

# MAINE YANKEE

321 Old Ferry Road, Wiscasset, Maine 04578

November 1, 2016

OMY-16-032

10 CFR 50.71(e)(4) and 10 CFR 71.106

10 CFR 50.4 and 10 CFR 71.1

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

Maine Yankee Atomic Power Company  
Maine Yankee Independent Spent Fuel Storage Installation  
NRC License No. DPR-36 (NRC Docket Nos. 50-309 and 71-0465)

Subject: Maine Yankee Quality Assurance Program – Revision 36

Pursuant to the requirements of 10 CFR 50.71(e)(4), 10 CFR 71.106, 10 CFR 50.4, and 10 CFR 71.1, Maine Yankee Atomic Power Company (Maine Yankee) is submitting a periodic update of the Maine Yankee Quality Assurance Program to the NRC. Enclosure 1 contains Revision 36 of the Maine Yankee Quality Assurance Program. Enclosure 2 contains a summary of the changes made since the last submittal to the NRC in November 1, 2014 (Reference 1).

The changes included in this revision were administrative improvements or editorial and did not reduce commitments in the program previously accepted by the NRC. The information contained in Enclosures 1 and 2 accurately reflects the changes made to the Maine Yankee Quality Assurance Program since the previous submittal.

This letter contains no commitments. If you have any questions regarding this submittal, please contact Mr. J. Stanley Brown at (207) 882-1303.

I declare under penalty of perjury that the foregoing is true and correct. Executed on November 1, 2016.

Sincerely,



Wayne Norton  
Chief Nuclear Officer

Reference: 1. Maine Yankee letter to the US NRC, "Submittal of the Maine Yankee Quality Assurance Program Rev. 35," dated November 1, 2014 (OMY-14-065)

Q004  
NMSS01  
NMSS

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- Enclosures: 1. Revision 36 to Maine Yankee Quality Assurance Program
2. Summary of Changes to Maine Yankee Quality Assurance Program Implemented in Revision 36

cc: D. Dorman, USNRC Region 1 Administrator  
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**ENCLOSURE 1 TO OMY-16-032**

**REVISION 36 TO MAINE YANKEE  
QUALITY ASSURANCE PROGRAM**

# Maine Yankee Atomic Power Company

## Quality Assurance Program

For The

Maine Yankee ISFSI

Revision 36

Prepared By: Joseph Bourassa Date: 12/16/15

Approved By: Joseph Bourassa Date: 12/16/15

Reviewed/Approved By: J. Bourassa Date: 12/16/15

# QUALITY ASSURANCE PROGRAM FOR THE MAINE YANKEE ISFSI

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# QUALITY ASSURANCE PROGRAM FOR THE MAINE YANKEE ISFSI

## A. MANAGEMENT

### 1. Methodology

- a. The Quality Assurance Program (QAP) provides a consolidated overview of the quality program controls that govern the operation and maintenance of the Maine Yankee Independent Spent Fuel Storage Installation (ISFSI). The QAP describes the quality assurance organizational structure, functional responsibilities, levels of authority and interfaces.
- b. The requirements and commitments contained in the QAP are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations. Employees are encouraged to actively participate in the continued development of the QAP as well as its implementation. Changes should be promptly communicated when identified.
- c. The QAP applies to all activities associated with structures, systems, and components (SSCs) which are Important to Safety (10 CFR 72). The QAP also applies to transportation packages licensed by the NRC under 10 CFR 71. Requirements of the QAP are done in a graded approach commensurate with an item or activities importance to safety. This graded approach is responsive to NRC Regulatory Guide 7.10. The applicability of the requirements of the QAP to other items and activities is determined on a case-by-case basis. The QAP satisfies the requirements of 10 CFR 50 Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G.
- d. The QAP is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of Important to Safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements.

### 2. Organization

The organizational structure responsible for implementation of the QAP is described below. The specific organization titles for the quality assurance functions described in this QAP are identified in implementing procedures. The authority to accomplish the quality assurance functions described is delegated to the incumbent staff, as necessary, to fulfill the identified responsibility.

- a. The President reports to the Board of Directors and has overall responsibility for the QAP and operation of the Maine Yankee ISFSI. The President resolves all disputes related to the implementation of the QAP for which resolution is not achieved at the appropriate organizational levels within Maine Yankee.
- b. The Chief Nuclear Officer (CNO) reports to the President and is responsible for the oversight of the implementation of the QAP.

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- c. The individuals fulfilling the following management functions report to the CNO. These individuals may report through an additional layer of management, but shall maintain sufficient authority and organizational freedom to implement the assigned responsibilities. These individuals may fulfill more than one function described below unless prevented by the need to maintain independence as required elsewhere in the QAP.
  - 1. ISFSI Manager – Reports to the CNO and is responsible for the direction and administration of ISFSI Operations, Site Training, Procurement, Security, Non-conformance and Corrective Actions Programs and Emergency Planning. The Independent Review Function (ISR) described in Section D reports to the ISFSI Manager.
  - 2. ISFSI Radiation Protection Manager – Reports to the ISFSI Manager and is responsible for the Radiation Protection Program.
  - 3. ISFSI Quality Assurance Representative – Reports to the CNO with a direct line of communication to the President and is responsible for the audit/survey and surveillance functions described in the QAP. The ISFSI Quality Assurance Representative is designated by CNO.

### 3. Responsibility

- a. Maine Yankee has the responsibility for the scope and implementation of an effective quality assurance program.
- b. Maine Yankee may delegate all or part of the activities of planning, establishing, and implementing the quality assurance program to others, but retains the responsibility for the program and its effectiveness.
- c. The Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAP and that the QAP is effectively implemented. This Independent Management Assessment is performed by individual(s) designated by the CNO and/or President, independent of activities assessed and who provide the appropriate level of expertise in the activities assessed. The Independent Management Assessment results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the President and CNO of Maine Yankee.
- d. Maine Yankee is responsible for ensuring that the applicable portion(s) of the Quality Assurance Program is properly documented, approved, and implemented (staff is trained, necessary materials and approved procedures are available) before an activity within the scope of the QAP is undertaken by Maine Yankee or by others who have been delegated the responsibility. As such, implementing controls and procedures for some elements of the QAP are not needed under normal ISFSI operations and will only be developed if and when a need is identified.



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- e. Individual managers are responsible for ensuring that personnel working under their cognizance are provided with the necessary training and resources to accomplish assigned tasks that fall within the scope of the QAP.
- f. Approval of QAP implementing procedures will be by the management responsible for the function. These procedures shall reflect the requirements of the QAP and work is required to be accomplished in accordance with them.

#### 4. Authority

- a. When Maine Yankee delegates responsibility for planning, establishing, or implementing any part of the QAP, sufficient authority to accomplish the assigned responsibilities is also delegated.
- b. The ISFSI Quality Assurance Representative provides management with objective evidence of the performance of activities affecting quality, independent of the individual or group directly responsible for performing the specific activity. This individual has the authority and organizational freedom to verify activities affecting quality and is independent of undue influences and responsibilities for schedules and costs. The ISFSI Quality Assurance Representative has the responsibility and authority to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming materials. This individual also has the responsibility and authority to identify quality problems, to recommend or provide solutions, and to verify their implementation.

#### 5. Personnel Training and Qualification

- a. Each member of the facility staff (including audit/survey, surveillance and inspection personnel) shall have sufficient qualifications to perform their assigned duties. Implementing procedures provide the guidance used for determining and assessing appropriate staff qualifications.
- b. Training programs are established and implemented to ensure that personnel achieve and maintain suitable proficiency.
- c. Personnel training and qualification records are maintained in accordance with procedures.
- d. In addition to the above, the following specific qualification requirements are required:
  - 1. The position of the ISFSI Quality Assurance Representative shall meet the following minimum qualifications:
    - a. Graduate of a four-year accredited engineering or science college or university, or the equivalent in practical experience plus five (5) or more years in positions of leadership, such as lead engineer, project engineer, audit team leader, etc.

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- b. At least two years of this experience should be associated with nuclear quality assurance activities, and at least one year of this experience shall be in a quality assurance organization. An additional two years of quality assurance program implementation may be substituted for the one-year experience within a quality assurance organization.
  - c. A master's degree in engineering or business management is considered equivalent to two years of experience.
2. The position of Radiation Protection Manager shall meet the following minimum qualifications:
- a. Academic degree in an engineering/science field or equivalent as provided for in paragraph c, below.
  - b. Minimum of five years professional experience in the area of radiological safety, three years of which shall be in applied radiation work in a nuclear facility.
  - c. Technical experience in the area of radiological safety beyond the five year minimum may be substituted on a one-for-one basis towards the academic degree requirement (four years of technical experience being equivalent to a four year academic degree).
  - d. Academic and technical experience must total a minimum of nine years.
3. The position of Independent Safety Reviewer (ISR), shall meet the following minimum qualifications:
- a. Knowledgeable of the regulatory requirements and operational aspects of an ISFSI.
  - b. At least 5 years of professional experience and either a Bachelor's Degree in Engineering or the Physical Sciences or shall have equivalent qualifications.
  - c. Knowledge in the subject areas requiring review.

The ISFSI Manager shall evaluate potential reviewers' qualifications and document the appointment of a reviewer(s) based on their qualifications.

### 6. Corrective Action

- a. Each individual working at Maine Yankee is responsible for promptly identifying and reporting conditions adverse to quality. Management at all levels encourages the identification of conditions that are adverse to quality.

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- b. The corrective action program will ensure the prompt identification, documentation, and correction of conditions adverse to quality. Significant conditions adverse to quality shall require cause determination and a corrective action plan that should prevent or lessen the likelihood of recurrence.
- c. Specific responsibilities within the corrective action program may be delegated, but Maine Yankee maintains responsibility for the program's effectiveness.
- d. Non-conforming items are properly controlled to prevent their inadvertent installation, or use. They are reviewed and either accepted, rejected, repaired, or reworked.
- e. Reports of conditions that are adverse to quality are analyzed to identify negative performance trends. Significant conditions adverse to quality and significant trends are reported to the appropriate levels of management.

### 7. Regulatory Commitments

Except when alternatives or exceptions are identified, the implementing procedures for the QAP shall comply with the quality assurance guidance documents listed in Appendix B. Additionally, the following clarifications apply to all guidance documents listed in Appendix B:

- a. If the guidance in any of the listed documents is in conflict with the QAP, the guidance provided in the QAP is the controlling document.
- b. Standards, guides, codes, etc., identified in any commitment document are not quality assurance program requirements unless that document is also listed in the Appendix.
- b. Guidance applicable to safety related items and activities (10 CFR 50) are applicable to comparable items and activities (Important to Safety) required by 10 CFR 71 and 10 CFR 72.

## B. PERFORMANCE/VERIFICATION

### 1. Methodology

- a. Personnel performing work activities such as design, engineering, procurement, installation, maintenance, modification, operation, and decommissioning are responsible for achieving acceptable quality.
- b. Personnel performing independent verification activities are responsible for verifying the achievement of acceptable quality and are different personnel than those who performed the work.
- c. Work is accomplished and verified using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.

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- d. Criteria that define acceptable quality are specified, and quality is verified against these criteria.

### 2. Design Control

- a. The program will ensure that the activities associated with the design of structures, systems and components and modifications thereto, are executed in a planned, controlled, and orderly manner.
- b. The program utilizes the guidance of NUREG/CR-6407 to classify structures, systems and components such that appropriate quality requirements are identified and documented on drawings, component lists, or procurement documents, as applicable.
- c. The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces.
- d. Design inputs (e.g., performance, conditions of the facility license, quality, and quality verification requirements) shall be correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions).
- e. The final design output shall relate to the design input in sufficient detail to permit verification.
- f. The design process shall ensure that materials, parts, equipment and processes are selected and independently verified consistent with their importance to safety to ensure they are suitable for their intended application.
- g. Changes to final designs (including field changes and modifications) and dispositions of non-conforming items to either use-as-is or repair shall be subjected to design control measures commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designee. The original design organizations for the Maine Yankee ISFSI are identified in Appendix A.
- h. Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs shall be defined in procedures.
- i. Design documentation and records, which provide evidence that the design and design verification process was performed in accordance with the QAP, shall be collected, stored, and maintained in accordance with documented procedures. This documentation includes final design documents, such as drawings, and specifications, and revisions thereto and documentation which identifies the important steps, including sources of design inputs that support the final design.

### 3. Design Verification

- a. The program will verify the acceptability of design activities and documents for the design of items. The selection and incorporation of design inputs and processes,

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outputs and changes are verified.

- b. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing. The extent of this verification will be a function of the importance to safety of the item, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Standardized or previously proven designs will be reviewed for applicability prior to use.
- c. When a test program is used to verify the acceptability of a specific design feature, the test program will demonstrate acceptable performance under conditions that simulate the most adverse design conditions expected to be encountered.
- d. Independent design verification is to be completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is to be identified and controlled. In all cases, the design verification is to be completed before relying on the item to perform its Important to Safety function.
- e. Individuals or groups responsible for design reviews or other verification activities shall be identified in procedures and their authority and responsibility shall be defined and controlled. Any competent individuals or groups other than those who performed the original design but who may be from the same organization shall perform design verification. The designer's immediate supervisor or manager may perform the design verification provided:
  - 1. The supervisor or manager is the only technically qualified individual capable of performing the verification.
  - 2. The need is individually documented and approved in advance by the supervisor's or managers management, and
  - 3. The frequency and effectiveness of the supervisors or managers use as a design verifier is independently verified to guard against abuse.
- f. Design verification procedures are to be established and implemented to ensure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria is identified, the verification is satisfactorily accomplished and the results are properly recorded.

#### 4. Procurement Control

- a. The program will ensure that purchased items and services are of acceptable quality.
- b. The program includes provisions for evaluating prospective suppliers and selecting only appropriate suppliers.

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- c. The program includes provisions for taking corrective action with suppliers (qualified or otherwise) whose products and services are not considered acceptable.
- d. The program includes provisions for source verification (inspection, audit, etc.) for accepting purchased items and services identified as important to safety when determined necessary.
- e. The program includes provisions for involving applicable technical, regulatory, administrative, and reporting requirements (e.g., specification, codes, standards, tests, inspections, special processes, records, certifications, 10 CFR 21) for procurement documents for items and services identified as important to safety.
- f. The program includes provisions for ensuring that documented evidence of an item's conformance to procurement requirements is available at the site before the item is placed in service or used unless otherwise specified in procedures.
- g. The program includes provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used unless otherwise specified in procedures.
- h. The program includes provisions for the identification of critical characteristics and methods of acceptance for the dedication of a commercial grade item or service for its use in an Important to Safety function(s).

### **5. Procurement Verification**

- a. The program will verify the quality of purchased items and services at intervals and to a depth consistent with the item's or service's importance to safety, complexity and quantity and the frequency of procurement.
- b. The program is executed in all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier.
- c. Controls for the audits or surveys of suppliers providing Important to Safety items and services are provided for in Section C.
- d. Controls for the inspection (source verification/surveillance/inspection) of suppliers providing Important to Safety items and services are provided for in Section B.12

### **6. Identification and Control of Items**

- a. The program will identify and control Important to Safety items to prevent the use of incorrect or defective items.
- b. Identification of each item is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation. Traceability is maintained to an extent consistent with the item's importance to safety.

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### 7. Handling, Storage, and Shipping

- a. The program will control the handling, storage, shipping, cleaning, and preserving of items to ensure the items maintain acceptable quality.
- b. Special protective measures (e.g., containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels, etc.) are specified and provided when required to maintain acceptable quality.
- c. Specific procedures shall be developed and used for cleaning, handling, storage, packaging, shipping and preserving items when required to maintain acceptable quality.
- d. Items are marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and identify the need for any special controls.

### 8. Test Control

- a. The program will demonstrate that items will perform satisfactorily in service.
- b. The test control program includes, as appropriate, proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests.
- c. Test procedures shall be developed which include:
  1. Instructions and prerequisites to perform the test.
  2. Use of proper test equipment.
  3. Acceptance criteria, and
  4. Mandatory inspections as required.
- d. Test results are evaluated to assure that test objectives and inspection requirements have been satisfied.
- e. Unacceptable test results shall be evaluated for impact on safety and reportability.

### 9. Control of Measuring and Test Equipment

- a. The program will control the calibration, maintenance, and use of measuring and test equipment consistent with an activity's importance to safety. Measuring and test equipment does not include permanently installed operating equipment or test equipment used for preliminary checks where data obtained will not be used to determine acceptability or be the basis for design or engineering evaluation. Additionally, calibration and control measures are not required for rulers, tape measures, levels and other such devices if normal commercial manufacturing

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practices provide adequate accuracy.

- b. The types of equipment covered by the program (e.g., instruments, tools, gages, and reference and transfer standards) are defined in procedures.
- c. Measuring and test equipment is calibrated at specified intervals or immediately before use on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics and other conditions affecting its performance.
- d. Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its traceability to calibration test data.
- e. Measuring and test equipment is calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that ensures the equipment being calibrated will be within the required tolerance.
- f. If nationally recognized standards exist, calibration standards are to be traceable to them.
- g. Measuring and test equipment found damaged or out of calibration is tagged or segregated. The acceptability shall be determined of items measured, inspected, or tested with a damaged or out-of-calibration device.

### 10. Inspection, Test, and Operating Status

- a. The program will ensure that required inspections and tests and the operating status of items important to safety is verified before release, fabrication, receipt, installation, test, and use, as applicable. This verification is to preclude inadvertent bypassing of inspections and tests and to prevent inadvertent operation of controlled equipment.
- b. Items whose required inspections and tests are incomplete or inconclusive may be released for further processing. Controls are provided in procedures for establishing limitations on the release, applying status indications and documenting the basis for the conditional release of the item and any limitations.
- c. The application and removal of inspection, test, and operating status indicators are controlled in accordance with procedures.

### 11. Special Process Control

- a. This program will ensure that special processes identified as Important to Safety are properly controlled.
- b. The criteria that establish which processes are special are described in procedures. The following are examples of special processes:
  - 1. Welding,



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2. Heat treating,
  3. NDE (Non Destructive Examination),
  4. Chemical cleaning, and
  5. Unique fabricating or test processes which require in-process controls.
- c. Shall be accomplished by qualified personnel, using appropriate equipment, and procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

### 12. Inspection

- a. The program will ensure the performance of inspections of Important to Safety activities in order to verify conformance with documented instructions, procedures and drawings for accomplishing the activity. The inspection program may be implemented by or for the organization performing the activity to be inspected.
- b. Provisions to ensure inspection planning is properly accomplished are to be established. Planning activities shall identify the characteristics and activities to be inspected, the inspection techniques, the acceptance criteria, and the organization responsible for performing the inspections.
- c. Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organization are to be defined.
- d. Inspection results are to be documented by the inspector and reviewed by qualified personnel.
- e. Unacceptable inspection results shall be evaluated and resolved in accordance with procedures.
- f. Inspections are performed by qualified personnel other than those who performed or directly supervised the work being inspected. While performing the inspection activity, inspectors functionally report to ISFSI QA.

### 13. Document Control

- a. The program will control the development, review, approval, issue, use, and revision of documents.
- b. The scope of the document control program includes, but is not limited to:
  1. Safety Analysis Report(s),
  2. NRC License Documents, including Technical Specifications,
  3. Design Documents,

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4. Procurement Documents,
  5. Procedures, Manuals, Plans, Directives, Policies, Instructions, etc.,
  6. Corrective Action Documents, and
  7. Other documents as defined in procedures.
- c. Revisions of controlled documents are reviewed for adequacy and approved for release by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable.
  - d. Copies of controlled documents are distributed to and used by the person performing the activity.
  - e. The distribution of new and revised controlled documents is in accordance with procedures. Superseded documents are controlled to prevent inadvertent use.

### 14. Records

- a. The program will ensure that sufficient records of important to safety items and activities are generated and maintained to reflect the completed work.
- b. Controls for the administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of records are provided in procedures.
- c. The scope of the records program includes but is not limited to:
  1. Records required by 10 CFR 20
  2. Records required by 10 CFR 50, except as permitted by the NRC exemption dated 11/21/03,
  3. Records required by 10 CFR 71
  4. Records required by 10 CFR 72
  5. Records of Review and Audit
- d. Controls for the retention of records are provided for in procedures. These controls include applicable record retention requirements of Title 10, Code of Federal Regulations and the following additional requirements:
  1. The following records, except as permitted by the NRC exemption dated 11/21/03, shall be retained for at least 5 years:
    - a. Records and logs of ISFSI operations,

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- b. Records and logs of principal maintenance activities, inspections, repair, and replacement of principal items of equipment related to nuclear safety,
  - c. All reportable events,
  - d. Records of surveillance activities, inspections, and calibrations required by the NAC UMS Certificate of Compliance or the NAC Universal Transport Cask Certificate of Compliance,
  - e. Records of tests and experiments,
  - f. Records of changes made to the procedures required by the NAC UMS Certificate of Compliance or the NAC Universal Transport Cask Certificate of Compliance,
  - g. Record of changes made to programs and procedures required by Appendix C,
  - h. Records of radioactive shipments, and
  - i. Records of annual physical inventory of all sealed source material.
2. The following records, except as permitted by the NRC exemption dated 11/21/03, shall be retained for the duration of the facility Operating License:
- a. Record and drawing changes reflecting facility design modifications made to systems and equipment described in the current DSAR,
  - b. Records of irradiated fuel inventory, fuel transfers, and assembly burn up histories,
  - c. Records of facility radiation and contamination surveys,
  - d. Records of radiation exposure for all individuals entering radiation control areas,
  - e. Records of gaseous and liquid radioactive material released to the environs,
  - f. Records of training and qualification for current members of the facility staff,
  - g. Records of reviews performed for changes made to procedures or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59 or 10 CFR 72.48,

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- h. Records of Independent Safety Reviews (ISR) and Independent Management Assessments, and
- i. Records of reviews performed for changes to the Offsite Dose Calculation Manual (ODCM) and Process Control Program (PCP).

## C. AUDIT

### 1. Methodology

- a. A program of planned and periodic audits will ensure that activities affecting quality comply with the QAP and that the QAP is being implemented effectively. Audit frequencies will be implemented as required by the applicable Code of Federal Regulations, Facility License, Final Safety Analysis Report and other commitments to the NRC.
- b. Organizations performing audits shall be technically and performance oriented commensurate with the activity being reviewed.
- c. Personnel performing audits shall have no direct responsibilities in the area they are assessing.
- d. Audits shall be accomplished using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.

### 2. Performance

- a. Audit schedules assure that the following areas are audited at the indicated frequencies or more frequently as performance dictates.
  - 1. The conformance of ISFSI operation to provisions contained within the Technical Specifications and applicable license conditions is audited at least once every 24 months. The audit shall include elements such as:
    - a. Training and qualifications of the staff,
    - b. Actions taken to correct deficiencies occurring with equipment, structure, systems, or method of operation that affect nuclear safety,
    - c. Performance of activities required by the QAP to meet the criteria of 10 CFR 50, Appendix B, 10 CFR 71, Subpart H and 10 CFR 72, Subpart G,
    - d. Implementation of Programs required by Appendix C, Sections 1.0 and 2.0.
  - 2. Other activities and documents as requested by the President or CNO.

The first part of the report deals with the general situation of the country and the progress of the work during the year. It is followed by a detailed account of the various projects and the results achieved. The report concludes with a summary of the work done and a list of the publications issued during the year.

The second part of the report deals with the financial situation of the institution. It gives a detailed account of the income and expenditure for the year and shows how the funds have been used for the various projects.

The third part of the report deals with the personnel of the institution. It gives a list of the staff and their duties and shows how the work has been distributed among them.

The fourth part of the report deals with the publications issued during the year. It gives a list of the titles and authors of the books and articles and shows how they have been distributed.

The fifth part of the report deals with the general progress of the work during the year. It shows how the various projects have been carried out and what results have been achieved.

The sixth part of the report deals with the future plans of the institution. It shows what work is planned for the next year and how the funds will be used for this purpose.

The seventh part of the report deals with the general situation of the country and the progress of the work during the year. It is followed by a detailed account of the various projects and the results achieved.

The eighth part of the report deals with the financial situation of the institution. It gives a detailed account of the income and expenditure for the year and shows how the funds have been used for the various projects.

The ninth part of the report deals with the personnel of the institution. It gives a list of the staff and their duties and shows how the work has been distributed among them.

The tenth part of the report deals with the publications issued during the year. It gives a list of the titles and authors of the books and articles and shows how they have been distributed.

The eleventh part of the report deals with the general progress of the work during the year. It shows how the various projects have been carried out and what results have been achieved.

The twelfth part of the report deals with the future plans of the institution. It shows what work is planned for the next year and how the funds will be used for this purpose.

## QUALITY ASSURANCE PROGRAM FOR THE MAINE YANKEE ISFSI

- b. External audits or surveys of suppliers providing Important to Safety materials, parts, equipment or services are performed at the indicated frequency or more frequently as performance dictates. Suppliers providing commercial grade calibration services who are accredited by a nationally recognized accrediting body, using procedures consistent with those found in ANSI/ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories", do not have to be periodically surveyed if the conditions of the NRC Safety Evaluation dated September 28, 2005 (see Appendix B) are met. Controls shall be established in applicable procedures to ensure the requirements of the NRC Safety Evaluation are satisfied.
- c. Implementing procedures for the audit/survey program include controls to ensure that the following are met:
  - 1. Audit/surveys shall provide an objective evaluation of quality related practices, procedures, instructions, activities, and items and a review of documents and records as applicable.
  - 2. Audit/surveys shall be performed in accordance with approved written procedures or checklists. Deficiencies from previous audits shall be reviewed and re-audited, as appropriate. The checklists are used as guides to the auditor.
  - 3. Scheduling and resource allocation are based on the status and safety importance of the activity, program or process being assessed.
  - 4. Audit/survey reports are written and distributed to the appropriate levels of management for review. Follow-up action, including re-audit/survey of deficient areas, is initiated as deemed appropriate.
  - 5. Implementation of any delegated elements of the quality assurance program is assessed.
  - 6. Audit/surveys are conducted using predetermined acceptance criteria.
  - 7. Audit/surveys are performed by appropriately trained and qualified personnel.

### D. INDEPENDENT SAFETY REVIEW

- 1. An Independent Safety Review shall be a thorough review conducted by one or more qualified Independent Safety Reviewers. Persons performing these reviews shall be knowledgeable in the subject area being reviewed. Independent Safety Reviews must be completed prior to implementation of the proposed activity requiring the review.
  - a. Independent Safety Reviewers shall be individuals without direct responsibility for the performance of these activities under review. These reviews may be from the same functionally cognizant organization as the individual or group performing the original work.

## QUALITY ASSURANCE PROGRAM FOR THE MAINE YANKEE ISFSI

- b. The following subjects shall be independently reviewed by a qualified Independent Safety Reviewer:
1. Review of proposed changes to the Maine Yankee Technical Specifications, and review of those changes submitted to Maine Yankee by the NRC Certificate Holder for the NAC-UMS System or the NAC Universal Transport Cask that are to be implemented at the Maine Yankee Site.
  2. Review of proposed tests and experiments not described in the SAR, NAC-UMS SAR or the NAC Universal Transport Cask SAR for activities being implemented at the Maine Yankee Site.
  3. Review of proposed changes or modifications to site or ISFSI systems or equipment that affect nuclear safety.
  4. Review of all procedures and programs required by Appendix C and changes thereto that require an evaluation in accordance with 10CFR50.59 or 10CFR72.48.
  5. Render determination in writing to the ISFSI Manager if any items considered under 1 through 4, above, as appropriate and as provided for in 10CFR50.59, 10CFR50.90 or 10CFR72.48 as requiring prior NRC approval, a license amendment or requires a significant hazards consideration determination.

## APPENDIX A

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### IMPORTANT-TO-SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

The pertinent quality assurance requirements of 10CFR50, Appendix B, 10CFR 71 Subpart H and 10 CFR 72 Subpart G will be applied, as a minimum, to all quality activities affecting the Important-to-Safety Structures, Systems and Components (SSCs) associated with spent fuel storage and transportation package.

#### NOTE

The safety classification of systems, structures and components (SSCs) of the Maine Yankee ISFSI Facility may be revised based on engineering evaluations and a revision to the Maine Yankee SAR. These modifications are controlled in accordance with the Design Control process and are not considered a reduction in the commitments to the QAP.

The quality classification of NRC Licensed ISFSI Dry Fuel Storage Components and Transportation Packages may not be revised using the Maine Yankee Design Control process. These modifications must be made by the NRC Certificate Holder. The Certificate Holder is responsible for design and licensing controls for these components under their NRC approved Quality Assurance Program. Maine Yankee utilizes these types of components and packages under the provisions of a NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel Storage (10 CFR 72).

Items and services associated with Radioactive Material Transport Packages as described in 10 CFR 71, and spent Fuel Storage as described in 10 CFR 72 will also fall under the requirements of the QAP.

Important-to-Safety SSCs associated with spent fuel storage and radioactive material transportation packages are defined below:

#### IMPORTANT-TO-SAFETY AS DEFINED BY 10 CFR 71 AND 10 CFR 72

##### A. Dry Spent Fuel Storage (10 CFR 72)

SSC	Quality Category	Design/License Responsible
Transportable Storage Canister and Fuel Basket Assembly	A	NAC Intl.
Vertical Concrete Cask	B	NAC Intl.
Transfer Cask and Adapter Plate	B	NAC Intl.
Lifting Yoke	B	NAC Intl.
Damaged Fuel Can	A	NAC Intl.
Reconfigured Fuel Assembly	A	NAC Intl.
ISFSI Pads	C	Maine Yankee



**APPENDIX A**

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IMPORTANT-TO-SAFETY, STRUCTURES, SYSTEMS AND COMPONENTS

**B. Transport of Spent Fuel and GTCC Waste (10 CFR 71)**

SSC	Quality Category	Design/License Responsible
Transportable Storage Canisters and Fuel Basket Assembly	A	NAC Intl.
Damaged Fuel Can	A	NAC Intl.
Reconfigured Fuel Assembly	A	NAC Intl.
Transportable Storage Canister and Basket Assembly For GTCC Waste Containers	A	NAC Intl.
Universal Transport Cask	A	NAC Intl.

**C. 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 QAP.

**NOTES:**

1. See NAC-UMS Safety Analysis Report (SAR) and associated NAC specifications for additional classification information.
2. See NAC Universal Transport Cask Safety Analysis Report and associated NAC specifications for additional classification information.
3. For the definition of Quality Categories A, B, and C refer to NUREG/CR-6407.

## APPENDIX B

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### REGULATORY COMMITMENTS, ALTERNATIVES AND EXCEPTIONS TO REGULATORY COMMITMENTS

Regulatory Guide 7.10, Revision 2 (3/05), "Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material."

NUREG/CR-6407, "Classification of Transportation Packaging and Dry Fuel Storage System Components According to Important to Safety (2/96)."

### ALTERNATIVES

Letter from NRC to Arizona Public Service Company titled "Palo Verde Nuclear Generating Station, Units 1, 2 and 3 – Approval of Change to Quality Assurance Program (Commercial-Grade Calibration Services) TAC Nos. MC4402, MC4403, and MC4404" and associated NRC Safety Evaluation dated September 28, 2005.

### EXCEPTIONS

Letter from NRC to Maine Yankee titled "Request for the Exemption from the Recordkeeping Requirements of 10CFR50, Appendix A Criterion 1, 10CFR50 Appendix B Section XVII and 10CFR50 Section 50.59(d)(3)", for the Maine Yankee Nuclear Power Plant, granting the exemption dated 11/21/03.

## APPENDIX C

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### ADMINISTRATIVE CONTROLS

#### SCOPE

This appendix contains additional administrative controls and specific license basis-related requirements relating to the Maine Yankee ISFSI. These requirements were previously included in the Technical Specifications and were relocated to the Quality Assurance Program.

#### 1) PROGRAMATIC ADMINISTRATIVE CONTROLS

##### a) PROCEDURES

Written procedures shall be established, implemented, and maintained covering the following activities:

- i) The procedures applicable to the safe storage of irradiated fuel,
- ii) Emergency Plan implementation,
- iii) Quality assurance for environmental monitoring,
- iv) Fire Protection Program implementation, and
- v) Radiation Protection and Offsite Dose Calculation Manual.

Each procedure and changes thereto, shall be independently reviewed in accordance with Section D and approved by the ISFSI Manager or designee prior to implementation.

The following programs shall be established, implemented and maintained.

##### b) RADIATION PROTECTION PROGRAM

Procedures for personnel radiation protection shall be prepared consistent with the requirements of 10 CFR 20 and shall be approved, maintained, and adhered to for all operations involving personnel radiation exposure.

##### c) OFFSITE DOSE CALCULATION MANUAL (ODCM)

The ODCM shall contain the methodology and parameters used in the calculation of off-site doses and in the conduct of the radiological environmental monitoring program; and the ODCM shall also contain the radiological environmental monitoring activities and descriptions of the information that should be included in the Annual Radiological Environmental Operating and Radioactive Effluent Release Reports required by Section 2 and the ODCM.

Licensee initiated changes to the ODCM shall be documented and records of reviews performed shall be retained. This documentation shall contain:

- (1) Sufficient information to support the change(s) together with the appropriate analyses or evaluations justifying the change(s),
- (2) A determination that the change(s) maintain the levels of radioactive effluent control required by 10 CFR 20.1302, and 40 CFR 190, 10 CFR 50.36a, 10 CFR 50, Appendix I and 10 CFR 72.104 and do not adversely impact the accuracy or reliability of dose calculations,
- (3) Shall become effective after approval by the ISFSI Manager or designee, and
- (4) Shall be submitted to the NRC in the form of a complete, legible copy of the entire ODCM as a part of or concurrent with the Annual Radiological Environmental Operating Report for the period of the report in which any change in the ODCM was made. Each change shall be identified by markings in the margin of the affected pages, clearly indicating the area of the page that was changed, and shall indicate the date (i.e., month and year) the change was implemented.

## APPENDIX C

(Page 2 of 3)

### ADMINISTRATIVE CONTROLS

#### 2) REPORTING REQUIREMENTS

The following report(s) shall be submitted in accordance with 10 CFR 50.4:

##### a) ANNUAL RADIOLOGICAL ENVIRONMENTAL OPERATING REPORT

The Annual Radiological Environmental Operating Report covering the plant activities during the previous calendar year shall be submitted by May 15 of each year. The report shall include summaries, interpretations, and analyses of trends of the results of the radiological environmental monitoring program for the reporting period. The material provided shall be consistent with the objectives outlined in the Offsite Dose Calculation Manual (ODCM).

The Annual Radiological Environmental Operating Report shall include the results of analyses of all radiological environmental samples and of all environmental radiation measurements taken during the period pursuant to the locations specified in the table and figures in the ODCM, as well as summarized and tabulated results of these analyses and measurements. In the event that some individual results are not available for inclusion with the report, the report shall be submitted noting and explaining the reasons for the missing results. The missing data shall be submitted in a supplementary report as soon as possible.

##### b) RADIOACTIVE EFFLUENT RELEASE REPORT

The Radioactive Effluent Release Report covering the activities of the site in the previous year shall be submitted prior to May 1 of each year in accordance with 10 CFR 50.36a. The report shall include a summary of the quantities of radioactive liquid and gaseous effluents and solid waste released from the plant. The material provided shall be consistent with the objectives outlined in the ODCM and in accordance with 10 CFR 50.36a and 10 CFR Part 50, Appendix I, Section IV.B.1.

#### 3) HIGH RADIATION AREA CONTROL

Pursuant to 10 CFR 20, paragraph 20.1601(c), in lieu of the requirements of 10 CFR 20.1601, each high radiation area, as defined in 10 CFR 20, in which the intensity of radiation is  $>100$  mrem/hr, but  $<1000$  mrem/hr, shall be barricaded and conspicuously posted as a high radiation area and entrance thereto shall be controlled by requiring issuance of a Radiation Work Permit (RWP). Individuals qualified in radiation protection procedures or personnel continuously escorted by such individuals may be exempt from the RWP issuance requirement during the performance of their assigned duties in high radiation areas with exposure rates  $\leq 1000$  mrem/hr, provided they are otherwise following site radiation protection procedures for entry into such high radiation areas.

Any individual or group of individuals permitted to enter such areas shall be provided with or accompanied by one or more of the following:

- i) A radiation-monitoring device that continuously indicates the radiation dose rate in the area.

## APPENDIX C

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### ADMINISTRATIVE CONTROLS

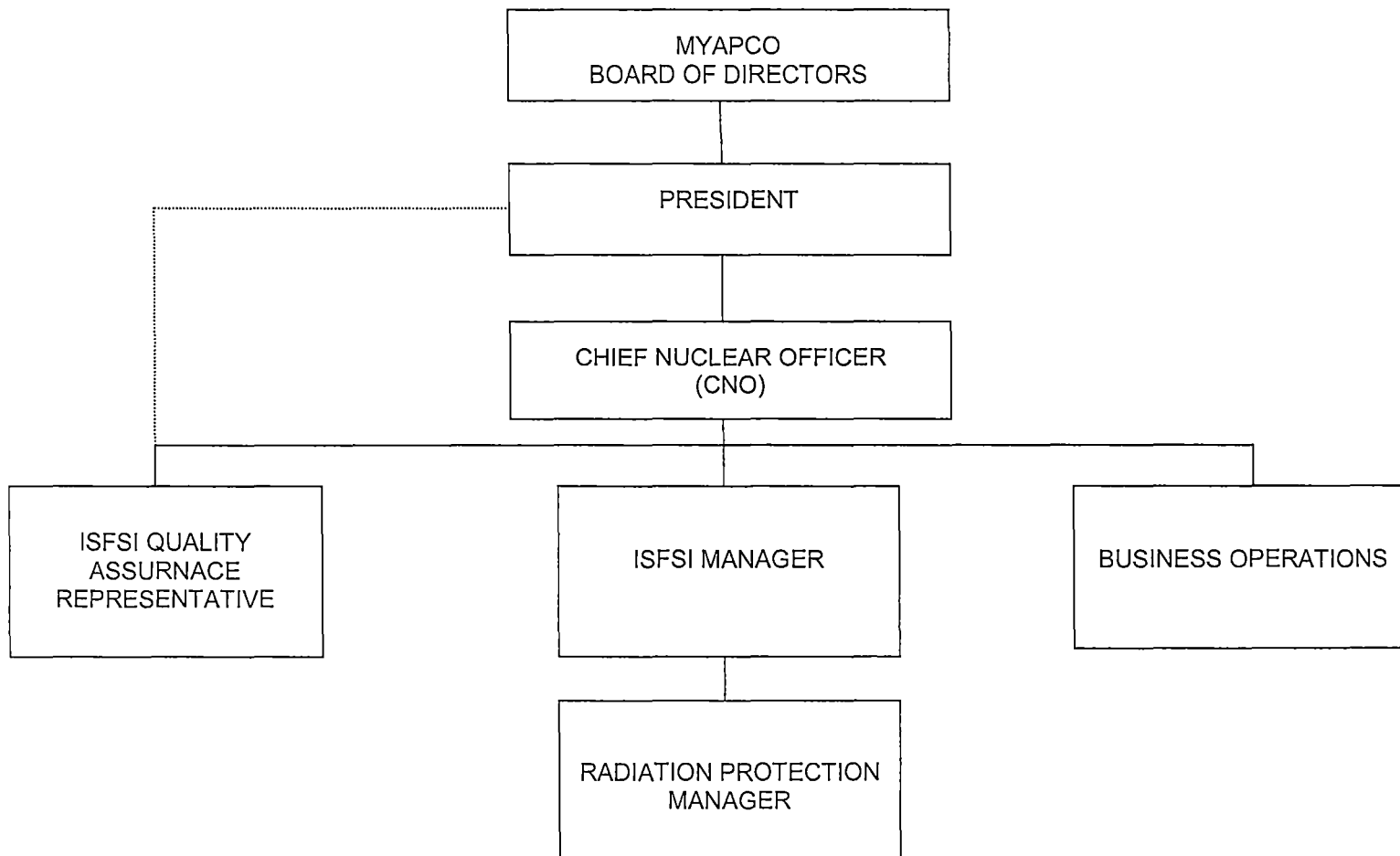
- ii) A radiation-monitoring device that continuously integrates the radiation dose rate in the area and alarms when a preset integrated dose is received. Entry into such area with this monitoring device may be made after the dose rate levels in the area have been established and personnel are aware of them.
  
- iii) An individual qualified in radiation protection procedures with a radiation dose rate-monitoring device, who is responsible for providing positive control over the activities within the area and shall perform periodic radiation surveillance at the frequency specified by Radiation Protection in the RWP.

In addition to the requirements above, each high radiation area, as defined in 10 CFR 20, with radiation levels  $\geq 1000$  mrem/hr shall be provided with locked or continuously guarded doors to prevent unauthorized entry and the keys shall be maintained under the administrative control of the ISFSI Manager on duty or radiation protection supervision. Doors shall remain locked except during periods of access by personnel under an approved RWP that shall specify the dose rate levels in the immediate work areas and the maximum allowable stay times for individuals in those areas. In lieu of the stay time specification of the RWP, direct or remote (such as closed circuit TV cameras) continuous surveillance may be made by personnel qualified in radiation protection procedures to provide positive exposure control over the activities being performed within the area.

For individual high radiation areas, as defined in 10 CFR 20, with radiation levels of  $\geq 1000$  mrem/hr, accessible to personnel, that are located within large areas, where no enclosure exists for purposes of locking, or that cannot be continuously guarded, and where no enclosure can be reasonably constructed around the individual area, that individual area shall be barricaded and conspicuously posted, and a flashing light shall be activated as a warning device.

QUALITY ASSURANCE PROGRAM  
FOR THE MAINE YANKEE ISFSI

**APPENDIX D**  
ORGANIZATION CHART



**ENCLOSURE 2 TO OMY-16-032**

**SUMMARY OF CHANGES TO  
MAINE YANKEE QUALITY ASSURANCE PROGRAM IMPLEMENTED IN  
REVISION 36**

The following changes were made in Revision 36 to the Maine Yankee Quality Assurance Program (QAP). Appendix A of the QAP was revised to define that the Independent Spent Fuel Storage Installation (ISFSI) Pads are Quality Category C as defined in Engineering Evaluation 14-002. This is an administrative change to establish consistency with the QAPs for the Haddam Neck and Yankee Rowe ISFSIs. Previously, the QAP for the Maine Yankee ISFSI simply referred to the Defueled Safety Analysis Report for a discussion of the ISFSI Pads Quality Category.

In addition, an administrative change to Section C.2.d of the QAP was made to refer to an additional section of the QAP.

These changes do not constitute a reduction in commitment to the previously accepted QAP.