HOLTEC DECOMMISSIONING INTERNATIONAL

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10 CFR 50.54(a)(4)

August 27, 2020

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

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

Pilgrim Nuclear Power Station
Renewed Facility License No. DPR-35
NRC Docket No. 50-293 and 72-1044

Subject: Request for Approval of HDI Fleet Decommissioning Quality Assurance Program, Revision 0

References: [1] Letter from U.S. Nuclear Regulatory Commission to Exelon Generation Company, LLC, "Oyster Creek Generating Station and Independent Fuel Storage Installation – Review and Acceptance of Changes RE: Decommissioning Quality Assurance Program (EPID L-2017-LLQ-0003)," June 27, 2018 (ML18165A136)

In accordance with 10 CFR 50.54(a)(4), Holtec Decommissioning International (HDI) is submitting a proposed HDI Fleet Decommissioning Quality Assurance Program (DQAP) for U.S. Nuclear Regulatory Commission (NRC) review and approval. The proposed HDI Fleet DQAP provides for the transition of the individual site-specific DQAPs currently in use at Oyster Creek Nuclear Generating Station (Oyster Creek) and Pilgrim Nuclear Power Station (Pilgrim) to a fleet-based DQAP. In addition, the proposed HDI Fleet DQAP is intended to be adopted by other HDI decommissioning sites as they are acquired and after site specific QA requirements are evaluated in accordance 10 CFR 50.54(a)(3).

The proposed revision is the initial issuance of the HDI Fleet DQAP. The proposed HDI Fleet DQAP mirrors the NRC approved Oyster Creek DQAP [Reference 1], with additional changes incorporated. The HDI Fleet DQAP is provided in Enclosure 1. The intent of the Fleet DQAP is to describe appropriate and sufficient requirements to establish how the quality assurance program meets 10 CFR 50, Appendix B criteria while allowing flexibility in how QA requirements are met.

In accordance with 10 CFR 50.54(a)(4)(ii), a comparison of the HDI DQAP to the current Oyster Creek and Pilgrim DQAPs, was performed. Enclosure 2 to this letter captures the evaluation that was performed. This evaluation identified that the proposed HDI QAP will continue to meet applicable regulatory requirements. However, the evaluation also concluded that the proposed changes resulted in a reduction in commitment from the DQAPs currently in use at Oyster Creek and Pilgrim Station. Based on identification of the reduction in commitment, the HDI Fleet DQAP requires NRC Approval prior to implementation.

Enclosures 3 and 4 to this letter provide a copy of the current site specific DQAPs in effect at both Oyster Creek and Pilgrim Station respectively.

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Once approved, the HDI Fleet DQAP will become the DQAP for both Oyster Creek and Pilgrim Stations. Since the proposed HDI Fleet DQAP is based on the Oyster Creek DQAP previously approved by NRC, HDI is requesting NRC review and approval by February 28, 2021. HDI is also requesting a 60-day implementation period following approval of the HDI Fleet DQAP.

There are no new commitments contained in this submittal.

Should you have any questions or require further information, please contact me at (856) 797-0900, x3813.

Respectfully,

Andrea L. Sterdis

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Andrea Sterdis
HDI VP Regulatory and Environmental Affairs
Holtec Decommissioning International, LLC

Enclosures:

[1] HDI Fleet Decommissioning Quality Assurance Program (DQAP) Proposed Rev A
[2] 10 CFR 50.54(a) Regulatory Evaluation of the HDI Fleet DQAP against Current Oyster Creek and Pilgrim Station DQAPs
[3] Oyster Creek Decommissioning Quality Assurance Program
[4] Pilgrim Station Decommissioning Quality Assurance Program

cc: (without Enclosures)
NRC Regional Administrator, Region 1
NRC NMSS Project Manager - Oyster Creek Nuclear Generating Station
NRC NMSS Project Manager - Pilgrim Nuclear Power Station
NRC Region 1, Lead Inspector Lead Inspector – Oyster Creek Nuclear Generating Station
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Enclosure 1

HDI-OC-20-064
HDI-PIL-20-019

Holtec Decommissioning International (HDI)

Decommissioning Quality Assurance Program (DQAP)

Proposed Rev A

(33 pages including cover page)

HOLTEC
DECOMMISSIONING
INTERNATIONAL

CD-020
Decommissioning Quality Assurance Program (DQAP)
Revision A
Effective Month, Day, Year

Oyster Creek Nuclear Generating Station
Docket No. 50-219
Renewed Facility Operating License No. DPR-16
Docket No. 72-0015
Docket No. 71-0964

Pilgrim Nuclear Power Station
Docket No. 50-293
Renewed Facility Operating License No. DPR-35
Docket No. 72-1044
Docket No. 71-0963

TABLE OF CONTENTS

Policy Statement		2
1.0	Organization	3
2.0	Quality Assurance Program	7
3.0	Design Control	9
4.0	Procurement Document Control	12
5.0	Instructions, Procedures, and Drawings	13
6.0	Document Control	14
7.0	Control of Purchased Material, Equipment, and Services	15
8.0	Identification and Control of Materials, Parts, and Components	18
9.0	Control of Special Processes	19
10.0	Inspection	20
11.0	Test Control	21
12.0	Control of Measuring and Test Equipment	22
13.0	Handling, Storage, and Shipping	23
14.0	Inspection, Test, and Operating Status	24
15.0	Nonconforming Material, Parts, or Components	25
16.0	Corrective Action	26
17.0	Quality Assurance Records	27
18.0	Audits	28
Appendix A	General Administrative Requirements	29
Appendix B	Site Specific Administrative Requirements	31

Policy Statement

The Decommissioning Quality Assurance Program (DQAP), is the highest tiered document that assigns major functional responsibilities for decommissioning facilities owned and operated by Holtec International and Holtec Decommissioning International respectively (referred to as HDI in this document). Implementing documents assign more specific responsibilities and define the organizational interfaces involved in conducting safety significant (term used in this DQAP to identify both 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 HDI 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.

HDI will maintain the decommissioning facilities in a manner that will ensure the health and safety of the public and the 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

HDI is responsible for the establishment and execution of the DQAP at the decommissioning facilities owned by Holtec and maintained by HDI. These decommissioning facilities have submitted a Certification of Permanent Cessation of Operations and Certification of Permanent Removal of Fuel to the Nuclear Regulatory Commission (NRC) per 10 CFR 50.82(a)(1)(i) and (ii), respectfully. 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.

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.

1.1.2. All personnel who work directly, or indirectly for HDI are responsible for the achievement of quality in their work. Accordingly, all HDI 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 HDI Senior Vice President and Chief Operating Officer (HDI COO) and is overseen by the Holtec International Senior Vice President and Chief Nuclear Officer (Holtec CNO). The HDI Site Vice President at each decommissioning facility 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 HDI Vice President, Quality Assurance and Nuclear Oversight. The management position responsible for Nuclear Oversight is responsible for periodically reporting to the HDI COO and Holtec CNO on the effectiveness of the DQAP implementation and immediately apprising them 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 NRC licenses including the site technical specifications, this DQAP, and implementing procedures.

1.2. Corporate Organizations

1.2.1. The HDI COO has the overall responsibility for the safety, operation, and decommissioning of the nuclear sites maintained by HDI including oversight of the decommissioning activities performed by CDI. This is the senior

executive responsible for providing strategic direction to the HDI organization and to the senior leadership of the decommissioning facilities maintained by HDI. This position is responsible for providing management direction, oversight and support to the site organizations and for setting and implementing policies, objectives, expectations, and priorities to ensure activities are performed in accordance with the DQAP and other requirements.

1.2.2. The Holtec CNO provides oversight of all HDI's nuclear activities including decommissioning of the nuclear sites maintained by HDI.

1.2.3. The HDI Vice President Quality Assurance and Nuclear Oversight reports to the Holtec CNO and the HDI COO. The position provides quality assurance oversight for the decommissioning facilities maintained by HDI. In addition, this position is responsible for verifying the DQAP is effectively implemented, that Quality Assurance (QA) personnel have sufficient authority and organizational freedom to identify quality problems and to verify implementation of corrective actions, and that QA personnel 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 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 Holtec CNO and HDI COO for resolution, as necessary.
- Reporting on oversight activities to the Holtec CNO and HDI COO.
- Authority to stop work when quality is adversely affected.

1.2.4. The following management positions report to and/or receive direction from the HDI COO with respect to their assigned roles and responsibilities associated with the execution of this DQAP:

- The HDI Vice President, Regulatory & Environmental Affairs is responsible for providing licensing oversight for the decommissioning facilities maintained by HDI. This position is responsible for overseeing and guiding development and submission of licensing, regulatory and environmental actions. This position also conducts routine assessments of the regulatory activities at each of the decommissioning facilities and supports the interface between the site and nuclear regulators while also taking a lead role on generic issues in decommissioning.

1.2.5. 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 decommissioning facility or by the corporate organizations.

1.3. Decommissioning Facility Management

The following are HDI decommissioning facility management positions and associated DQAP functional responsibilities which may be delegated to others as established in this document. These individuals may report through an additional layer of management but shall maintain sufficient authority and organizational freedom to implement assigned responsibilities.

1.3.1. The HDI Site Vice President for each decommissioning facility maintained by HDI is responsible for providing day-to-day on-site leadership and direction to the associated decommissioning facility to assure the safe decommissioning, maintenance, and regulatory compliance of the station including 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, licenses, Technical Specifications dry storage system Certificate of Compliance and training. The HDI Site Vice President, 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. The following positions report to the HDI Site Vice President:

- A management position responsible for operational activities necessary for safe storage and maintenance of spent fuel including maintaining the facility within the constraints of applicable regulatory requirements and the decommissioning facility licenses.
- A management position responsible for radiation protection, ALARA planning, chemistry, and environmental activities.
- A management position responsible for supporting the HDI VP of Regulatory and Environmental Affairs in maintaining an interface between the station and federal, state, and local regulators. Also, responsible for Emergence Preparedness, the Corrective Action Program, and document control and records management functions.
- A management position responsible for managing decommissioning projects within the constraints of the decommissioning facility licenses and regulatory requirements.
- 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.

- A management position responsible for the execution of maintenance and modification activities.
- A management position responsible for implementation of the decommissioning facility security plan.

This following position may be included in the decommissioning facility management or in the corporate organization.

- A management position responsible for material management and decommissioning facility supply, which coordinates, evaluates, and procures materials for the decommissioning facility.

2. QUALITY ASSURANCE PROGRAM

2.1. The Quality Assurance (QA) Program for HDI decommissioning facilities as described in this DQAP 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 HDI 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 significant, applicable regulatory programs, and for other applicable activities and SSCs identified in either the facility-specific Decommissioning Safety Analysis Report (DSAR) or Appendices 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*. HDI also commits to NUREG/CR-6407, Classification of Transportation Packaging and Dry Fuel Storage System Components According to Important to Safety (2/1996).

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 HDI VP Quality and 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.

2.5.2. Additional requirements for specific programs are described in the Administrative Controls section of the applicable decommissioning facility Technical Specifications or in the DSAR, 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 A 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.

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. 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, as applicable, 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.

- A certificate of qualification, as applicable, clearly delineates the specific quality assurance functions personnel are qualified to perform and the criteria used to qualify personnel in each function.

3.0. DESIGN CONTROL

3.1. Measures are 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. HDI 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 as appropriate. 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 decommissioning facility changes or modifications may be performed by HDI 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 significant 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 used to derive 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.

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 change process criteria (e.g., 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 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 as applicable 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 safety significant 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 safety significant 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 are 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. HDI maintains an Approved Vendor List (AVL) for those vendors qualified to perform safety significant work. The qualification requirements for vendors on the AVL are described in controlling procedures except for procurement from other licensees that have an NRC approved quality program. Vendor qualification processes use a graded approach based on the qualification level of the vendor.

4.3. 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 safety significant function, complexity of the design, manufacturing, degree of inspection/testability upon receipt and other factors which affect the quality of products and services. In addition, procurement documents will, as applicable, require vendors to a) invoke applicable requirements on their vendors; b) allow for right of access for further evaluations as needed.

4.4. Procedures that implement procurement document control shall describe the organizational responsibilities for procurement planning, preparation, review, approval and control of procurement documents, and vendor selection.

4.5. 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 are 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. The activities shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.

5.3. Controls are established which ensure that instructions, procedures, and drawings are current and accurately reflect decommissioning facility design and regulatory requirements.

6.0. DOCUMENT CONTROL

6.1. Measures are 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.

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 are established for the control of purchased material, equipment (identified as items), 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 vendor, source inspection, audit, and examination of items or services. Procedures shall describe each organization's responsibilities for the control of items and services, including the interfaces between all affected organizations. Documentation of acceptance of items shall be available prior to installation or acceptance for use.

7.2 Verification that a vendor can meet the specified technical and quality requirements shall be documented. HDI maintains an Approved Vendor List (AVL) for those vendors qualified to perform safety significant work. The qualification requirements for vendors on the AVL are described in controlling procedures. Vendor qualification processes use a graded approach based on the qualification level of the vendor.

7.3 This DQAP considers that other 10 CFR Part 50 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-17025:2017 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 vendor’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-17025:2017, "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-17025:2017 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.
- Supplier shall not sub-contract the service to any other supplier.

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-17025:2017 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 vendor's s QA program shall be assessed at intervals consistent with the importance, complexity, and quantity of the item or service. Vendor performance and compliance with procurement documents are monitored by source verification, receipt inspection, audit, or a combination to ensure continued acceptable vendor performance. Receiving inspection shall verify, by objective evidence, the acceptability of items in accordance with decommissioning facility procedures. Accepted items are appropriately marked and located in a controlled storage area until use. Documentary evidence shall be retained in accordance with decommissioning 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 items.

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 vendors whose QA Program has not been reviewed or accepted, those vendors 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. Additional controls will be approriately identified and implemented.

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 vendors are performed as necessary.

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

8.1. Measures are established for the identification and control of material, parts, and components, including partially fabricated assemblies and consumables (identified as items), 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, HDI 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.

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.

8.4 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 are 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, as applicable, 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.

10. INSPECTION

10.1. Measures are established for inspection of activities within the scope of this DQAP by or for the organization performing the activity, 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. 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 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. Inspection records shall identify the item inspected, date of inspection, inspector's identity, and results of inspection.

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.

11. TEST CONTROL

11.1. Measures are established for a documented test program in accordance with applicable Technical Specifications, license conditions, and design documents to assure that all required testing demonstrate that the SSCs 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 safety significant 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.

11.3 Test results are evaluated by the responsible organization to determine compliance with established acceptance criteria. Test results which do not meet acceptance criteria, shall be documented and evaluated to determine the appropriate corrective actions.

11.4 The test program shall require that modifications, repairs, and replacement of items that have a current safety significant function be tested, utilizing the same criteria as the original items to the extent applicable to the current safety significant 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 are 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 M&TE traceability to calibration test data. For the purposes of this section, M&TE is considered to include both portable and permanently installed instrument and control devices.

12.2. Organizational responsibilities are 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, are of appropriate type, and maintained within prescribed accuracy limits, suitable range and accuracy in order to verify conformance to specified requirements.

12.3. Procedures for the control and calibration of M&TE 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.

12.4. 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 to maintain accuracy and operating characteristics of the M&TE.

12.5. 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).

12.6. 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 are established to control the handling, storage, shipping, packaging, cleaning and preservation of items within the scope of this DQAP in order to prevent damage or deterioration.

13.2. Special coverings, equipment and protective environments shall be specified and provided where necessary for the protection of items 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 their intended function. Special handling tools and equipment shall be provided, where necessary, to ensure items 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 are 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.

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. 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 are 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 are established to 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.

15.3 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 in the decommissioning facility requires the approval of the designated management.

15.4 Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety significant 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.

15.5. 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 are 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 vendors performing activities within the scope of this DQAP 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 are 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 decommissioning 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.

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 vendors 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.

17.5 The program includes provisions for the use of various record storage media to maintain QA records. Procedures are developed to implement the regulatory guidance associated with the media used. The NRC Generic Letter 88-18 “Plant Record Storage on Optical Disk” is implemented for optical disk media. The Regulatory Issue Summary 2000-18 “Guidance on Managing QA Records in Electronic Media” is implemented for electronic media.

17.6. 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 are established for a system of planned and documented audits to verify compliance with all aspects of the DQAP and determine the effective implementation of programs covered by the DQAP.

18.2 Internal and vendor audits are conducted in accordance with written procedures or checklists. Audit personnel shall not have direct responsibilities in the areas to be audited.

18.3. 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.

18.4 The vendor 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 36-months, unless otherwise required by regulation.

A. A maximum extension not to exceed 25 percent of the audit interval shall be allowed except that a total combined time interval for any three consecutive audit intervals should not exceed 3.25 times the specified audit interval, unless otherwise required by regulation.

18.5 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.

18.6 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.

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

Appendix A

Page 1 of 2

GENERAL ADMINISTRATIVE REQUIREMENTS

A.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 decommissioning facility 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.

A.2 Transport of Radioactive Waste

A.2.1 When HDI contracts with vendors to transport radioactive waste in NRC approved shipping packages, the contract is written such that the requirements of 10 CFR 71, Subpart H and Regulatory Guide 7.10, Revision 3 (6/15), “Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material” are met. HDI 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.

Appendix A

Page 2 of 2

GENERAL ADMINISTRATIVE REQUIREMENTS

A.3. Services

A.3.1. HDI procures services from qualified vendors. It is not necessary that these vendors have a quality assurance program approved by the licensee, however, vendors 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.

A.4. License Renewal

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

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

A.5. Safety Review Committee

A.5.1. The Safety Review Committee (SRC) serves the HDI COO 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.

Appendix B

Page 1 of 1

SITE SPECIFIC ADMINISTRATIVE REQUIREMENTS

B.1. Regulatory Guide 1.33

B.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.

B.2 Regulatory Guide 1.88

B.2.1 Procedures for the collection, storage, and maintenance of decommissioning facility quality assurance records will be consistent with Regulatory Guide 1.88 Revision 2, dated October 1976. (Collection, storage, and maintenance of decommissioning facility quality assurance records).

B.3. Independent Spent Fuel Storage Installation (ISFSI) SSC

B.3.1. 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 decommissioning facility ISFSI specific license.

B.3.2 Radioactive Material Transport Packages (10 CFR 71)

Radioactive Material Transport Packages subject to the provisions of 10 CFR 71, Subpart C, “General Licenses” are “Important-to-Safety” and subject to the applicable requirements of the DQAP.

HOLTEC DECOMMISSIONING INTERNATIONAL

Krishna P. Singh Technology Campus, 1 Holtec Blvd., Camden, NJ 08104
Telephone (856) 797-0900
Fax (856) 797-0909

Enclosure 2

HDI-OC-20-064
HDI-PIL-20-019

10 CFR 50.54(a) Regulatory Evaluation of
HDI Fleet DQAP Rev A Changes Against Current
Oyster Creek and Pilgrim Station DQAPs

(25 pages including cover page)

DQAP Change Evaluation

NOTE - The basis for the answers should be of sufficient depth and detail to support the conclusions reached and allow for independent review. Simply stating the change does not decrease the effectiveness without stating why is not acceptable.

Editorial corrections (i.e., spelling, punctuation, typographical or grammatical errors, and incorrect cross-references) are not considered changes and therefore, a Quality Assurance Program Regulatory Review is not required. All boxes should be checked "N/A" and proceed to signature page of the evaluation form.

	YES, NO, or N/A
1. Is this change an editorial change as defined in 10 CFR 50.54(a)(3) and 10 CFR 71.106? (If yes, provide basis, mark remaining questions "N/A" and state "not a reduction in commitment") Proceed to approval page of attachment. Basis for Answer: Some of these changes are not considered editorial. See Attachment A for the details of the changes in each of the sections and the associated evaluation.	NO
2. For any YES answer in the 10 CFR 50.54(a) Screening or for the QA-initiated change, does the proposed change represent a reduction in commitment or process(es) described or established in the approved QA Program? Basis for Answer: Basis for Answer: The 10CFR50.54(a) evaluation concluded that several of the proposed changes (organizational, administrative, editorial and clarification) can be made without prior NRC approval, based on the guidance provided within 10CFR50.54(a)(3). There are three (3) changes that are considered reductions in commitments to the previously approved Oyster Creek and Pilgrim DQAPs that cannot be implemented without prior NRC approval. The three (3) changes representing reductions in commitments are as follows: 1. The Fleet DQAP Section 18.2.B states: "A maximum extension not to exceed 25 percent of the audit interval is allowed unless restricted by regulation." For twenty-four month frequency audits that would allow an extension of up to six months. The Pilgrim DQAP states: "A maximum extension not to exceed 90 days is allowed unless restricted by regulation." The maximum extension allowed in the Fleet DQAP is approximately twice that allowed in the Pilgrim DQAP. This constitutes a reduction in commitment for the Pilgrim DQAP. 2. Section 12.3 of the Oyster Creek DQAP states: "Power Labs is responsible for the governance of M&TE and oversight of the site	YES

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." This paragraph is not in the Fleet DQAP. Oyster Creek is now HDI and no longer associated with the Exelon fleet for any governance or oversight. Not including this information is a reduction in commitment and the change requires NRC approval prior to implementation in accordance with 10CFR50.54(a)(4). 3. The site Quality Assurance Manager position and associated responsibilities from the Station Management Section of the Pilgrim DQAP is not included in the Fleet DQAP. This is a reduction in commitment since there is no longer a requirement for a Quality Assurance Manager permanently stationed at the Pilgrim site. This change is a reduction in commitment and requires NRC approval prior to implementation in accordance with 10CFR50.54(a)(4). This change does not reduce the overall effectiveness of the DQAP. Site Quality assurance personnel will report to a Manager at the Corporate level with a reporting chain up through the Chief Nuclear Officer. This review verified that under the HDI Fleet Decommissioning Quality Assurance Program Oyster Creek and PNPS will continue to comply with 10 CFR Part 50 Appendix B, Standard Review Plan 17.3, NUREG-0800 and 10CFR50.54(a)(3). It will also continue to satisfy the requirements of 10CFR71 Subpart H and 10CFR72 Subpart G. See Attachment A for the details of the changes in each of the sections and the associated evaluation. See Attachment A for the details of the changes in each of the sections and the associated evaluation.	
3. If item 2 above is YES, is the proposed change limited to the use of a quality assurance alternative or exception approved by the NRC Safety Evaluation Report (SER), for which the bases of the NRC approval are applicable to Oyster Creek and PNPS? If YES, explain how all of the NRC approval bases from the SER are incorporated or covered by the PNPS QA Program. **<u>This exemption is not allowed under 10 CFR 71.106 and cannot be used to reduce commitments under part 71.</u>** A quality assurance alternative or exception approved by the NRC Safety Evaluation Report (SER), for which the bases of the NRC approval are applicable to Oyster Creek and PNPS will not be used for the three changes representing a reduction in commitment. These changes will require NRC approval in accordance with 10CFR50.54(a)(4) prior to implementation.	NO
4. Is the proposed change a change to a QA standard approved by the	NO

NRC which is more recent than the QA standard currently established in the Program? Basis for Answer: None of the proposed changes affect the current QA standards being applied to implement QAPM requirements to the PNPS.	

	YES, NO, or N/A
5. Is the proposed change a change involving the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles? Basis for Answer: None of the proposed changes affect the use of generic organizational position titles. The approach to describing organizational positions and functions remain the same. See Attachment A for the details of the changes in each of the sections and the associated evaluation.	NO
6. Is the proposed change a change involving the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternately, the use of descriptive text? Basis for Answer: None of the proposed changes include the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities. See Attachment A for the details of the changes in each of the sections and the associated evaluation.	NO
7. Is the proposed change an elimination of Quality Assurance Program information that duplicates language in Quality Assurance Regulatory Guides and Quality Assurance Standards to which HDI is committed? Basis for Answer: None of the proposed changes include the elimination of Quality Assurance Program information that duplicates language in Quality Assurance Regulatory Guides and Quality Assurance Standards. See Attachment A for the details of the changes in each of the sections and the associated evaluation.	NO
8. Does the proposed change continue to ensure that persons and organizations performing Quality Assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations? Basis for Answer: The site Quality Assurance Manager position and responsibilities in the Pilgrim DQAP are not included in the Fleet DQAP. As discussed in question 2. above, this is a reduction in commitment requiring NRC approval prior to implementation.	NO
9. Is a change to the DQAP required? If YES, process change per EN-LI-113. If NO, distribute as indicated below. Basis for Answer: The revision to the PNPS QAPM requires the EN-LI-113 to be implemented along with the development of an LBDCR.	YES

QAPM CHANGE REVIEW RESULTS

[ ] Change is editorial in accordance with 10 CFR 50.54(a)(3) and 10 CFR 71.106 thus, does not represent a reduction in commitment. The change can be implemented upon approval of parent change document. (Question 1 is YES)

[ ] Does not represent a reduction of commitment, and can be implemented upon approval of parent change document. (Questions 4, 5, 6, 7, 8 and 9 are YES or N/A)

[ ] Represents a reduction of commitment with prior NRC approval. The safety evaluation issued by the NRC has been evaluated and it directly applies to the proposed changes. The change can be implemented upon approval of parent change document. (Question 3 is YES)

[X] Represents a reduction of commitment; however, the change has sufficient basis to demonstrate continued compliance with Appendix B and USAR commitments. Therefore, the proposed change should be submitted for NRC review/approval. (Questions 2 is YES and Question 3 is NO)

[ ] Represents a reduction of commitment with insufficient basis to demonstrate continued compliance. Therefore, the activity should not be processed.

Michael Jacobs/ _____ / 7/30/20
Preparer Date

Paul Sullivan/ _____ / 7/30/20
Manager, QA / QA Supervisor Date

QA Site Supervisor Review:

Applicable Site QA Reviews Required ☒Yes ☐No
(see attached sheets for documentation of reviews)

Oyster Creek	☒Yes	☐No	PNPS	☒Yes	☐No

Site Review Due Date: 7/30/20

Site Review Input:
Record references below. If there are none state **None.**

Oyster Creek:	PNPS: **None**

Site QA acknowledges completion of reviews below

Oyster Creek ☐ Pilgrim ☒

Site QA Supervisor acknowledgement (print & sign) /date

Paul Sullivan/ _____ / 7/30/20
Site QA Supervisor / Date

CHANGE DISPOSITION

☐ Approved for implementation

☐ Disapproved

☒ Approved for submittal to the NRC

Approved by/Date: Andrea L. Sterdis Digitally signed by Andrea L. Sterdis DN: cn=Andrea L. Sterdis, c=US, o=HDI, ou=Holtec Decommissioning International, email=andrea.sterdis@holtec.com Date: 2020.08.27 17:11:57 -04'00' /

Andrea Sterdis - VP of Regulatory & Environmental Affairs, Nuclear Oversight — Date

Distribution: Original – Attach to Parent Document;
Copy – Quality Assurance

Attachment A
HDI Fleet DQAP Initial Issue Change Request LIC 2020-003 – 10CFR50.54(a) Evaluation

Purpose

The purpose of this 10CFR50.54(a) Evaluation is to assess the changes being proposed associated with transitioning the Oyster Creek Nuclear Generating Station (Oyster Creek) Decommissioning Quality Assurance Program (DQAP) and Pilgrim Nuclear Power Station (Pilgrim) DQAP to a new Holtec Decommissioning International (HDI) Fleet (DQAP).

Discussion

The PNPS QAPM Revision 3 will be issued prior to submittal of the Fleet DQAP to the NRC on or about July 27, 2020. Revision 3 revised the QAPM to mirror the Oyster Creek DQAP and included changing the title to "Pilgrim Decommissioning Quality Assurance Program" (Pilgrim DQAP). This Fleet DQAP will also mirror the Oyster Creek DQAP with some additional changes representing a decrease in commitments that will require NRC prior approval. Revising the Pilgrim QAPM to mirror Oyster Creek DQAP allowed for an easier transition to the fleet DQAP applicable to both Oyster Creek and Pilgrim once NRC approval is obtained. This 50.54(a) evaluation (Change Request LBDCR 2020-003) is performed for the purposes of determining if any of the changes associated with transitioning Oyster Creek and Pilgrim to the new HDI Fleet DQAP require prior NRC approval pursuant to the requirements of 10CFR50.54(a)(3).

The primary focus of the change is to align Oyster Creek and Pilgrim to a Fleet DQAP. In addition, the HDI Fleet DQAP will be adapted by other HDI decommissioning sites as they are acquired. The intent of the Fleet DQAP is to describe appropriate and sufficient requirements to establish how the Quality Assurance Program meets 10CFR50 Appendix B while allowing flexibility in the manner by which a requirement is met.

Several of the proposed changes (organizational, administrative, editorial and clarification) associated with transitioning the current Oyster Creek and Pilgrim DQAPs to this Fleet DQAP can be made without prior NRC approval, based on the guidance provided within 10CFR50.54(a)(3).

However, implementing the Fleet DQAP results in three changes that represent a reduction in commitment for Oyster Creek or Pilgrim requiring NRC approval prior to implementation. These changes are as follows:

1. The maximum extension allowed in the Fleet DQAP is approximately twice that allowed in the Pilgrim DQAP. This constitutes a reduction in commitment for the Pilgrim DQAP. This change reflects the reduced risk of a permanently shut down facility and is aligned with the current Oyster Creek DQAP previously reviewed by the NRC. Though a reduction in commitment, this does not reduce the overall effectiveness of the QAPM and continues to ensure compliance with 10 CFR 50, Appendix B.
2. Section 12.3 of the Oyster Creek DQAP states: "Power Labs is responsible for the governance of M&TE and oversight of the site calibration process for Exelon operating and decommissioning facilities..." This paragraph is not in the Fleet DQAP. Oyster Creek is now HDI and no longer associated with the Exelon fleet for any governance or oversight. This is a reduction in commitment. The change is not a reduction in effectiveness; HDI provides governance and oversight of M&TE and the Oyster Creek site calibration process.

3. The site Quality Assurance Manager position and associated responsibilities from the Station Management Section of the Pilgrim DQAP is not included in the Fleet DQAP. This is a reduction in commitment since there is no longer a requirement for a Quality Assurance Manager permanently stationed at the Pilgrim site. This change does not reduce the overall effectiveness of the DQAP. Site Quality assurance personnel will report to a Manager at the Corporate level with a reporting chain up through the Chief Nuclear Officer.

The evaluation of each of the changes and the conclusions are presented in the attached table on a section by section basis. A copy the proposed new HDI Fleet DQAP is provided as Attachment B to this 10CFR50.54(a) Evaluation. A copy of the current Oyster Creek DQAP is provided as Attachment C and a copy of the Pilgrim DQAP is provided as Attachment D.

Conclusion

The 10CFR50.54(a) evaluation concluded that several of the changes associated with transitioning Oyster Creek and Pilgrim DQAPs to the new Fleet DQAP (organizational, administrative, editorial and clarification) can be made without prior NRC approval, based on the guidance provided within 10CFR50.54(a)(3).

However, there are three (3) changes that are considered reductions in commitments to the previously approved Oyster Creek or Pilgrim DQAPs that cannot be implemented without prior NRC approval:

1. The maximum extension allowed in the Fleet DQAP is approximately twice that allowed in the Pilgrim DQAP.
2. Section 12.3 of the Oyster Creek DQAP regarding Power Labs responsibility for governance of M&TE and oversight of the site calibration process is not included in the Fleet DQAP. Oyster Creek is now HDI and no longer associated with the Exelon fleet for any governance or oversight.
3. The site Quality Assurance Manager position and associated responsibilities from the Station Management Section of the Pilgrim DQAP is not included in the Fleet DQAP.

Transitioning Oyster Creek and Pilgrim DQAPs to this new Fleet DQAP cannot be implemented without prior NRC approval in accordance with 10CFR50.54(a). The specific discussion for each of the proposed changes for each of the sections and the associated evaluation is included in the attached table.

Attachment A Table of Changes and the Associated Evaluation

HDI Fleet DQAP Initial Issue Change Request LIC 2020-003 – 10CFR50.54(a) Evaluation

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
Cover Page			
The title of the new HDI Fleet Quality Assurance Program will be "Holtec Decommissioning International Decommissioning Quality Assurance Program" (Fleet DQAP). The cover page will include Oyster Creek Nuclear Generating Station and Pilgrim Nuclear Power Station with associate Docket and License numbers.		These changes to the Cover Page are minor administrative changes, which are considered editorial and do not constitute a reduction in commitments to the previously approved QAPM Revision 2 or Oyster Creek DQAP NO-DC-10. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No
Policy Statement			
This fleet DQAP changes the language from that currently in the Oyster Creek DQAP. Specifically, reference to Exelon Generation Company, LLC was removed and replaced with Holtec Decommissioning International (HDI) and the document number, NO-DC-10 was removed. Added clarification that Holtec International and Holtec Decommissioning International will be referred to as HDI throughout the document. Also, HDI is used throughout the fleet DQAP in place of the term Company. The term Safety Significant was added to the fleet DQAP to encompass both safety related and important to safety activities. Regarding Pilgrim, the fleet DQAP Policy statement is unchanged from the wording in the Pilgrim DQAP.		These Policy Statement wording changes that differ from the Oyster Creek DQAP are minor administrative changes, which are considered editorial and do not constitute a reduction in commitments to the previously approved DQAP. HDI is the licensee for Oyster Creek. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No
Table of Contents			
No change other than referenced page numbers. The table of contents in the Fleet DQAP is the same as the Oyster Creek and Pilgrim DQAPs.		No changes to evaluate for the Table of Contents. Evaluations for the changes in each section are addressed separately.	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
Section 1.0 Organization			
1.0	Organization - The Fleet DQAP and Pilgrim DQAP wording is the same. Oyster Creek DQAP language regarding applicability to other Exelon plants and discussion of site organizations in different decommissioning phases is not included in the HDI fleet DQAP. Starting in this section and throughout the Fleet DQAP, the terms site, plant, and facility are replaced with the term, decommissioning facility.	Oyster Creek is no longer an Exelon plant. Therefore, the language was not included in the HDI Fleet DQAP since it is no longer applicable. These changes are considered editorial and administrative improvements. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No
1.1	Responsibilities - The Responsibilities section of the Fleet DQAP represents several administrative and editorial changes from the Oyster Creek DQAP. For example, all references to Exelon are HDI in the Fleet DQAP. The Fleet DQAP reflects the current HDI organization vice the previous Exelon organization in the Oyster Creek DQAP. There is no overall change to the reporting function, which continues to report through a site executive up to the chief nuclear officer. Regarding the Pilgrim DQAP, the Fleet DQAP Station Management Section does not include the PNPS site Quality Assurance Manager position and responsibilities. In the Fleet DQAP the management position responsible for Nuclear Oversight is part of the corporate organization. The remaining differences between the Fleet and Pilgrim DQAPs represent organizational revisions to align with the current site and corporate	These changes to the organizational structure and responsibilities from those in the Oyster Creek DQAP do not impact the ultimate reporting relationship with the HDI chief nuclear officer. Requisite authority and organizational independence are maintained including sufficient independence from cost and schedule. The quality assurance function continues to report up through the Chief Nuclear Officer (CNO). These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3). The differences between the Fleet and Pilgrim DQAPs in the Responsibilities section represent organizational revisions to align with the current site and corporate organization structures. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3) Not including in the Fleet DQAP, the Quality Assurance Manager position and associated responsibilities from the Station Management Section of the Pilgrim DQAP, is a reduction in commitment since there is no longer a	Yes

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	organization structures.	requirement for a Quality Assurance Manager permanently stationed at the Pilgrim site. This change is a reduction in commitment and requires NRC approval prior to implementation in accordance with 10CFR50.54(a)(4). This change does not reduce the overall effectiveness of the DQAP. Site Quality assurance personnel will report to a Manager at the Corporate level with a reporting chain up through the Chief Nuclear Officer.	
2.0	Quality Assurance Program – Other than some administrative editorial changes, there is one difference of note between the Fleet DQAP and the Pilgrim and Oyster Creek DQAP in Section 2.0; Appendix C was removed in the Fleet DQAP and the NUREG/CR-6407 regulatory requirement was added to section 2.2. Also, the fifth and last bullet under Section 2.7.2 of the Oyster Creek and Pilgrim DQAPs was not included in the fleet DQAP. There is an additional difference from the Oyster Creek DQAP; the reference to Exelon in Section 2.1 is changed to HDI.	With the exception of NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety", the remaining regulatory requirements in Appendix C were already stated in Section 2.2. Adding the NUREG/CR-6407 to Section 2.2 regulatory requirement results in all of the Appendix C regulatory requirements being included in this section. Thus, no need for carrying redundant information in Appendix C into the Fleet DQAP. The fifth bullet in the Oyster Creek and Pilgrim DQAPs was not included in the Fleet DQAP; this bullet added unnecessary additional information. The change, Exelon to HDI, that differs from the Oyster Creek DQAP is a minor administrative change, which is considered editorial and does not constitute a reduction in commitments to the previously approved Oyster Creek DQAP. HDI is now the licensee for Oyster Creek. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No
3.0	Design Control – Other than some editorial changes, there is only one difference between the Fleet DQAP and the Pilgrim and Oyster	The following sentence in Section 3.4 was deleted and not included in the Fleet DQAP: "The final design output shall relate to the design input in sufficient detail to facilitate	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	Creek DQAPs in Section 3.0: The last sentence in Section 3.4 was removed. There is one additional difference from the Oyster Creek DQAP; the references to Exelon in Sections 3.1 and 3.2 are changed to HDI.	design verification." This is not a reduction in commitment. The previous sentence covers the intent of the deleted sentence. This is considered an administrative improvement. The change, Exelon to HDI, that differs from the Oyster Creek DQAP is a minor administrative change, which is considered editorial and does not constitute a reduction in commitments to the previously approved Oyster Creek DQAP. HDI is now the licensee for Oyster Creek. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	
4.0	Procurement Document Control - There are some administrative and editorial differences between the Fleet DQAP and the Pilgrim and Oyster Creek DQAPs in Section 4.0. Section 4.3 in the Oyster Creek and Pilgrim DQAPs was not included in the Fleet DQAP. In addition, the wording in Section 4.5 was revised in the Fleet DQAP (now Section 4.4 in the fleet DQAP since Section 4.3 was deleted. There is one additional difference from the Oyster Creek DQAP; the reference to Exelon in Section 4.2 is changed to HDI.	Section 4.3 was not included in the Fleet DQAP as this paragraph is redundant in intent to information already stated in Section 4.1. These changes to Sections 4.2 and 4.4 are minor administrative changes, which are considered editorial and do not constitute a reduction in commitments to the Oyster Creek and Pilgrim DQAPs. The change, Exelon to HDI, that differs from the Oyster Creek DQAP is a minor administrative change, which is considered editorial and does not constitute a reduction in commitments to the previously approved Oyster Creek DQAP. HDI is now the licensee for Oyster Creek. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No
5.0	Instructions, Procedures and Drawings - Section 5.2 of the fleet DQAP was revised from the wording in the Pilgrim DQAP and the Oyster Creek DQAP. The last sentence in Section 5.3 of the Oyster Creek and Pilgrim DQAPs was not	Section 5.2 wording was revised in the fleet DQAP to add clarity. This change is a minor administrative change, which is considered editorial and does not constitute a reduction in commitments. This change can be implemented without prior NRC approval, based on the	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	included in the fleet DQAP.	guidance provided in 10CFR50.54(a)(3). The last sentence is Section 5.3 was not included in the fleet DQAP. The intent of the information in this sentence is covered in Section 5.1. "Documented and approved instructions, procedures, and drawings are required..." This change is considered administrative and editorial and is not a reduction in commitment. This change can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	
6.0	Document Control – The last sentence in Section 6.2 of the Oyster Creek and Pilgrim DQAPs was not included in the fleet DQAP.	The last sentence in Section 6.2 was not included in the fleet DQAP. The intent of the information in this sentence is covered in Section 6.1. This change is considered administrative and editorial and is not a reduction in commitment. This change can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No
7.0	Control of Purchased Material, Equipment and Services - There are administrative and editorial changes in Section 7.0 of the Fleet DQAP that differ from the Oyster Creek and Pilgrim DQAPs. Wording changes were made in Section 7.2 to provide more succinct information. Sections 7.4.1 and 7.4.2 of the Fleet DQAP cites the ISO/IEC-17025:2017 standard for accredited calibration or test laboratories. The Oyster Creek and Pilgrim DQAPs cite the 2005 version of this standard. The last sentence in Section 7.8 of the Oyster Creek and Pilgrim DQAPs was moved to the end	Wording changes were made in Section 7.2 to provide more succinct information. These changes, including the administrative and editorial changes, do not reduce the commitments in the program and can be implemented without prior NRC approval, based on the guidance in 10CFR50.54(a). Sections 7.4.1 and 7.4.2 of the Fleet DQAP cites the ISO/IEC-17025:2017, "General Requirements For the Competence of Testing and Laboratories", which is the standard for accredited calibration or test laboratories. The Oyster Creek and Pilgrim DQAPs cite the 2005 version of this standard. The NRC, in a letter dated April 16, 2019 to Mark A. Richter, Ph.D. of NEI provided acceptance of	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	of Section 7.1 in the Fleet DQAP. There are two differences from the Oyster Creek DQAP; the reference to Exelon in Section 7.2 is changed to HDI and the term vendor is used in the fleet DQAP vice the term supplier in the Oyster Creek DQAP.	ISO/IEC 17025:2017 applicable during the transition period set to expire on November 30, 2020. This change can be implemented without prior NRC approval, based on 10CFR50.54(a)(3)(i). However, the change would only be valid through Nov. 30, 2020 unless the NRC does not provide final acceptance. The last sentence in Section 7.8 of the Oyster Creek and Pilgrim DQAPs was moved to Section 7.1 in the Fleet DQAP; the sentence states: "Documentation of acceptance shall be available prior to installation or acceptance for use." This change is considered editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3). The changes, Exelon to HDI, and supplier to vendor, that differ from the Oyster Creek DQAP are minor administrative changes, which are considered editorial and do not constitute a reduction in commitments to the previously approved Oyster Creek DQAP. HDI is now the licensee for Oyster Creek. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	
8.0	Identification and Control of Materials, Parts, and Components - The Fleet DQAP incorporates the term "items" for materials, parts, and components, including partially fabricated assemblies and consumables in Section 8.1. This term is not incorporated in the Oyster Creek DQAP. The last sentence in Section 8.2 of the Oyster Creek and Pilgrim DQAPs was not included in the Fleet DQAP.	Incorporation of the term "items" for materials, parts, and components and breaking up Section 8.3 into two sections are considered to be editorial changes. The last sentence in Section 8.2 of the Oyster Creek and Pilgrim DQAPs states: "When codes, standards, or specifications require specific identification or traceability requirements of an item, procedures shall describe how to maintain traceability as applicable." The intent of this sentence is already met in Section 8.1 which states in part: "Measures are established for the identification and control of material, parts, and components...". Splitting Section 8.3 into two sections is	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	In the Fleet DQAP and the Pilgrim DQAP, Section 8.3 is broken up into two sections resulting in a Section 8.4.	considered and editorial change. These changes are considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	
9.0	Control of Special Processes - There is no difference between the Fleet DQAP and the Pilgrim DQAP in Section 9.0. There is one difference from the Oyster Creek DQAP; Section 9.2 of the Oyster Creek DQAP is not in the Fleet DQAP.	Section 9.2 in the Oyster Creek DQAP states: "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." The intent of this statement is already met in Section 9.1. This change is considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	No
10.0	Inspection – Administrative and editorial changes were incorporated in the Fleet DQAP. Specifically, Sections 10.2, 10.5, and 10.6 wording is different than that in the Oyster Creek and Pilgrim DQAPs.	Sections 10.2, 10.5, and 10.6 wording differs from that in the Oyster Creek and Pilgrim DQAPs. These sections were revised to be more succinct and provide clarity. These changes do not constitute a reduction in commitments. These changes are considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	No
11.0	Test Control - There are only minor editorial differences between the Fleet DQAP, the Pilgrim DQAP and the Oyster Creek DQAP in Section 11.0. Section 11.2 of the Oyster Creek DQAP was split into three sections in the Fleet DQAP.	Splitting Section 11.2 into three separate sections is an editorial change. This change does not constitute a reduction in commitments. The changes in Section 11.0 are considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	No
12.0	Control of Measuring and Test Equipment - There are administrative and editorial differences between the Fleet DQAP and the Oyster Creek and Pilgrim DQAPs in Section 12.0. Specifically,	Sections 12.1 and 12.3 were re-worded to provide clarity between portable and permanently installed M&TE. These changes do not constitute a reduction in commitments. These changes are considered administrative and editorial	Yes

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	Sections 12.1 and 12.3 in the Pilgrim DQAP (12.1 and 12.4 of the Oyster Creek DQAP) were re-worded. There is one difference from the Oyster Creek DQAP; Section 12.3 of the Oyster Creek DQAP is not in the Fleet DQAP.	and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3). Section 12.3 of the Oyster Creek DQAP states: "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." This paragraph is not in the Fleet DQAP. Oyster Creek is now HDI and no longer associated with the Exelon fleet for any governance or oversight. Not including this information is a reduction in commitment and the change requires NRC approval prior to implementation in accordance with 10CFR50.54(a)(4). This is not a reduction in effectiveness; HDI provides governance and oversight of M&TE and the Oyster Creek site calibration process.	
13.0	Handling, Storage, and Shipping - There are only minor editorial differences between the Fleet DQAP, the Pilgrim DQAP and the Oyster Creek DQAP in Section 13.0.	There are only minor editorial differences in the Fleet DQAP as compared to the Oyster Creek and Pilgrim DQAPs. These changes do not constitute a reduction in commitments. These changes are considered editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	No
14.0	Inspection, Test, and Operating Status - There are administrative and editorial differences between the Fleet DQAP, the Pilgrim DQAP and the Oyster Creek DQAP in Sections 14.1 and	Wording changes were made in Sections 14.1 and 14.3 to provide more succinct information. These changes do not constitute a reduction in commitments. These changes are considered	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
	14.3.	administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	
15.0	Nonconforming Material, Parts, or Components - There are only minor editorial differences between the Fleet DQAP, the Pilgrim DQAP and the Oyster Creek DQAP in Section 15.0. Section 15.2 was split into three sections in the Fleet DQAP.	Splitting Section 15.2 into three separate sections is an editorial change. This change does not constitute a reduction in commitments. The changes in Section 11.0 are considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	No
16.0	There are only minor editorial differences between the Fleet DQAP, the Pilgrim DQAP and the Oyster Creek DQAP in Section 16.0.	There are only minor editorial differences in the Fleet DQAP as compared to the Oyster Creek and Pilgrim DQAPs. These changes do not constitute a reduction in commitments. These changes are considered editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3).	No
17.0	There are administrative and editorial differences between the Fleet DQAP, the Pilgrim DQAP and the Oyster Creek DQAP in Section 17.0. The last two sentences in Section 17.2 of the Oyster Creek and Pilgrim DQAPs is not included in the Fleet DQAP. There is one difference from the Oyster Creek DQAP; the information in Section 17.5 of the Fleet DQAP is not in the Oyster Creek DQAP.	The last two sentences in Section 17.2 of the Oyster Creek and Pilgrim DQAPs regarding receipt controls is not included in the Fleet DQAP. The intent of these sentences is met in Section 17.1. These changes do not constitute a reduction in commitments. These changes are considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3). Section 17.5 of the Fleet DQAP provides information regarding record storage of electronic media. This information is not in the Oyster Creek DQAP. The addition of this information is an administrative improvement and clarification and does not constitute a reduction in commitments to the previously approved Oyster Creek DQAP. This change can be implemented without prior NRC approval, based on the guidance provided in	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
		10CFR50.54(a)(3).	
18.0	Audits - There are several editorial differences between the Fleet DQAP and the Oyster Creek and Pilgrim DQAPs in Section 18.0. There is one difference from the Pilgrim DQAP; the information in Section 18.2.B of the Fleet DQAP differs from that in the Pilgrim DQAP. The Fleet DQAP allows a maximum audit extension of 25%; the Pilgrim DQAP allows a maximum audit extension of 90 days which is more restrictive.	There are several editorial differences between the Fleet DQAP and the Oyster Creek DQAP in Section 18.0. For clarity Section 18.1 was split into two separate sections. Also, to add clarity, several editorial changes were made and new sections added to separate out internal audit and vendor audit requirements. These changes did not remove or reduce the requirements or commitments of the Audits program. These changes do not constitute a reduction in commitments. These changes are considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3). The Fleet DQAP Section 18.2.B states: "A maximum extension not to exceed 25 percent of the audit interval is allowed unless restricted by regulation." For twenty four month frequency audits that would allow an extension of up to six months. The Pilgrim DQAP states: "A maximum extension not to exceed 90 days is allowed unless restricted by regulation." The maximum extension allowed in the Fleet DQAP is approximately twice that allowed in the Pilgrim DQAP. This constitutes a reduction in commitment for the Pilgrim DQAP. This change reflects the reduced risk of a permanently shut down facility and is aligned with the current Oyster Creek DQAP previously reviewed by the NRC. This does not reduce the overall effectiveness of the QAPM and continues to ensure compliance with 10 CFR 50, Appendix B. This change requires NRC approval prior to implementation in accordance with 10CFR50.54(a)(4).	Yes
App. A	The Fleet DQAP Appendix A and B are the same	The change in Appendices numbering of the Fleet DQAP	No

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
& App. C	respectively as the Pilgrim DQAP Appendix D and E. Appendix A and B in the Pilgrim DQAP are titled "Not Used". Appendix C in the Oyster Creek and Pilgrim DQAPs was removed in the Fleet DQAP and the NUREG/CR-6407 regulatory requirement was added to section 2.2. Appendix A and B of the Fleet DQAP are the same as Appendix D and E in the Oyster Creek DQAP. Appendix A, Terms and Definitions, and Appendix B, Writing Reference Documents of the Oyster Creek DQAP are not included in the Fleet DQAP. The information in Appendix A of the Fleet DQAP is the same as that in Appendix D of the Oyster Creek DQAP. The information in Appendix B of the Fleet DQAP is the same as that in Appendix E of the Oyster Creek DQAP with one exception: The Fleet DQAP contains information in Appendix A Section A.2.1 that is not in the Oyster Creek DQAP (Appendix D Section D.2.1.	as compared to the Oyster Creek and Pilgrim DQAPs is considered administrative and editorial. These changes can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3). With the exception of NUREG/CR-6407, the remaining regulatory requirements in Appendix C of the Pilgrim and Oyster Creek DQAPs were already stated in Section 2.2. Adding the NUREG/CR-6407 to Section 2.2 regulatory requirement results in all of the Appendix C regulatory requirements being included in this section. Thus, no need for carrying redundant information in Appendix C into the Fleet DQAP. The information in Appendix A, Terms and Definitions, and Appendix B, Writing Reference Documents of the Oyster Creek DQAP, are not included in the Fleet DQAP. These Appendices are administrative providing additional information but no additional requirements or commitments. Not including this information in the Fleet DQAP is considered an administrative improvement and does not constitute a reduction in commitments to the previously approved Oyster Creek DQAP. This change can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3). The Fleet DQAP contains information in Section A.2.1 that is not in the corresponding Oyster Creek DQAP Appendix D Section D. 2.1. A.2.1 includes the following statement: "...Regulatory Guide 7.10, Revision 3 (6/15), "Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material." Including this reference as a general guidance document is an administrative improvement and does not constitute a reduction in commitment. This change can be implemented	

QAPM Section	Change(s)	Evaluation and Justification	Prior NRC Approval Yes, No or N/A
		without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	
App. B	Site Specific Administrative Requirements – Fleet DQAP Appendix B is the same as the Oyster Creek and Pilgrim DQAP equivalent, Appendix E, with the following exceptions. 1. Section E.4 of the Oyster Creek and Pilgrim DQAPs is not included in the Fleet DQAP. 2. Regarding the Oyster Creek DQAP, Appendix B of the Fleet DQAP corresponds to Appendix E of the Oyster Creek DQAP. The Fleet DQAP Appendix B has additional information as compared to the Oyster Creek DQAP Appendix E. Section B.2, Regulatory Guide 1.88 and Section B.3.2, Radioactive Material Transport Packages (10CFR71) are not in the Oyster Creek DQAP.	1. Section E.4 of the Oyster Creek and Pilgrim DQAPs list specific and detailed information regarding record retention requirements. This level of detail is not consistent with the rest of the DQAP and is not necessary to be included in the DQAP. Section 17.0 of the Fleet DQAP already addresses requirements for records. This change does not constitute a reduction in commitments. The change is considered administrative and editorial and can be implemented without prior NRC approval, based on 10CFR50.54(a)(3). 2.The additional information in Sections B.2 and B.3.2, of the Fleet DQAP represent administrative improvements as compared to the Oyster Creek DQAP. This is not a reduction in commitment. This change can be implemented without prior NRC approval, based on the guidance provided in 10CFR50.54(a)(3).	No

Attachment B

Copy of HDI Fleet DQAP

Included as Enclosure 1 to HDI-OC-20-064/HDI-PIL-20-019

Attachment C

Copy of Oyster Creek Nuclear Generating Station DQAP

Included as Enclosure 3 to HDI-OC-20-064/HDI-PIL-20-019

Attachment D

Copy of Pilgrim Nuclear Power Station DQAP

Included as Enclosure 4 to HDI-OC-20-064/HDI-PIL-20-019

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Enclosure 3 to

HDI-OC-20-064
HDI-PIL-20-019

Oyster Creek Decommissioning Quality Assurance Program

(44 pages including cover page)

Exelon Generation Company, LLC

DECOMMISSIONING QUALITY ASSURANCE PROGRAM (DQAP)

NO-DC-10

Revision 0

Exelon Nuclear

Corporate Headquarters

4300 Winfield Road
Warrenville, IL 60555

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Decommissioning Quality Assurance Program (NO-DC-10) - Revision 0 Transmittal and Summary of Changes

To: All Site Document Control Centers

These changes are effective September 21, 2018.

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

- This is the initial implementation of the Exelon Fleet DQAP

This DQAP has been reviewed in accordance with 10CFR50.54 (a) and approved by the NRC. (Ref. AT 2740777-10 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 4074879-10-11.

The specific change is described as follows:

This is revision 0 of the DQAP and is being issued as approved by the NRC.

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: 9/20/18
Mike Porter / Date
Nuclear Oversight Quality Assurance Specialist

Approved BY: Rob Radulovich 9/20/2018
Rob Radulovich / Date
Nuclear Oversight Audit and Programs Director

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TABLE OF CONTENTS

Policy Statement		2
1.0	Organization	3
2.0	Quality Assurance Program	7
3.0	Design Control	9
4.0	Procurement Document Control	12
5.0	Instructions, Procedures, and Drawings	14
6.0	Document Control	15
7.0	Control of Purchased Material, Equipment, and Services	16
8.0	Identification and Control of Materials, Parts, and Components	19
9.0	Control of Special Processes	20
10.0	Inspection	21
11.0	Test Control	22
12.0	Control of Measuring and Test Equipment	23
13.0	Handling, Storage, and Shipping	25
14.0	Inspection, Test, and Operating Status	26
15.0	Nonconforming Material, Parts, or Components	27
16.0	Corrective Action	28
17.0	Quality Assurance Records	29
18.0	Audits	30
Appendix A	Terms and Definitions	32
Appendix B	Writing Reference Documents	34
Appendix C	Regulatory Commitments	35
Appendix D	General Administrative Requirements	36
Appendix E	Oyster Creek Site Specific Administrative Requirements	38

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.
    - Employee Concerns Program.

- Reporting on oversight activities to the CNO.
- 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 I 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.

APPENDIX E

OYSTER CREEK SITE SPECIFIC ADMINISTATIVE 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. Oyster Creek DC Technical Specification Section 6.8 Procedures and Programs)

E.2. Independent Spent Fuel Storage Installation (ISFSI) SSC

E.2.2. 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.

E.3. Records Retention

E.3.1 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, inspections, repair and replacement of principal items of equipment related to safe storage of irradiated fuel.
- All Licensee Event Reports.
- Records of surveillance activities, inspections and calibrations required by technical specifications.
- Records of changes made to the procedures required by technical specification.
- Records of sealed source leak tests and results.
- Records of annual physical inventory of all source material of record.

E.3.2 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 final Safety Analysis Report.
- Records irradiated fuel inventory, fuel transfers and assembly burnup histories.
- Records of facility radiation and contamination surveys.
- Records of doses received by all individuals for whom monitoring was required.
- Records of gaseous and liquid radiative material released to the environs.
- Records of training and qualification for current members of the facility staff.
- Records to reviews performed for changes made to procedure or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59.
- Records of results of analyses required by the Radiological Environmental Monitoring Program.
- Records of reviews performed for changes made to the Offsite dose Calculation Manual and Process Control Plan.
- Records of radioactive shipments.

Enclosure 4 to

HDI-OC-20-064
HDI-PIL-20-019

Pilgrim Station Decommissioning Quality Assurance Program

(39 pages including cover page)

Decommissioning Quality Assurance Program (DQAP)

(Formerly QAPM)

Pilgrim Nuclear Power Station

Docket No. 50-293

Renewed Facility Operating License No. DPR-35
Docket No. 72-1044

Docket No. 71-0963

TABLE OF CONTENTS

Policy Statement		2
1.0	Organization	3
2.0	Quality Assurance Program	7
3.0	Design Control	9
4.0	Procurement Document Control	12
5.0	Instructions, Procedures, and Drawings	14
6.0	Document Control	15
7.0	Control of Purchased Material, Equipment, and Services	16
8.0	Identification and Control of Materials, Parts, and Components	19
9.0	Control of Special Processes	20
10.0	Inspection	21
11.0	Test Control	22
12.0	Control of Measuring and Test Equipment	23
13.0	Handling, Storage, and Shipping	24
14.0	Inspection, Test, and Operating Status	25
15.0	Nonconforming Material, Parts, or Components	26
16.0	Corrective Action	27
17.0	Quality Assurance Records	28
18.0	Audits	29
Appendix A	Not Used	31
Appendix B	Not Used	32
Appendix C	Regulatory Commitments	33
Appendix D	General Administrative Requirements	34
Appendix E	Site Specific Administrative Requirements	36

Policy Statement

The Decommissioning Quality Assurance Program (DQAP), is the highest tiered document that assigns major functional responsibilities for decommissioning facilities owned and operated by Holtec International and Holtec Decommissioning International respectively (referred to as HDI in this document). Implementing documents assign more specific responsibilities and define the organizational interfaces involved in conducting safety significant (term used in this DQAP to identify both 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 HDI 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.

HDI will maintain the decommissioning facilities in a manner that will ensure the health and safety of the public and the 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

HDI is responsible for the establishment and execution of the DQAP at the decommissioning facilities owned by Holtec and maintained by HDI. These decommissioning facilities have submitted a Certification of Permanent Cessation of Operations and Certification of Permanent Removal of Fuel to the Nuclear Regulatory Commission (NRC) per 10 CFR 50.82(a)(1)(i) and (ii), respectfully. 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.

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.

1.1.2. All personnel who work directly, or indirectly, for HDI are responsible for the achievement of quality in their work. Accordingly, all HDI 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 HDI Senior Vice President and Chief Operating Officer (HDI COO) and is overseen by the Holtec International Senior Vice President and Chief Nuclear Officer (Holtec CNO). The HDI Site Vice President at each decommissioning facility 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 HDI Vice President, Quality Assurance and Nuclear Oversight. The management position responsible for Nuclear Oversight is responsible for periodically reporting to the HDI COO and Holtec CNO on the effectiveness of the DQAP implementation and immediately apprising them 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 NRC licenses including the site technical specifications, this DQAP, and implementing procedures.

1.2. Corporate Organizations

1.2.1. The HDI COO has the overall responsibility for the safety, operation, and decommissioning of the nuclear sites maintained by HDI including oversight of the decommissioning activities performed by CDI. This is the senior

executive responsible for providing strategic direction to the HDI organization and to the senior leadership of the decommissioning facilities maintained by HDI. This position is responsible for providing management direction, oversight and support to the site organizations and for setting and implementing policies, objectives, expectations, and priorities to ensure activities are performed in accordance with the DQAP and other requirements.

1.2.2. The Holtec CNO provides oversight of all HDI's nuclear activities including decommissioning of the nuclear sites maintained by HDI.

1.2.3. The HDI Vice President Quality Assurance and Nuclear Oversight reports to the Holtec CNO and the HDI COO. The position provides quality assurance oversight for the decommissioning facilities maintained by HDI. In addition, this position is responsible for verifying the DQAP is effectively implemented, that Quality Assurance (QA) personnel have sufficient authority and organizational freedom to identify quality problems and to verify implementation of corrective actions, and that QA personnel 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 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 Holtec CNO and HDI COO for resolution, as necessary.
- Reporting on oversight activities to the Holtec CNO and HDI COO.
- Authority to stop work when quality is adversely affected.

1.2.4. The following management positions report to and/or receive direction from the HDI COO with respect to their assigned roles and responsibilities associated with the execution of this DQAP:

- The HDI Vice President, Regulatory & Environmental Affairs is responsible for providing licensing oversight for the decommissioning facilities maintained by HDI. This position is responsible for overseeing and guiding development and submission of licensing, regulatory and environmental actions. This position also conducts routine assessments of the regulatory activities at each of the decommissioning facilities and supports the interface between the site and nuclear regulators while also taking a lead role on generic issues in decommissioning.

1.2.5. 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. Decommissioning Facility Management

The following are HDI decommissioning facility management positions and associated DQAP functional responsibilities which may be delegated to others as established in this document. These individuals may report through an additional layer of management but shall maintain sufficient authority and organizational freedom to implement assigned responsibilities.

1.3.1. The HDI Site Vice President for each decommissioning facility maintained by HDI is responsible for providing day-to-day on-site leadership and direction to the associated decommissioning facility to assure the safe decommissioning, maintenance, and regulatory compliance of the station including 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, licenses, Technical Specifications dry storage system Certificate of Compliance and training. The HDI Site Vice President, 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. The following positions report to the HDI Site Vice President:

- A management position responsible for operational activities necessary for safe storage and maintenance of spent fuel including maintaining the facility within the constraints of applicable regulatory requirements and the decommissioning facility licenses.

- A management position responsible for radiation protection, ALARA planning, chemistry, and environmental activities.

- A management position responsible for supporting the HDI VP of Regulatory and Environmental Affairs in maintaining an interface between the station and federal and state, and local regulators. Also, responsible for Emergence Preparedness, the Corrective Action Program, and document control and records management functions.

- A management position responsible for managing decommissioning projects within the constraints of the decommissioning facility licenses and regulatory requirements.

- 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.

- The Pilgrim Nuclear Power Station (PNPS) site Quality Assurance Manager is responsible for site execution of the PNPS quality assurance program. This position has overall authority and responsibility for establishing, controlling, and verifying the implementation and adequacy of the quality assurance program as described in this DQAP under the direction of the HDI Vice President of Quality Assurance. This position has the authority and responsibility to escalate matters directly to the highest-level nuclear executive of HDI if necessary.
- A management position responsible for the execution of maintenance and modification activities.
- A management position responsible for implementation of the decommissioning facility site security plan.

This following position may be included in station management or in the corporate organization.

- A management position responsible for material management and site supply, which coordinates, evaluates, and procures materials for the decommissioning facility.

2. QUALITY ASSURANCE PROGRAM

2.1. The Quality Assurance (QA) Program for HDI decommissioning facilities as described in this DQAP 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 HDI 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 significant, applicable regulatory programs, and for other applicable activities and SSCs identified in either the facility-specific Decommissioning Safety Analysis Report (DSAR) or Appendices 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 HDI VP Quality and 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 Quality Assurance (QA) matter that cannot be resolved at a lower level of management will be referred to the HDI COO.

2.5.2. Additional requirements, for specific programs are described in the Administrative Controls section of the applicable decommissioning facility Technical Specifications or in the DSAR, 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 Quality Assurance 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. 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, as applicable, 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.

- A 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 are 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. HDI 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 as appropriate. 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 decommissioning facility changes or modifications may be performed by HDI 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 significant 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 used to derive 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 change process criteria (e.g., 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 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 as applicable 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 safety significant 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 safety significant 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 are 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. HDI maintains an Approved Vendor List (AVL) for those vendors qualified to perform safety significant work. The qualification requirements for vendors on the AVL are described in controlling procedures except for procurement from other licensees that have an NRC approved quality program. Vendor qualification processes use a graded approach based on the qualification level of the vendor.

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. In addition, procurement documents will, as applicable, require vendors to a) invoke applicable requirements on its vendors; b) allow for right of access for further evaluations as needed.

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 are 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 decommissioning facility design and regulatory requirements. Documents comprising of instructions, procedures, specifications, and drawings prepared by outside contractors for the performance of decommissioning facility activities are reviewed and approved by the responsible manager or designated representative as applicable.

6.0. DOCUMENT CONTROL

6.1. Measures are 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 are established for the control of purchased material, equipment (identified as items) 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 vendor, source inspection, audit, and examination of items or services. Procedures shall describe each organization's responsibilities for the control of items and services, including the interfaces between all affected organizations.

7.2 Verification that a vendor can meet the specified technical and quality requirements shall be documented. HDI maintains an Approved Vendor List (AVL) for those vendors qualified to perform safety significant work that are audited on a triennial basis. Documented vendor performance monitoring is performed in accordance with approved procedures as an acceptable alternate to the performance of the annual evaluation of vendors. The evaluated list of such vendors is described in controlling procedures for the appropriate safety significant classification except for procurement from other licensees that have an NRC approved quality program. Vendors of commercial grade calibration and testing services may be qualified based on their accreditation by a nationally - recognized accrediting body, as an alternative to qualification by vendor 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 vendor'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 vendor's QA program shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or service. Vendor performance and compliance with procurement documents are monitored by source verification, receipt inspection, audit, or a combination to ensure continued acceptable vendor 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 vendors whose QA Program has not been reviewed or accepted, those vendors 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. Additional controls will be approriately identified and implemented.

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 vendors 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 are established for the identification and control of material, parts, and components, including partially fabricated assemblies and consumables (identified as items), 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 HDI 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.

8.4 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, as applicable, 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.

10. INSPECTION

10.1. Measures are established for inspection of activities within the scope of this DQAP by or for the organization performing the activity, 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 areestablished for a documented test program in accordance with applicable Technical Specifications, license conditions, and design documents to assure that all required testing demonstrate that the SSCs 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 safety significant 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.

11.3 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.

11.4 The test program shall require that modifications, repairs, and replacement of items that have a current safety significant function be tested, utilizing the same criteria as the original items to the extent applicable to the current safety significant 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 are 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 are 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, are of appropriate type, and maintained within prescribed accuracy limits, suitable range and accuracy in order to verify conformance to specified requirements.

12.3. 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.

12.4. 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 to maintain accuracy and operating characteristics of the M&TE.

12.5. 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).

12.6. 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 are established to control the handling, storage, shipping, packaging, cleaning and preservation of items 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 are 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 are 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 are established to 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 safety significant 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 are 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 vendors 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 are 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 decommissioning 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 HDI locations, vendors and HDI, and from HDI 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 vendors 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 The program includes provisions for the use of various record storage media to maintain QA records. Procedures are developed to implement the regulatory guidance associated with the media used. The NRC Generic Letter 88-18 “Plant Record Storage on Optical Disk” is implemented for optical disk media. The Regulatory Issue Summary 2000-18 “Guidance on Managing QA Records in Electronic Media” is implemented for electronic media.

17.6. 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 are established for a system of planned and documented audits to verify compliance with all aspects of the DQAP and determine the effective implementation of programs covered by the DQAP. Internal and vendor 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 90 days 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 vendor 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 vendors 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 vendor'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

NOT USED

APPENDIX B

Not Used

Appendix C

Page 1 of 1

REGULATORY COMMITMENTS

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

C.2. 10 CFR 71, *Packaging and Transportation of Radioactive Material,* Subpart H, *Quality Assurance*

C.3. 10 CFR 72, *Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste,* 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

Page 1 of 2

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

When HDI contracts with vendors to transport radioactive waste in NRC approved shipping packages, the contract is written such that the requirements of 10 CFR 71, Subpart H and Regulatory Guide 7.10, Revision 3 (6/15), “Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material” are met. HDI 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.

Appendix D

Page 2 of 2

GENERAL ADMINISTRATIVE REQUIREMENTS

D.3. Services

D.3.1. HDI procures services from qualified vendors. It is not necessary that these vendors have a quality assurance program approved by the licensee, however, vendors 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), HDI implements the requirements of DQAP Section 1 through 18 for aging management activities related to safety significant SSCs as described by licensing documents for those systems that remain active.

D.4.2. Additionally, to manage the aging effects of non-safety significant SSCs that were determined to be within the scope of License Renewal, HDI 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 HDI COO 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.

Appendix E

Page 1 of 1

SITE 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. (reference Oyster Creek Technical Specifications Section 6.8 Procedures and Programs; reference Pilgrim Technical Specifications Section 5.4 Procedures).

E.2 Regulatory Guide 1.88

E.2.1 Procedures for the collection, storage, and maintenance of nuclear plant quality assurance records will be consistent with Regulatory Guide 1.88 Revision 2, dated October 1976. (Collection, storage, and maintenance of nuclear power plant quality assurance records).

E.3. Independent Spent Fuel Storage Installation (ISFSI) SSC

E.3.1. 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 decommissioning site specific license.

E.3.5 Radioactive Material Transport Packages (10 CFR 71)

Radioactive Material Transport Packages subject to the provisions of 10 CFR 71, Subpart C, “General Licenses” are “Important-to-Safety” and subject to the applicable requirements of the DQAP.

E.4. Records Retention

E.4.1 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, inspections, repair and replacement of principal items of equipment related to safe storage of irradiated fuel.
- All Licensee Event Reports.

- Records of surveillance activities, inspections and calibrations required by technical specifications.
- Records of changes made to the procedures required by the Technical Specifications.
- Records of sealed source leak tests and results.
- Records of annual physical inventory of all source material of record.

E.4.2. 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.
- Records of facility radiation and contamination surveys.
- Records of doses received by all individuals for whom monitoring was required.
- Records of gaseous and liquid radiative material released to the environs.
- Records of training and qualification for current members of the facility staff.
- Records to reviews performed for changes made to procedure or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59.
- Records of results of analyses required by the Radiological Environmental Monitoring Program.
- Records of reviews performed for changes made to the Offsite dose Calculation Manual and Process Control Plan.
- Records of radioactive shipments.