certification of Permanent Cessation of Operations and Certification of Permanent Removal of Fuel to the NRC per 10 CFR 50.82(a)(1)(i) and (ii), respectfully. This DQAP does not include Dresden Unit 1 and Peach Bottom Unit 1 that meet quality program requirements established in the Exelon Fleet Quality Assurance Topical Report. The titles of managers used in the DQAP are generic, or functional titles and their formal titles may vary. Unless otherwise specifically prohibited, responsibilities of managers described in the DQAP may be delegated to, and be performed by, other qualified individuals. Site organizations will be commensurate with the activities and risks associated with Decommissioning (DC) Phases 2, 3, and 4. The different phases are defined in Appendix A of this DQAP.

1.1. Responsibilities

1.1.1. The authorities and duties of persons and organizations performing activities within the scope of this DQAP are established and delineated in writing. These activities include both performing the functions of attaining quality objectives and the Quality Assurance functions.

1.1.2. 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 decommissioning activities shall comply with the requirements of this DQAP.

1.1.3. The overall responsibility for operation, maintenance, inspection, test, modification, decommissioning, and storage of spent fuel resides with the Sr. Executive Vice President, Exelon Generation and President and Chief Nuclear Officer (CNO), Exelon Nuclear. The Decommissioning Plant Manager is responsible for the administration and implementation of the DQAP at the applicable facility.

1.1.4. The DQAP is reviewed and approved by the management position responsible for Nuclear Oversight. The management position responsible for Nuclear Oversight is responsible for periodically appraising the CNO on the effectiveness of the DQAP implementation and immediately apprises the CNO of significant problems affecting quality.

1.1.5. Management of line organizations at the decommissioning facilities are responsible to ensure that the quality of work and activities meets the requirements set forth in the DC technical specifications, this DQAP, and implementing procedures.

1.2. Corporate Organizations

1.2.1. The Sr. Executive Vice President, Exelon Generation and President and Chief Nuclear Officer (CNO), Exelon Nuclear, has overall responsibility for the safe and reliable operation of the Company's nuclear stations. This is the senior executive responsible for setting and implementing policies, objectives, expectations, and priorities to ensure activities are performed in accordance with the DQAP and other requirements. The following management positions and committees report to and / or receive direction from the CNO with respect to their assigned roles and responsibilities associated with the execution of this DQAP:

- A management position responsible for Strategic Planning, Project Management, License Renewal, Nuclear Projects, and Decommissioning. This position reports to the CNO and is responsible 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.
- A management position responsible for Nuclear Oversight, Organizational Effectiveness and Integrated Performance Assessment (OR&IPA) reports to the CNO and is responsible to provide management and oversight to ensure compliance with the DQAP. The following management position reports to OR&IPA:
  - A management position responsible for Nuclear Oversight maintains a staff of supervisory, administrative, and technical personnel to verify the DQAP is effectively implemented. Nuclear Oversight personnel shall have sufficient authority and organizational freedom to identify any quality problems and to verify implementation of corrective actions. Additionally, Nuclear Oversight personnel shall have direct access to appropriate levels of management necessary to perform their function and shall be independent from cost and schedule when opposed to quality and safety considerations. Functional responsibilities include:
    - Managing the performance of periodic audits and quality verification inspections in order to verify that activities within the scope of this DQAP have been correctly performed.
    - Establishing quality assurance practices and policies.
    - Authority and obligation to raise any conditions adverse to quality to the CNO for resolution as necessary.
    - Assuring quality activities are performed in accordance with implementing procedures.

- o Employee Concerns Program.
- o Reporting on oversight activities to the CNO.
- o Authority to stop work when quality is adversely affected.

1.2.2. Additional support organizational activities such as Emergency Preparedness, calibrations, procurement, training, legal, communications, records and document control, information technology, business operations, and human resources may be provided by the site or by the corporate organizations.

1.3. Station Management

1.3.1. The Decommissioning Plant Manager shall be responsible for overall safe operation of the facility and shall have control over those onsite activities necessary for safe storage and maintenance of spent nuclear fuel, including maintaining the facility within the constraints of applicable regulatory requirements, license, DC technical specifications and training. The Decommissioning Plant Manager, or specified designee, shall approve, prior to implementation, all tests, experiments, and modifications to systems or equipment that affect the safe storage and maintenance of spent nuclear fuel. Supervisory direction is provided for the technical review program, including approval of individuals as technical reviewers as applicable. The following positions report to the plant manager:

- · A management position responsible for Operations, with responsibility for operating strategies that support nuclear and personnel safety within the constraints of the decommissioning license and regulatory requirements. (DC Phases 2 and 3).
- · A management position responsible for managing decommissioning projects that support nuclear and personnel safety within the constraints of the decommissioning license and regulatory requirements. (DC Phases 2, 3, and 4). The following management positions report to this position:
- · A management position responsible for analysis, problem solving, abandonment, and modification development of systems, components, and structures supporting storage of nuclear fuel. (DC Phases 2, 3, and 4).
- · A management position responsible for development, coordination, and implementation of decommissioning project plans. This position is also responsible for material management and site supply, which coordinates, evaluates, and procures materials for the site. (DC Phases 2, 3, and 4).
- · A management position responsible for coordination of decommissioning resources, and execution of maintenance and modification activities. (DC Phase 2).

- A management position responsible for maintenance activities. (DC Phases 2, 3, and 4).
- A management position responsible for engineering support activities, development and maintenance of engineering programs, policies, procedures, and providing engineering services in accordance with the DQAP. Also, responsible for document control and records management functions. (DC Phases 2 and 3).
- A management position responsible for implementation of the site security plan. (DC Phases 2, 3, and 4).
- A management position responsible for ALARA planning, chemistry and environmental activities. (DC Phases 2, 3, and 4).
- A management position responsible for maintaining an interface between the station and federal and state regulators. Also, has a functional responsibility that includes Emergency Preparedness. (DC Phases 2, 3, and 4).
- A management position responsible for the Corrective Action Program. (DC Phases 2 and 3).

2. QUALITY ASSURANCE PROGRAM

2.1. The QA Program for Exelon decommissioning facilities is described in this DQAP which provides control over activities affecting quality to an extent consistent with their importance to safety and compliance. The DQAP includes specific monitoring activities which are measured against acceptance criteria in a manner sufficient to provide Exelon management assurance that the activities affecting quality are performed in an acceptable manner. The DQAP requirements apply to (i.e. the following are in the scope of the DQAP) structure, system, or components (SSCs) designated as safety related and important to safety, regulatory programs, and for other activities and SSCs identified in either the facility specific DSAR or Appendix of this DQAP.

2.2. The DQAP satisfies the requirements of 10 CFR 50 Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants,* 10 CFR 71 Subpart H, *Quality Assurance for Packaging and Transportation of Radioactive Material,* and 10 CFR 72 Subpart G, *Quality Assurance for Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste*. Regulatory commitments are listed within Appendix C of the DQAP. Implementation of this DQAP is controlled through separately issued procedures, instructions, and drawings. Each organization is responsible for the establishment and implementation of procedures and instructions prescribing the activities within the scope of this DQAP for which they are responsible.

2.3. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The DQAP takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test where required.

2.4. Changes to the DQAP will be implemented in accordance with 10 CFR 50.54(a).

2.5. Program Control and Authority

2.5.1. The management position responsible for Nuclear Oversight is responsible for ensuring that the applicable portions of the DQAP are properly documented, approved and implemented before an activity within the scope of the DQAP is executed. Disputes arising between departments or organizations on any QA matter that cannot be resolved at a lower level of management will be referred to the CNO.

2.5.2. Additional requirements for specific programs are described in Administrative Controls, of the applicable facility DC technical specifications or in the DQAP, with the exception of security requirements which are contained in the applicable facility Physical Security Plan; and Emergency Plan requirements which are contained within the applicable facility Site Emergency Plan. Fire Protection Program requirements are addressed in Appendix D of this DQAP.

2.6. Program Review

2.6.1. The status and effectiveness of the DQAP and its implementation is periodically reviewed by the management of the organization responsible for its execution. In addition, the effectiveness of the DQAP is evaluated and reported by Nuclear Oversight through the audit and inspection functions.

2.7. Personnel Training and Qualifications

2.7.1. Formal indoctrination and training programs for personnel performing or verifying activities within the scope of this DQAP are established and maintained. The indoctrination and training programs are established by on-site and/or off-site organizational units responsible for the performance or verification of activities within the scope of this DQAP.

2.7.2. All personnel shall have sufficient qualifications, as applicable, to perform their assigned duties. Implementing procedures provide the criteria utilized for determining and assessing appropriate staff qualifications. Indoctrination, training, and qualification programs are established such that:

- Personnel performing and/or verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed.
- Formal training and qualification program documentation includes the objective, content of the program, attendees, and date of attendance.
- Proficiency tests are given as applicable 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, as applicable, 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 recertifying as determined by management or program commitment.

3.0. DESIGN CONTROL

3.1. Measures shall be established to assure that the designs, including applicable regulatory requirements and design bases, technical and quality requirements are correctly translated to design documents which include specifications, drawings, procedures and instructions. Exelon has overall responsibility for design and design control activities including, preparing, reviewing, approving, and verifying design documents related to the facility's structures, systems, and components (SSCs) within the scope of the DQAP.

3.2. Design changes to SSCs within the scope of this DQAP shall be properly controlled using design control measures commensurate with those applied to the original design. Design changes are reviewed and approved by the same design groups cognizant in the discipline affected by the change that reviewed and approved the original documentation unless alternative design groups are designated. Design activities associated with the facility changes or modifications may be performed by Exelon or qualified contractors. Design groups shall have access to background information, shall be competent in the specific area of design interest, and shall understand the requirements and intent of the original design.

3.3. Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to SSCs that have current safety-related and important to safety functions. Design control implementing procedures shall define responsibility for the following:

- Design Input
- Design Performance
- Design Interface Control
- Design Verification
- Design Change

3.4. Design inputs shall be identified, documented and correctly translated into design outputs. Design inputs shall be specified to a level of detail necessary to allow the design activities to be carried out in a controlled manner. The final design output shall relate to the design input in sufficient detail to facilitate design verification.

3.5. The design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be completed in a correct manner which permits verification that the design meets requirements. Design documents shall support facility design, construction, safe storage and handling of spent fuel, and decommissioning projects. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. Deviations from original design standards shall be reviewed to ensure that the designated quality requirements remain in the design of SSCs as applicable.

3.6. Design control measures shall be applied to those SSCs within the scope of this DQAP. Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without additional input.

3.7. Design interfaces for SSCs within the scope of this DQAP shall be identified and controlled. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations. Controls shall be established for the review, approval, release, distribution and revision of documents involving design interfaces. Design information transmitted across interfaces shall be documented and controlled.

3.8. Changes or modifications to designated SSCs shall be approved by the Design Authority or designee. Procedures for implementing design changes and field changes shall assure that the impact of the change is considered, required actions documented, and information concerning the change transmitted to affected persons or organizations. Applicable regulatory criteria (i.e. 10 CFR 50.59, 10 CFR 50.82(a), or 10 CFR 72.48) shall be used to determine if NRC approval is required prior to implementation of a design change. For SSCs within the scope of this DQAP, these changes shall be subject to design control measures commensurate with those applied to the original design.

3.9. Design verification for SSCs within the scope of this DQAP shall provide assurance that the final design is correct and has been performed in accordance with approved procedures describing position responsibilities and authorities for the design reviews. Documentation to be reviewed for this design work includes the necessary calculations and/or analysis, design criteria specifications, drawings, procedures, and instructions to permit a comprehensive review.

3.10. Design verification may be accomplished through design reviews, alternate calculations, or qualification testing. These methods of design verification are defined in design procedures as applicable. The results of the design verification activities shall be documented with the identification of the verifier clearly documented. 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. Design verification shall be completed prior to relying upon the SSC to perform its important to safety function.

3.11. Nonconforming activities such as deviations, errors, or deficiencies in the approved design documents, including design methods (e.g., computer codes), shall be identified, documented, and controlled. Computer programs used to calculate or develop data for important to safety activities shall be subject to validation and verification.

3.12. Design documentation and records which provide evidence that the design and design verification process was performed in accordance with the DQAP, shall be collected, stored and maintained in accordance with approved procedures. This documentation includes final design documents, such as drawings, specifications, calculations, and revisions there to and documentation which identifies important steps, including sources of design inputs that support the final design.

4.0. PROCUREMENT DOCUMENT CONTROL

4.1. Measures shall be established for the preparation, review, and approval of procurement documents for those items and activities within the scope of this DQAP. Procurement documents include or reference the appropriate regulatory, technical, and quality requirements necessary to assure adequate quality for those materials, equipment, and services that are within the scope of this DQAP. Measures are established to assure that, to the extent necessary, contractors or subcontractors provide a QA Program consistent with the provisions of 10 CFR 50 Appendix B, 10 CFR 71 Subpart H, or 10 CFR 72 Subpart G, and 10 CFR 21, as applicable.

4.2. Exelon maintains 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 important to safety classification except for procurement from other licensees that have a NRC approved quality program.

4.3. 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.

4.4. Procurement document control applies to SSCs within the scope of this DQAP and any spare or replacement parts for those SSCs. Procurement documents shall include those requirements necessary to assure that the items and services to be provided meet the specified technical and quality requirements. Specifically, the procurement system assures that the appropriate technical and quality requirements are specified for procurement of items and services considering the important to safety function, complexity of the design, manufacturing, degree of inspection/testability upon receipt and other factors which affect the quality of products and services.

4.5. Procedures that implement procurement document control shall describe the organizational responsibilities for procurement planning, preparation, review, approval and control of procurement documents; supplier selection; bid evaluation; identification of replacement parts where applicable; and review and evaluation of supplier's QA Program prior to release for bid and contract award for activities within the scope of this DQAP.

4.6. Procedures shall be established to review the adequacy of the technical and QA requirements specified within procurement documents. 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 to ensure the adequacy of the technical and QA requirements. Changes to procurement documents shall be subject to the same controls as the original documents.

5.0. INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1. Measures shall be established to assure that quality activities are prescribed by and performed in accordance with documented instructions, procedures, or drawings. Documented and approved instructions, procedures, and drawings are required to accomplish work on SSCs within the scope of this DQAP.

5.2. These instructions, procedures, and drawings include, as appropriate, quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. 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 manufacturer's instructions shall be readily available for use as appropriate.

5.3. Controls are established which ensure that instructions, procedures, and drawings are current and accurately reflect plant design and regulatory requirements. Documents comprising of instructions, procedures, specifications, and drawings prepared by outside contractors for the performance of site activities are reviewed and approved by the responsible manager or designated representative.

6.0. DOCUMENT CONTROL

6.1. Measures shall be established to control the issuance of documents, such as instructions, procedures, drawings, including changes thereto, which prescribe activities affecting quality and activities within the scope of this DQAP. These measures assure that documents, such as procedures, instructions and drawings, are reviewed for adequacy by qualified personnel other than the personnel that prepared the document, approved for release and use, and available at the location where the activity is performed. Written procedures shall define the type of documents to which the document control system applies. These procedures also define the process for controlling the preparation, review, approval, issuance, and distribution.

6.2. Documents and changes to documents that prescribe or verify activities within the scope of this DQAP shall be controlled in a manner that precludes the use of inappropriate or outdated documents. The document control system procedures shall be established to identify the current revision of instructions, procedures, specifications, drawing and procurement documents.

6.3. Changes to documents shall be reviewed and approved by the same organization that performed the original review and approval unless another qualified organization has been designated. Administrative controls shall be established that provide the methods by which temporary changes can be made to procedures which are approved, including the designation of persons authorized to approve such changes, and the time period during which they may be used. 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.

7.0. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1. Measures shall be established for the control of purchased material, equipment, and services to assure they conform to the procurement documents as they apply to activities within the scope of this DQAP. These measures 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. Procedures shall describe each organization's responsibilities for the control of purchased material, equipment, and services, including the interfaces between all affected organizations.

7.2 Verification that a supplier can meet the specified technical and quality requirements shall be documented. Exelon maintains a controlled list of evaluated suppliers that are audited on a triennial basis. Documented supplier performance monitoring is performed in accordance with approved procedures as an acceptable alternate to the performance of the annual evaluation of suppliers. The evaluated list of such vendors, suppliers, and contractors is described in controlling procedures for the appropriate important to safety classification except for procurement from other licensees that have an NRC approved quality program. Suppliers of commercial grade calibration services may be qualified based on their accreditation by a nationally - recognized accrediting body, as an alternative to qualification by supplier audit, commercial grade survey, or in-process surveillance as described below.

7.3 This DQAP considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to the facility are not required to be evaluated or audited.

7.4 Commercial grade calibration and/or testing services may be procured from domestic and international commercial calibration and/or testing laboratories based on the laboratory's accreditation to ISO/IEC-17025 by an Accreditation Body (AB) which is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) provided all of the following are met:

7.4.1 A documented review of the supplier's accreditation is performed and includes a verification of the following:

- The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."
- For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
- For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances / uncertainty.

7.4.2. The purchase documents require that:

- The service must be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
- As found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. (For calibration services only)
- The equipment /standards used to perform the calibration must be identified in the certificate of calibration. (For calibration services only)
- The customer must be notified of any condition that adversely impacts the laboratory’s ability to maintain the scope of accreditation.
- Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

7.4.3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:

- The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program, and has been performed within their scope of accreditation; and
- The purchase order's requirements are met.

7.5. The effectiveness of contractors and supplier's QA program shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or service. Supplier performance and compliance with procurement documents are monitored by source verification, receipt inspection, audit, or a combination to ensure continued acceptable supplier performance. Receiving inspection shall verify, by objective evidence, the acceptability of items in accordance with facility procedures. Accepted items are appropriately marked and located in a controlled storage area until use. Documentary evidence shall be retained in accordance with facility requirements and applicable regulatory requirements and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.

7.6. For acquiring of services only, such as: third-party inspection, engineering and consulting services; auditing and installation; and repair, overhaul, or maintenance work, from suppliers whose QA Program has not been reviewed or accepted, those suppliers may be used provided additional controls such as technical verification of data produced, surveillance and/or audit of the activity, or review of objective evidence are employed. These additional controls shall be documented in the request for services and approved by the appropriate level of management.

7.7. Spare and replacement parts are procured such that their performance and quality are at least equivalent to those of the parts that will be replaced, as determined by engineering where applicable.

7.8. Designated quality personnel or other personnel with appropriate qualifications are responsible for assuring source inspections, surveys, or audits of suppliers are performed as necessary. Documentation of acceptance shall be available prior to installation or acceptance for use.

8.0. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1. Measures shall be established for the identification and control of material, parts, and components, including partially fabricated assemblies and consumables, to assure that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items, and physical identification shall be used to the maximum extent possible. 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.

8.2. Markings are applied using materials and methods that are clear, legible and do not detrimentally affect the function or service life of the items that are marked. Markings are transferred to each part of an identified item prior to being subdivided. Markings are not obliterated or masked by surface treatments or coatings unless alternative identification methods are established. When codes, standards, or specifications require specific identification or traceability requirements of an item, procedures shall describe how to maintain traceability as applicable.

8.3. Provisions are made in procedures for maintenance or replacement of markings or identification due to damage from handling or aging, excessive deterioration due to environmental exposure, and for updating records while in storage. Items having limited shelf or operating life are controlled to preclude use after the shelf life or operating life has expired.

9.0. CONTROL OF SPECIAL PROCESSES

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

9.2. Exelon qualifies NDE personnel in accordance with the applicable editions of the codes and standards accepted by the NRC as identified in Company NDE procedures.

10. INSPECTION

10.1. Measures shall be established for inspection of activities within the scope of this DQAP by or for the organization performing the activity, in order to verify conformance with approved instructions procedures, drawings, and specifications for accomplishing the task.

10.2. A comprehensive program of inspections shall be established and implemented to verify conformance of an item or activity with the specified requirements and inspection methods used and will be performed by personnel qualified to validate that the activities meet this acceptance criteria specified in applicable design documents. Inspections shall be performed by qualified individuals other than those who perform or directly supervise the activity being inspected.

10.3. Where mandatory hold or witness points are required for witness or inspection activities by designated personnel, the designated hold points shall be indicated in appropriate documentation. Work shall not progress beyond the point of an assigned hold point unless the inspection is complete or consent to waive the hold point is given by the designated organization.

10.4. Inspections shall be planned to ensure the characteristic to be inspected and the methods used to perform the inspection and acceptance criteria are documented. If inspection of processed or fabricated items is impractical, monitoring of the processing method and equipment shall be utilized. Process monitoring shall be performed by qualified personnel or a qualified automated process. Inspection and process monitoring shall both be used if quality control is inadequate without both.

10.5. Final inspections shall include record review and examinations, measurements / tests as appropriate to verify adequate quality measures were employed in the construction, fabrication and/or processing. Final inspection results shall document the as-found condition including final acceptance / rejection criteria evaluation.

10.6. Unacceptable inspection results shall be evaluated and resolved in accordance with approved procedures. Any modifications, repairs, and replacements are re-inspected to the same standard or method to verify acceptability of the items. Inspection records shall identify the item inspected, date of inspection, inspector's identity, results of inspection, and reference to information taken in connection with nonconformances.

11. TEST CONTROL

11.1. Measures shall be established for a documented test program in accordance with applicable DC technical specifications, license conditions, and design documents to assure that all required testing demonstrate that the structures, systems, or components within the scope of this DQAP will perform satisfactorily in service. The test program shall ensure that design and performance criteria have been satisfied and that the testing does not adversely affect the important to safety SSCs.

11.2. The test program shall include criteria for determining when testing is required, such as proof tests prior to installation, preoperational tests, and operational tests of SSCs. The procedures that implement testing shall specify the appropriate prerequisites for the test (e.g., personnel qualification requirements, environmental conditions, equipment requirements) sufficient instruction for the performance of the testing, hold or witness points, acceptance / rejection criteria and limits, and the required test documentation. Test results are evaluated by qualified personnel to determine compliance with established acceptance criteria. Test results which do not meet acceptance criteria, shall be documented and evaluated in order to determine the appropriate corrective actions. The test program shall require that modifications, repairs, and replacement of items that have a current important to safety function be tested, utilizing the same criteria as the original items to the extent applicable to the current important to safety function. If alternative tests are required, the alternative tests must be reviewed and approved by the same organization that established the original requirements unless the applicable manager designates another responsible organization. Test records shall be maintained in accordance with approved procedures.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

12.1. Measures shall be established to assure those tools, gauges, instruments, and other measuring and test equipment (M&TE), used for activities within the scope of this DQAP, are controlled, calibrated and adjusted in order to maintain accuracy within necessary limits and to ensure its traceability to calibration test data. Measures shall also be established for the control of permanently installed instrument and control devices that are within the scope of this DQAP.

12.2. Organizational responsibilities shall be delineated for establishing, implementing, and assuring the effectiveness of the calibration program for M&TE. Reference standards used to determine the acceptability of items and activities, shall be of appropriate type, and maintained within prescribed accuracy limits, suitable range and accuracy in order to verify conformance to specified requirements.

12.3. Power Labs is responsible for the governance of M&TE and oversight of the site calibration process for Exelon operating and decommissioning facilities. This includes the establishment of calibration practices, intervals, accuracy requirements, certification/de-certification, and equivalency decisions, as well as the resolution of technical issues regarding M&TE calibration. Corporate Maintenance is responsible for governance and oversight of site M&TE Control. This includes assessment of site compliance to the control of M&TE as defined in corporate maintenance procedural guidance.

12.4. Procedures for the control and calibration of permanently installed plant equipment that are within the scope of this DQAP shall specify identification requirements (labeling, codes, or other documented control system), the recall process and calibration process and frequencies (including documented pre-calibration checks) of the M&TE to nationally recognized standards. Calibration methods are documented and performed by competent personnel in an environment that does not adversely affect the calibration. The calibration procedures shall specify recording of as-found conditions and a means for determining which equipment shall be included in the calibration program. M&TE used in the calibration of permanently installed plant equipment shall have ranges, precision, and accuracy equal to or greater than that to be calibrated and where this is impractical; the cognizant authority shall document rationale for accuracy.

12.5. The calibration procedures shall delineate special controls where applicable, for usage, handling, and storage required for environmental conditions such as temperature, humidity, cleanliness, or radiation in order to maintain accuracy and operating characteristics of the M&TE.

12.6. Calibration reference standards shall be based on nationally recognized standards or accepted values of natural physical constants. Where national standards do not exist, the basis for the calibration shall be documented. Special calibration and control measures are not required when normal commercial practices provide adequate accuracy (e.g. rulers, tape measures, levels, and other such devices).

12.7. M&TE which is found to be damaged, out-of-calibration or for which accuracy is suspect, shall be tagged and segregated and processed in accordance with approved procedures. When M&TE is found to be out-of-tolerance, an evaluation is made of its previous uses to determine corrective action.

13. HANDLING, STORAGE, AND SHIPPING

13.1. Measures shall be established to control the handling, storage, shipping, packaging, cleaning and preservation of items, material and equipment within the scope of this DQAP, in accordance with applicable design, work, and procurement requirements in order to prevent damage or deterioration during handling, packaging, preservation, storage, and shipping.

13.2. Special coverings, equipment and protective environments shall be specified and provided where necessary for the protection of items, material, and equipment from damage and deterioration. Special protective measures are specified and provided when required to maintain acceptable quality. When special protective features are required, their existence shall be verified and monitored as necessary to assure that the special protective features continue to serve its intended function. Special handling tools and equipment shall be provided, where necessary, to ensure items, material and equipment can be handled safely and without damage.

13.3. Controls for hoisting, rigging, and transporting shall be established to protect SSCs within the scope of this DQAP as applicable. Markings or labeling shall be used to indicate the presence of special environments, or the need for special controls. Provisions shall be described for the storage of chemicals, reagents (including control of shelf life), lubricants and other combustible materials. Cleanliness controls shall be implemented to protect applicable SSCs from the introduction of foreign material and maintain system cleanliness as applicable throughout maintenance and modification activities.

14. INSPECTION, TEST, AND OPERATING STATUS

14.1. Measures shall be established for indicating the status of items within the scope of this DQAP undergoing inspections and tests to prevent the inadvertent bypassing or altering the sequence of such inspections or tests and avoid inadvertent operation. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels. The methods used to indicate inspection, test and operating status, including control of these indicators, are prescribed by approved procedures and shall be readily apparent and verifiable.

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

14.3. Deviations from the required sequence shall be subject to the same level of control as the generation of the original sequence to prevent the bypassing or omission of required test or inspection. The operating status of nonconforming, inoperable or malfunctioning SSCs shall be identified and documented to prevent inadvertent operation.

15. NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

15.1. Measures shall be established for the identification, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations. Items (including applicable services) that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.

15.2. Measures shall require that the individual (or designee), discovering a nonconformance, identify, describe, and document the nonconformance in accordance with the requirements of the corrective action program. Actions taken to address nonconforming items shall be documented. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended important to safety function. Nonconformances to design requirements dispositioned as repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Significant trends in nonconformances are reported to management in accordance with applicable procedures, regulatory requirements, and industry standards.

15.3. Nonconforming items that are being used for training must be controlled (e.g., administratively controlled, permanently identified, marked, obliterate Material ID Tag or Q level indicators) to prevent inadvertent or inappropriate use of the item.

16. CORRECTIVE ACTION

16.1. Measures shall be established to promptly identify, control, document, classify, and correct conditions adverse to quality. Procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Procedures require personnel to identify known conditions adverse to quality. When a complex issue arises where it cannot be readily determined if a condition adverse to quality exists, measures shall be established for documentation and timely evaluation of the issue. Significant conditions adverse to quality are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken and followed up on to verify implementation.

16.2. In the case of suppliers performing activities within the scope of this DQAP, or other similar situations, the applicable manager may delegate specific responsibilities for corrective actions but maintains responsibility for the effectiveness of corrective action measures.

17. QUALITY ASSURANCE RECORDS

17.1. Measures shall be established which define the requirements and responsibilities for identification, generation, collection, compilation, storage, maintenance, retention, and retrieval of records necessary to provide objective evidence that activities within the scope of this DQAP are in compliance with the regulations and facility implementing procedures.

17.2. Distribution of records shall be controlled in accordance with written procedures. Measures are established for replacement, restoration, or substitution of lost or damaged records. 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.

17.3. 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 as applicable.

17.4. Record storage facilities are established and maintained in a manner that minimizes the risk of damage or destruction. Records may be kept by suppliers and maintained on an available basis for a specified period of time. Records may be stored in electronic media provided that the process for managing and storing data is documented in procedures that comply with applicable regulations, including NRC guidance in RIS 2000-18 and as recognized in NIRMA (Nuclear Information Records Management Association) technical guides TG-11, TG-15, TG-16, and TG-21 as approved in NRC SERs.

17.5. Record retention periods are established to meet regulatory, UFSAR / DSAR, DQAP, and License requirements. The most stringent retention period is implemented when multiple requirements exist. Records are dispositioned at the end of the prescribed retention period.

18. AUDITS

18.1. Measures shall be established for a system of planned and documented audits in order to verify compliance with all aspects of the DQAP and determine the effective implementation of programs covered by the DQAP. Internal and supplier audits are conducted in accordance with written procedures or checklists. Audit personnel shall not have direct responsibilities in the areas to be audited.

18.2. The internal audit program is conducted on a performance driven frequency that is commensurate with the status and importance of the activity to be completed but does not exceed 24-months, unless otherwise required by regulation. Audits may be extended beyond their originally scheduled due date based on the following criteria:

A. Audits shall be performed at the intervals designated and the schedules are based on the month in which the audit starts.

B. A maximum extension not to exceed 25 percent of the audit interval is allowed unless restricted by regulation.

C. When an audit interval extension greater than one month is used, the next audit for that particular audit area is scheduled from the original anniversary month rather than from the month of the extended audit.

D. Item B applies to supplier audits and evaluations except that a total combined interval for any three (3) consecutive inspection or audit intervals does not exceed 3.25 times the specified inspection or audit interval.

18.3. Audit scheduling, preparation, personnel selection, personnel qualification, performance, reporting, response, follow-up, and records management for audits are performed in accordance with written procedures. Audit scopes and schedules are based upon the status of work progress, activities being performed, regulatory requirements, and/or experience with the organization being audited. An audit schedule shall be maintained, reviewed, and revised as necessary at least annually, to ensure that programs receive necessary audits to support regulatory compliance.

18.4. External audits of suppliers providing materials, parts, equipment or services within the scope of this DQAP are scheduled and performed based on the importance of the activity and to confirm implementation of the supplier's Quality Assurance Program at a frequency of not less than three (3) years with an audit extension period identified in D above.

18.5. Audit reports shall be prepared, reviewed, approved and distributed in accordance with approved procedures.

APPENDIX A

TERMS AND DEFINITIONS

A.1. DC Phase 1

- The period from Permanent Shutdown until permanent fuel removal

A.2. DC Phase 2

- The period from permanent fuel removal until end of the Zirconium (Zr) Fire Analysis (a.k.a. zirc-fire) period

A.3. DC Phase 3

- The period from the end of the Zr Fire Analysis period until fuel pool is empty (fuel is in the Independent Spent Fuel Storage Installation (ISFSI))

A.4. DC Phase 4

- The period from fuel in the ISFSI until License termination

A.5. Important to safety (for this DQAP)

- Systems, structures, and components (SSC) whose functions are to protect spent fuel and / or the capability to prevent or mitigate the consequences of accidents that could result in potential for offsite exposure comparable to the guidelines in 10 CFR 50.34(a)(1), 10 CFR 50.67(b)(2) or 10 CFR 100.11, as applicable. These SSCs are typically listed in site specific DSARs or ISFSI design documents. Refer to NUREG/CR-6407, Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety, for application of this term to transportation packaging and dry fuel storage systems for compliance with 10 CFR 71 and 10 CFR 72.
- Safety Related - Systems, structures and components, which are considered important to safety because they perform safety actions, are required to avoid or mitigate the consequences of abnormal conditions or accidents. These SSCs are typically listed in site specific DSARs or ISFSI design documents.

A.6. For other terms and definitions refer to the applicable standard or guidance such as:

- ASME NQA-1, 1994, Quality Assurance Requirements for Nuclear Facility Applications
- 10 CFR 50.2, Definitions
- 10 CFR 71.4, Definitions
- 10 CFR 72.3, Definitions

APPENDIX B

WRITING REFERENCE DOCUMENTS

B.1. Quality Standards and Regulatory Guidance

- ASME NQA-1, 1994, Quality Assurance Requirements for Nuclear Facility Applications" Part I and Part II.
- Regulatory Guide 7.10, Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Materials (Revision 2-March 2005.

B.2. Safety Evaluation Reports

- Revision 1, U.S. NRC, Safety Evaluation by the Office of Nuclear Reactor Regulation quality assurance independent review program alternative, Duane Arnold Energy Center, Kewaunee Nuclear Power Plant, Monticello Nuclear Plant, Palisades Nuclear Plant, Point Beach Nuclear Plant, Units 1 and 2, Docket No. 50-331, 50-305, 50-263, 50-255, 50-266, 50-301, 50- 282, and 50-306, Dated January 13, 2005, ADAMS Accession No. ML050210276
- U.S. NRC, Safety Evaluation by the Office of Nuclear Reactor Regulation related to revision 15 of the operational quality assurance manual, Entergy operations, Inc. Grand Gulf Nuclear Station, Unit 1, Docket No. 50-416, November 18, 1997
- U.S. Nuclear Regulatory Commission, Safety Evaluation by the Office of Nuclear Reactor Regulation request for change to the operating quality assurance manual, revision 31, change notice 15-002, Union Electric Company, Callaway Plant, Unit 1, Docket No. 50-483, April 1, 2016, ADAMS Accession No. ML16089A167
- U.S. NRC, Safety Evaluation by the Office of Nuclear Reactor Regulation proposed change to the Quality Assurance Program Common Safety Review Board Conduct of Operations Southern Nuclear Operating Company, INC. for Joseph M. Farley Nuclear Plants, Units 1 and 2; Edwin I. Hatch Plant, Units 1 and 2; Vogtle Electric Generating Plant, Units 1 and 2, Docket Nos. 50-348, 50-364, 50-321, 50-366, 50-424, and 50-425. June 17, 2005, ADAMS Accession No. ML051570349
- U.S. NRC, Safety Evaluation by the Office of Nuclear Reactor Regulation Decommissioning Quality Assurance Program changes San Onofre Nuclear Generating Station, Units 1, 2, and 3 and the Independent Spent Fuel Storage Installation Docket NOS. 50-206, 50-361, 50-362, and 72-041Common Safety Review Board Conduct of Operations. July 23, 2015, ADAMS Accession No. ML15191A461

APPENDIX C

REGUALTORY COMMITMENTS

C.1. 10 CFR 50 Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants*

C.2. 10 CFR 71 Subpart H, Quality Assurance

C.3. 10 CFR 72, Subpart G, Quality Assurance

C.4. NUREG/CR-6407, Classification of Transportation Packaging and Dry Fuel Storage System Components According to Important to Safety (2/1996)

APPENDIX D

GENERAL ADMINISTRATIVE REQUIREMENTS

D.1. Fire Protection

10 CFR 50.48(f) requires that licensees that have submitted the certification required under 50.82(a)(1) shall maintain a fire protection program to address the potential for fires that could cause the release or spread of radioactive materials. The quality assurance program established for these fire protection SSCs ensures that design, procurement, instruction, procedures, drawings, inspection, installation, testing, maintenance, operations, nonconforming Items, corrective action, records, audits and administrative controls meet the applicable quality assurance guidelines as described in the applicable edition of Branch Technical Position (BTP) 9.5-1 for each facility during decommissioning and permanent shutdown. Engineering determines what fire protection SSCs are required to prevent fires, rapidly detect, control, and extinguish fires that do occur and could result in a radiological hazard and, minimize the risk the public, environment, and plant personnel resulting from fires that could result in a release of radioactive materials. Engineering also establishes the requirements for the design, procurement, fabrication, installation and/or modification of these fire protection SSCs. All other fire protection equipment and supplies will be of commercial quality, in accordance with National Fire Protection Association (NFPA) guidelines.

D.2. Transport of Radioactive Waste

D.2.1 When the Company contracts with vendors to transport radioactive waste in NRC approved shipping packages, it meets the requirements of 10 CFR 71, 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) 49 CFR. 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 49 CFR.

D.3. Services

D.3.1. The Company procures services from qualified suppliers. It is not necessary that these suppliers have a quality assurance program approved by the licensee, however, suppliers should provide a quality assurance program that includes the quality assurance program elements presented in Regulatory Guide 4.15, Quality Assurance for Radiological Monitoring Programs (Normal Operations) – Effluent Streams and the Environment, and routinely provide program data summaries sufficiently detailed to permit evaluation of the program for the following areas:

- Meteorology.
- Offsite Dose Calculation Manual.
- Radiological environmental monitoring.

D.4. License Renewal

D.4.1. Consistent with the requirements of 10 CFR 54.21(a)(3), the Company implements the requirements of DQAP Section 1 through 18 for aging management activities related to safety related SSCs as described by licensing documents for those systems that remain active.

D.4.2. Additionally, to manage the aging effects of non-safety related SSCs that were determined to be within the scope of License Renewal, the Company implements the administrative controls, corrective actions and confirmation processes described in DQAP Sections 6, 16 and the applicable requirements of this appendix.

D.5. Safety Review Committee

D.5.1. The Safety Review Committee (SRC) serves the CNO as an on-site review body that performs procedure and program reviews for decommissioning activities and ISFSI operation as necessary on matters of Nuclear Safety. Details regarding the membership, quorum, agenda, and meeting schedule are contained in implementing procedures.

D.6. Independent Spent Fuel Storage Installation (ISFSI) SSC

D.6.1. ISFSI quality assurance program requirements are performed in accordance with the applicable 10 CFR 72.212 report which invokes the portions of the NRC approved 10 CFR 50 Appendix B quality assurance program as described in this DQAP, commensurate with the safety classification of the component and quality requirements specified in the cask vendor Final Safety Analysis Report (FSAR) or site-specific license.

APPENDIX E

THREE MILE ISLAND (UNIT 1) SPECIFIC ADMINISTRATIVE REQUIREMENTS

E.1. Regulatory Guide 1.33

E.1.1. Written procedures applicable to safe storage of nuclear fuel recommended in Appendix A of Regulatory Guide 1.33, shall be established, implemented, and maintained. (ref. TMI DC Technical Specification Section 6.8.1 Procedures and Programs)

E.2. Records Retention

E.2.1 The following records shall be retained for at least five years:

- Records and logs of activities related to the safe storage of irradiated fuel.
- Records and logs of principle maintenance activities, including inspection, repairs, substitution, or replacement of principal items of equipment related to safe storage of irradiated fuel.
- All REPORTABLE EVENTS.
- Records of periodic checks, tests and calibrations.
- Changes to the procedures required by the Technical Specification 6.8.1.
- Test results, in units of microcuries, for leak tests performed on licensed seal sources on record.
- Records of annual physical inventory verifying accountability of licensed sources on record.

E.2.2. The following records shall be retained for the duration of the Facility Operating License:

- Records and drawing changes reflecting facility design modification made to systems and equipment needed for the safe storage of irradiated fuel as described in the Safety Analysis Report.
- Records of irradiated fuel inventory, fuel transfers and assembly burnup histories.
- Routine unit radiation surveys and monitoring records.
- Records of doses received by all individuals for whom monitoring was required.

- Records of radioactive liquids and gaseous wastes released to the environment, and records of environmental monitoring surveys.
- Records of training and qualification for current members of the unit staff.
- Records of reviews performed for changes made to procedures or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59.
- Records of analyses required by the radiological environmental monitoring program.
- Records of solid radioactive shipments.
- Records of reviews performed for changes made to the Offsite dose Calculation Manual and the Process Control Plan.

E.3. Facility Staff Qualifications

E.3.1 Each member of the facility staff shall meet or exceed the minimum qualifications of ANSI/ANS 3.1 of 1978 for comparable positions unless otherwise noted in the Technical Specifications. Individuals who do not meet ANSI/ANS 3.1 of 1978, Section 4.5, are not considered technicians or maintenance personnel for purposes of determining qualifications but are permitted to perform work for which qualification has been demonstrated.

E.3.2 The management position responsible for radiological controls shall meet or exceed the qualifications of Regulatory Guide 1.8 of 1977. Each radiological control technician/supervisor shall meet or exceed the qualifications of ANSI-N 18.1-1971, paragraph 4.5.2/4.3.2, or be formally qualified through an NRC approved TMI-l Radiation Controls training program. All radiological controls technicians will be qualified through training and examination in each area or specific task related to their radiological controls' functions prior to their performance of those tasks.