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**Billy E. Reid, Jr.**
Site Vice President

10 CFR 50.54(a)(3)
10 CFR 71.106(b)
10 CFR 72.140(d)

BVY 20-014

April 30, 2020

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

SUBJECT: Biennial report for Quality Assurance Program Manual changes under 10 CFR 50.54(a)(3), 10 CFR 71.106, and 10 CFR 72.140(d) Notification of Application of Approved Appendix B to 10 CFR 72 Subpart G.
Vermont Yankee Nuclear Power Station
Docket Nos. 50-271, 71-0907 and 72-59
License No. DPR-28

REFERENCES:

1. Letter, Entergy Nuclear Operations, Inc. to USNRC, "Annual report for Quality Assurance Program Manual changes under 10 CFR 50.54(a)(3), 10 CFR 71.106, and 10 CFR 72.140(d) Notification of Application of Approved Appendix B to 10 CFR 72 Subpart G," BVY 18-012, dated April 12, 2018 (ML18102B249)

2. Letter, Entergy Nuclear Operations, Inc. to USNRC, "Proposed Revision to the Entergy Vermont Yankee Quality Assurance Program Manual (VY QAPM)," BVY 17-023, dated September 19, 2017 (ML17268A152)

3. Letter, USNRC to Entergy Nuclear Operations, Inc., "Entergy Vermont Yankee Quality Assurance Program Manual Vermont Yankee Nuclear Power Station and Independent Spent Fuel Storage Facility – Review and Acceptance of Changes," (NVY 18-011), dated May 1, 2018 (ML18099A166)

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Dear Sir or Madam:

NorthStar Nuclear Commissioning Co., LLC, is submitting the Vermont Yankee Quality Assurance Program Manual (VY QAPM) in accordance with 10 CFR 50.54(a)(3) and 10 CFR 71.106(b). The last submittal, dated April 12, 2018, encompassed the VY QAPM thru Revision 5 (Reference 1). Since that date, Revision 6 to the VY QAPM was issued following implementation of a License Amendment and Permanently Defueled Technical Specifications to reflect removal of all spent nuclear fuel from the spent fuel pool and its transfer to dry cask storage within an Independent Spent Fuel Storage Installation (ISFSI). This was superseded by Revision 7, which was submitted to the NRC (Reference 2) for prior approval as it constituted a

reduction in commitment since, along with other changes, the program basis was changed from the ANSI/ANS standards to the use primarily of Regulatory Guide 7.10 "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material", Revision 3. This request was subsequently approved by the NRC (Reference 3) and implemented on August 23, 2018.

On January 11, 2019, Revision 8 of the VY QAPM was issued reflecting the transfer of the Vermont Yankee license from Entergy Nuclear Operations, Inc. to NorthStar Nuclear Decomissioning Co., LLC. Since Revision 7 of the VY QAPM was reviewed and approved by the NRC, this biennial report on changes made to the QAPM is focused on the revision from Revision 7 to Revision 8.

The VY QAPM continues to satisfy the requirements of 10 CFR 50 Appendix B and the Regulatory Guides and ANSI Standards referenced in the VY QAPM. As such, it also meets the requirements of 10 CFR 72.140(d) for Independent Spent Fuel Storage Installations and 10 CFR 71.101(f) for Packaging and Transportation of Radioactive Material.

A synopsis of the changes associated with Revision 8 is provided as Enclosure 1. The 10 CFR 50.54(a)(3) and 10 CFR 71.106 evaluations are included as Enclosure 2. The VY QAPM Revision 8 remains in effect and is included as Enclosure 3.

This letter contains no new regulatory commitments.

Should you have any questions concerning this letter, or require additional information, please contact Mr. Thomas B. Silko at (802) 451-5354, Ext 2506.

Sincerely,

Billy E. Reid, Jr.

BER/tbs

Enclosures:

1. Synopsis of VY QAPM Revision 8 Changes.
2. VY QAPM Revision 8.

cc: Regional Administrator, Region 1
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Enclosure 1

Vermont Yankee Nuclear Power Station

Synopsis of VY QAPM Revision 8 Changes
(1 page excluding this cover sheet)

**VERMONT YANKEE NUCLEAR POWER STATION**

**Synopsis of VY QAPM Revision 8 Changes**

**Docket Nos. 50-271, 71-0907 and 72-59**

VY QAPM Revision 8:

This change to the Vermont Yankee Nuclear Power Station (VYNPS) Quality Assurance Program Manual (QAPM) was prepared to support the transfer of the VYNPS NRC License from Entergy Nuclear Operations, Inc. to NorthStar Nuclear Decommissioning Company (NorthStar). The changes incorporated affected the organizational positions, company name, restating information from Appendix A. section C, note 1 in the policy, restating in the methodology section the graded approach to the application of the QAPM from section A.7.5 and including plans in the various examples. The final item addressed revising the Radiation Protection Manager (RPM) qualifications as defined within the NRC's Safety Evaluation Report for the License Transfer. These qualifications are equivalent to or more stringent than the qualifications defined within the QAPM Revision 7, Appendix B. The other changes included some minor formatting and grammatical changes, which are considered administrative. This review verified that the VYNPS QAPM continues to comply with 10 CFR 50 Appendix B, Standard Review Plan 17.3, NUREG-0800 and 10 CFR 50.54(a)(3). It will also continue to satisfy the requirements of 10 CFR 71 Subpart H and 10 CFR 72 Subpart G.

In summary, the QAPM changes associated with transitioning from Revision 7 to Revision 8 did not constitute a reduction in commitments to the QAPM previously accepted by the NRC.

Enclosure 2

Vermont Yankee Nuclear Power Station

VY QAPM Revision 8
(33 pages excluding this cover sheet)

# Vermont Yankee Nuclear Power Station

Docket No. 50-271
License No. DPR-28
Docket No. 72-59
Docket No. 71-0907

# Quality Assurance Program Manual

# VY QUALITY ASSURANCE PROGRAM MANUAL

## POLICY STATEMENT

NorthStar Nuclear Decommissioning Company, LLC and NorthStar Vermont Yankee, LLC (NorthStar) shall maintain and operate Vermont Yankee Nuclear Power Station (VY) in a manner that will ensure the health and safety of the public and workers. The facility shall be maintained in compliance with the requirements of the Code of Federal Regulations, the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, and applicable laws and regulations of the state and local governments.

The Quality Assurance Program (QAP) described herein and associated implementing documents provide for control of activities that affect the quality of structures, systems, and components (SSCs)classified as important-to-safety (ITS) to satisfy the requirements of 10 CFR 71 and 10 CFR 72. There are no longer any safety-related SSCs or activities remaining at VY controlled under 10 CFR 50.

The Quality Assurance Program Manual (QAPM) is the top-level policy document that establishes the manner in which quality is to be achieved and presents our overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAPM. Compliance with the QAPM and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the QAP.

Responsibility for developing, implementing, and verifying execution of the Quality Assurance Program is delegated to the nuclear executive and authority for developing and verifying execution of the program to the management position responsible for oversight.

# VY QUALITY ASSURANCE PROGRAM MANUAL

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# VY QUALITY ASSURANCE PROGRAM MANUAL

## A. MANAGEMENT

### 1. Methodology

a. The Quality Assurance Program Manual (QAPM) provides an overview of the quality program controls which governs the operation and maintenance of VY important-to-safety (ITS) items and activities. The QAPM describes the quality assurance organizational structure, functional responsibilities, levels of authority, and interfaces.

b. The requirements and commitments contained in the QAPM 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 QAPM as well as its implementation. Changes should be promptly communicated when identified.

c. The QAPM applies to all activities associated with structures, systems, and components that are ITS controlled by 10 CFR 72, as defined in Appendix A. The QAPM also applies to transportation packages controlled by 10 CFR 71. The methods of implementation of the requirements of the QAPM are commensurate with the item's or activity's importance to safety. The applicability of the requirements of the QAPM to other items and activities is determined on a case-by-case basis as defined within approved procedures. The QAPM implements 10 CFR 50 Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G.

d. The QAPM is implemented in a graded approach through the use of approved procedures (e.g., policies, directives, procedures, instructions, plans, or other documents) which provide written guidance for the control of ITS related activities (termed quality related activities) and provide for the development of documentation to provide objective evidence of compliance.

### 2. Organization

The organizational structure responsible for implementation of the QAPM is described below. The organizational structure consists of corporate and VY functions. The specific organization titles for the quality assurance functions described are identified in procedures. The authority to accomplish the quality assurance functions described is delegated to the incumbent's staff as necessary to fulfill the identified responsibility.

**A. 2. (continued)**

**a. Corporate Organization**

1. The NorthStar president is responsible for overall corporate policy and provides executive direction and guidance for the corporation as well as promulgates corporate policy through the Company's senior management staff. Responsibility for developing, implementing, and verifying execution of the Quality Assurance Program is delegated to the nuclear executive. The authority for developing and verifying execution of the program is delegated to the management position responsible for nuclear oversight.

2. The nuclear executive is responsible for providing top-level direction for the safe management of VY's nuclear site. This executive provides guidance with regards to the company quality assurance policy. The results of Independent Management Assessments are reported to this executive. The nuclear executive establishes the policies, goals, and objectives of the quality assurance policy and ensures guidance and interpretation for implementing the company quality assurance policy are provided. The management position responsible for nuclear oversight is the individual responsible for ensuring the implementation of the quality assurance program is in accordance with regulatory requirements.

**A. 2. (continued)**

**b. VY Site Organization**

The following site management positions describe the typical site QAPM functional responsibilities, which may be delegated to others as established in this document. These functions may be performed by the same individuals and may report through an additional layer of management, but shall maintain sufficient authority and organizational freedom to implement the assigned responsibilities.

1. The VY top level management position reports to the nuclear executive and is responsible for VY site activities and implementing quality assurance policies, goals and objectives. These responsibilities also include, but are not limited to functional areas, such as engineering, procurement, security, information technology, project management, emergency planning, and technical services.

2. A management position that is responsible for overall spent fuel safety operational activities is accountable for maintaining the facility within the constraints of applicable regulatory requirements and the operating license, including training. Different aspects of these responsibilities may be fulfilled by separate management positions. This management position is responsible for operation of the Independent Spent Fuel Storage Installation (ISFSI). The independent safety review function reports to the management position responsible for facility operations.

3. A management position that is responsible for engineering and technical services is responsible for the development and maintenance of engineering programs, facility design bases, policies, and procedures and for providing engineering services. Other responsibilities include licensing, corrective action program, records management, document control and information technology. Different aspects of these responsibilities may be fulfilled by separate managers.

4. The management position that is responsible for quality assurance has overall authority and responsibility for establishing, controlling, and verifying the implementation and adequacy of the quality assurance program as described in this QAPM. This position has the authority and responsibility to escalate matters directly to the nuclear executive, if necessary.

**A. 2.b. (continued)**

5. A management position that is responsible for materials, purchasing, and contracts is responsible for procurement, services, receipt, storage, and issue of materials, parts, and components. Different aspects of these responsibilities may be fulfilled by separate site managers.
6. A management position that is responsible for radiation protection and chemistry activities. This management position is responsible for the implementation of the Radiation Protection Program, Radiological Environmental Monitoring Program, Radiological Effluent Controls Program, radioactive waste shipping, Process Control Program and chemistry activities.

c. The Independent Safety Review function and Independent Management Assessments independently review activities to provide additional assurance that VY is maintained in accordance with the Operating License and applicable regulations that address nuclear safety. The independent safety review function is described in Appendix D. The Independent Management Assessment function is described in A.3.f.

**3. Responsibility**

a. VY has the responsibility for the scope and implementation of an effective quality assurance program.

b. VY 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's effectiveness.

c. VY is responsible for ensuring that the applicable portion(s) of the quality assurance program is properly documented, approved, and implemented (people are trained and resources are available) before an activity within the scope of the QAPM is undertaken by VY or by others.

d. Individual management positions are to ensure that personnel working under their management cognizance are provided the necessary training and resources to accomplish their assigned tasks within the scope of the QAPM.

**A 3. (continued)**

e. Procedures that implement the QAPM are approved by the management responsible for the applicable quality function. These procedures are to reflect the QAPM and work is to be accomplished in accordance with them.

f. The Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is effectively implemented. This Independent Management Assessment is performed by individual(s) designated by the nuclear executive, 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 nuclear executive.

**4. Authority**

a. When VY delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibilities is delegated.

b. The management position responsible for quality assurance has the responsibility and the authority to stop unsatisfactory work and control further processing, delivery, installation, or use of non-conforming items or services. Cost and schedule considerations will not override safety considerations.

**5. Personnel Training and Qualification**

a. Personnel assigned to implement elements of the quality assurance program are capable of performing their assigned tasks.

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. Additional details concerning Personnel Training and Qualification may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

**6. Corrective Action**

a. It is the responsibility of each individual to promptly identify and report conditions adverse to quality. Management at all levels encourages the identification of conditions that are adverse to quality.

**A 6. (continued)**

b. A corrective action program is established and implemented that includes prompt identification, documentation, and correction of conditions adverse to quality. The corrective action program for significant conditions adverse to quality shall require cause determination and a corrective action plan that precludes repetition.

c. Specific responsibilities within the corrective action program may be delegated, but VY maintains responsibility for the program's effectiveness.

d. Non-conforming items are properly controlled to prevent their inadvertent test, 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 trends in quality performance. Significant conditions adverse to quality and significant trends are reported to the appropriate level of management.

f. Additional details concerning corrective action activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 7. Regulatory Commitments

a. Except where alternatives are identified, VY complies with the QA guidance documents listed on Appendix B. If the guidance in one of these documents is in conflict with the QAPM, the guidance provided in the QAPM is the controlling guidance. Additionally, the following clarifications apply to all guidance documents listed in Appendix B:

1. For modifications and nonroutine maintenance of ITS SSCs, guidance applicable to construction-like activities is applicable to comparable facility activities. Except that the inspection of modifications, repairs, rework, and replacements shall be in accordance with the original design and inspection requirements or a documented approved alternative.

2. The associated clarifications as described in Appendix B apply wherever the defined term is used in the QAPM and associated guidance documents.

3. Clarification to a guidance document applies wherever the guidance document is invoked.

**A 7. (continued)**

4. In each of the standards, other documents (e.g., other standards, codes, regulations, tables, or appendices) are referenced or described. These other documents are only quality assurance program requirements if explicitly committed to in the QAPM. If not explicitly committed to, these documents are not considered as quality assurance program requirements, although they may be used as guidance.

5. Guidance is applicable to ITS SSCs, items and activities controlled by 10 CFR 72 and transportation packages controlled by 10 CFR 71. Regulatory Guide 7.10, as defined in Appendix B, provides guidance associated with quality assurance controls that are designated as ITS and the application of these controls in a graded approach. The associated ITS SSCs are defined in Appendix A.

b. The NRC is to be notified of QAPM changes in accordance with 10 CFR 50.54(a)(3) and 10 CFR 71.106 or 10 CFR 50.54(a)(4).

## B. PERFORMANCE/VERIFICATION

### 1. Methodology

a. Personnel performing work activities such as design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, modification, operation, and decommissioning are responsible for achieving acceptable quality.

b. Personnel performing 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.

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

### 2. Design Control

a. The design control program is established and implemented to assure that the activities associated with the design of systems, components, structures, and equipment and modifications thereto, are executed in a planned, controlled, and orderly manner.

**B 2. (continued)**

b. The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces.

c. Design inputs (e.g., performance, regulatory, quality, and quality verification requirements) are to be correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions).

d. The final design output is to relate to the design input in sufficient detail to permit verification.

e. The design process is to ensure that items and activities are selected and independently verified consistent with their importance to safety to ensure they are suitable for their intended application.

f. Changes to final designs (including field changes and modifications) and dispositions of non-conforming items to either use-as-is or repair are to 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.

g. 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 are defined in procedures.

h. Design documentation and records, which provide evidence that the design and design verification process was performed in accordance with this program, 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.

i. Additional details concerning design control activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

**3. Design Verification**

a. A program is established and implemented to verify the acceptability of design activities and documents for the design of items. The selection and incorporation of design inputs and design processes, 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.

**B. 3. (continued)**

c. When a test program is used to verify the acceptability of a specific design feature, the test program is to demonstrate acceptable performance under conditions that simulate the most adverse design conditions that are 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 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. Design verification shall be performed by any competent individuals or groups other than those who performed the original design but who may be from the same organization. The designer's immediate supervisor may perform the design verification provided:

1. the supervisor 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 management, and

3. the frequency and effectiveness of the supervisor's use as a design verifier are 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 are identified, the verification is satisfactorily accomplished, and the results are properly recorded.

g. Additional details concerning design verification activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

**4. Procurement Control**

a. A program is established and implemented to ensure that purchased items and services are of acceptable quality.

b. The program includes provisions for evaluating prospective suppliers and selecting only qualified suppliers.

**B. 4. (continued)**

c. The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services.

d. The program includes provisions (e.g., source verification, receipt inspection, pre-installation and post-installation tests, and certificates of conformance) for accepting purchased items and services.

e. Applicable technical, regulatory, administrative, and reporting requirements (e.g., specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are invoked for procurement of items and services.

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 procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service.

i. Appropriate controls for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and quality evaluation of commercial grade items are to be imposed to ensure that the items will perform satisfactorily in service.

j. Additional details concerning procurement control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

**5. Procurement Verification**

a. A program is established and implemented to 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. Additional details concerning procurement verification may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 6. Identification and Control of Items

a. A program is established and implemented to identify and control 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.

c. Additional details concerning identification and control of items may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 7. Handling, Storage, and Shipping

a. A program is established and implemented to 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) are specified and provided when required to maintain acceptable quality.

c. Specific procedures are 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 items' integrity and indicate the need for special controls.

e. Additional details concerning handling, storage, and shipping activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B).

## 8. Test Control

a. A test control program is established and implemented to demonstrate that items will perform satisfactorily in service.

b. Criteria are defined that specify when testing is required.

c. The test control program includes, as appropriate, proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests.

d. Test procedures are developed that include:

1. instructions and prerequisites to perform the test,
2. use of proper test equipment,
3. acceptance criteria, and
4. mandatory inspections as required.

e. Test results are evaluated to assure that test objectives and inspection requirements have been satisfied.

f. Unacceptable test results shall be evaluated.

g. Additional details concerning test control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 9. Measuring and Test Equipment Control

a. A program is established and implemented to control the calibration, maintenance, and use of measuring and test equipment. 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 practices provide adequate accuracy.

b. The types of equipment covered by the program (e.g., instruments, tools, gauges, 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, and stability characteristics and other conditions affecting its performance.

d. Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.

**B. 9. (continued)**

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. Except where calibration standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.

g. Measuring and test equipment found out of calibration is tagged or segregated. The acceptability shall be determined of items measured, inspected, or tested with an out-of-calibration device.

h. Additional details concerning measuring and test equipment control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

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

a. The status of required inspections and tests and the operating status of items 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. The application and removal of inspection, test, and operating status indicators are controlled in accordance with procedures.

c. Additional details concerning inspection, test, and operating status control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

**11. Special Process Control**

a. A program is established and implemented to ensure that special processes are properly controlled.

b. The criteria that establish which processes are special are described in procedures. The following are special processes:

1. welding,
2. heat-treating,
3. NDE (Non-Destructive Examination),
4. chemical cleaning, and

**B. 11.b (continued)**

5. unique fabricating or testing processes that require in-process controls.

c. Special processes are accomplished by qualified personnel, using appropriate equipment, and procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

d. Additional details concerning special process control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 12. Inspection

a. A program is established and implemented for inspections of activities in order to verify conformance to the 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 are to identify the characteristics and activities to be inspected, the inspection techniques, the acceptance criteria, and the organization responsible for performing the inspection.

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 the inspectors functionally report to the associated manager responsible for quality assurance.

g. Additional details concerning inspections may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 13. Corrective Action

a. Procedures shall provide for identification, evaluation, and resolution of conditions adverse to quality.

b. Reworked, repaired, and replacement items are to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

c. Additional details concerning corrective action activities may be found in Section A.6 and the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## 14. Document Control

a. A program is established and implemented to control the development, review, approval, issue, use, and revision of documents.

b. The scope of the document control program includes:

1. safety analysis report,
2. design documents,
3. procurement documents,
4. Technical Specifications,
5. procedures, manuals, and plans,
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.

f. Additional details concerning document control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

### 15. Records

a. A program is established and implemented to ensure that sufficient records of items and activities (e.g., design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits) are generated and maintained to reflect completed work.

b. The program provides provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of records.

c. 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.

d. Additional details concerning record requirements may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## C. AUDIT

### 1. Methodology

a. Personnel responsible for carrying out audits are maintained cognizant of day-to-day activities by the ongoing involvement in the quality assurance program requirements so that they can act in a management advisory function.

b. Organizations performing audits are to be technically and performance oriented commensurate with the activity being reviewed.

c. Personnel performing audits have no direct responsibilities in the area they are assessing.

d. Audits are 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. A program of planned and periodic audits is established and implemented to confirm that activities affecting quality comply with the QAPM and that the QAPM has been implemented effectively. Audit frequencies will be implemented as required by the applicable Code of Federal Regulations, safety analysis report, and commitments by various correspondences to the NRC. Audits will be conducted at a frequency in accordance with either Section C.2.a.1 or Section C.2.a.2 below.

1. Audit frequencies are determined based on regulatory commitments or site requirements.

2. Audit schedules assure that the following areas are audited at the indicated frequencies, or more frequently as performance dictates.

a. The conformance of each unit's operation to provisions contained within the Technical Specifications and applicable license conditions is audited at least once every 24 months.

b. The performance, training, and qualifications of the entire staff are audited at least once every 24 months.

c. The results of actions taken to correct deficiencies occurring in unit equipment, structure, systems, or method of operation that affect nuclear safety is audited at least once every 24 months.

d. The performance of activities required by the QAPM to meet the criteria of 10 CFR 50, Appendix B is audited at least once every 24 months.

e. The Offsite Dose Calculations Manual and Process Control Program and implementing procedures are audited at least once every 24 months.

f. The radiological environmental monitoring program and the results thereof is audited at least once every 24 months.

g. The fire protection program and implementing procedures audit shall be performed at least once every 24 months.

**C. 2. (continued)**

3. A grace period of 90 days may be applied to the 24-month frequency for internal audits. For activities deferred in accordance with the 90-day grace period, the next performance due date will be based on their originally scheduled date.

4. The audit schedule for the ISFSI may combine audits to cover the areas defined in section C.2.a.2 that are invoked by the ISFSI technical specifications.

b. Audits shall provide an objective evaluation of quality related practices, procedures, instructions, activities, and items and a review of documents and records, as applicable.

c. Audits shall be performed in accordance with approved written procedures or checklists. Items from previous audits shall be reviewed and reaudited, as appropriate. The checklists are used as guides to the auditor.

d. Scheduling and resource allocation are based on the status and safety importance of the activity or process being assessed.

e. Scheduling is dynamic and resources are supplemented when the effectiveness of the quality assurance program is in doubt.

f. Audit reports are written and distributed to the appropriate levels of management for review. Follow-up action, including re-look at deficient areas, is initiated as deemed appropriate.

g. Implementation of delegated portions of the quality assurance program is assessed.

h. Audits are conducted using predetermined acceptance criteria.

i. Additional details concerning audits may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B.

## D. INDEPENDENT SAFETY REVIEW

### 1. Description

a. The independent safety review function is described in Section A.2.c and Appendix D, Section 1.0.

# Appendix A

## 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 safety related and Important-to-Safety SSCs associated with spent fuel storage and transportation package.

**NOTE**

**The safety classification of systems, structures and components (SSCs) at the VY facility and the VY Independent Spent Fuel Storage Installation (ISFSI) may be revised based on engineering evaluations and a revision to the VY safety analysis report. These modifications are controlled in accordance with the design control process and are not considered a reduction in the commitments to the QAPM.**

**The quality classification of NRC Licensed ISFSI Dry Fuel Storage Components and Transportation Packages may not be revised using the VY 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. VY 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).**

Safety related SSCs are defined within the site specific system safety function sheet process and are controlled through engineering processes.

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-SAFTY AS DEFINED BY 10 CFR 71 AND 10 CFR 72**

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

| SSC | Quality Category | Design/Licensee Responsible |
|---|---|---|
| Multipurpose Canister and Fuel Basket Assembly | A | Holtec Intl. |
| Vertical Concrete Cask | B | Holtec Intl. |
| ISFSI Pad | C | VY |
| Lifting Yoke | A | Holtec Intl. |
| Damaged Fuel Container | C | Holtec Intl. |

# Appendix A

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

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

| SSC | Quality Category | Design/Licensee Responsible |
|---|---|---|
| Multipurpose Canister and Fuel Basket Assembly | A | Holtec Intl. |
| Damaged Fuel Container | C | Holtec Intl. |
| Transportable Storage Canister and Basket Assembly For GTCC Waste Containers | A | TBD |
| Transport Cask | A | Holtec 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. There are no longer any safety related SSCs at the VY facility.

2. See Holtec Intl. Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information. Holtec defines the classification of the SSCs and VY reflects this information in Appendix A for those SSCs described.

3. See Holtec Transport Cask Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information.

4. For the definition of Quality Categories A, B, and C refer to NUREG/CR-6407.

5. VY procedures define the safety classification assigned to the ISFSI pad.

# Appendix B
# Regulatory Commitments

## A. Regulatory Guide 1.8 Revision 1, dated September 1975

| | | Clarification/Exception |
|---|---|---|
| 1. | General | VY is committed to Sections 1 – 4 of ANSI/ANS 3.1-1978 with following clarifications and exceptions.<br><br>Qualification requirements for personnel shall meet ANSI/ANS 3.1-1978 except the following:<br><br>a. The radiation protection manager shall meet or exceed the qualifications of ANSI/ANS 3.1-2014 (Section 4.3.3, Radiation Protection). |
| 2. | General | The following qualifications may be considered equivalent to a bachelor's degree:<br><br>a. 4 years of post-secondary schooling in science or engineering,<br><br>b. 4 years of applied experience at a nuclear facility in the area for which qualification is sought,<br><br>c. 4 years of operational or technical experience/training in nuclear power, or<br><br>d. any combination of the above totaling 4 years.<br><br>Years of experience used to meet the education requirements as allowed by this exception shall not be used to also meet the experience requirements. |

# Appendix B
# Regulatory Commitments

| | | |
|---|---|---|
| **3.** | ANSI/ANS 3.1 Section 4 | Individuals assigned to professional-technical comparable positions shall have the authority and specified qualifications to accomplish the functional responsibilities of the position. |
| **4.** | ANSI/ANS 3.1 Section 4.4.5 | Individuals who do not possess the formal education and minimum experience requirements for the manager responsible for quality assurance should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management. As a minimum, the Special Requirements of ANSI/ANS 3.1-1993 Section 4.3.7 must be met if the manager responsible for Quality Assurance does not meet the requirements of section 4.4.5 of ANSI/ANS 3.1-1978. |
| **5.** | ANSI/ANS 3.1 Section 5 | VY will maintain a training program for the unit staff that meets the applicable regulations and meets the standards of section 5 of ANSI/ANS 3.1-1978. |

# Appendix B
# Regulatory Commitments

A. Regulatory Guide 7.10, Revision 3 (6/15), "Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material" is used as a guidance document.

B. NUREG/CR-6407, "Classification of Transportation Packaging and Dry Fuel Storage System Components According to Important to Safety (2/96)" is used as a guidance document.

# Appendix C

## Other General Guidance Documents

Documents Deleted-not currently used.

# Appendix D
# Administrative Controls

## 1.0 INDEPENDENT SAFETY REVIEW

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 proposed activities.

1. 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.

2. Independent Safety Reviewers shall have at least 5 years of professional experience and either a Bachelor's Degree in Engineering or the Physical Sciences or shall have equivalent qualifications in accordance with ANSI/ANS 3.1-1978. The manager responsible for the overall operational activities (or designee) shall document the appointment of Independent Safety Reviewers.

3. The following subjects shall be independently reviewed by a qualified Independent Safety Reviewer:

   a) Evaluations for changes to the facility as described in the Defueled Safety Analysis Report (DSAR). Changes to procedures as described in the DSAR and tests or equipment not described in the DSAR to verify that such actions do not involve a change to the Technical Specifications or will not require prior NRC approval as defined in 10 CFR 50.59 or 10 CFR 72.48, and

   b) Proposed changes to the programs required by the Technical Specifications to verify that such changes do not involve a change to the Technical Specifications or will not require prior NRC approval as defined in 10 CFR 50.59 or 10 CFR 72.48.

## 2.0 ADMINISTRATIVE CONTROLS RELOCATED FROM TECHNICAL SPECIFICATIONS

The following information was administrative controls relocated from the defueled Technical Specifications.

### 2.1 RESPONSIBILITY

A. The management position responsible for overall operational activities shall delegate in writing the succession to this responsibility during absences.

B. The management position responsible for overall operational activities or designee shall approve, prior to implementation, each proposed test, experiment, or modification to systems or equipment that affect nuclear safety.

## 2.2 ORGANIZATION

A. Onsite and Offsite Organizations

Organizations shall be established for facility staff and corporate management. These organizations shall include the positions for activities affecting safety of the nuclear fuel.

1. Lines of authority, responsibility, and communication shall be established and defined for the highest management levels through intermediate levels to and including all operating organizational positions. These relationships shall be documented and updated, as appropriate, in the form of organizational charts, functional descriptions of departmental responsibilities and relationships, and job descriptions for key personnel positions, or in equivalent forms of documentation. These requirements shall be documented in the Quality Assurance Program Manual. The plant-specific titles of those personnel fulfilling the responsibilities of the positions delineated in these requirements shall be documented.

2. The management position responsible for overall operational activities shall have control over those on-site activities necessary for safe storage and maintenance of the nuclear fuel.

3. A specified corporate officer (nuclear executive) shall have corporate responsibility for overall site nuclear safety and shall take any measures needed to ensure acceptable performance of the staff in operating, maintaining, and providing technical support to the facility to ensure safe management of nuclear fuel.

4. The individuals who carry out health physics, or perform quality assurance functions may report to the appropriate on-site management position; however, these individuals shall have sufficient organizational freedom to ensure their ability to perform their assigned functions.

B. Facility Staff Qualifications

1. Each member of the facility staff shall meet or exceed the minimum qualifications of ANSI/ANS 3.1-1978 for comparable positions with exceptions specified in the Quality Assurance Program Manual (QAPM).

## 3 PROCEDURES

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

A. Normal startup, operation and shutdown of systems and components needed for the safe storage of nuclear fuel.

B. Actions to be taken to correct specific and foreseen potential malfunctions of

systems or components needed for the safe storage of nuclear fuel.

C. Emergency conditions involving potential or actual release of radioactivity.

D. Preventative and corrective maintenance operations which could have an effect on the safety of the nuclear fuel.

E. Surveillance and testing requirements.

F. Fire protection program implementation.

G. Process Control Program in-plant implementation.

H. Off-Site Dose Calculation Manual implementation

## 2.4 REPORTING REQUIREMENTS

The following reports shall be submitted in accordance with 10 CFR 50.4.

A. Radioactive Effluent Release Report

The Radioactive Effluent Release Report covering the operation of the facility shall be submitted by May 15 of each year and 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 facility. The material provided shall be consistent with the objectives outlined in the Offsite Dose Calculation Manual (ODCM) and Process Control Program and in conformance with 10 CFR 50.36a and 10 CFR 50, Appendix I, Section IV.B.1.

B. Annual Radiological Environmental Operating Report

The Annual Radiological Environmental Operating Report covering the operation of the facility during the previous calendar year shall be submitted by May 15 of each year. The report shall include summaries, interpretations, and an analysis of trends of the results of the radiological environmental surveillance activities for the report period. The material provided shall be consistent with the objectives outlined in the Offsite Dose Calculation Manual (ODCM) and in 10 CFR 50, Appendix I, Sections IV.B.2, IV.B.3, and IV.C.

The Annual Radiological Environmental Operating Report shall include summarized and tabulated results of all radiological environmental samples taken during the report period pursuant to the table and figures in the ODCM. In the event that some 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 as soon as possible in a supplementary report.

## 2.5 PROGRAMS AND MANUALS

The following programs shall be established, implemented and maintained:

A. OFF-SITE DOSE CALCULATION MANUAL (ODCM)

An Off-Site Dose Calculation Manual shall contain the current methodology and parameters used in the calculation of off-site doses due to radioactive gaseous and liquid effluents for the purpose of demonstrating compliance with 10 CFR 50, Appendix I, in the calculation of gaseous and liquid effluent monitoring alarm/trip setpoints, and in the conduct of the environmental radiological monitoring program.

The ODCM shall also contain the radioactive effluent controls and radiological environmental monitoring activities and descriptions of the information that should be included in the Radioactive Effluent Release Report and the Annual Radiological Environmental Operating Report.

1. Licensee initiated changes to the ODCM:

   a. Shall be submitted to the Commission in the Radioactive Effluent Release Report for the period in which the change(s) was made effective. This submittal shall contain:

      i. Sufficient information to support the change together with appropriate analyses or evaluations justifying the change(s) and

      ii. A determination that the change will maintain the level of radioactive effluent control required by 10 CFR 20.1302, 40 CFR 190, 10 CFR 50.36a, and Appendix I to 10 CFR Part 50, and do not adversely impact the accuracy or reliability of effluent dose or setpoint calculations.

   b. Shall become effective upon approval by the manager responsible for overall operational activities.

   c. Shall be submitted to the Commission in the form of a legible copy of the affected pages of the ODCM as a part of or concurrent with the Radioactive Effluent Release Report for the period of the report in which any change to 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 (e.g., month/year) the change was implemented.

B. Radioactive Effluent Controls Program

This program conforming to 10 CFR 50.36.a provides for the control of radioactive effluents and for maintaining the doses to members of the public from radioactive effluents as low as reasonably achievable. The program shall be contained in the ODCM, shall be implemented by operating

procedures, and shall include remedial actions to be taken whenever the program limits are exceeded. The program shall include the following elements:

a. Limitations on the functional capability of radioactive liquid and gaseous monitoring instrumentation, including surveillance tests and setpoint determination in accordance with the methodology in the ODCM;

b. Limitations on the concentrations of radioactive material released in liquid effluents from the site to unrestricted areas, conforming to 10 times the concentration values in Appendix B, Table 2, Column 2, to 10 CFR 20.1001 - 20.2402;

c. Monitoring, sampling, and analysis of radioactive liquid and gaseous effluents pursuant to 10 CFR 20.1302 and with the methodology and parameters in the ODCM;

d. Limitations on the annual and quarterly doses or dose commitment to a member of the public from radioactive materials in liquid effluents released from the facility to unrestricted areas, conforming to 10 CFR 50, Appendix I;

e. Determination of cumulative and projected dose contributions from radioactive effluents for the current calendar quarter and current calendar year in accordance with the methodology and parameters in the ODCM at least every 31 days;

f. Limitations on the functional capability and use of the liquid and gaseous effluent treatment systems to ensure that appropriate portions of these systems are used to reduce releases of radioactivity when the projected doses in a period of 31 days would exceed 2 percent of the guidelines for the annual dose or dose commitment, conforming to 10 CFR 50, Appendix I;

g. Limitations on the dose rate resulting from radioactive material released in gaseous effluents from the site to areas at or beyond the site boundary shall be limited to the following:

    1. For tritium, and for all radionuclides in particulate form with half lives greater than 8 days: less than or equal to a dose rate of 1500 mrems/yr to any organ;

h. Limitations on the annual and quarterly doses to a member of the public from tritium, and all radionuclides in particulate form with half lives greater than 8 days in gaseous effluents released from the facility to areas beyond the site boundary, conforming to 10 CFR 50, Appendix I; and

i. Limitations on the annual dose or dose commitment to any member of the public, beyond the site boundary, due to releases of radioactivity and to radiation from uranium fuel cycle sources, conforming to 40 CFR 190.