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CNRO-2018-00016  
BVY 18-012

April 12, 2018

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

SUBJECT: 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.

Vermont Yankee Nuclear Power Station  
Docket No. 50-271  
License No. DPR-28  
Docket No. 72-59  
Docket No. 71-0907

- REFERENCES:
1. Letter, Entergy Nuclear Operations, Inc., to USNRC, "Technical Specifications Proposed Change No. 313, Revision to License and Permanently Defueled Technical Specifications to Reflect Permanent Removal of Spent Fuel from the Spent Fuel Pool," BVY 17-004, dated July 20, 2017 (ML17206A200)
  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)

Dear Sir or Madam:

Entergy Nuclear Operations, Inc., (ENO) is submitting the Entergy Vermont Yankee Quality Assurance Program Manual (VY QAPM) in accordance with 10 CFR 50.54(a)(3) and 10 CFR 71.106. The last submittal, dated April 4, 2016, encompassed VY QAPM Revision 3. Since that date there have been two updates, Revisions 4 and 5, incorporated to the VY QAPM. A synopsis of each revision is provided as Enclosure A. The 10 CFR 50.54(a)(3) and 10 CFR 71.106 evaluations are included as Enclosure B. The VY QAPM Revision 5, which encompasses Revision 4, remains effective and is included as Enclosure C. Revision 5 has an effective date of September 7, 2016.

There are two pending changes to the VY QAPM, Revision 6 and Revision 7. Revision 6 is based on changes proposed by a License Amendment Request (LAR) to revise the License 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) (Reference 1). Proposed changes in the LAR include the relocation of certain administrative controls from the facility Technical Specifications to the QAPM. Revision 6 is anticipated to be implemented following NRC approval of Reference 1. Revision 7 is also a pending change which has been submitted to NRC for prior approval and is a substantial revision to the VY QAPM which reflects the decommissioning status of the VY facility with all spent fuel in dry storage on the VY ISFSI (Reference 2). The proposed Revision 7 is a reduction in commitment since, along with other changes, the program basis will be changed from the ANSI/ANS standards to use primarily Regulatory Guide 7.10 "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material", Revision 3. The highest level of safety significance items at the VY facility will be items designated as Important to Safety (ITS) under 10 CFR 71 and 10 CFR 72. There will not be any safety-related structures, systems or components at the VY facility as defined in 10 CFR 50 Appendix B. Once Reference 2 is approved, Revision 7 will be implemented consistent with, but not earlier than, the implementation schedule described in Reference 1.

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 Appendix B. 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.

This letter contains no new regulatory commitments.

Should you have any questions, please contact Mr. Edward D. Harris, Manager - QA at (601) 368-5649.

Sincerely,



OL/EDH/BLH

- Enclosures:
- A. Synopsis of Entergy VY QAPM Revision Changes, Revisions 4 and 5 (1 page)
  - B. Entergy VY QAPM Revision 10 CFR 50.54(a)(3) AND 10 CFR 71.106 Evaluation Forms and Affected Pages (44 pages)
  - C. Entergy VY QAPM Revision 5 (58 pages)



cc: C. Bakken (ECH)  
C. Constanza (ECH)  
O. Limpas (ECH)  
C. Daniels (VY)  
C. Chappell (VY)  
K. Jury (ECH)  
M. Halter (ECH)  
R. Gaston (ECH)  
B. S. Ford (ECH)

All above w/o enclosures

NRC Region I Administrator  
NRC Project Manager (VY)  
Vermont Department of Public Service

Enclosure A  
CNRO2018-00016  
Synopsis of Entergy VY QAPM Revision Changes  
Revisions 4 and 5

## Synopsis of QAPM Revision Changes

### VY QAPM Revision 4:

This revision to the QAPM included both administrative and reduction in commitment changes. The administrative changes were made to Organization section to reflect changes to the VY site specific organization that is responsible for the implementation of the QAPM functions.

- The changes added new managerial positions responsible for ISFSI construction, dry fuel transfer activities, radiation protection and chemistry.
- Responsibilities were realigned for other positions, but there is no overall change to the reporting function, which continues to report through a site executive up to the chief nuclear officer.

The reduction in commitment changes were as follows:

- Clarified the applicability of the QAPM to safety related and important to safety items and activities,
- Removed the need for maintaining NRC Licensed Operators as part of the site organization,
- Clarified the Certified Fuel Handler Training program requirements,
- Added an exception to ANSI/ANS 3.1-1978 to allow nuclear power plant experience to include experience acquired at a defueled reactor site directly related to the storage or handling of spent fuel in a spent fuel pool.
- States that individuals will obtain the necessary onsite experience to fill the position of Certified Fuel Handlers or operators, based on assigned functions and validation of equivalent training and experience rather than requiring at least 6 months of nuclear power plant experience to be attained a Vermont Yankee,
- Included changes involving the transitioning of the onsite-review function to an independent review function and modifying the function of the off-site safety review to reflect the complexity of operation of a decommissioning facility. This change also included a description of the independent safety review and safety review committee organizational structure, functional responsibilities, level of authorities, and interfaces.

### ENTERGY VY QAPM Rev. 5

This revision to the QAPM included the following reduction in commitment changes (previously NRC approved Rev.4):

- Clarified the applicability of the QAPM to safety related and important to safety items and activities,
- Clarified the Certified Fuel Handler Training program requirements,
- Added an exception to ANSI/ANS 3.1-1978 to allow nuclear power plant experience to include experience acquired at a defueled reactor site directly related to the storage or handling of spent fuel in a spent fuel pool.
- States that individuals will obtain the necessary onsite experience to fill the position of Certified Fuel Handlers or operators, based on assigned functions and validation of equivalent training and experience rather than requiring at least 6 months of nuclear power plant experience to be attained a Vermont Yankee,
- Included changes involving the transitioning of the onsite-review function to an independent review function and modifying the function of the off-site safety review to reflect the complexity of operation of a decommissioning facility. This change also included a description of the independent safety review and safety review committee organizational structure, functional responsibilities, level of authorities, and interfaces..



Enclosure B  
CNRO2018-00016  
Entergy VY QAPM Revision 10 CFR 50.54(a)(3) and 10 CFR 71.106  
Evaluation Forms and Affected Pages  
Revisions 4 and 5

**10 CFR 50.54(a) Evaluation**

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

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

	YES	NO	N/A
<p>1. Is this change an editorial change as defined in 10CFR 50.54(a)(3)? (If yes, provide basis, mark remaining questions "N/A" and state "not a reduction in commitment") Proceed to approval page of attachment.</p> <p>Basis for Answer: The proposed changes are not considered editorial as defined in 10 CFR 50.54(a)(3). See the Attachment A for the details of each change.</p>		X	
<p>2. For any YES answer in the 10 CFR 50.54(a) Screen or for the QA-initiated change, does the proposed change represent a reduction in commitment or process(es) described or established in the approved QA Program?</p> <p>Basis for Answer: Appendix B was modified to eliminate redundant training commitments between Licensed Basis Documents. The requirements for the training and qualification of Certified Fuel Handlers (CFH) are described in the VY approved Technical Specifications.</p>	X		
<p>3. If item 2 above is YES, does the proposed change include the basis to conclude that the revised program incorporating the change continues to meet the criteria of 10CFR50, Appendix B and other previously accepted USAR commitments?</p> <p>Basis for Answer: The revised Technical Specification (TS) 6.2.C was issued in Amendment No. 260 to the VYNPS Administrative Controls Technical Specifications, by letter from NRC to Entergy, dated December 22, 2014 (ADAMS Accession No. ML14217A072). The Safety Evaluation statements related to revised TS 6.2.C.2</p>	X		

	YES	NO	N/A
reference the Certified Fuel Handler training and retraining program for VY, approved by the NRC staff on October 1, 2014 (ADAMS Accession No. ML14162A209), and concluded that this TS appropriately requires the establishment and maintenance of a program to train and retrain Certified Fuel Handlers for positions requiring such qualification that are specified in the TS.			
<p>4. Is the proposed change a change to a QA standard approved by the NRC which is more recent than the QA standard currently established in the Program?</p> <p>Basis for Answer: This review ensures continued compliance with 10CFR50 Appendix B, NUREG-0800 and 10CFR50.54(a)(3) commitments.</p>			X
<p>5. Is the proposed change a change involving the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles?</p> <p>Basis for Answer: A number of changes were made with the Organization section to reflect changes to the proposed VY site specific organization that is responsible for the implementation of the QAPM functions. The changes add new positions responsible for ISFSI construction, fuel transfer activities, radiation protection and chemistry. Responsibilities are realigned for other positions, but there is no overall change to the reporting function, which continues to report through a site senior management position up to the chief nuclear officer.</p> <p>The site organizational positions and responsibilities continue to report up through a site executive with ultimate reporting to the chief nuclear officer. Generic titles continue to be used, which is consistent with Revisions 0, 1, 2 and 3 of the VY QAPM. These generic position titles remain in lower case in keeping with QAPM format and 10CFR50.54(a)(3).iii that allows "the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles."</p>	X		



	YES	NO	N/A
<p>6. Is the proposed change a change involving the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternately, the use of descriptive text?</p> <p>Basis for Answer: The VY QAPM does not use organizational charts to indicate functional relationships, authorities, or responsibilities.</p>			X
<p>7. Is the proposed change an elimination of Quality Assurance Program information that duplicates language in Quality Assurance Regulatory Guides and Quality Assurance Standards to which EN is committed?</p> <p>Basis for Answer: This revision does not eliminate a quality assurance standard to which the QAPM commits to, as denoted in Appendix B of the QAPM.</p>			X
<p>8. Does the proposed change continue to ensure that persons and organizations performing Quality Assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations?</p> <p>Basis for Answer: This revision changes the VY organization as defined in the VY QAPM due to the addition of new manager level positions to the VY organizational structure that are responsible for ISFSI construction and fuel transfer activities and also realigns some responsibilities. The changes add new positions responsible for ISFSI construction, fuel transfer activities, radiation protection and chemistry. Responsibilities are realigned for other positions, but there is no overall change to the reporting function, which continues to report through a site senior management position up to the chief nuclear officer. No responsibilities as previously committed to were eliminated.</p> <p>No changes were made to the nuclear oversight organization. The vice president oversight remains responsible for governance and implementation of the Quality Assurance Program in accordance with regulatory requirements and the establishment of policies, goals, and objectives of the quality assurance</p>	X		

	YES	NO	N/A
<p>policy. This position provides guidance and interpretation for implementing the company quality assurance policy. Organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations. This revision does not change the reporting relationship of this executive up to the chief nuclear officer.</p> <p>The organizational related changes are not reductions in commitments. The changes are enhancements to improve site organizational alignment support a shutdown facility and continue to maintain adequate independence between the performing and verifying activities. No responsibilities were eliminated. See the Attachment A for details of the proposed changes.</p>			
<p>9. Is a change to the QAPM required? If YES, process change per EN-LI-113. If NO, distribute as indicated below.</p> <p>Basis for Answer: The changes to organizational responsibilities and other minor changes are considered administrative and do not impact the ultimate reporting relationship with the chief nuclear officer. The quality assurance function continues to report up through the senior management position responsible for nuclear oversight to the chief nuclear officer. The executive management position and the quality assurance organization (through the nuclear oversight executive) continue to report to the chief nuclear officer, which is consistent with previous organizational relationships for the QAPM functions. New positions of manager responsible for ISFSI construction and fuel transfer activities and a manager responsible for radiation protection and chemistry have been added to the organization. These clarifications and administrative changes do not constitute a reduction in commitment to the previously approved QAPM as defined in 10CFR50.54(a)(3). See the Attachment A for details of the proposed changes.</p>	X		

## 10 CFR 50.54 REVIEW RESULTS

- ☐ Change is editorial in accordance with 10CFR50.54(a)(3) and thus, does not represent a reduction in commitment. The change can be implemented upon approval of parent change document. (Question 1 is YES)
- ☒ Does not represent a reduction of commitment, and can be implemented upon approval of parent change document. (Questions 5, 6, 7, 8, and 9 are YES or N/A)
- ☐ Represents a reduction of commitment with prior NRC approval for another Licensee. The safety evaluation issued by the NRC has been evaluated and it directly applies to the changes being proposed for EN. The change can be implemented upon approval of parent change document. (Question 3 is YES)
- ☐ Represents a reduction of commitment; however, the change has sufficient basis to demonstrate continued compliance with Appendix B and USAR commitments. Therefore, the proposed change should be submitted for NRC review/approval. (Questions 2 and 4 are YES)
- ☐ Represents a reduction of commitment with insufficient basis to demonstrate continued compliance. Therefore, the activity should not be processed. (Question 4 is NO)

Norman Ernst / [Signature] , 4/25/2016  
Corporate Quality Assurance Department Preparer Date

[Signature] , 4/25/2016  
Manager, Corporate QA Approver Date

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



CHANGE DISPOSITION

- ☒ Approved for implementation
- ☐ Disapproved
- ☐ Approved for submittal to the NRC

Approved by Date:



Vice President, Oversight

4/25/16

Date

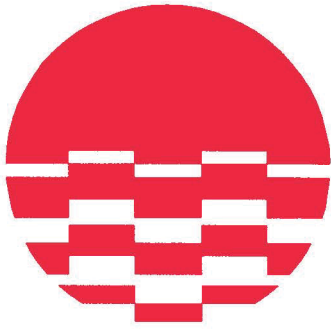
**Attachment A**  
**Supporting Information for the 10CFR50.54.a Evaluation**

<b>QAPM Section</b>	<b>Change(s)</b>	<b>Evaluation and Justification</b>	<b>Reduction in Commitment?</b>
<b><i>Cover Page</i></b>			
No changes		N/A	N/A
<b><i>Policy Statement</i></b>			
	Modified CNO title to lower case, and replaced executive responsible for oversight for the Vice President Nuclear Oversight to be consistent with the corporate oversight description in section A.2.a	This is an administrative change that does not involve a reduction in commitment.	No
<b><i>Table of Contents</i></b>			
	Aligned sections with starting page numbers.	This is an administrative change that does not involve a reduction in commitment.	No
<b><i>Section A - Management</i></b>			
A.1	The changes clarify procedures as the administrative controls.	This is an administrative change that does not involve a reduction in commitment.	No
A.2	A number of changes were made with the Organization section to reflect changes to the proposed VY site specific organization that is responsible for the implementation of the QAPM functions. The changes add new positions responsible for ISFSI construction, fuel transfer activities, radiation protection and chemistry. Responsibilities are realigned for other	These changes to the titles and organizational responsibilities are considered administrative and do not impact the ultimate reporting relationship with the chief nuclear officer. The quality assurance function continues to report up through the senior management position responsible for nuclear oversight to the chief nuclear officer. The senior management position and the quality assurance organization (through the nuclear oversight executive) continue to report to the chief nuclear officer,	No

<b>QAPM Section</b>	<b>Change(s)</b>	<b>Evaluation and Justification</b>	<b>Reduction in Commitment?</b>
	positions, which continues to report through a site senior management position up to the chief nuclear officer.	which is consistent with previous organizational relationships for the QAPM functions. New positions of manager responsible for ISFSI construction and fuel transfer activities and a manager responsible for radiation protection and chemistry have been added to the organization. These clarifications and administrative changes do not constitute a reduction in commitment to the previously approved QAPM.	
A.3 to 7	No changes	N/A	N/A
<b>Section B - Performance/Verification</b>			
	No changes	N/A	N/A
<b>Section C - Audit</b>			
	No changes	N/A	N/A
<b>Section D – Independent Safety Review Function</b>			
	No changes	N/A	No
<b>Appendix A – Safety Related and Important-to-Safety Structures, Systems and Components</b>			
	A minor editorial change was made to a note.	This is an administrative change and does not constitute a reduction in commitment to the previously approved QAPM	No
<b>Appendix B – Regulatory Commitments</b>			
	The appendix has been modified to reflect “A Certified Fuel Handler shall be qualified in accordance with the Technical Specifications.”	This is an administrative change and does not constitute a reduction in commitment to the previously approved QAPM. The appendix was changed to eliminate redundant commitments between Licensed Basis	No



QAPM Section	Change(s)	Evaluation and Justification	Reduction in Commitment?
		<p>Documents. The requirements for the training of and qualification of CFH are described in Technical Specifications. The revised Technical Specification (TS) 6.2.C was issued in Amendment No. 260 to the VYNPS Administrative Controls Technical Specifications, by letter from NRC to Entergy, dated December 22, 2014 (ADAMS Accession No. ML14217A072). The Safety Evaluation statements related to revised TS 6.2.C.2 reference the Certified Fuel Handler training and retraining program for VY, approved by the NRC staff on October 1, 2014 (ADAMS Accession No. ML14162A209), and concluded that this TS appropriately requires the establishment and maintenance of a program to train and retrain Certified Fuel Handlers for positions requiring such qualification that are specified in the TS.</p>	
<b>Appendix C – Other General Guidance Documents</b>			
No changes		N/A	N/A
<b>Appendix D – Administrative Controls</b>			
No changes		N/A	N/A



# *Entergy*

## **Vermont Yankee Nuclear Power Station**

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

## **Quality Assurance Program Manual**



### POLICY STATEMENT

Entergy Nuclear Vermont Yankee, LLC (ENVY) and Entergy Nuclear Operations, Inc. (ENOI) 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 operated 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 safety-related nuclear plant structures, systems, and components (SSCs). The QAP is also applied to SSCs classified as important-to-safety (ITS) to satisfy the requirements of 10CFR71 and 10CFR72. Approved administrative controls are also used to implement controls for certain quality-related equipment and activities that are not safety-related, but support safe storage of spent fuel, or where other regulatory or industry guidance establishes program requirements.

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 chief nuclear officer (highest level nuclear executive) and authority for developing and verifying execution of the program to the executive responsible for oversight.

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**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 quality related 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 safety related or 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 through the use of approved procedures (e.g., policies, directives, procedures, instructions, or other documents) which provide written guidance for the control of 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.b. (continued)

1. The VY executive management position reports to the chief nuclear officer 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. The manager responsible for overall 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 managers. This manager is responsible for operation of the Independent Spent Fuel Storage Installation (ISFSI). The onsite safety review function reports to the manager responsible for facility operations.
3. A manager 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. A manager responsible for quality assurance who 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 highest level nuclear executive officer when needed. This position reports to the executive responsible for nuclear oversight through the corporate management position responsible for nuclear oversight (offsite).
5. A manager 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. Supply chain and information technology are no longer a functional area exclusively within the nuclear organizational structure. However, the oversight and governance of these functional areas remain within the nuclear organization through the VY executive management position. The site personnel organizationally report to an executive (supply chain – offsite) who has a functional interface with the VY executive management position.

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

6. A manager responsible for fuel transfer and storage related activities. This manager is responsible for construction of the ISFSI pad and facility and fuel transfer activities.
  7. A manager responsible for radiation protection and chemistry activities. This manager 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 on-site and off-site safety review function independently reviews activities to provide additional assurance that VY is maintained in accordance with the Operating License and applicable regulations that address nuclear safety.

**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 managers 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.
- 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.

**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 manager 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.



## Appendix A

### SAFETY RELATED AND 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-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
Multipurpose Canister and Fuel Basket Assembly	A	Holtec Intl.
Vertical Concrete Cask	B	Holtec Intl.
Transfer Cask and Adapter Plate	B	Holtec Intl.
ISFSI Pad	C	VY
Lifting Yoke	B	Holtec Intl.
Damaged Fuel Can	A	Holtec Intl. (Later)

## 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.

Qualification requirements for personnel shall meet ANSI/ANS 3.1-1978 except the following:

- a. The radiation protection manager shall meet or exceed the qualifications of Regulatory Guide 1.8, Revision 2, 1987.
- b. Managers required to be a Certified Fuel Handler are specified in the Technical Specifications.
- c. **A Certified Fuel Handler shall be qualified in accordance with the Technical Specifications.**

Individuals filling positions who met the previous commitment at the time of implementation of this commitment can be considered to meet any more restrictive aspects of the requirements of this commitment for that position without further review and documentation.

##### 2. General

The following qualifications may be considered equivalent to a bachelor's degree:

- a. 4 years of post-secondary schooling in science or engineering,
- b. 4 years of applied experience at a nuclear facility in the area for which qualification is sought,
- c. 4 years of operational or technical experience/training in nuclear power, or
- d. any combination of the above totaling 4 years.

Years of experience used to meet the education requirements as allowed by this exception shall not be used to also meet the experience requirements.

**10 CFR 50.54(a) Evaluation**

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

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

	YES	NO	N/A
<p>1. Is this change an editorial change as defined in 10 CFR 50.54(a)(3)? (If yes, provide basis, mark remaining questions "N/A" and state "not a reduction in commitment") Proceed to approval page of attachment.</p> <p>Basis for Answer: The proposed changes are not considered editorial as defined in 10 CFR 50.54(a)(3).</p>		X	
<p>2. For any YES answer in the 10 CFR 50.54(a) Screen or for the QA-initiated change, does the proposed change represent a reduction in commitment or process(es) described or established in the approved QA Program?</p> <p>Basis for Answer: The changes to be implemented are a reduction in commitments to the previously approved program. These were previously submitted to the NRC and were not implemented in Revision 4 of the QAPM because the reductions in commitments had not been approved by the NRC. Specifically, there are three (3) changes that are considered a reduction in commitments that will be implemented in Revision 5. The three (3) changes that are considered a reduction in commitments to the previously approved program are as follows:</p> <ul style="list-style-type: none"> <li>• Reduction with the applicability of the QAPM to only include safety-related and important-to-safety (ITS) structures, systems and components (SSCs) and associated activities.</li> <li>• Addition of exceptions to ANSI/ANS 3.1-1978 regarding staff qualification requirements, specifically with requirements for prior experience.</li> <li>• Addition of exceptions to ANSI N18.7 regarding the on and off-site review functions, which specifically</li> </ul>	X		



	YES	NO	N/A
<p>includes the applicable requirements within Appendix D of the QAPM.</p> <p>These changes were submitted to the NRC and have been reviewed and approved under NRC Letter from Jack D. Parrott, Senior Project Manager to Mr. Michael Perito, "Entergy Vermont Yankee Quality Assurance Program Manual and Independent Spent Fuel Storage Facility – Review and Acceptance of Changes (CAC NO. L53120)" dated June 16, 2016. Revision 5 of the QAPM will implement these previously approved changes.</p>			
<p>3. If item 2 above is YES, does the proposed change include the basis to conclude that the revised program incorporating the change continues to meet the criteria of 10CFR50, Appendix B and other previously accepted USAR commitments?</p> <p>Basis for Answer: The NRC review and approval concluded that the revised program continues to meet the criteria of 10 CFR 50, Appendix B and other previously accepted USAR/DSAR commitments. (ADAMS Accession No. ML16165A465)</p>	X		
<p>4. Is the proposed change a change to a QA standard approved by the NRC which is more recent than the QA standard currently established in the Program?</p> <p>Basis for Answer: These changes are limited to modifications to existing standards through the use of new or modified exceptions. The details of each of the changes are discussed in Attachment 2. The changes continue to ensure compliance with 10 CFR 50 Appendix B, although prior NRC approval is required because several changes are considered reductions in commitments to the previously approved QAPM.</p>		X	
<p>5. Is the proposed change a change involving the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles?</p> <p>Basis for Answer: The Organization section of the QAPM was not changed as part of this revision.</p>		X	
<p>6. Is the proposed change a change involving the use of generic organizational charts to indicate functional</p>			

	YES	NO	N/A
relationships, authorities, and responsibilities, or alternately, the use of descriptive text?  Basis for Answer: The QAPM does not use organizational charts to indicate functional relationships, authorities, or responsibilities.			X
7. Is the proposed change an elimination of Quality Assurance Program information that duplicates language in Quality Assurance Regulatory Guides and Quality Assurance Standards to which EN is committed?  Basis for Answer: This revision does not eliminate a quality assurance standard to which the QAPM commits to, as denoted in Appendix B of the QAPM. The changes do provide more detail on implementation criteria for Quality Assurance Regulatory Guides and Standards to which VY is committed.		X	
8. Does the proposed change continue to ensure that persons and organizations performing Quality Assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations?  Basis for Answer: This revision does not change the VY organization as defined in the QAPM. The vice president oversight remains responsible for governance and implementation of the Quality Assurance Program in accordance with regulatory requirements and the establishment of policies, goals, and objectives of the quality assurance policy. This position provides guidance and interpretation for implementing the company quality assurance policy. Organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations. This revision does not change the reporting relationship of this executive up to the chief nuclear officer.	X		
9. Is a change to the QAPM required? If YES, process change per EN-LI-113. If NO, distribute as indicated below.  Basis for Answer:	X		

	YES	NO	N/A
The QAPM does need to be changed to reflect the organizational changes, scope of the program to safety-related and ITS SSCs and activities and the modifications to regulatory commitments.			

**10 CFR 50.54 REVIEW RESULTS**

- [ ] Change is editorial in accordance with 10CFR50.54(a)(3) and thus, does not represent a reduction in commitment. The change can be implemented upon approval of parent change document.
- [ ] Does not represent a reduction of commitment, and can be implemented upon approval of parent change document.
- [X] Represents a reduction of commitment with prior NRC approval. The safety evaluation issued by the NRC has been evaluated and it directly applies to the changes being proposed for EN. The change can be implemented upon approval of parent change document.
- [ ] Represents a reduction of commitment; however, the change has sufficient basis to demonstrate continued compliance with Appendix B and USAR commitments. Therefore, the proposed change should be submitted for NRC review/approval.
- [ ] Represents a reduction of commitment with insufficient basis to demonstrate continued compliance. Therefore, the activity should not be processed.

Norma Evans / Norma Evans, 8/29/2016  
Corporate Quality Assurance Department Preparer Date

[Signature], 8/29/2016  
Manager, Corporate QA Approver Date

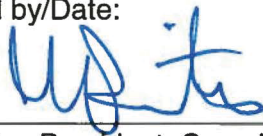
Distribution: Original – Attach to Parent Document;  
Copy – Quality Assurance



CHANGE DISPOSITION

- ☒ Approved for implementation
- ☐ Disapproved
- ☐ Approved for submittal to the NRC

Approved by/Date:



Vice President, Oversight

8/29/16

Date





# *Entergy*

## **Vermont Yankee Nuclear Power Station**

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

## **Quality Assurance Program Manual**



### POLICY STATEMENT

Entergy Nuclear Vermont Yankee, LLC (ENVY) and Entergy Nuclear Operations, Inc. (ENOI) 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 operated 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 safety-related nuclear plant structures, systems, and components (SSCs). The QAP is also applied to SSCs classified as important-to-safety (ITS) to satisfy the requirements of 10CFR71 and 10CFR72. ~~Approved administrative controls are also used to implement controls for certain quality-related equipment and activities that are not safety-related, but support safe storage of spent fuel, or where other regulatory or industry guidance establishes program requirements.~~

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 chief nuclear officer (highest level nuclear executive) and authority for developing and verifying execution of the program to the executive responsible for oversight.

**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 ~~quality-safety-related~~ **and 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 ~~safety-related~~ or **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 through the use of approved procedures (e.g., policies, directives, procedures, instructions, or other documents) which provide written guidance for the control of ~~safety-related and ITS quality 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.b. (continued)**

6. A manager responsible for fuel transfer and storage related activities. This manager is responsible for construction of the ISFSI pad and facility and fuel transfer activities.
7. A manager responsible for radiation protection and chemistry activities. This manager 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 on-site and off-site safety review function independently reviews activities to provide additional assurance that VY is maintained in accordance with the Operating License and applicable regulations that address nuclear safety. **These functions are described in Appendix D.**

**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 managers 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.
- 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.

**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 manager 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.



**A.2. (continued)****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 safety-related or 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 definitions provided by Regulatory Guide 1.74 and 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.
  4. In each of the ANSI 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 applicable to safety related items and activities is applicable to comparable 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 C, 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) or 10 CFR 50.54(a)(4).

**C. 2. (continued)**

- 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 (e.g., Regulatory Guides 1.33 and 1.144).

**D. INDEPENDENT SAFETY REVIEW****1. Description**

- a. Independent safety review is performed to meet VY's commitment to NUREG-0737, Section I.B.1.2, "Independent Safety Engineering Group," as described in the unit's safety analysis report. **This function is described in Appendix D, Section 1.0.**

## **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.

Qualification requirements for personnel shall meet ANSI/ANS 3.1-1978 except the following:

- a. The radiation protection manager shall meet or exceed the qualifications of Regulatory Guide 1.8, Revision 2, 1987.
- b. Managers required to be a Certified Fuel Handler are specified in the Technical Specifications.
- c. A Certified Fuel Handler shall be qualified in accordance with the Technical Specifications.

~~Individuals filling positions who met the previous commitment at the time of implementation of this commitment can be considered to meet any more restrictive aspects of the requirements of this commitment for that position without further review and documentation.~~

##### **2. General**

The following qualifications may be considered equivalent to a bachelor's degree:

- a. 4 years of post-secondary schooling in science or engineering,
- b. 4 years of applied experience at a nuclear facility in the area for which qualification is sought,
- c. 4 years of operational or technical experience/training in nuclear power, or
- d. any combination of the above totaling 4 years.

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**

#### **A. Regulatory Guide 1.8 (continued)**

- |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>3. ANSI/ANS 3.1<br/>Section 4</b>                    | Individuals assigned to professional-technical comparable positions shall have the authority and specified qualifications to accomplish the functional responsibilities of the position.                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>4. ANSI/ANS 3.1<br/>Section 4.4.5</b>                | 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.                                                                          |
| <b>5. ANSI/ANS 3.1<br/>Section 5</b>                    | VY will maintain a training program for the unit staff that meets the applicable regulations and either a) is accredited by the National Nuclear Accrediting Board (NNAB) or b) meets the standards of section 5 of ANSI/ANS 3.1-1978.                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>6. ANSI/ANS 3.1<br/>Sections 4.3.1 and<br/>4.5.1</b> | Nuclear power plant experience is amended to also include experience acquired at a defueled reactor site that is directly related to the storage or handling of spent nuclear fuel in a spent fuel pool. Specifically, individuals will obtain the necessary on site experience to fill the position of Certified Fuel Handler or operators, based on their assigned functions and validation of equivalent training and experience rather than requiring at least six months of the nuclear power plant experience at the plant for which an individual seeks a license or to be an operator as defined in Sections 4.3.1 and 4.5.1 of ANSI/ANS 3.1-1978. |



## **Appendix B Regulatory Commitments**

### **C. Regulatory Guide 1.33 Revision 2, dated February 1978**

#### **Clarification/Exception**

- |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Section C.1                       | VY will provide procedures for the guide's Appendix A activities as discussed, applicable to VY. However, VY does not consider all activities listed to be "safety-related" (e.g., activities in 7.e).                                                                                                                                                                                                                                                         |
| 2. Section C.4                       | This section establishes minimum 2-year audit frequency for all safety related functions and recommends audit frequencies specific to Corrective Action, Facility Operation, and Staff Performance, Training, and Qualifications. VY will perform audits at frequencies as discussed in QAPM Section C.2.a instead of this section.                                                                                                                            |
| 3. ANSI N18.7<br>Section 1           | Sentences 4 and 5 state, "However, applicable sections of this standard should be used as they apply to related activities. Activities included are: Design Changes, Purchasing, Fabricating..." With regard to radioactive material transportation activities, VY will only implement the requirements associated with those activities conducted in accordance with the applicable NRC Quality Assurance Program Approval for Radioactive Material Packages. |
| 4. ANSI N18.7<br>Section 4.3.1       | The on and off-site review committee requirements will be satisfied as described in Appendix D of the QAPM. <del>The specific areas of experience described in this section are not applicable to the on-site safety review committee, but the committee must be comprised of site operating or engineering supervisory personnel. Additionally, the off-site safety review committee needs to contain experience in only a majority of the areas.</del>       |
| 5.-10. ANSI N18.7<br>Section 4.3.2.3 | <del>DeletedThe statement that "no more than a minority of the quorum shall have line responsibility for the operation of the plant" is not applicable to the on-site safety review committee.</del>                                                                                                                                                                                                                                                           |

## **Appendix B**

### **Regulatory Commitments**

#### **C. Regulatory Guide 1.33 (continued)**

##### **Clarification/Exception**

- |                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>6.</b> ANSI N18.7<br>Section<br>4.3.4.(1) & (2) | 10 CFR 50.59 was revised through Federal Register Notice 19991001 R1N3150-AF94 eliminating the terms "safety evaluation" and "unreviewed safety question." The term "safety evaluation" has been replaced with 10 CFR 50.59 "evaluation." The term "unreviewed safety question," as defined in the previous version of 10 CFR 50.59 (a)(2), was replaced by criteria provided in 50.59(c)(2) to determine if a license amendment pursuant to 50.90 is required prior to implementing the change, test, or experiment. |
| <b>7.</b> ANSI N18.7<br>Section 4.3.4(2)           | Reviews associated with changes to the technical specifications will be performed in accordance with Section 4.3.4(3) instead of this section.                                                                                                                                                                                                                                                                                                                                                                        |
| <b>8.</b> ANSI N18.7<br>Section 4.3.4(3)           | Revision to proposed Technical Specification changes only requires review in accordance with this section when the revision involves a significant change to the technical basis for the proposed change. The independent review body discussed in this section is the on-site safety review committee. Voting members having a potential conflict of interest refrain from voting on documents under review.                                                                                                         |
| <b>9.</b> ANSI N18.7<br>Section 4.3.4(4)           | In place of the requirements of this section, the on-site and off-site safety review committees shall review facility operations to detect potential nuclear safety hazards and all reports made in accordance with 10 CFR 50.73.                                                                                                                                                                                                                                                                                     |
| <b>10.</b> ANSI N18.7<br>Section 4.3.4(5)          | An example of the matters reviewed by the on-site safety review committee in accordance with this section is a change to the Emergency Plan (except editorial changes).                                                                                                                                                                                                                                                                                                                                               |
| <b>11.</b> ANSI N18.7<br>Section 4.5               | This section establishes minimum 2-year audit frequency for all safety related functions. VY will perform audits at frequencies as discussed in QAPM Section C.2.a instead of this section.                                                                                                                                                                                                                                                                                                                           |
| <b>12.</b> ANSI N18.7<br>Section 4.5               | The independent review body discussed in this section is the off-site safety review committee.                                                                                                                                                                                                                                                                                                                                                                                                                        |



## **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 10CFR50.59 or 10CFR72.48, 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 10CFR50.59 or 10CFR72.48.

#### **2.0 SAFETY REVIEW COMMITTEE (SRC)**

The SRC is responsible for reviewing, auditing, and advising the chief nuclear officer and the VY executive on matters related to the safe storage of irradiated fuel. This review and audit function is independent of line organization responsibilities.

1. The SRC shall include a minimum of three members. Alternates may be substituted for regular members. The licensee shall designate in writing the chairman, the members, and alternates for the SRC. The Chairman shall not have management responsibilities for, or report to, the line organizations responsible for operation and maintenance of the facility.
2. The SRC shall collectively have experience and knowledge in the following functional areas:
  - a) fuel handling and storage (including the potential for criticality),
  - b) chemistry and radiochemistry,



- c) engineering,
  - d) radiation protection and
  - e) quality assurance.
3. The SRC shall collectively possess the necessary expertise and experience to provide an independent review of problems in the majority of the areas described in Section 2.2.
  4. If necessary, individuals with knowledge and experience in other functional areas may be utilized to provide advice to the SRC.
  5. As a minimum, the SRC shall conduct two designated meetings per year.
  6. A quorum shall consist of not less than a majority of the number of standing SRC members, or their duly appointed alternates. Those members representing the line organizations responsible for the operation and maintenance of the facility shall not constitute a majority of the quorum. At least one member of the quorum shall be the Chairman or the Chairman's designated alternate.
  7. As a minimum, the SRC shall perform the following functions:
    - a) Advise the Chief Nuclear Officer and the VY Executive on all matters related to safe storage of irradiated fuel.
    - b) Advise the management of the audited organization and the Chief Nuclear Officer and the VY Executive of review results as they relate to safe storage of irradiated fuel.
    - c) Recommend to management of the assessed organization, and its management, any corrective action to improve the safe storage of irradiated fuel.
    - d) Notify the Chief Nuclear Officer and the VY Executive of any safety significant disagreement between the SRC and Site Management within 24 hours.
  8. The SRC shall be responsible for reviewing:
    - a) The evaluations for procedures, and changes thereto, completed under the provisions of 10 CFR 50.59 or 10 CFR 72.48 to verify that such actions do not require prior NRC approval or a license amendment as defined in 10 CFR 50.59 or 10 CFR 72.48. This review may be completed after implementation of the affected procedure;
    - b) Changes to structures, systems or components important to the safe storage of irradiated fuel to verify that such changes do not require prior NRC approval or a license amendment as defined in 10 CFR 50.59 or 10 CFR 72.48. This review may be completed after implementation of the change;
    - c) Test or experiments involving the safe storage of irradiated fuel to verify that such tests or experiments do not require prior NRC approval or a license amendment as defined in 10 CFR 50.59 or 10 CFR 72.48. This review may be completed after performance of the test or experiment;
    - d) Proposed changes to the Technical Specifications or the operating license. This review may be completed after submittal;
    - e) Violations of codes, regulations, orders, license requirements, or internal procedures/instructions having nuclear safety significance;
    - f) Indications of unanticipated deficiencies in any aspect of design or operation of structures, systems, or components that could affect safe storage of irradiated fuel;



- g) Significant accidental, unplanned, or uncontrolled radioactive releases. Including corrective action(s) to prevent recurrence;
- h) Significant operating abnormalities or deviations from normal and expected performance of equipment that affect safe storage of irradiated fuel;
- i) The performance of the corrective action system; and
- j) Internal and external experience information related to the safe storage of irradiated fuel that may indicate areas for improving facility safety.

Reports or records of these reviews shall be forwarded to the Chief Nuclear Officer and the VY Executive within 30 days after completion of the review.

- 9. The SRC's responsibility shall include oversight of the Audit Program. Audits shall be performed of the activities and at the associated frequencies defined in Section C.
- 10. Written records of reviews and audits shall be maintained. As a minimum, these records shall include:
  - a) Results of the activities conducted under the provisions of QAPM;
  - b) Recommendations to the management of the audited organization;
  - c) Documentation of reviews conducted by the SRC; and
  - d) Determination of whether changes to procedures and programs require prior NRC approval as defined in 10 CFR 50.59 and 10 CFR 72.48.

Written records of reviews and audits shall be maintained. As a minimum, these records shall include results of the activities conducted under the provisions of Section B.15.

This appendix **also** provides for **the** future relocation of Administrative Controls from other license basis documents, such as from the defueled Technical Specifications.

VERMONT YANKEE LICENSING DEPARTMENT  
NRC INCOMING CORRESPONDENCE DISTRIBUTION

NVY 16-020

Agency Letter Date: June 16, 2016

**SUBJECT:** ENTERGY VERMONT YANKEE QUALITY ASSURANCE PROGRAM MANUAL  
VERMONT YANKEE NUCLEAR POWER STATION AND INDEPENDENT  
SPENT FUEL STORAGE FACILITY – REVIEW AND ACCEPTANCE OF  
CHANGES (CAC NO. L53120) (ML 16165A465)

**TECHNICAL LEAD:** Joe Laughney

**RESPONSE DUE TO NRC:**

N/A

**LICENSING LEAD:** Tom Silko (x3166)

☐ YES ☒ NO 10CFR19.11(a)(4) action? If yes,  
posting is required within 2 working days of receipt.

**COMMITMENT IDENTIFIED:** YES/NO (If yes, enter  
EN-LI-110)

**COMMENTS:**

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- ☒ Michael T Twomey, VP, External Affairs-Wholesale, WPO
- ☐ Other:

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| <input type="checkbox"/> Jim Cordell             |                                       |
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**All:**

- ☒ Coley Chappell, Manager, Design & Programs (see note 2)
- ☒ Dodi Emery (Chronological File)

**By Subject:**

- ☒ Jack Boyle, Decommissioning Director
- ☒ Corey Daniels, Senior Manager, Production
- ☒ Steve Naeck, Manager, Emergency Preparedness
- ☒ Ken Swanger, Manager Construction
- ☒ Patrick Ryan, Manager, Security (IR)
- ☒ Joe Laughney, Manager, QA (IR)
- ☒ Mike Pletcher, Manager, Chemistry/RP
- ☒ John Card, State Liaison Engineer
- ☐ Dodi Emery (all IRs to SRC members)
- ☒ Tom Silko, Licensing (IR) Notes: 2 and 3
- ☒ Joe Lynch, External Affairs Mgr.
- ☒ Martin Cohn, Communications Manager (IR)
- ☐ Other:

☐ Paper distribution or ☒ Electronic distribution

Distributed by: DME Date: 6/23/16

**Latest update: May 9, 2016 (DME)**

**NOTES:**

- 1) (IR) – Inspection Reports
- 2) For IRs, Licensing verifies that CRs generated adequately recognize and address any violations/findings identified in the IR. If necessary, the responsible manager is contacted to resolve discrepancies (e.g. update CR, initiate a CRCA to address, initiate new CR). Also ensure a CA is created to perform a closure review per EN-LI-102.
- 3) For annual and semi-annual assessment letters, coordinate a SARB meeting to determine the pre-inspection assessments that will be performed and ensure CA&A issues the associated LOs (EN-LI-104).





UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20566-0001

*NVY 16-020*

June 16, 2016

**received**  
*6/23/2016*

Mr. Michael Perito  
Vice President, Oversight  
Entergy Nuclear Operations, Inc.  
1340 Echelon Parkway  
Jackson, MS 39213

SUBJECT: ENTERGY VERMONT YANKEE QUALITY ASSURANCE PROGRAM MANUAL  
VERMONT YANKEE NUCLEAR POWER STATION AND INDEPENDENT  
SPENT FUEL STORAGE FACILITY – REVIEW AND ACCEPTANCE OF  
CHANGES (CAC NO. L53120)

Dear Mr. Perito:

The U.S. Nuclear Regulatory Commission (NRC) has completed its review of the proposed changes to the Entergy Nuclear Operations, Inc. (ENO) Vermont Yankee Nuclear Power Station (VYNPS) Quality Assurance Program Manual (QAPM) in response to your letter dated February 4, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16035A506), as supplemented by letter dated May 5, 2016. The VY QAPM is associated with license DPR-28 for the VYNPS and docket no. 72-059 for the Independent Spent Fuel Storage Installation.

The proposed QAPM reflects changes and simplifications based on the VYNPS decommissioning status. Changes include those to the scope of structures, systems and components, due to the decommissioning status; removing the need for maintaining NRC Licensed Operators as part of the site organization; the qualification of Certified Fuel Handlers; transitioning the onsite-review function to an independent review function; and, modifying the function of the off-site safety review to reflect the complexity of operations for a decommissioning facility. The changes, some of which are considered to be reductions in commitments, were submitted for NRC review and approval in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) paragraph 50.54(a)(4).

The NRC staff has completed its review of your request and has determined that the Quality Assurance Program, as described in the VYNPS QAPM, is in conformance with the applicable portions of Appendix B to 10 CFR Part 50. The NRC staff concludes that the proposed Vermont Yankee QAPM Revision 4 follows the NRC guidance in the attached NRC safety evaluation, conforms to the format of NUREG-0800, Section 17.3, complies with Appendix B to 10 CFR Part 50 requirements for the QA program and is, therefore, acceptable.

M. Perito

2

If you have any questions, please contact me at (301) 415-6634 or via e-mail at [Jack.Parrott@nrc.gov](mailto:Jack.Parrott@nrc.gov).

Sincerely,

/RA/

Jack D. Parrott, Senior Project Manager  
Reactor Decommissioning Branch  
Division of Decommissioning, Uranium  
Recovery, and Waste Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket Nos. 50-271 and 72-059

Enclosure:  
Safety Evaluation

cc: Distribution via Listserv



M. Perito

3

If you have any questions, please contact me at (301) 415-6634 or via e-mail at [Jack.Parrott@nrc.gov](mailto:Jack.Parrott@nrc.gov).

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Office of Nuclear Material Safety  
and Safeguards

Docket Nos. 50-271 and 72-059

Enclosure:  
Safety Evaluation

cc: Distribution via Listserv

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OPA

**ADAMS Accession No. ML16165A465** \* via e-mail

OFFICE	NMSS	NMSS	NMSS*	NRO*	NMSS	NMSS
NAME	J. Parrott	C. Holston	P. Silva	K. Kavanagh	B. Watson	J. Parrott
DATE	06/14/2016	06/14/2016	06/15/2016	06/14/2016	06/16/2016	06/16/2016

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SAFETY EVALUATION OF THE ENTERGY VERMONT YANKEE QUALITY ASSURANCE  
PROGRAM MANUAL, REVISION 4  
DOCKET NOS. 50-271 AND 72-59

## 1.0 INTRODUCTION

By letter dated February 4, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16035A506), Entergy Nuclear Operations, Inc. (Entergy) submitted for the U.S. Nuclear Regulatory Commission (NRC) staff's review, a revision to the Vermont Yankee Quality Assurance Program Manual (QAPM), in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) section 50.54(a)(4).

The QAPM provides a top-level overview of the quality program controls applied to quality related items and activities at the Vermont Yankee Nuclear Power Plant during the decommissioning phase of the plant life. The QAPM is based on the applicable portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor Related Greater than Class C Waste," Subpart G, "Quality Assurance," and 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," Subpart H, "Quality Assurance."

## 2.0 REGULATORY BASIS

The Commission's regulatory requirements related to Quality Assurance (QA) programs are set forth in Appendix B to 10 CFR Part 50 (Appendix B), 10 CFR 50.34(b)(6)(ii), and 10 CFR 50.54(a). In addition, the Commission's regulatory requirements related to QA programs for the independent storage of spent nuclear fuel and packaging and transportation of radioactive material are addressed in 10 CFR Part 71, Subpart H, and 10 CFR Part 72, Subpart G.

Appendix B establishes the requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) for the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

The regulations in 10 CFR 50.34, "Content of applications; technical information," require that every applicant for an operating license include information in its Final Safety Analysis Report on the managerial and administrative controls to be used to ensure safe operation. The information on the controls shall also include a discussion on how the applicable requirements of Appendix B will be satisfied.

The regulations in 10 CFR 50.54 require each power plant subject to the requirements of Appendix B to implement a QA program and 10 CFR 50.54(a)(4) require licensees to submit to the NRC, changes to their QA Program that reduce commitments.

The regulations in 10 CFR Part 71, Subpart H, establishes the quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.

The regulations in 10 CFR Part 72, Subpart G, establishes the quality assurance requirements that apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification of SSCs, and decommissioning that are important to safety.

### 3.0 EVALUATION

The request for review and approval of the Vermont Yankee QAPM, considered a reduction in commitment, was submitted by the February 4, 2016, letter, in accordance with the provisions of 10 CFR 50.54(a)(4). The letter included Revision 4 to the QAPM (provided in Enclosure 2 thereto).

In evaluating the adequacy of the revisions to the QAPM, the NRC staff used the guidance contained in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.3, "Quality Assurance Program Description," dated August 1990 (ADAMS Accession No. ML052350376), hereafter referred to as Section 17.3, which provides acceptance criteria for quality assurance program descriptions.

The changes made to the QAPM Revision 4 include the following:

- a. Changes to the policy statement and QAPM involving limiting the application of the QAPM to safety related and important to safety SSCs. In the proposed change, the QAPM is only applicable to safety related SSCs, important to safety SSCs controlled by 10 CFR 72 and transportation packages controlled by 10 CFR 71. The applicability to other items and activities will be determined on a case-by-case basis and controlled by approved procedures. Limiting the application of the QAPM to safety related and important to safety SSCs is adequate after cessation of power operations. The staff determined these changes continue to meet the guidance of NUREG-0800, Section 17.3, and, therefore, meet the requirements of Appendix B.
- b. Changes involving removing the need for maintaining NRC Licensed Operators as part of the site organization. Upon the certification of the end of reactor operations, the 10 CFR Part 50 license no longer authorizes operation of the reactor or placement or retention of fuel into the reactor vessel. 10 CFR 50.54(m) is not applicable to a facility that has permanently ceased operations; therefore there are no longer requirements to maintain NRC Licensed Operators at a decommissioning facility. The staff determined



the change regarding NRC Licensed Operators is not considered to be a reduction in commitment.

- c. Changes made in response to the Request for Additional Information (RAI) (ADAMS Accession No. ML16090A029) issued on April 5, 2016, included in Entergy's response letter (ADAMS Accession ML16126A579) dated May 5, 2016. The RAI requested clarification on the Certified Fuel Handler Training Program under which non-licensed operators will be qualified. In response, Entergy included a statement in Revision 4 of the QAPM that stated Certified Fuel Handlers shall be qualified in accordance with Vermont Yankee Nuclear Power Station's (VYPS's) technical specification. The VYPS technical specification references an NRC approved training and retraining program for Certified Fuel Handlers, in accordance with 10 CFR 50.2. The proposed changes, upon implementation, will ensure that personnel achieve and maintain suitable proficiency through established training programs. The staff determined these changes continue to meet the guidance of NUREG-0800, Section 17.3, and, therefore, meet the requirements of Appendix B.
- d. Changes involving adding an exception to American National Standards Institute (ANSI) and American Nuclear Society (ANS) 3.1-1978 to allow nuclear power plant experience to include experience acquired at a defueled reactor site, directly related to the storage or handling of spent fuel in a spent fuel pool. The QAPM also states individuals will obtain the necessary onsite experience to fill the position of Certified Fuel Handlers or operators, based on assigned functions and validation of equivalent training and experience rather than requiring at least 6 months of nuclear power plant experience to be attained at Vermont Yankee. The proposed exemption to ANSI/ANS 3.1-1978, when implemented, ensures personnel performing activities affecting quality achieve and maintain suitable proficiency. The staff determined these changes continue to meet the guidance of NUREG-0800, Section 17.3, and, therefore, meet the requirements of Appendix B.
- e. Changes involving transitioning the onsite-review function to an independent review function and modifying the function of the off-site safety review to reflect the complexity of operations for a decommissioning facility. The proposed changes to the QAPM include a description of the independent safety review and safety review committee organizational structure, functional responsibilities, level of authorities and interfaces. The proposed organizational changes provide sufficient authority and organizational freedom. The staff determined these changes continue to meet the guidance of NUREG-0800, Section 17.3, and, therefore, meet the requirements of Appendix B.

#### 4.0 CONCLUSION

The NRC staff used the acceptance criteria of SRP Section 17.3 as the basis for evaluating the acceptability of the changes to the Entergy Vermont Yankee QAPM in conformance with the applicable portions of Appendix B to 10 CFR Part 50. The program description adequately describes the provisions to meet the requirements of Appendix B. The NRC staff concludes that the proposed Vermont Yankee QAPM Revision 4 follows the NRC guidance contained within,



and conforms to the format of NUREG-0800, Section 17.3, complies with Appendix B to 10 CFR Part 50 requirements for the QA program and is, therefore, acceptable.

## 5.0 REFERENCES

1. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.3, "Quality Assurance Program Description" dated August 1990 (ADAMS Accession No. ML052350376)
2. RG 1.28, "Quality Assurance Program Requirements (Design and Construction)" Revision 4, dated June 2010 (ADAMS Accession No. ML100160003)
3. Perito, Michael, Entergy Nuclear Operations, Inc. letter to the U.S. Nuclear Regulatory Commission, "Entergy Vermont Yankee Quality Assurance Program Manual Yankee Nuclear Power Station Docket 50-271, License No. DPR -28, Docket No. 72-59," dated February 4, 2016 (ADAMS Accession No. ML16035A506)
4. Parrott, Jack D., U.S. Nuclear Regulatory Commission, letter to Mr. Michael Perito, Entergy Nuclear Operations, Inc., "Request for Additional Information Related to Proposed Changes to Quality Assurance Program Manual, Vermont Yankee Nuclear Power Station (CAC No. L53120)," dated April 5, 2016 (ADAMS Accession No. ML16090A029)
5. Perito, Michael, Entergy Nuclear Operations, Inc. letter to the U.S. Nuclear Regulatory Commission, "Response to Request for Additional Information Pertaining to a Change to Entergy Vermont Yankee Quality Assurance Program Manual (VY QAPM)," dated May 5, 2016 (ADAMS Accession No. ML16126A579)
6. American National Standards Institute (ANSI) and American Nuclear Society (ANS), ANSI/ANS 3.1, "Selection and Training of Nuclear Power Plant Personnel," La Grange Park, IL, 1978.

Enclosure C  
CNRO2018-00016  
Entergy VY QAPM Revision 5



# *Entergy*

## **Vermont Yankee Nuclear Power Station**

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

## **Quality Assurance Program Manual**





### POLICY STATEMENT

Entergy Nuclear Vermont Yankee, LLC (ENVY) and Entergy Nuclear Operations, Inc. (ENOI) 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 operated 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 safety-related nuclear plant structures, systems, and components (SSCs). The QAP is also applied to SSCs classified as important-to-safety (ITS) to satisfy the requirements of 10CFR71 and 10CFR72.

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 chief nuclear officer (highest level nuclear executive) and authority for developing and verifying execution of the program to the executive responsible for oversight.

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**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 **safety-related and 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 safety-related or **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 through the use of approved procedures (e.g., policies, directives, procedures, instructions, or other documents) which provide written guidance for the control of **safety-related and 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 Entergy Corporation chief executive officer (CEO) 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 chief nuclear officer, the highest level nuclear executive, and authority for developing and verifying execution of the program to the executive responsible for nuclear oversight.
2. The chief nuclear officer, the highest level nuclear executive officer, is responsible for providing top-level direction for the safe and reliable operation of VY's nuclear site. The highest level nuclear executive officer provides guidance with regards to company quality assurance policy. The off-site safety review committee reports to this executive.
3. The executive responsible for oversight establishes the policies, goals, and objectives of the quality assurance policy and provides guidance and interpretation for implementing the company quality assurance policy and is responsible for governance and implementation of the quality assurance program in accordance with regulatory requirements. Independent oversight groups report to this executive.

(a) The following management positions report to this executive:

- A management position that is responsible for nuclear oversight activities and is independent of production. This position provides overall direction for the implementation of the quality assurance program.
- A management position that is responsible for oversight and governance of the QAPM. This manager has authority and responsibility for establishing, controlling, and verifying the implementation and adequacy of the quality assurance program as described in this QAPM including activities related to vendor quality. This position has the authority for Stop Work and responsibility to escalate matters directly to the highest level nuclear executive officer when needed.

**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 individuals may report through an additional layer of management, but shall maintain sufficient authority and organizational freedom to implement the assigned responsibilities.

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

1. The VY executive management position reports to the chief nuclear officer 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. The manager responsible for overall 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 managers. This manager is responsible for operation of the Independent Spent Fuel Storage Installation (ISFSI). The onsite safety review function reports to the manager responsible for facility operations.
3. A manager 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. A manager responsible for quality assurance who 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 highest level nuclear executive officer when needed. This position reports to the executive responsible for nuclear oversight through the corporate management position responsible for nuclear oversight (offsite).
5. A manager 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. Supply chain and information technology are no longer a functional area exclusively within the nuclear organizational structure. However, the oversight and governance of these functional areas remain within the nuclear organization through the VY executive management position. The site personnel organizationally report to an executive (supply chain – offsite) who has a functional interface with the VY executive management position.

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

6. A manager responsible for fuel transfer and storage related activities. This manager is responsible for construction of the ISFSI pad and facility and fuel transfer activities.
  7. A manager responsible for radiation protection and chemistry activities. This manager 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 on-site and off-site safety review function independently reviews activities to provide additional assurance that VY is maintained in accordance with the Operating License and applicable regulations that address nuclear safety. **These functions are described in Appendix D.**

**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 managers 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.
- 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.

**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 manager 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 (e.g., Regulatory Guides 1.8, 1.58, and 1.146).

**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.
- 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 (e.g., Regulatory Guide 1.33).

## **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 safety-related or 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 definitions provided by Regulatory Guide 1.74 and 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.
  4. In each of the ANSI 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 applicable to safety related items and activities is applicable to comparable 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 C, 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) 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. 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.

**B. 2. (continued)**

- 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 (e.g., Regulatory Guide 1.64).

**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.
- 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:



**B. 3.e (continued)**

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 (e.g., Regulatory Guide 1.64).

**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.
- 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.

**B. 4 (continued)**

- 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 (e.g., Regulatory Guides 1.33 and 1.123).

**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 (e.g., Regulatory Guides 1.123 and 1.144).

**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 (e.g., Regulatory Guide 1.33).

**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 (e.g., Regulatory Guide 1.38).

**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 (e.g., Regulatory Guide 1.33).

**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.
- 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 (e.g., Regulatory Guides 1.30, 1.33, 1.94, 1.116, and 1.123).

**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. 10. (continued)**

- 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 (e.g., Regulatory Guide 1.33).

**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
  - 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 (e.g., Regulatory Guide 1.33).

**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.

**B. 12. (continued)**

- 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 (e.g., Regulatory Guides 1.33 and 1.58).

**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 (e.g., Regulatory Guide 1.33).

**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

**B. 14. (continued)**

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 (e.g., Regulatory Guide 1.33).

**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 (e.g., Regulatory Guide 1.88).

**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.



**C.2.a.2 (continued)**

- 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. A fire protection and loss prevention program inspection and audit shall be performed using either off-site licensee personnel or an outside fire protection firm at least once every 24 months.
  - h. The fire protection program and implementing procedures audit shall be performed at least once every 24 months.
  - i. A fire protection and loss prevention program inspection and audit shall be performed using an outside fire consultant at least once every 36 months.
- 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.

**C. 2. (continued)**

- 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 (e.g., Regulatory Guides 1.33 and 1.144).

**D. INDEPENDENT SAFETY REVIEW****1. Description**

- a. Independent safety review is performed to meet VY's commitment to NUREG-0737, Section I.B.1.2, "Independent Safety Engineering Group," as described in the unit's safety analysis report. **This function is described in Appendix D, Section 1.0.**

## Appendix A

### **SAFETY RELATED AND 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-SAFETY AS DEFINED BY 10 CFR 71 AND 10 CFR 72**

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

<b>SSC</b>	<b>Quality Category</b>	<b>Design/License Responsible</b>
Multipurpose Canister and Fuel Basket Assembly	A	Holtec Intl.
Vertical Concrete Cask	B	Holtec Intl.
Transfer Cask and Adapter Plate	B	Holtec Intl.
ISFSI Pad	C	VY
Lifting Yoke	B	Holtec Intl.
Damaged Fuel Can	A	Holtec Intl. (Later)

**Appendix A****SAFETY RELATED AND IMPORTANT-TO-SAFETY STRUCTURES,  
SYSTEMS AND COMPONENTS****B. Transport of Spent Fuel and GTCC Waste (10 CFR 71)**

<b>SSC</b>	<b>Quality Category</b>	<b>Design/License Responsible</b>
Multipurpose Canister and Fuel Basket Assembly	A	Holtec Intl.
Damaged Fuel Can	A	Holtec Intl. (Later)
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. See Holtec Intl. Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information.
2. See Holtec Transport Cask Safety Analysis Report and associated Holtec specifications for additional classification information.
3. For the definition of Quality Categories A, B, and C refer to NUREG/CR-6407.
4. VY engineering 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.

Qualification requirements for personnel shall meet ANSI/ANS 3.1-1978 except the following:

- a. The radiation protection manager shall meet or exceed the qualifications of Regulatory Guide 1.8, Revision 2, 1987.
- b. Managers required to be a Certified Fuel Handler are specified in the Technical Specifications.
- c. A Certified Fuel Handler shall be qualified in accordance with the Technical Specifications.

##### **2. General**

The following qualifications may be considered equivalent to a bachelor's degree:

- a. 4 years of post-secondary schooling in science or engineering,
- b. 4 years of applied experience at a nuclear facility in the area for which qualification is sought,
- c. 4 years of operational or technical experience/training in nuclear power, or
- d. any combination of the above totaling 4 years.

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**

#### **A. Regulatory Guide 1.8 (continued)**

- |                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>3.</b> ANSI/ANS 3.1<br>Section 4                   | Individuals assigned to professional-technical comparable positions shall have the authority and specified qualifications to accomplish the functional responsibilities of the position.                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>4.</b> ANSI/ANS 3.1<br>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.                                                                          |
| <b>5.</b> ANSI/ANS 3.1<br>Section 5                   | VY will maintain a training program for the unit staff that meets the applicable regulations and either a) is accredited by the National Nuclear Accrediting Board (NNAB) or b) meets the standards of section 5 of ANSI/ANS 3.1-1978.                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>6.</b> ANSI/ANS 3.1<br>Sections 4.3.1 and<br>4.5.1 | Nuclear power plant experience is amended to also include experience acquired at a defueled reactor site that is directly related to the storage or handling of spent nuclear fuel in a spent fuel pool. Specifically, individuals will obtain the necessary on site experience to fill the position of Certified Fuel Handler or operators, based on their assigned functions and validation of equivalent training and experience rather than requiring at least six months of the nuclear power plant experience at the plant for which an individual seeks a license or to be an operator as defined in Sections 4.3.1 and 4.5.1 of ANSI/ANS 3.1-1978. |

## **Appendix B**

### **Regulatory Commitments**

#### **B. Regulatory Guide 1.30, dated August 1972**

##### **Clarification/Exception**

- |                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. ANSI N45.2.4<br>General       | ANSI N45.2.4 identifies various tests to be performed. The applicability of these tests will be determined as discussed in QAPM Section B.8 and based upon the significance of change or modification.                                                                                                                                                                                                                                                                 |
| 2. ANSI N45.2.4<br>Section 3     | Documented routine inspections and audits of the storage area may be performed instead of the requirements of this Section.                                                                                                                                                                                                                                                                                                                                            |
| 3. ANSI N45.2.4<br>Section 5.2   | In some cases, testing requirements may be met by post-installation surveillance testing in lieu of a special post-installation test.                                                                                                                                                                                                                                                                                                                                  |
| 4. ANSI N45.2.4<br>Section 6.2.1 | The last sentence of this section states: "Items requiring calibration shall be tagged or labeled on completion indicating date of calibration and identity of the person that performed the calibration." Instead of requiring the tagging or labeling of all equipment this statement is changed to require the equipment to be suitably marked to indicate the date of the next required calibration and the identity of the person that performed the calibration. |

## **Appendix B**

### **Regulatory Commitments**

#### **C. Regulatory Guide 1.33 Revision 2, dated February 1978**

##### **Clarification/Exception**

- |                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Section C.1                   | VY will provide procedures for the guide's Appendix A activities as discussed, applicable to VY. However, VY does not consider all activities listed to be "safety-related" (e.g., activities in 7.e).                                                                                                                                                                                                                                                         |
| 2. Section C.4                   | This section establishes minimum 2-year audit frequency for all safety related functions and recommends audit frequencies specific to Corrective Action, Facility Operation, and Staff Performance, Training, and Qualifications. VY will perform audits at frequencies as discussed in QAPM Section C.2.a instead of this section.                                                                                                                            |
| 3. ANSI N18.7<br>Section 1       | Sentences 4 and 5 state, "However, applicable sections of this standard should be used as they apply to related activities. Activities included are: Design Changes, Purchasing, Fabricating..." With regard to radioactive material transportation activities, VY will only implement the requirements associated with those activities conducted in accordance with the applicable NRC Quality Assurance Program Approval for Radioactive Material Packages. |
| 4. ANSI N18.7<br>Section 4.3     | The on and off-site review committee requirements will be satisfied as described in Appendix D of the QAPM.                                                                                                                                                                                                                                                                                                                                                    |
| 5. ANSI N18.7<br>Section 4.3.2.3 | Deleted                                                                                                                                                                                                                                                                                                                                                                                                                                                        |



## **Appendix B Regulatory Commitments**

### **C. Regulatory Guide 1.33 (continued)**

		<b>Clarification/Exception</b>	
<b>6.</b>	ANSI N18.7 Section 4.3.4.(1) & (2)	Deleted	
<b>7.</b>	ANSI N18.7 Section 4.3.4(2)	Deleted	
<b>8.</b>	ANSI N18.7 Section 4.3.4(3)	Deleted	
<b>9.</b>	ANSI N18.7 Section 4.3.4(4)	Deleted	
<b>10.</b>	ANSI N18.7 Section 4.3.4(5)	Deleted	
<b>11.</b>	ANSI N18.7 Section 4.5	This section establishes minimum 2-year audit frequency for all safety related functions. VY will perform audits at frequencies as discussed in QAPM Section C.2.a instead of this section.	
<b>12.</b>	ANSI N18.7 Section 4.5	Deleted	

## **Appendix B**

### **Regulatory Commitments**

#### **C. Regulatory Guide 1.33 (continued)**

##### **Clarification/Exception**

- |                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>13.</b> ANSI N18.7<br>Section 5.1     | Instead of the requirements of this section to have a summary document, a method of cross-referencing these requirements to the implementing procedures will be maintained.                                                                                                                                                                                                                                                                                                                                                                          |
| <b>14.</b> ANSI N18.7<br>Section 5.2.2   | The person who is a Certified Fuel Handler, based on the Technical Specifications for VY and approves a temporary change to a procedure is not required to be in charge of the shift.                                                                                                                                                                                                                                                                                                                                                                |
| <b>15.</b> ANSI N18.7<br>Section 5.2.2   | In addition to the temporary procedure change process described for changes which clearly do not change the intent of a procedure, temporary procedure changes which may change the intent of a procedure may be made following the process described in this section. Except that the person normally responsible for approving revisions to the procedure is the approval authority for the change.                                                                                                                                                |
| <b>16.</b> ANSI N18.7<br>Section 5.2.6   | Instead of the requirements of this section concerning non-conforming conditions, non-conforming conditions will be evaluated and controlled in accordance with the corrective action program.                                                                                                                                                                                                                                                                                                                                                       |
| <b>17.</b> ANSI N18.7<br>Section 5.2.6   | The requirement of the fifth paragraph of this section to have a log of the status of temporary modifications is not applicable to temporary modifications for routine tasks installed in accordance with procedures. These procedures shall provide assurance that approvals are obtained, temporary modification activities are independently verified by an individual cognizant of the purpose and the effect of the temporary modification, and that activities are adequately documented to indicate the status of the temporary modification. |
| <b>18.</b> ANSI N18.7<br>Section 5.2.7.1 | This section will be implemented by adding the words “Where practical” in front of the first and fourth sentences of the fifth paragraph. For modifications where the requirements of the fourth sentence are not considered practical, a review in accordance with the provisions of 10 CFR 50.59 will be conducted.                                                                                                                                                                                                                                |

## **Appendix B**

### **Regulatory Commitments**

#### **C. Regulatory Guide 1.33 (continued)**

##### **Clarification/Exception**

- |                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 19. ANSI N18.7<br>Section 5.2.8    | In lieu of a “master surveillance schedule,” the following requirement shall be complied with: “A surveillance testing schedule(s) shall be established reflecting the status of all in-plant surveillance tests and inspections.”                                                                                                                                                                                              |
| 20. ANSI N18.7<br>Section 5.2.9    | The requirements of the Physical Security Plan shall be implemented in place of these general requirements.                                                                                                                                                                                                                                                                                                                     |
| 21. ANSI N18.7<br>Section 5.2.13.1 | Consistent with ANSI N45.2.11 Section 7.2, minor changes to documents, such as inconsequential editorial corrections, or changes to commercial terms and conditions may not require that the revised document receive the same review and approval as the original documents.                                                                                                                                                   |
| 22. ANSI N18.7<br>Section 5.2.14   | Where marking, tagging, or physical separation of the non-conforming item is not feasible, the non-conforming item may be controlled by the use of appropriate documentation.                                                                                                                                                                                                                                                   |
| 23. ANSI N18.7<br>Section 5.2.15   | Required procedure reviews following the occurrences discussed in Section 5.2.15, paragraph 3, sentence 3, are determined and controlled in accordance with the QAPM Section A.6 instead of this section.                                                                                                                                                                                                                       |
| 24. ANSI N18.7<br>Section 5.2.15   | This section requires plant procedure review by an individual knowledgeable in the area affected by the procedure no less frequently than every two years to determine if changes are necessary or desirable. Instead of this review, controls are in effect to ensure that procedures are reviewed for possible revision upon identification of new or revised source material potentially affecting the intent of procedures. |
| 25. ANSI N18.7<br>Section 5.3.9    | Instead of the requirements of this section, the format and content of the emergency operating procedures follow the applicable NRC approved format for VY.                                                                                                                                                                                                                                                                     |
| 26. ANSI N18.7<br>Section 5.3.9.3  | VY's NRC accepted Emergency Plan will be implemented in lieu of the requirements in this section.                                                                                                                                                                                                                                                                                                                               |

## **Appendix B**

### **Regulatory Commitments**

#### **D. Regulatory Guide 1.37, dated March 1973**

##### **Clarification/Exception**

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|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. General</b>                    | Instead of using the cleanliness level classification system of ANSI N45.2.1, the required cleanliness for specific items and activities is addressed on a case-by-case basis. Cleanliness is maintained, consistent with the work being performed to prevent introduction of foreign material. As a minimum, cleanliness inspections are performed prior to system closure and such inspections are documented. |
| <b>2. Section C.3</b>                | The water quality for final flushes of fluid systems and associated components is at least equivalent to the quality of the operating system water, except for the oxygen and nitrogen content.                                                                                                                                                                                                                  |
| <b>3. Section C.4</b>                | As an alternate to the requirements of this section, contamination levels in expendable products may be based upon safe practices and industrial availability with documented engineering evaluations. Contaminant levels are controlled such that subsequent removal by standard cleaning methods results in the achievement of final acceptable levels that are not detrimental to the materials.              |
| <b>4. ANSI N45.2.1<br/>Section 5</b> | Any nonhalogenated material may be used which is compatible with the parent material not just plastic film.                                                                                                                                                                                                                                                                                                      |



## **Appendix B**

### **Regulatory Commitments**

#### **E. Regulatory Guide 1.38 Revision 2, dated May 1977**

##### **Clarification/Exception**

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|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. ANSI N45.2.2<br>Section 3.2   | Storage of an item in a higher-level storage area meets the lower level storage requirements.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2. ANSI N45.2.2<br>Section 3.2   | As an alternate to the requirements in Section 3.2.1 items (4), (5), and 7, Section 3.2.2, Section 3.2.3 item (1), and Section 3.2.4 item (2), the storage atmosphere may be controlled such that it is free of harmful contaminants in concentration that could produce damage to the stored item and protecting weld end preparations and threads by controlling the manner in which the item is stored.                                                                                                                                                                                                                                                                                                                                                                                |
| 3. ANSI N45.2.2<br>Section 3.7.1 | Cleated, sheathed boxes may be used up to 1000 lb. rather than 500 lb. as specified in 3.7.1(1). Special qualification testing may be required for loads over 1000 lb.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 4. ANSI N45.2.2<br>Section 3.7.2 | Skids and runners will normally be fabricated from a minimum 2 X 4 inch nominal lumber size and laid flat except where this is impractical because of the small dimensions of the container. If forklift handling is required, minimum floor clearance for forklift tines will be provided.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 5. ANSI N45.2.2<br>Section 4.3.4 | Inspections of packages and/or preservative coatings are made immediately prior to loading rather than after loading.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6. ANSI N45.2.2<br>Section 5.2.1 | Warehouse personnel will normally visually scrutinize incoming shipments for damage of the types listed in this section, this activity is not necessarily performed prior to unloading. Separate documentation of the shipping damage inspection is not necessary. Release of the transport agent after unloading and the signing for receipt of the shipment provides adequate documentation of completion of the shipping damage inspection. Any non-conformances noted will be documented and dispositioned. Persons performing the visual scrutiny during unloading are not considered to be performing an inspection function as defined under Reg. Guide 1.74; therefore, while they will be trained to perform this function, they may not be certified (N45.2.6) as an inspector. |

## **Appendix B**

### **Regulatory Commitments**

#### **E. Regulatory Guide 1.38 (continued)**

##### **Clarification/Exception**

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| <b>7.</b> ANSI N45.2.2<br>Section 5.2.2  | <p>The second division of this subsection requires six additional inspection activities if an item was not inspected or examined at the source. VY will consider that a source inspection has been conducted if the supplier of the item is required to comply with ANSI N45.2.2 for the purchased item and if the supplier's program has been audited and found acceptable in the area (i.e., the supplier performs a source inspection of his supplier or conducts a receipt inspection that includes, as applicable, the six additional items listed).</p> <p>Instead of the requirement that receiving inspections be performed in an area equivalent to the level of storage required for the item, receiving inspections will be performed in a manner and in an environment which does not endanger the requisite quality of an item. The receiving inspection's location environmental controls may be less stringent than storage environmental requirements for that item; however, the short time spent in the less stringent receiving inspection area shall be of such duration that it will not adversely affect the item being received.</p> |
| <b>8.</b> ANSI N45.2.2<br>Section 5.2.3  | <p>The "Special Inspection" procedure is not required to be attached to the item or container but shall be readily available to inspection personnel.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>9.</b> ANSI N45.2.2<br>Section 6.2.1  | <p>Items which fall within the Level D classification of the standard will be stored in an area which may be posted to limit access, but other positive controls such as fencing or guards may not be provided.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>10.</b> ANSI N45.2.2<br>Section 6.2.4 | <p>The sentence is replaced with the following: "The use or storage of food, drinks, and salt tablet dispensers in any storage area shall be controlled and shall be limited to designated areas where such use or storage is not deleterious to stored items."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

## **Appendix B**

### **Regulatory Commitments**

#### **E. Regulatory Guide 1.38 (continued)**

##### **Clarification/Exception**

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| <b>11.</b> ANSI N45.2.2<br>Section 6.2.5 | The sentence is replaced with the following: "Exterminators or other appropriate measures shall be used to control animals to minimize possible contamination and mechanical damage to stored material. If evidence of animal activity is detected, a survey or inspection will be utilized to determine the extent of the damage."                                                                          |
| <b>12.</b> ANSI N45.2.2<br>Section 6.3.3 | An alternate to the stated requirement is the following: "Hazardous chemicals, paints, solvents, and other materials of a like nature shall be stored in approved cabinets or containers which are not in close proximity to installed systems required for safe shutdown."                                                                                                                                  |
| <b>13.</b> ANSI N45.2.2<br>Section 6.4.2 | Care of items in storage shall be exercised in accordance with the following: "Types of components that could require maintenance while in storage shall be identified and evaluated for specific maintenance requirements. Maintenance activities 6.4.2 (6) through 6.4.2 (8) listed in this requirement shall be considered during this evaluation and any deviations shall be justified and documented."  |
| <b>14.</b> ANSI N45.2.2<br>Section 6.5   | The last sentence of this section is not applicable to the operations phase.                                                                                                                                                                                                                                                                                                                                 |
| <b>15.</b> ANSI N45.2.2<br>Section 6.6   | VY will comply with this section's requirements with the clarification that, for record purposes, only the access of personnel without key cards into indoor storage areas shall be recorded. Unloading or pickup of material shall not be considered "access," nor shall inspection by NRC or other regulatory agents, nor shall tours by non-licensee employees who are accompanied by licensee employees. |

## **Appendix B**

### **Regulatory Commitments**

#### **E. Regulatory Guide 1.38 (continued)**

##### **Clarification/Exception**

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| <b>16.</b> ANSI N45.2.2<br>Section 7.3                       | Re-rating hoisting equipment will be considered only when necessary. Prior to performing any lift above the load rating, the equipment manufacturer must be contacted for his approval and direction. The manufacturer must be requested to supply a document granting approval for a limited number of lifts at the new rating and any restrictions involved, such as modifications to be made to the equipment and the test lift load. At all times, the codes governing re-rating of hoisting equipment must be observed. |
| <b>17.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.4.1 | During printing of the standard, a transposition occurred between the last sentence of A3.4.1(4) and A3.4.1(5). The correct requirements are: (4) "However, preservatives for inaccessible inside surfaces of pumps, valves and pipe systems containing reactor coolant water shall be the water flushable type." (5) "The name of the preservative used shall be indicated to facilitate touch up."                                                                                                                         |
| <b>18.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.4.2 | There may be cases involving large or complex shaped items for which an inert or dry air purge is provided, rather than a static gas blanket, in order to provide adequate protection due to difficulty of providing a leak proof barrier. In these cases, a positive pressure purge flow may be utilized as an alternate to a leak-proof barrier.                                                                                                                                                                           |
| <b>19.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.5.1 | Instead of the requirement for non-metallic plugs and caps to be brightly colored, non-metallic plugs and caps shall be an appropriately visible color.                                                                                                                                                                                                                                                                                                                                                                      |
| <b>20.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.5.2 | This paragraph limits halogen and sulfur content of tape. The use of tapes containing greater amounts of halogens than those identified will be allowed after appropriate evaluation; however, the quantities shall not be such that harmful concentrations could be leached or released by breakdown of the compounds under expected environmental conditions.                                                                                                                                                              |



## **Appendix B**

### **Regulatory Commitments**

#### **E. Regulatory Guide 1.38 (continued)**

##### **Clarification/Exception**

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| <b>21.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.7.1 | In lieu of A.3.7.1(3) and (4), VY will comply with the following: Fiberboard boxes shall be securely closed either with a water resistant adhesive applied to the entire area of contact between the flaps, or all seams and joints shall be sealed with not less than 2-inch wide, water resistant tape.                                                                                                                                                                     |
| <b>22.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.9   | Instead of the requirement that container markings appear on a minimum of two sides of the container, preferably on one side and one end, VY will comply with the following: Containers are adequately marked for storage, identification, and retrieval. Multiple marking requirements are imposed, where necessary.                                                                                                                                                         |
| <b>23.</b> ANSI N45.2.2,<br>Appendix (A-3)<br>Section A.3.9  | Instead of the requirement that container markings be no less than 3/4" high, VY will comply with the following: Container markings are of a size which permits easy recognition.                                                                                                                                                                                                                                                                                             |
| <b>24.</b> ANSI N45.2.2,<br>Appendix (A-3)<br>Section A.3.9  | Instead of the specific container marking requirements, VY will comply with the following: The information required in container marking is evaluated on a case-by-case basis.                                                                                                                                                                                                                                                                                                |
| <b>25.</b> ANSI N45.2.2<br>Appendix (A-3)<br>Section A.3.9   | The last paragraph of A.3.9 could be interpreted as prohibiting any direct marking on bare austenitic stainless steel and nickel alloy metal surfaces. As an alternate, paragraphs A.3.9.(1) and (2) may be used to control marking on the surface of austenitic stainless steels and nickel base alloys based on documented engineering evaluations. Contamination levels are controlled such that the material used for marking is not detrimental to the materials marked. |

## **Appendix B**

### **Regulatory Commitments**

#### **F. Regulatory Guide 1.39 Revision 2, dated September 1977**

##### **Clarification/Exception**

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| 1. ANSI N45.2.3<br>General       | The ANSI five level zone designation system may not be utilized, but the intent of the standard will be met for the areas of housekeeping, plant and personnel safety, and fire protection. |
| 2. ANSI N45.2.3<br>Section 3.1   | This section is not applicable.                                                                                                                                                             |
| 3. ANSI N45.2.3<br>Section 3.2.3 | The Fire Protection Program shall be used in lieu of the general requirements in this section.                                                                                              |
| 4. ANSI N45.2.3<br>Section 3.3   | The first paragraph is not applicable to the operations phase.                                                                                                                              |
| 5. ANSI N45.2.3<br>Section 3.4   | This section is not applicable.                                                                                                                                                             |
| 6. ANSI N45.2.3<br>Section 3.5   | Subparagraph (1) is not applicable to the operations phase; (2), (3), and (4) will be implemented.                                                                                          |

## **Appendix B**

### **Regulatory Commitments**

#### **G. Regulatory Guide 1.58 Revision 1, dated September 1980**

##### **Clarification/Exception**

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| 1. General                     | VY may choose not to apply the requirements of this guide to those personnel who are involved in day-to-day operations, surveillance, maintenance, and certain technical and support services whose qualifications are controlled by the Technical Specifications or other QAPM commitment requirements.                                                                                              |
| 2. General                     | General certification of inspectors in accordance with this guide is approved by a manager responsible for quality.                                                                                                                                                                                                                                                                                   |
| 3. ANSI N45.2.6<br>Section 1.2 | Paragraph 4 requires that the standard be imposed on personnel other than licensee employees; the applicability of this standard to suppliers will be documented and applied, as appropriate, in procurement documents for such suppliers.                                                                                                                                                            |
| 4. ANSI N45.2.6<br>Section 1.2 | The requirements of this standard do not apply to personnel using later editions of ASNT contained within 10CFR50.55a approved ASME editions or addenda.                                                                                                                                                                                                                                              |
| 5. ANSI N45.2.6<br>Section 2.3 | This section requires, in part, that any person who has not performed inspection, examination, or testing activities in his qualified area for a period of one year shall be re-evaluated. A 90-day grace period may be applied to this activity. For activities deferred in accordance with the 90-day grace period, the next performance due date will be based on their originally scheduled date. |
| 6. ANSI N45.2.6<br>Section 2.5 | This section's requirements are clarified with the stipulation that, where no special physical characteristics are required, none will be specified. The converse is also true: if no special physical requirements are stipulated, none are considered necessary.                                                                                                                                    |
| 7. ANSI N45.2.6<br>Section 3.5 | VY reserves the right to use personnel who do not meet these experience requirements but have shown capability through training and testing or capability demonstration.                                                                                                                                                                                                                              |

## **Appendix B**

### **Regulatory Commitments**

#### **H. Regulatory Guide 1.64 Revision 2, dated June 1976**

##### **Clarification/Exception**

1. ANSI N45.2.11  
Section 5.2.4 For the documentation of inter-disciplinary design reviews, there must be documented evidence of the acceptability of design documents, or portions thereof, prior to release (material, stress, physics, mechanical, electrical, concrete, etc.). Indication of the positive concurrence of those who determine the design acceptability relative to their respective disciplinary area of concern should be on the document or on a separate form traceable to the document. A document that indicates the reviewer's comments need not be retained.

## **Appendix B**

### **Regulatory Commitments**

#### **I. Regulatory Guide 1.74, dated February 1974**

##### **Clarification/Exception**

1. ANSI N45.2.10, Section 2      Definitions for “Certificate of Conformance” and “Certificate of Compliance” will be exchanged based upon the guidance in ANSI N45.2.13 Section 10.2.



## **Appendix B**

### **Regulatory Commitments**

#### **J. Regulatory Guide 1.88 Revision 2, dated October 1976**

##### **Clarification/Exception**

- 1. RG 1.88  
Section C**

VY will meet the requirements of NFPA No. 232-1975, "Standards for the Protection of Records", as allowed by the Regulatory Guide 1.88 – 1976 or ANSI/ ASME NQA-1-1983, Supplement 17S-1 Section 4.4 in lieu of N45.2.9 Section 5.6 or the discussions in this section for Records Storage Facilities with the clarification that penetrations providing fire protection, lighting, temperature/humidity control, or communications are acceptable as long as the penetration maintains the required fire resistance.

Except that as an alternate to these requirements non-permanent records (e.g., 3 years retention records) may be stored and maintained by the originating organization in one-hour minimum fire rated file cabinets located in environmentally controlled facilities that have suitable fire protection. Suitable fire protection is provided by either an automatic sprinkler system or a combination of two or more of the following: 1) automatic fire alarms, 2) hose stations, or 3) portable extinguishers.
- 2. ANSI N45.2.9  
Section 1.4**

Documents are considered completed when they are "completely filled out" (i.e., when sufficient information is recorded to fulfill the record's intended purpose) and the adequacy of the document (e.g., legibility) has been accepted by the document control or records management organizations or designees.
- 3. ANSI N45.2.9  
Section 3.2.2**

The requirements for an index discussed in this section are considered to only require that a method of retrieving the record and controlling the identified information be established.
- 4. ANSI N45.2.9  
Section 5.4.2**

Instead of the requirements of this section, VY will comply with the following: Records shall not be stored loosely. They shall be secured for storage in file cabinets or on shelving in containers. Methods other than binders, folders, or envelopes (e.g., dividers or boxes) may be used to organize records for storage. This section is not applicable to special processed records controlled in accordance with Section 5.4.3 when the requirements of this section are not appropriate for the record type.

## **Appendix B**

### **Regulatory Commitments**

#### **J. Regulatory Guide 1.88 (continued)**

##### **Clarification/Exception**

5. ANSI N45.2.9  
Section 5.4.3  
Instead of the requirements of this section, VY will comply with the following: Provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm, and magnetic media to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity as appropriate to the record type with appropriate consideration of packaging and storing recommendations as provided by the manufacturer of these materials.
6. ANSI N45.2.9  
Section 5.5  
Routine general office and nuclear site security systems and access controls are provided; no special security systems are required to be established for record storage areas.
7. ANSI N45.2.9  
Section 5.6  
VY will meet the requirements of NFPA No. 232 – 1975, “Standards for the Protection of Records”, as allowed by the Regulatory Guide 1.88 – 1976 or ANSI/ASME NQA-1-1983, Supplement 17S-1 Section 4.4 in lieu of this section for Records Storage Facilities with the clarification that penetrations providing fire protection, lighting, temperature/humidity control, or communications are acceptable as long as the penetration maintains the required fire resistance.

Except that as an alternate to these requirements non-permanent records (e.g., 3 years retention records) may be stored and maintained by the originating organization in one-hour minimum fire rated file cabinets located in environmentally controlled facilities that have suitable fire protection. Suitable fire protection is provided by either an automatic sprinkler system or a combination of two or more of the following: 1) automatic fire alarms, 2) hose stations, or 3) portable extinguishers.

## **Appendix B**

### **Regulatory Commitments**

#### **K. Regulatory Guide 1.94 Revision 1, dated April 1976**

##### **Clarification/Exception**

1. ANSI N45.2.5  
Section 2.5.2      The last sentence requires that all items inspected with maintenance and test equipment, which is found to be out of calibration, shall be considered unacceptable. VY will comply with QAPM Section B.9.g as an alternate. QAPM Section B.9.g requires an evaluation to determine the validity of previous measurements.
2. ANSI N45.2.5  
Section 4.5      When using ACI-305-72 and ACI-306-66, VY may apply the following requirements:

##### PLACING TEMPERATURES OF CONCRETE

A. During hot weather concreting, placing temperatures of concrete will be limited to the following: 1) Concrete members less than 3 feet in least dimension will not exceed 90°F; 2) Concrete members from 3 feet to 6 feet in least dimension will not exceed 70°F; and 3) Concrete members more than 6 feet in least dimension will have placing temperature as near 50°F as can be obtained by use of ice as necessary up to 100 percent of adding mixing water; and by shading aggregate and sprinkling the coarse aggregate the day it is to be used. Care will be taken so that no unmelted ice remains in the concrete at the end of the mixing period.

B. During cold weather concreting: In heating the water and aggregate, live steam to heat the fine and coarse aggregate shall not be used. The permissible range for concrete temperature shall be as follows: 1) Sections less than 3 feet in least dimensions 55°F to 75°F; and 2) Mass concrete 3 feet or more in least dimension 45°F to 65°F. The mixing water and aggregate will be purchased as required. The materials will be free of ice, snow and frozen lumps before they enter the mixer.

3. ANSI N45.2.5  
Table B      As an alternate to daily testing grout for compressive strength, for prepackaged shelf item, non-shrink grout, the grout's compressive strength tests may be performed once on each batch of non-shrink grout received, rather than each day grout is placed.

## **Appendix B**

### **Regulatory Commitments**

#### **K. Regulatory Guide 1.94 (continued)**

##### **Clarification/Exception**

**4. ANSI N45.2.5  
Section 4.8**

For the performance of correlation tests, the requirements of this standard may be modified as discussed below:

Table B, REINFORCING STEEL: In-process testing of reinforcing steel will include the mechanical properties of yield strength, tensile strength and percent elongation on full size specimens for each bar size for each 50 tons or fraction thereof from each mill heat. Bend tests are performed during material qualification testing only, except as noted below for bar sizes #14 through #18.

Table A, "Required Qualification Tests" as applied to reinforcing steel will include bend tests as required by ASTM A615 and summarized in the following: a) For bar sizes #3 through #11, one full size specimen from largest bar size rolled from each mill heat, unless material from one heat differs by three or more designation numbers. When this occurs, one bend test shall be made from both the highest and lowest designation number of the deformed bars rolled; b) For bar sizes #14 through #18, Supplementary Requirements S1 of ASTM A615 will be applied, i.e., one fullsize specimen for each bar size for each mill heat. If supplementary requirements are not followed for mill tests, they will be applied as in-process tests.

In-process test specimens may be selected at the rebar fabrication shop, prior to start of fabrication of the rebar from the heat or fraction thereof represented by the test specimen.

Acceptance criteria for any failed test (qualifications as well as in-process) may be the same as that for tensile tests specified in Subarticle CC-2331.2 of ASME Section III, Div. 2 Code (1975). This states that if a test specimen fails to meet the specified strength requirements, two (2) additional specimens from the same heat and of the same bar size would be tested, and if either of the two additional specimens fails to meet the specified strength requirements, the material represented by the tests would be rejected for the specified use. Alternative use of rejected material under strict control may be subject to evaluation by engineering.

## **Appendix B**

### **Regulatory Commitments**

#### **K. Regulatory Guide 1.94 (continued)**

##### **Clarification/Exception**

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| <b>5.</b> ANSI N45.2.5<br>Section 4.9 | VY may interpret the terms "horizontal, vertical and diagonal bars" to apply respectively to the following types of splice positions: a. Horizontal, including 10° to horizontal; b. Vertical, including 10° to vertical; and c. 45° angle, including 10° to 80° angle. The words "splicing crew" are interpreted to refer to all project members that are actively engaged in preparing and assembling cadweld mechanical splices at the final splice location. Separate test cycles will be established for each bar size and each splice position. |
| <b>6.</b> ANSI N45.2.5<br>Section 5.5 | VY will comply with inspection requirements of the applicable welding codes and any exceptions instead of this section.                                                                                                                                                                                                                                                                                                                                                                                                                               |



## **Appendix B**

### **Regulatory Commitments**

#### **L. Regulatory Guide 1.116 Revision 0-R, dated June 1976**

##### **Clarification/Exception**

1. ANSI N45.2.8  
Section 3 Documented routine inspections and audits of the storage area may be performed instead of the requirements of this section.

## **Appendix B**

### **Regulatory Commitments**

#### **M. Regulatory Guide 1.123 Revision 1, dated July 1977**

##### **Clarification/Exception**

1. RG 1.123  
Paragraph C.6.e

This paragraph shall be implemented as originally written in N45.2.13 (i.e., with the verb “should” instead of the verb “shall”). VY retains the ultimate responsibility for performance of purchased equipment. The appropriate engineering discipline will exercise this management/engineering prerogative with respect to the final decision on post installation test requirements.
2. ANSI N45.2.13  
Section 1.2.2

Item c is an option which may be used to assure quality; however, any option given in 10 CFR 50 Appendix B, Criterion VII as implemented by the QAPM may also be used.
3. ANSI N45.2.13  
Section 1.3

Instead of the definition provided for QA Program Requirements, VY will comply with the following: “Those individual requirements of the QAPM which, when invoked in total or in part, establish quality assurance program requirements for the activity being controlled. Although not specifically used in the QAPM, ANSI N45.2 may be imposed upon suppliers.”
4. ANSI N45.2.13  
Section 3.1

The “same degree of control” is stipulated to mean “equivalent level of review and approval.” The changed document may not always be reviewed by the originator; however, at least an equivalent level of management/supervision shall review and approve any changes.
5. ANSI N45.2.13  
Section 3.1

Changes to procurement documents which are changes in quantity, estimated price, cost codes, taxes, format or editorial changes that do not affect the quality of the item or service do not require an equivalent level of review and approval as the original document.

## **Appendix B**

### **Regulatory Commitments**

#### **M. Regulatory Guide 1.123 (continued)**

##### **Clarification/Exception**

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|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>5a.</b> ANSI N45.2.13<br>Section 3.2          | <p>When purchasing commercial-grade (as defined in 10CFR21) calibration services from NVLAP or A2LA accredited calibration laboratories, procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2-1971. In such cases, accreditation may be accepted in lieu of the Purchaser imposing a QA Program consistent with ANSI N45.2-1971, provided all the following are met:</p> <ul style="list-style-type: none"><li>• The accreditation is to ANSI/ISO/IEC 17025.</li><li>• The accrediting body is either NVLAP A2LA.</li><li>• The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.</li><li>• The purchase documents require calibration/report to include identification of the laboratory equipment/standards used.</li><li>• The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.</li></ul> |
| <b>6.</b> ANSI N45.2.13<br>Section 3.4           | <p>The requirements of the QAPM will be implemented instead of this section.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>7.</b><br>ANSI N45.2.13<br>Section 4.2        | <p>Supplier evaluations may be performed any time prior to placing the purchased item in service.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>8.</b> ANSI N45.2.13<br>Section 8.2<br>Item b | <p>Non-conformance notices for conditions described in this section are only required to be submitted to VY when the non-conformance could adversely affect the end use of an item relative to safety, interchangeability, operability, reliability, integrity or maintainability.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

## **Appendix B**

### **Regulatory Commitments**

#### **M. Regulatory Guide 1.123 (continued)**

##### **Clarification/Exception**

- 9.** ANSI N45.2.13  
Section 10.2  
Item d

The section states that the certificate should be attested to by a person who is responsible for this QA function whose function and position are described in the Purchaser's/Supplier's QA program. As an alternate to this requirement, VY will use the following: "The person attesting to a certificate shall be an authorized and responsible employee of the supplier, and shall be identified by the supplier."

## **Appendix B**

### **Regulatory Commitments**

#### **N. Regulatory Guide 1.144 Revision 1, dated September 1980**

##### **Clarification/Exception**

1. RG 1.144  
Section C.3.a.(2) This section is not applicable.
2. RG 1.144  
Section C.3.b.(2) In addition to the requirements of this section, previously evaluated and approved active suppliers for which auditing is not the selected method of source verification should be evaluated concurrent with the award of a contract. Regardless of the evaluation results, active suppliers (except those excluded under C.3.b(1)) are source verified (audit, surveillance or inspection) within two years prior to award of a contract or have source verification performed. Inactive suppliers are evaluated prior to supplying items or services. An audit shall be conducted if required to determine the acceptability of procured items or services (i.e., acceptability cannot be determined by receipt inspection or another method allowable under 10 CFR 50 Appendix B, Criterion VII).
3. RG 1.144  
Section C.3.b.(2) This section requires that supplier audits be performed on a triennial basis. A 90-day grace period may be applied to this activity. For activities deferred in accordance with the 90-day grace period, the next performance date will be based on their originally scheduled date.
4. RG 1.144  
Section C.3.b.(2) Instead of the annual documented evaluation of suppliers discussed in this section, an ongoing evaluation of supplier performance is conducted which takes into account, where applicable, the other considerations of this section and paragraph of the Regulatory Guide.



## **Appendix B**

### **Regulatory Commitments**

#### **N. Regulatory Guide 1.144 (continued)**

##### **Clarification/Exception**

- |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>4a.</b> RG 1.144<br>Section C.3.b.(2)   | For suppliers of commercial-grade (as defined in 10CFR21) calibration services with accreditation by NVLAP or A2LA, a documented review of the supplier's accreditation by the purchaser may be used in lieu of performing an audit, accepting an audit by another licensee, performing a commercial-grade survey, inspecting or testing following delivery, or performing in-process surveillances during performance of the service. This review shall include, at a minimum, verification of all the following: <ul style="list-style-type: none"><li>• The accreditation is to ANSI/ISO/IEC 17025.</li><li>• The accrediting body is either NVLAP A2LA.</li><li>• The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.</li></ul> |
| <b>5.</b> ANSI N45.2.12<br>Section 4.3.1   | Pre-audit and post-audit conferences may be fulfilled by a variety of communications, such as telephone conversation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>6.</b> ANSI N45.2.12<br>Section 4.3.1   | Pre-audit and post-audit conferences are only held when deemed necessary by quality assurance or when requested by the audited organization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>7.</b> ANSI N45.2.12<br>Section 4.3.2.2 | This subsection could be interpreted to limit auditors to the review of only objective evidence; sometimes and for some program elements, no objective evidence may be available. VY will comply with an alternate sentence which reads: "When available, objective evidence shall be examined for compliance with QAPM requirements. If subjective evidence is used (e.g., personnel interviews) then the audit report must indicate how the evidence was obtained."                                                                                                                                                                                                                                                                                                                                                    |

## **Appendix B**

### **Regulatory Commitments**

#### **N. Regulatory Guide 1.144 (continued)**

##### **Clarification/Exception**

- |                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>8.</b> ANSI N45.2.12<br>Section 4.3.3  | Pre-audit and post-audit conferences are only held when deemed necessary by quality assurance or when requested by the audited organization.                                                                                                                                                                                                                                                                                                                                                                           |
| <b>9.</b> ANSI N45.2.12<br>Section 4.3.3  | Pre-audit and post-audit conferences may be fulfilled by a variety of communications, such as telephone conversation.                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>10.</b> ANSI N45.2.12<br>Section 4.4   | Instead of the last sentence of the last paragraph of the section, VY will comply with the following: The audit report shall be issued within thirty working days after the last day of the audit. The last day of an audit shall be considered to be the day of the post-audit conference. If a post-audit conference is not held because it was deemed unnecessary, the last day of the audit shall be considered to be the date the post-audit conference was deemed unnecessary as documented in the audit report. |
| <b>11.</b> ANSI N45.2.12<br>Section 4.5.1 | The QAPM Section A.6 corrective action program may be used instead of these requirements as long as the appropriate time limits are applied to significant conditions adverse to quality. Also, no additional documentation is necessary if needed corrective actions are taken and verified prior to audit report issuance.                                                                                                                                                                                           |

## **Appendix B**

### **Regulatory Commitments**

#### **O. Regulatory Guide 1.146 Revision 0, dated August 1980**

##### **Clarification/Exception**

1. ANSI N45.2.23  
Section 2.3.1.3      Holders of NRC-issued Reactor Operator/Senior Reactor Operator Licenses comply with the requirements of this section and may be awarded two credits.
2. ANSI N45.2.23  
Section 2.3.4      Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and lead an audit team. They shall have participated in at least one audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively lead audits, licensee management may designate a prospective lead auditor as a "lead auditor".
3. ANSI N45.2.23  
Sections 3.2 and 5.3      These sections require that an annual assessment be performed of each lead auditor's qualification and that each lead auditor's records be updated annually. A 90-day grace period may be applied to these activities. For activities deferred in accordance with the 90-day grace period, the next performance due date will be based on their originally scheduled date.

## **Appendix C**

### **Other General Guidance Documents**

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).”

## **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 10CFR50.59 or 10CFR72.48, 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 10CFR50.59 or 10CFR72.48.

#### **2.0 SAFETY REVIEW COMMITTEE (SRC)**

The SRC is responsible for reviewing, auditing, and advising the chief nuclear officer and the VY executive on matters related to the safe storage of irradiated fuel. This review and audit function is independent of line organization responsibilities.

1. The SRC shall include a minimum of three members. Alternates may be substituted for regular members. The licensee shall designate in writing the chairman, the members, and alternates for the SRC. The Chairman shall not have management responsibilities for, or report to, the line organizations responsible for operation and maintenance of the facility.
2. The SRC shall collectively have experience and knowledge in the following functional areas:
  - a) fuel handling and storage (including the potential for criticality),
  - b) chemistry and radiochemistry,



- c) engineering,
  - d) radiation protection and
  - e) quality assurance.
3. The SRC shall collectively possess the necessary expertise and experience to provide an independent review of problems in the majority of the areas described in Section 2.2.
  4. If necessary, individuals with knowledge and experience in other functional areas may be utilized to provide advice to the SRC.
  5. As a minimum, the SRC shall conduct two designated meetings per year.
  6. A quorum shall consist of not less than a majority of the number of standing SRC members, or their duly appointed alternates. Those members representing the line organizations responsible for the operation and maintenance of the facility shall not constitute a majority of the quorum. At least one member of the quorum shall be the Chairman or the Chairman's designated alternate.
  7. As a minimum, the SRC shall perform the following functions:
    - a) Advise the Chief Nuclear Officer and the VY Executive on all matters related to safe storage of irradiated fuel.
    - b) Advise the management of the audited organization and the Chief Nuclear Officer and the VY Executive of review results as they relate to safe storage of irradiated fuel.
    - c) Recommend to management of the assessed organization, and its management, any corrective action to improve the safe storage of irradiated fuel.
    - d) Notify the Chief Nuclear Officer and the VY Executive of any safety significant disagreement between the SRC and Site Management within 24 hours.
  8. The SRC shall be responsible for reviewing:
    - a) The evaluations for procedures, and changes thereto, completed under the provisions of 10 CFR 50.59 or 10 CFR 72.48 to verify that such actions do not require prior NRC approval or a license amendment as defined in 10 CFR 50.59 or 10 CFR 72.48. This review may be completed after implementation of the affected procedure;
    - b) Changes to structures, systems or components important to the safe storage of irradiated fuel to verify that such changes do not require prior NRC approval or a license amendment as defined in 10 CFR 50.59 or 10 CFR 72.48. This review may be completed after implementation of the change;
    - c) Test or experiments involving the safe storage of irradiated fuel to verify that such tests or experiments do not require prior NRC approval or a license amendment as defined in 10 CFR 50.59 or 10 CFR 72.48. This review may be completed after performance of the test or experiment;
    - d) Proposed changes to the Technical Specifications or the operating license. This review may be completed after submittal;
    - e) Violations of codes, regulations, orders, license requirements, or internal procedures/instructions having nuclear safety significance;
    - f) Indications of unanticipated deficiencies in any aspect of design or operation of structures, systems, or components that could affect safe storage of irradiated fuel;

- g) Significant accidental, unplanned, or uncontrolled radioactive releases. Including corrective action(s) to prevent recurrence;
- h) Significant operating abnormalities or deviations from normal and expected performance of equipment that affect safe storage of irradiated fuel;
- i) The performance of the corrective action system; and
- j) Internal and external experience information related to the safe storage of irradiated fuel that may indicate areas for improving facility safety.

Reports or records of these reviews shall be forwarded to the Chief Nuclear Officer and the VY Executive within 30 days after completion of the review.

- 9. The SRC's responsibility shall include oversight of the Audit Program. Audits shall be performed of the activities and at the associated frequencies defined in Section C.
- 10. Written records of reviews and audits shall be maintained. As a minimum, these records shall include:
  - a) Results of the activities conducted under the provisions of QAPM;
  - b) Recommendations to the management of the audited organization;
  - c) Documentation of reviews conducted by the SRC; and
  - d) Determination of whether changes to procedures and programs require prior NRC approval as defined in 10 CFR 50.59 and 10 CFR 72.48.

Written records of reviews and audits shall be maintained. As a minimum, these records shall include results of the activities conducted under the provisions of Section B.15.

This appendix **also** provides for **the** future relocation of Administrative Controls from other license basis documents, such as from the defueled Technical Specifications.