Entergy Nuclear Operations, Inc.
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10 CFR 50.54(a)

CNRO-2017-00017
BVY 17-023

September 19, 2017

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

SUBJECT: Proposed Revision to the Entergy Vermont Yankee Quality Assurance Program Manual (VY QAPM)
Vermont Yankee Nuclear Power Station
Docket Nos. 50-271, 72-59 and 71-0907
License No. DPR-28

REFERENCES:
1. Letter, USNRC to Entergy Nuclear Operations, Inc., "Entergy Vermont Yankee Quality Assurance Program Manual Vermont Yankee Nuclear Power Station and Independent Spent Fuel Storage Facility – Review and Acceptance of Changes (CAC No. L53120)," NVY 16-020, dated June 16, 2016 (ML16165A465)

2. 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)

Dear Sir or Madam:

Pursuant to 10 CFR 50.54(a), Entergy Nuclear Operations, Inc. (ENO) is proposing changes to the Entergy Vermont Yankee Quality Assurance Program Manual (QAPM) for Vermont Yankee Nuclear Power Station (VY) and Independent Spent Fuel Storage Installation (ISFSI). The proposed changes described below and in the attachments to this letter represent reductions in commitment to the previously approved VY QAPM (Reference 1):

- The program basis is changed from ANSI/ANS standards to primarily use Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," Revision 3, as a guidance document. Regulatory Guide 7.10, Revision 2 was previously included in QAPM Appendix C as an additional guidance document. This change involves the elimination of commitments to standards and Regulatory Guides that will no longer be necessary following completion of the transfer of

all spent nuclear fuel from the spent fuel pool to dry fuel storage in the ISFSI. Subsequent to this transition, there will be no structures, systems and components (SSCs), items or activities classified as safety-related as defined in 10 CFR 50 Appendix B, and the highest level of safety significance for items and activities remaining at the facility are designated as Important-to-Safety (ITS) under 10 CFR 71 and 10 CFR 72, as defined in Appendix A of the QAPM. Regulatory Guide 7.10 includes Quality Assurance Program guidance for ITS activities under 10 CFR 71 and 10 CFR 72.

- The Safety Review Committee (SRC) is removed from Appendix D of the QAPM and replaced with the Independent Management Assessment (IMA) function described in QAPM Section A.3.f. The IMAs are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is effectively implemented. IMAs are performed by individual(s) designated by the chief nuclear officer, who are independent of the activities assessed and provide the appropriate level of expertise. The IMAs will ensure that independent oversight of activities being performed at VY will continue during dry fuel storage and decommissioning.

- Requirements for fire protection and loss prevention program inspections and audits have been eliminated from QAPM Section C.2.a.2, based on all spent nuclear fuel being moved from the spent fuel pool to the ISFSI. However, there continues to be a requirement for audits of the fire protection program and implementing procedures once every 24 months.

Other corresponding changes to the QAPM have also been designated as reductions in commitments to the previously approved QAPM, and are described in the attachments. The attachments also contain other changes to the QAPM that are not considered to be reductions in commitments. The changes that are not considered to be reductions in commitments are provided for information and are planned to be implemented in Revision 7 to the QAPM or in a separate revision.

Attachment 1 provides a detailed discussion and justification of the proposed changes, including a comparison to Regulatory Guide 7.10. The comparison matrix demonstrates that the provisions included in Regulatory Guide 7.10 have been adequately addressed in the QAPM and implementing procedures. Attachment 1 also includes a comparison of the 10 CFR 71, Subpart H requirements to the QAPM that demonstrates these criteria are adequately addressed. The proposed changes will also continue to meet the requirements of 10 CFR 50, Appendix B and 10 CFR Part 72, Subpart G. Attachment 2 includes a summary of the proposed changes. Attachment 3 includes the revision to the QAPM with the proposed changes shown.

VY is currently implementing Revision 5 of the QAPM. A revision to the QAPM, based on the changes proposed in Reference 2, which included the relocation of administrative controls from the facility Technical Specifications to the QAPM, and other conforming changes, is anticipated to be implemented following NRC approval of Reference 2. Revisions to the QAPM other than those proposed in Reference 2 and in this submittal may also be warranted. Therefore, the QAPM revision numbers used in this submittal are for reference information only and are subject to change

ENO requests review and approval of these changes by May 31, 2018. Once approved, the changes will be implemented consistent with, but not earlier than, the implementation schedule described in Reference 2 (i.e., within 60 days following ENO notification to the NRC that all spent nuclear fuel has been transferred out of the spent fuel pool and placed within the ISFSI).

This letter contains no new regulatory commitments. Should you have any questions, please contact me at (802) 451-3374.

Sincerely,

CCC/jal

Attachments:

1. Description and Justification of the Proposed Changes to the VY QAPM, Including a Comparison Matrix of Regulatory Guide 7.10
2. Summary of Proposed Changes to the VY QAPM
3. VY QAPM Proposed Revision 7

cc: Mr. Daniel H. Dorman
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ATTACHMENT 1

Vermont Yankee Nuclear Power Station

Description and Justification of the Proposed Changes to the VY QAPM, Including a Comparison Matrix of Regulatory Guide 7.10

Description and Justification of the Proposed Changes to the VY QAPM

QAPM Section	Change(s)	Evaluation and Justification
Cover Page		
No changes were made with the cover page.		Since there were no changes made with the cover page, there are no reductions in commitments to the previously approved QAP.
Policy Statement		
No changes were made with the policy statement.		Since there were no changes made with the policy statement, there are no reductions in commitments to the previously approved QAP.
Table of Contents		
Minor change was made to the table of contents to reflect update made to Appendix A header. This is based on elimination of the term “safety-related” from items and activities since there are no longer any SSCs classified as classified as safety-related.		The changes reflects that the facility has completed the transfer of spent nuclear fuel from the Spent Fuel Pool to the ISFSI so there are no longer any safety-related SSCs, items of activities at the VYNPS.
Section A - Management		
A-1	Eliminated the term “safety-related” from items and activities since there are no longer any SSCs classified as classified as safety-related.	The changes reflects that the facility has completed the transfer of spent nuclear fuel from the Spent Fuel Pool to the ISFSI so there are no longer any safety-related SSCs, items of activities at the VYNPS.
A-2	A number of changes were made with the Organization section to reflect modifications to the proposed VY site specific organization that is responsible for the implementation of the QAPM functions. The changes eliminate positions that are no longer necessary, modify position titles and realigning responsibilities for others, but there is no overall change to the reporting relationship, which continues to report through a top level site manager up to the chief nuclear officer. Also, the Safety Review Committee (SRC) has been removed from the QAPM and has been	These changes to the 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 executive responsible for nuclear oversight to the chief nuclear officer. The top level 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. The elimination and consolidation of positions, functions and responsibilities are acceptable since the changes are being made, based on the site completing the transfer of spent nuclear fuel from the Spent Fuel Pool to the ISFSI. The functions and positions being modified or eliminated are no longer necessary. The majority of these changes are considered clarifications or administrative and do not constitute a reduction in commitments to the previously

QAPM Section	Change(s)	Evaluation and Justification
	replaced with an Independent Management Assessment (IMA) function.	approved QA Program. These changes also are being made to reflect the organizational changes that were approved by the NRC with the associated LAR for the Defueled Technical Specifications. The last change was the SRC being removed from Section A.2.C and is being replaced with an IMA function, which is a reduction in commitments to the previously approved QA Program. The majority of the changes can be implemented without prior NRC approval, based on the guidance provided in 10 CFR 50.54.a.3 with the exception of the transition of the SRC to an IMA function. These changes do not reduce the effectiveness of the QAPM and continue to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.
A-3	A detailed discuss of the IMA function was added in Section A-3.f.	This is a corresponding change to the proposed modification with the SRC being removed from Section A.2.c and appendix D , section A.3.f was added to describe the IMA function. This describes the IMA function, which is a reduction in commitments to the previously approved QA Program. These changes do not reduce the effectiveness of the QAPM and continue to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.
A-4	No changes were made with this section.	No changes were made with this section so there are no reductions in commitments to the previously approved QA Program.
A-5 & 6	Editorial changes were made with these sections to eliminate associated regulatory guide examples.	The changes made with this section are editorial so there are no reductions in commitments to the previously approved QA Program.
A-7	The primary changes made were to reflect that there are no longer any safety-related items or activities at the VYNPS and the change to regulatory commitments provided in Appendix B of the QAPM. Some editorial changes were also made.	The changes reflect that the facility has completed the transfer of spent nuclear fuel from the Spent Fuel Pool to the ISFSI so there are no longer any safety-related SSCs, items of activities at the VYNPS. Although the editorial changes are not reductions in commitments to the previously approved QA Program, the change to regulatory commitments is a reduction in commitments. These changes do not reduce the effectiveness of the QAPM and continue to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.

QAPM Section	Change(s)	Evaluation and Justification
Section B - Performance/Verification		
Editorial changes were made with each section to eliminate associated regulatory guide examples.		The changes made with this section are editorial so there are not reductions in commitments to the previously approved QA Program.
Section C - Audit		
The primary changes that were made to this section were to modify the fire protection audit requirements. There were previously three (3) separate audit requirements that collectively included a minimum frequency of once per 24 months. The change eliminates two (2) of the audit requirements, but the minimum frequency to perform an audit of the fire protection program at least once per 24 months remains. Also, an editorial change was made with to eliminate associated regulatory guide examples.		The changes reflect that the facility has completed the transfer of spent nuclear fuel from the Spent Fuel Pool to the ISFSI, so the fire protection program audit requirements are being modified concurrently. Although the editorial change is not a reduction in commitments to the previously approved QA Program, the changes to the audit requirements of the fire protection program is a reduction in commitments. These changes do not reduce the effectiveness of the QAPM and continue to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.
Section D – Independent Safety Review Function		
Reworded the section to refer to the other parts of the QAPM that address the independent safety review function and deleted the reference to NUREG-0737, Section I.B.1.2, “Independent Safety Engineering Group.”		The elimination of the reference to NUREG-0737, Section I.B.1.2, “Independent Safety Engineering Group” is a reduction in commitments to the previously approved QA Program; however, it is not necessary for a facility that is in decommissioning and has transferred all spent nuclear fuel from the Spent Fuel Pool to the ISFSI. These changes do not reduce the effectiveness of the QAPM and continue to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.
Appendix A – Safety Related and Important-to-Safety Structures, Systems and Components		
Editorial changes were made to this Appendix header to reflect that there are no longer any safety-related items or activities at the VYNPS. In addition a note was added further indicating that there are no longer any safety related SSCs at the VY facility.		The changes made to this entire section are editorial so there are no reductions in commitments to the previously approved QAPM. The note reflects that the facility has completed the transfer of spent nuclear fuel from the Spent Fuel Pool to the ISFSI so there are no longer any safety-related SSCs, items of activities at the VYNPS.
Appendix B – Regulatory Commitments		

QAPM Section	Change(s)	Evaluation and Justification
	The program's Regulatory Commitments basis was changed from ANSI/ANS standards to primarily using Regulatory Guide 7.10 "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material", Revision 3 as a guidance document. The only previously remaining standard is ANSI/ANS 3.1, which was modified to eliminate those specific exceptions that are no longer applicable.	Changing the QAPM's Regulatory Commitments basis from ANSI/ANS standards to primarily Regulatory Guide 7.10 "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material." Revision 3 and modifying the specific exceptions to ANSI/ANS 3.1 are acceptable for a facility that is in decommissioning and has transferred all spent nuclear fuel from the Spent Fuel Pool to the ISFSI. Regulatory Guide 7.10 was previously included in Appendix C as an additional guidance document. The highest level of safety significance items and activities remaining at the VYNPS are designated as Important-to Safety (ITS) under 10 CFR 71 and 10 CFR 72 as defined in Appendix A. There are no SSCs, items or activities remaining at the VYNPS site that are classified as safety-related as defined in 10 CFR 50 Appendix B. The NRC Quality Assurance Program guidance for ITS activities under 10 CFR 71 and 10 CFR 72 is included in Regulatory Guide 7.10. The change in base guidance documents is a reduction in commitment to the previously approved QA Program, but it is acceptable due to the current state of decommissioning at the VYNPS and the passive operational status of the VY ISFSI. This is a reduction in commitment, but it is acceptable due to the current state of decommissioning at the VYNPS site and the passive operational status of the VY ISFSI. Similar changes have been previously approved by the NRC at other facilities in a similar configuration as is being described. These changes do not reduce the effectiveness of the QAPM and continue to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.
Appendix C – Administrative Controls		
	Appendix C was modified to delete the guidance documents references which were added to Appendix B.	The changes made with this section are editorial so there are not reductions in commitments to the previously approved QA Program.
Appendix D – Administrative Controls		
	Appendix D was modified to reflect the removal of SRC and some minor administrative changes.	The change to remove the SRC from the QAPM and replacing it with an IMA function is a reduction in commitments to the previously approved QA Program. The other changes are considered administrative and reflect that all fuel has

QAPM Section	Change(s)	Evaluation and Justification	
		been transferred from the Spent Fuel Pool to the ISFSI. The change with eliminating the SRC cannot be implemented without prior NRC approval, based on the guidance provided in 10 CFR 50.54.a.3. The other changes (i.e., title updates and some minor administrative modifications) can be implemented without prior NRC approval. The overall changes do not reduce the overall effectiveness of the QAPM and it continues to ensure compliance with 10 CFR 50, Appendix B and the SAR quality assurance program description commitments previously accepted by the NRC, but will require prior NRC approval.	

VY QAPM Revision 7 "Regulatory Guide 7.10 (Revision 3) Compliance Matrix"

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
1. GUIDANCE ON § 71.103, QUALITY ASSURANCE ORGANIZATION 1.1 Structure and Authority For each function, the structure of the organization and the assignment of responsibility should ensure that the following requirements are fulfilled: The formal structure of the organization is documented by organization charts that identify each organizational element that functions under the QA program. • The discussion specifies the required authority and organizational responsibility, including sufficient independence from influences of cost and schedule. • The specified quality requirements are achieved and maintained by those who have been assigned the responsibility for performing the work. • The QA program user has established measures to provide adequate control over activities important to safety (e.g., inspecting, cleaning, purchasing, and preparing the packaging for delivery). • The conformance to established requirements is verified by individuals and groups not directly responsible for performing the work. *Note:* If, because of staffing limitations, the same individuals perform multiple functions (including QA), the QA program user should establish measures to ensure that the designated individuals performing QA and QC functions have the responsibility and authority to stop unsatisfactory work and delivery or installation of nonconforming material. These individuals also should have direct access to management levels that can ensure that QA procedures important to safety have been accomplished. In addition, the QA program user should establish and document the	An organizational discussion is provided in the QAPM Section A.2 consistent with the previously approved QAPM that has approved organizational charts maintained independent of the QAPM. The organizational structure consists of corporate and VY functions. As defined, the specific organization titles for the quality assurance functions described are identified in procedures. Section A-4 states that "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. 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." The VYNPS organization has the authority to accomplish the quality assurance functions described, which is delegated to the incumbent's staff as necessary to fulfill the identified responsibility. The authority, duties, responsibilities, and interface requirements are addressed in QAPM. These activities include performing activities affecting the functions of structures, systems, and components, which are important to safety, those associated with attaining quality objectives and the QA functions. Section B.1.c states that "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." Section A.2.b.4 states that "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)." Section A.2.b.4 states that "The executive responsible for oversight

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
required duties and qualifications for (1) the individual who has overall authority and responsibility for the QA program, as well as (2) other personnel performing QA and QC functions. Individuals with QA and QC functions should have the written endorsement of upper management. 1.2 Senior Management Endorsement of a QA Program Senior management, the company or corporate president or chief executive officer, should maintain a continuing involvement in QA matters to ensure that the QA program is effective. Senior management should establish a written company or corporate policy to perform work on items important to safety in accordance with the requirements of 10 CFR Part 71, Subpart H. This policy should be described in or incorporated into the QA program plan and implemented through the QA program procedures. The policy statement should also identify the functions and positions that have delegated authority for the following tasks: • Implement and revise the provisions of the described QA program. • Regularly assess the scope, status, implementation, and effectiveness of the QA program.	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. 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." Section A.5 Personnel Training and Qualification states that "Personnel assigned to implement elements of the quality assurance program are capable of performing their assigned tasks. Training programs are established and implemented to ensure that personnel achieve and maintain suitable proficiency. Personnel training and qualification records are maintained in accordance with procedures." Commitments are provided within this section of the QAPM with ANSI/ANS 3.1-1978 being the base commitment personnel training and qualifications. The Policy Statement states that "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." Section A.2.a.1, 2 & 3 state that "the Entergy Corporation chief executive officer (CEO) is responsible for overall corporate policy and provides

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
	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. 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 Independent Management Assessments report to this executive. 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. Section A.3.f states that "the Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
	effectively implemented. This Independent Management Assessment is performed by individual(s) designated by the chief nuclear officer, independent of activities assessed and who provide the appropriate level of expertise in the activities assessed. The Independent Management Assessment results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the chief nuclear officer." Section A.3.f states that "The Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is effectively implemented. This Independent Management Assessment is performed by individual(s) designated by the chief nuclear officer, independent of activities assessed and who provide the appropriate level of expertise in the activities assessed. The Independent Management Assessment results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the chief nuclear officer." Policy V-EN-PL-100, "Nuclear Excellence Model" defines organizational roles and responsibilities, which are defined in organization charts that reflect the responsibilities contained within the QAPM.
2. GUIDANCE ON §71.105, "QUALITY ASSURANCE PROGRAM" 2.1. General Guidance on QA Programs In its program description submittal, the QA program user should describe to the NRC how each of the requirements in Subpart H of 10 CFR Part 71 applies to its particular situation and how each requirement will be satisfied. The information supplied for NRC review will vary as a function of the nature of activities in which the QA program user is involved. For example, an individual or organization using a general license solely for transportation of radioactive material in packages purchased or leased for that purpose would be expected to address regulations governing activities such as procurement, shipment, and handling. By contrast, someone who designs and fabricates packaging would be expected to address	The QAPM has been previously approved to the NRC under Appendix B to 10 CFR Part 50 and was also subsequently accepted under 10 CFR 71.101(f). This compliance matrix is intended to identify to the NRC how each of the regulations in Subpart H of 10 CFR Part 71 applies to the VY situation and how it will be satisfied. The NRC also has been previously notified that the QAPM will be applied to ITS SSCs and activities associated with dry fuel storage to satisfy the requirements of 10 CFR 72 Subpart G. Section A.7.b states that "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)." These requirements, along with 10 CFR 71.106 provide the requirements for making changes to the QAPM. Section B.1.c states that "Work is accomplished and verified using

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
criteria for design and testing, as well as material procurement activities. Elements common to all QA program descriptions include the quality organization and program, corrective action, QA records, and audits. In developing its program, a prospective QA program user can refer to the NRC's guidance in this regulatory guide, as well as the additional guidance on graded QA approach in NUREG/CR-6407 (Ref. 7). In developing its program, a QA program user should apply each of the applicable Subpart H regulations in a graded approach (i.e., to an extent that is consistent with items important to safety). Following the NRC staff's technical review and determination that the QA program submittal meets regulatory requirements, the Commission issues a QA program approval. Changes to an approved QA program are specifically addressed in new §71.106 as described in Section B, "DISCUSSON," of this Regulatory Guide. Based on NRC approval of its QA program description submittals, a QA program user will translate the regulations discussed in its submittals into lower-level (working-level) implementing procedures that govern the conduct of QA activities important to safety. If the NRC staff reviews a QA program submittal and finds that it inadequately describes how the requirements will be met or fails to specifically address some Subpart H regulation(s), the staff will either reject the QA program submittal or ask the QA program user to submit additional information to correct the deficiencies. 2.2. Scope of QA Program The QA program user should establish measures for identifying: (1) the components, structures, and systems that the QA program will cover, and (2) the approach for verifying that the applicable components, structures, and systems meet design objectives. Although 10 CFR Part 71 allows the development of a "graded" QA program, this does not preclude the alternative of defining a program with additional measures if such a program is deemed	instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety." For item (1), Appendix A addresses all SSCs to which the QAPM is applicable. For item (2), various sections of the QAPM identify the approach for verifying that the applicable components, structures, and systems meet design objectives. For bullet 1, Section B identifies the controls and practices necessary to ensure that activities important to safety are performed using specified equipment and under suitable environmental conditions. For bullet 2, various sections of the QAPM specify the QA and QC responsibilities applicable to the implementation of activities important to safety. For bullet 3, Section A.5 establishes the requirements for indoctrination and training programs to ensure that personnel performing activities important to safety are trained and qualified to perform those activities. Appendix A of the QAPM address the applicability of the QAPM, including all SSCs, In Appendix A, the Holtec Safety Analysis Report (SAR) for the storage system, the Holtec Safety Analysis Report (SAR) for the transportation system and associated Holtec specifications. NUREG/CR-6407 is identified as input reference for determining ITS classifications. The Policy Statement states "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." Section B.1.c states that "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." (The Quality Assurance Criterion to Implementing Procedure Matrix is contained in Table 1 below)

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
necessary to attain the confidence needed for meeting design objectives. In particular, the QA program user should establish measures to ensure that the following requirements are fulfilled: • Activities important to safety are performed using specified equipment and under suitable environmental conditions. • QA and QC manuals specify the designated responsibilities for implementation of activities important to safety. • The QA program user has established indoctrination programs to ensure that personnel performing activities important to safety are trained and qualified to perform those activities. 2.3. Applicability of QA Program Measures that the QA program covers should be compatible with and emphasize characteristics identified in the manufacturer's QA program. The QA program user should establish the rationale for identifying items classified as important to safety and subject to the user's QA program. 2.4. Documentation The QA program user should ensure that written procedures and instructions: (1) describe all activities that are important to safety and applicable to the design, procurement, fabrication, and testing of packaging, and (2) will be in place before the QA program user engages in those activities. If the QA program user has not yet initiated activities important to safety, the user should identify the implementing procedures for such activities by title and procedure number and provide a brief description of the content of those procedures with an estimated date for their completion. The following table shows a suitable format for listing procedures to demonstrate implementation of a documented QA program. To demonstrate that written procedures fully implement and reflect	Section 2.0 "Quality Responsibilities" provides general responsibilities by functional areas. Section 1.1 states that "The QAPM is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of important to safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements." Section 3.5 states that "Management is responsible for ensuring that ITS activities are described in instructions, procedures, or drawings, which are prepared and approved prior to commencing activities. All project personnel are responsible to perform their activities in accordance with the requirements of these documents. These documents include appropriate quantitative and qualitative acceptance criteria to verify that the activity has been satisfactorily accomplished."

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the current status of the documented QA program, the QA program user should establish and maintain a master index of QA procedures related to all activities important to safety, as well as a matrix of the QA procedures that implement each section of 10 CFR Part 71, Subpart H. These written procedures should also address the use, management, and storage of electronic records and data. 2.5. Controlled Conditions and Assignment of Responsibilities The QA program user should establish measures to ensure that activities important to safety are accomplished using appropriate production and test equipment, suitable environmental conditions, applicable codes and standards, and proper work instructions. The QA program user should also document the assignment of responsibility for each task and method used to verify conformance to these quality requirements.	
3. GUIDANCE ON §71.107, "PACKAGE DESIGN CONTROL" Essential elements of adequate design control are (1) clearly-established working relationships among those responsible for preparing design disclosures, (2) conducting independent design analyses, (3) coordinating interfaces, and (4) maintaining lines of communication. To ensure an adequate commitment to control of design activities, applicants should consider the three principal areas of (1) control of the design process, (2) control of design input, and (3) control of design verification, as defined in regulatory positions 4.1 - 4.3. Computer-aided design (CAD) is extensively used in current design applications. Designs developed using CAD methods are prepared and stored electronically. Thus, applicable QA procedures for verification and validation, management of electronic records, and quality control of electronic data should address the control of electronic data in design applications to ensure authenticity and technical accuracy. The Nuclear Information and Records Management Association (NIRMA), ANSI, and the Electric Power Research Institute (EPRI) provide guidance for use in developing QA programs for managing electronic data. In addition, NRC	VY does not design packages to be licensed under 10 CFR 71 or 10 CFR 72. Per the Regulatory Guide 7.10, guidance on 10 CFR 71.07 (see left column), "Since users of packaging do not normally perform design activities, this section of Subpart H should not be applicable to users of packaging. However, users should establish and verify that the packaging was designed under the control of an NRC-approved QA program." VY has verified that the Holtec System was designed under the control of an NRC-approved QA Program (the Holtec QA Program). VY has also verified that 10 CFR 71 licensed shipments of B and C waste from the VY site contracted to EnergySolutions were designed under the control of an NRC-approved QA Program (the EnergySolutions QA Program). Therefore, this section of Subpart H is not applicable to VY, as we are users of the packaging was designed under the control of an NRC- approved QA program. However, guidance is provided in this section primarily for two purposes: 1) To provide for an appropriate interface with the NRC packaging Certificate Holder to ensure ISFSI or site

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Generic Letter 88-18, "Plant Record Storage on Optical Disks" (Ref. 11), and Regulatory Information Summary 00-18, "Guidance on Managing Quality Assurance Records in Electronic Media" (Ref. 13), provide guidance on the use of optical disc document imaging systems for retrieving record copies of QA records. 3.1. Control of the Design Process The QA program user should establish measures such as "classification of characteristics" to ensure that packaging designs are reviewed to emphasize parameters important to safety that can be controlled by inspections or tests and to identify test and inspection criteria and quality standards. To control the preparation of drawings and specifications, the QA program user should establish recognized engineering practices. Engineering practices may include: (1) prescribing drafting room standards, (2) checking methods, establishing review and approval and issuance and distribution requirements (including revisions to them), (3) maintaining current "as-built" configurations, and (4) storing and controlling original and master copies. 3.2. Control of Design Input The QA program user should establish measures to ensure that appropriate codes and standards are used in the design of the packaging. In the absence of such codes and standards for formulation of the design activities, the QA program user should identify alternative approaches. The QA program user should establish measures to ensure that (1) the responsible design organization has properly considered, reviewed, and approved all design parameters (e.g., criticality physics, cooling, and decontamination of an item), (2) the parameters are in accordance with the applicable performance codes, standards, and	SSCs do not adversely affect the important-to safety SSCs at the ISFSI, and 2) To provide guidance for the engineering of ISFSI and decommissioning activities, and ensuring adequate technical review is applied to changes, tests and experiments. Appendix A to the QAPM explains the interface between VY engineering and design and the design authority for the packaging design (the Certificate Holder, Holtec) as follows: "The safety 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 NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel Storage (10 CFR 72)." Section B.2.a states that "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." Section B.2.b states that "The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces." Section B.3.a states that "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. Specific measures applicable for control of "records" are addressed in subsequent sections of this matrix.

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regulatory requirements, and (3) design documents specify the related maintenance, repair, inservice inspection, handling, storage, and cleaning requirements. 3.3. Control of Design Verification The QA program user should establish methods for use in verifying the adequacy of the design (e.g., qualification testing, design review, or alternative calculations, including use of computer programs). Technically qualified individuals or groups responsible for design verification should not be in the administrative line of authority of the original designer, with the exception that the designer's immediate supervisor may perform the verification, provided that the following criteria are met: • The supervisor is the only technically qualified individual. • The supervisor's management documents and approves the need in advance. • The QA audits cover the effectiveness of the use of supervisors as design verifiers to guard against abuse of this practice. Changes to the final design may arise during the sequence of design verification. Consequently, the QA program user should establish measures to ensure that drawing and specification changes are reviewed and approved by the same individuals or organizations that reviewed and approved the original documents. Changes in design that could result in conditions different from those prescribed in the Certificate of Compliance (CoC) should be approved by the NRC prior to implementation. Design verification, if other than by qualification testing of a prototype or lead production unit, should be satisfactorily completed before release (1) for procurement or fabrication and (2) to other organizations for use in other design activities, except when this timing cannot be met. In such cases, design verification may be	

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deferred, provided that the justification for this action is documented and the unverified portion of the design output documents are appropriately identified and controlled. When a test program is used to verify the adequacy of a design, the prototype should be subjected to the most adverse design conditions. Even though users of packaging do not normally perform design activities, users should establish and verify that the packaging was designed under the control of an NRC-approved QA program.	
4. GUIDANCE ON §71.109, "PROCUREMENT DOCUMENT CONTROL" The QA program user should establish measures to control the preparation, review, concurrence, and approval of all procurement documents. 4.1. Content of Procurement Documents The QA program user should establish measures to ensure that procurement documents include the following information (to the extent applicable to their respective operations): • The scope of work to be performed by the prospective supplier. • The design-basis technical requirements (or references thereto), including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and standards, special process instructions, and test and inspection requirements. • Applicable Subpart H requirements that should be complied with and described in the supplier's QA program (e.g., qualified QA personnel from the purchaser's organization should review and provide review concurrence on the supplier's QA program or portions thereof before the purchaser initiates activities that the program affects. Also, if subtier suppliers are involved, the QA program user should specify the QA provisions appropriate to those procurements. The extent of the supplier's and subtier supplier's QA	Section B.4 states that: 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." Section B.5.a states that "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." Section B.5.b states that "The program is executed in all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier." An approved procurement procedure (V-EN-MP-101, "Procurement") is in place that controls all aspects of the procurement process. These procedures provide for the review requirements, which do not include a specific QA personnel review and approval for technical and quality requirements as was previously approved by the NRC. Section B.1.b states that "Personnel performing work activities such as design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, modification, operation, and decommissioning are responsible

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programs will depend on the particular item or service being procured). • Permission to gain access to the supplier's and subtier supplier's plant facilities and records for inspection and audit purposes (e.g., procurement documents should identify the type of verification activities required of any subtier suppliers for supplied materials, as well for any design, fabrication, assembly, testing, maintenance, and repair services or activities supplied). • Identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) that the supplier(s) must prepare, maintain, and submit to the purchaser for approval. • Requirements for reporting and approving disposition of nonconformances. • Identification of records that the supplier must retain, control, and maintain, as well as those records that the supplier must deliver to the purchaser before installation of hardware. These records should include the pertinent documentation to be furnished with the procured materials or services (e.g., CoC, as-built drawings, photographs, sketches, and use and maintenance manuals). If the pertinent documentation is in an electronic format, the QA program user also should maintain information on the specific software applications and storage or computing hardware. 4.2. Replacement Part Procurement Measures should be established to require that the QA program user reviews procurements of replacement parts important to safety to ensure that appropriate technical and QA requirements are included in purchase orders and that the purchase orders are placed with suppliers previously qualified during packaging fabrication. If	for achieving acceptable quality." Measures are provided for the review of and changes to procurement documents. Section B.1.c states that "Criteria that define acceptable quality are specified, and quality is verified against these criteria."

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replacement parts are purchased from suppliers not previously identified as qualified sources, the QA program user should ensure that the replacement parts meet requirements at least as stringent as the original criteria. 4.3. Review and Changes to Procurement Documents The QA program user should establish measures to ensure that review and approval of procurement documents are recorded before release, and that changes and revisions to those documents are subject to at least the same review and approval process as the original documents.	
5. GUIDANCE ON §71.111, "INSTRUCTIONS, PROCEDURES, AND DRAWINGS" 5.1. Quality Assurance Program Procedures The QA program user should establish measures to ensure that the following requirements are fulfilled: • Activities important to safety are prescribed and accomplished in accordance with current documented instructions, procedures, or drawings that have been approved by appropriate levels of management. • Instructions, procedures, and drawings specify the methods for complying with each of the applicable sections of Subpart H of 10 CFR Part 71. • All work activities are coordinated with QA personnel to ensure that the work- controlling documents incorporate appropriate inspection and hold points to verify that initial work, planned work, effective repairs, or rework have been performed satisfactorily. • Instructions, procedures, and drawings include quantitative acceptance criteria (e.g., dimensions, tolerances, and operating limits) and qualitative acceptance criteria (e.g.,	Section B.1.c states that "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." Section A.1.c states that "The QAPM applies to all activities associated with structures, systems, and components that are ITS controlled by 10 CFR 72, as defined in Appendix A. The QAPM also applies to transportation packages controlled by 10 CFR 71. The methods of implementation of the requirements of the QAPM are commensurate with the item's or activity's importance to safety. The applicability of the requirements of the QAPM to other items and activities is determined on a case-by-case basis as defined within approved procedures. The QAPM implements 10 CFR 50 Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G." (See Table 1 below for list of procedures.) Section A.3.e states that "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. Procedure AP-0096, "Control of Procedure" describes the process for development, review approval and revision of procedures, including the

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workmanship samples) to verify that activities important to safety have been accomplished satisfactorily. • Written procedures address the use, management, storage, and protection of electronic records and data. The QA program user should also maintain information on the specific software applications and storage or computing hardware. 5.2. QA Review and Concurrence The QA program user should establish measures to ensure that the QA organization reviews and concurs in inspection plans; test, calibration, and special process procedures; and specifications as well as any changes thereto. Before fabrication of an item, the QA organization should review and concur in the related manufacturing plans, as they relate to scheduled witness and hold points during fabrication.	review and approval by appropriate levels of management responsible for the quality activity. This includes the interaction with quality assurance personnel for verification activities, including establishing the appropriate qualitative and quantitative acceptance criteria. Procedure V-EN-AD-103, "Document Control and Records Management Programs" identifies the types of acceptable storage media and associated acceptance and maintenance criteria for each. Records are processed to the VY site electronic records system in accordance with approved procedures, as are any supporting corporate Entergy records.
6. GUIDANCE ON §71.113. "DOCUMENT CONTROL" 6.1. Controlled Documents The QA program user should maintain control of each of the documents of the QA program to reflect the current status. As a minimum, the QA program user should exercise control over the following: • design documents (e.g., drawings, specifications, and computer codes) • procurement documents • QA and QC manuals • operating, maintenance, and modification procedures • inspection and test procedures • nonconformance reports • design change requests • corrective action reports 6.2. Control of Document Generation and Issuance	Section B.14.a states, "A program is established and implemented to control the development, review, approval, issue, use, and revision of documents." In nearly each section of the QAPM where the various types of documents are described, the QAPM specifies appropriate controls for quality documents, regardless of the media and calls for specific controls to be contained in implementing procedures. Procedure V-EN-AD-103, "Document Control and Records Management Programs" describes the process for development, review approval and revision of procedures. Procurement documents, nonconformance reports and corrective action reports are not controlled documents at VY. They function as QA records rather than controlled documents. Section B.14.a states that "A program is established and implemented to control the development, review, approval, issue, use, and revision of documents."

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The QA program user should establish controls to ensure that all documents and any changes are adequately reviewed and approved before they are issued. These controls should include measures (e.g., the use of a master document list) to ensure that current issues of applicable documents are available at the location where the activity is being performed, to preclude use of obsolete or superseded documents. The QA program user also should check all packaging affected by design changes to verify that it is in accordance with the appropriate revision. In addition, the QA program user should identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto. 6.3. Control of Document Changes The QA program user should establish measures to ensure that changes to documents are reviewed and approved by the same organization that performed the original review and approval, and the changes are in accordance with established configuration control procedures. 6.4. Control of Electronic Documents If the documents are stored electronically, the QA program user should establish controls over access to the documents to ensure that the latest versions are available and changes are properly authorized and implemented. The software and hardware systems used to store electronic information should be reliable and secure to avoid alteration or corruption of the information.	Section B.14.c states that "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." The numerous implementing procedures that describe the creation and control of the various types of documents generated identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto. Implementing Procedure V-EN-AD-103, "Document Control and Records Management Programs" provides requirements for control of documents of all types of media. Procedure V-EN-AD-103, "Document Control and Records Management Programs" identifies the types of acceptable storage media and associated acceptance and maintenance criteria for each. Records are processed from the VY site into the Exelon electronic records system in accordance with approved procedures.
7. GUIDANCE ON §71.115, "CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES" The QA program user should establish measures in the areas identified below to ensure that materials, equipment, and services conform to procurement documents.	The QAPM (as delineated below) establishes the measures necessary to assure that purchased material, equipment, and services, whether purchased directly or through contractors or subcontractors, conform to the requirements of the procurement documents. These measures shall be specified in implementing procedures. For Important to Safety procurements, Procedure V-EN-MP-101, "Procurement" assigns

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7.1. Procurement Document Planning The QA program user should establish procurement planning procedures that describe each procurement step leading to contract award for items and services. These procedures should identify the organizations responsible for each procurement step. 7.2. Selection of Procurement Sources The QA program user should establish measures for evaluating and selecting procurement sources, including the extent of QA and engineering involvement. Specifically, the QA program user should consider establishing the following provisions (if applicable): • the supplier's capability to comply with applicable sections of Subpart H • results of the survey of the supplier's facility and QA program • review of the supplier's previous records and performance 7.3. Bid Evaluation and Award The QA program user should establish measures to ensure that designated individuals or organizations evaluate proposed suppliers, as applicable to the type of procurement, based on technical considerations, conformance to QA requirements, production capability, and past performance. Before contract award, the QA program user should resolve (if possible) all unacceptable conditions identified during the bid evaluation. If any unacceptable conditions cannot be resolved before contract award, the QA program user should obtain the supplier's commitment that the conditions will be resolved at a mutually agreeable date during the contract period. 7.4. Supplier Performance Control The QA program user should establish measures for pre- and post-award activities. These activities may include meetings and other communications, to ensure that the supplier understands procurement requirements, including, if applicable, "hold points" (i.e., pre-established inspection points in the manufacturing process that require inspection approval and release by the QA organization	responsibility for implementation of specific program elements. Section B.4.a states that "A program is established and implemented to ensure that purchased items and services are of acceptable quality." Section B.4.b states that "The program includes provisions for evaluating prospective suppliers and selecting only qualified suppliers." Section B.4.c states that "The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services." Section B.4.d states that "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." Section B.4.e states that "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." Section B.4.f states that "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." Section B.4.g states that "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." Section B.4.h states that "The procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service. Section B.4.i states that "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." Section B.5.a states that "A program is established and implemented to verify the quality of purchased items and services at intervals and to a depth

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before further processing) during manufacturing and testing and before shipment. 7.5. Verification Activities The QA program user should establish the extent to which source surveillance will be performed during fabrication, assembly, maintenance, modification, repair, inspection, testing, and shipment to ensure conformance with the purchase order requirements. The source surveillance should cover the following aspects: • instructions specifying characteristics or processes to be witnessed, inspected, or verified • the documentation required • identification of those responsible for implementing source surveillance The QA program user also should establish the extent to which inspection will be performed upon receipt of supplier-furnished hardware to ensure that items are properly identified and correspond with procurement documentation. When acceptance of an item is contingent on tests after installation in the package, the QA program user and item supplier should mutually establish the relevant acceptance documentation before its use. In addition, the QA program user should take appropriate measures (such as source surveillance and audits of records) to ensure that the supplier performed the design and fabrication of packaging under the control of an NRC-approved QA program. 7.6. Controlling Nonconformances The QA program user should establish measures to ensure the proper disposition of items or services that do not meet procurement requirements. These measures should include evaluation of nonconforming items categorized by the supplier, along with technical justification and recommended disposition (e.g., “use as is” or “repair”).	consistent with the item's or service's importance to safety, complexity, and quantity and the frequency of procurement.” Section B.5.b states that “The program is executed in all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier.” Procedure V-EN-MP-101, “Procurement,” in conjunction with other quality procedures provides guidance to ensure the following specific points are adequately addressed in procurement documents for important-to-safety scope: • ensure that the supplier understands procurement requirements, • establishing, if applicable, "hold points" • provide for the evaluation of nonconforming items categorized by the supplier, along with technical justification and recommended disposition (e.g., "use as is" or "repair") • establish requirements for supplier CofC • establish documentation and records requirements, including requirements for electronic media, if applicable, and retention requirements. Procedure V-EN-MP-120, “Quality Receipt Inspections” provides measures for performing receipt of supplier-furnished Important to Safety hardware upon delivery to ensure the quality and technical requirements are satisfied.

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7.7. Records The QA program user should establish measures to ensure that the supplier furnishes the following records to the purchaser (as a minimum): • documentation that identifies material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications met by the items) • documentation that identifies any procurement requirements that have not been met, along with a description of those nonconformances designated "use as is" or "repair" • documentation that the supplied material and equipment meets the applicable procurement requirements before installation or use • appropriate documentation, as identified in the purchase order, which will accompany the NRC-approved packaging during transport and be received at the destination by the user Such documents should (1) be referenced in the CoC, (2) relate to the use and maintenance of the packaging, and (3) identify necessary actions to be taken before delivery of the licensed material to a carrier for transport. If the pertinent documentation is in an electronic format, the QA program user should also maintain information on the specific software applications and storage or computing hardware that must be used to prepare and deliver the documentation. The QA program user should retain the documentation at the facility or site of material or equipment use.	
8. GUIDANCE ON §71.117, "IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS" The QA program user should establish measures to ensure that materials, parts, and components, including partially fabricated assemblies, are adequately identified to preclude the use of incorrect or defective items. These measures should provide the means for physical identification (e.g.,	Section B.6.a states that "A program is established and implemented to identify and control items to prevent the use of incorrect or defective items." Section B.6.b states that "Identification of each item is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation. Traceability is maintained to an extent consistent with the item's importance to safety."

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stamping, tags, labels, or lot-follower cards) and traceability to appropriate documentation (e.g., mill reports, drawings, or specifications) throughout fabrication, installation, and use. Also, when replacement of limited-life items is specified, the QA program user should establish measures to preclude use of items for which the shelf life or prescribed operation time has expired. In addition, the QA program user should establish measures to facilitate continued processing, when required inspections or tests have not been completed, to maintain physical identity and control over affected materials.	Procedure V-EN-MP-101, "Procurement" and Procedure V-EN-MP-125, "Warehousing" includes guidance to ensure the identification and control are adequately addressed for Important to Safety scopes of work in the procurement stages through its use. The implementation of any Important to Safety work at the ISFSI would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review. Any appropriate in- process inspections / Hold Points would be included in the Work Order to verify adequate identification and control of Important to Safety items.
9. GUIDANCE ON §71.119, "CONTROL OF SPECIAL PROCESSES" Special processes are not normally performed by the user of packaging. However, if packaging maintenance requires the use of special processes (e.g., welding or heat treating) or nondestructive testing, or if special processes are required to meet CoC requirements, the QA program user should establish measures to ensure that the special processes are controlled in accordance with the following suggested elements of process control: • Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards, and specifications. • The operations are performed by qualified personnel and accomplished in accordance with written process or procedure sheets that direct the recording of evidence of verification. • Qualification records of procedures, equipment, and personnel are established, filed, and kept current.	Section B.11.a states that "A program is established and implemented to ensure that special processes are properly controlled." Section B.11.b states that "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." Section B.11.c states that "Special processes are accomplished by qualified personnel, using appropriate equipment, and procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements." Procedure V-EN-MP-101, "Procurement" includes guidance to ensure the requirements for Important to Safety services are adequately addressed for applicable scope during the procurement stages. The implementation of any Important to Safety work at the ISFSI would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review. Any

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	appropriate in-process inspections / Hold Points would be included in the Work Order to verify special process procedures, equipment, and personnel are currently qualified in accordance with applicable codes, standards, and specifications.
10. GUIDANCE ON §71.121, "INTERNAL INSPECTION" 10.1. The QA program user should establish measures for internal inspection that consider the following recommendations: • The prerequisites to be satisfied before inspection are identified, including operator qualification and equipment calibration. Where sampling is used, the standard used as the basis for verifying acceptability of a group of items should be identified. • Inspection procedures, instructions, or checklists should be available for each work operation, where necessary to ensure quality. • Documents developed should include methods for identifying characteristics and activities to be inspected, acceptance and rejection criteria, and the individuals or groups responsible for performing the inspection. • "Hold" or witness points should be identified. • Inspection results should be recorded and objectively verifiable. • The appropriate personnel should approve data to ensure that all inspection requirements have been satisfied. 10.2. Inspections 10.2.1. Receiving Inspections The QA program user should establish measures to ensure that items that are important to safety meet the requirements specified on the purchase order when the items are received at the plant. The QA program user should establish the criteria for	Section B.12.a states that "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." Section B.12.b states that "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." Section B.12.c states that "Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organization, are to be defined." Section B.12.d states that "Inspection results are to be documented by the inspector and reviewed by qualified personnel." Section B.12.e states that "Unacceptable inspection results shall be evaluated and resolved in accordance with procedures." The implementation of any Important to Safety work at the ISFSI would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review. Any appropriate in-process inspections / Hold Points would be included in the Work Order. For receiving inspections, Section B.5.a states that "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." This is implemented through Procedure V-EN-MP-120, "Quality Receipt Inspections," which provides measures for performing receipt of supplier-furnished Important to Safety hardware upon delivery to ensure the quality and technical

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acceptance of each of these inspections, as well as the action to be taken, if noncompliance is encountered. These visual inspections should include the following aspects: • surface conditions • weld and structural integrity • the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves, and pressure relief devices • the condition of tie-down members (if applicable) • labeling and marking • leak-tightness of the packaging In addition, the QA program user should establish provisions to control accepted items until they are placed in stock or released for use, as well as provisions for the proper disposition of rejected items. 10.2.2. In-Process Inspections The QA program user should establish measures to ensure that process specifications and their supporting documentation provide for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is impractical. 10.2.3. Final Inspections The QA program user should establish measures to ensure the following: (1) final inspections provide for resolution of nonconformances identified in earlier inspections, (2) the inspected item is identifiable and traceable to specific records and is adequately protected from physical or environmental damage, and (3) supervisors review inspection records to verify that all inspection requirements have been satisfied, as described in Section 11.2 of this document.	requirements are satisfied. Procedure OP-0150 performs the daily inspections of temperature monitoring and Work Orders are used for the Annual Inspection of the Hi-Storm Spent Fuel Cask on Storage Pad. These provide the measures for the maintenance inspection to ensure adequate maintenance of the Important to Safety SSCs. These measures include identification of the items to be maintained, criteria for acceptability or replacement, and frequencies of inspection assigned to each item. Sections A.5.a through c state that "Personnel assigned to implement elements of the quality assurance program are capable of performing their assigned tasks. Training programs are established and implemented to ensure that personnel achieve and maintain suitable proficiency. Personnel training and qualification records are maintained in accordance with procedures." Section B.12.d states that "Inspection results are to be documented by the inspector and reviewed by qualified personnel." Section B.12.e states that "Unacceptable inspection results shall be evaluated and resolved in accordance with procedures." Section B.12.f states that "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." Procedure V-EN-AD-103, "Document Control and Records Management Programs" identifies the types of records considered QA records, and establishes the retention periods for each.

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For packaging use, the QA program user should establish checklists to ensure that inspections are performed to verify the following: • Packages are properly assembled. • Moderators and neutron absorbers are present (if applicable). • Valves through which primary coolant flows are protected against tampering. • Valves are set to specifications. • All shipping papers are properly completed. • Packages are conspicuously and durably marked as required by the regulations set forth by the U.S. Department of Transportation (DOT). • Measures are established to ensure that appropriate personnel designated by the package user sign the shipping tags or indicators before authorization for shipping. 10.2.4. Maintenance Inspections The QA program user should establish measures for an inspection program to ensure adequate maintenance of packaging. This inspection program should identify the items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item. 10.2.5. Inspectors The QA program user should establish measures to ensure that (1) inspectors are qualified in accordance with applicable codes, standards, and company training programs, (2) such qualifications and certifications are kept current, and (3) inspection personnel are independent from all individuals performing the activity being inspected. 10.2.6. Inspection Documentation The QA program user should maintain inspection records as QA records to document performance of inspection activities.	

Regulatory Guide 7.10 Revision 3	QAPM Revision 7 References
11. GUIDANCE ON §71.123, " TEST CONTROL" 11.1. Requirements The QA program user should establish measures to ensure that applicable test programs, including prototype qualification tests, production tests, proof tests, and operational tests, are accomplished in accordance with written procedures. The QA program user should also establish measures to ensure that modifications, repairs, and replacements are tested in accordance with the original design and testing requirements. 11.2. Procedures The QA program user should establish measures to ensure that test prerequisites identified in the appropriate design disclosures are properly translated into test procedures. For example, design closures may include instrument calibrations, monitoring to be performed, mandatory "hold" points, suitable environmental conditions to be maintained, condition of the test equipment, methods for physical identification of test specimen, methods for documenting or recording test data, and criteria for acceptance of the package. 11.3. Acceptance Tests The QA program user should establish measures, as appropriate, to ensure that acceptance tests are conducted before delivering packages for transport to a carrier. These measures should identify the basis for acceptance criteria (e.g., CoC, maintenance and operational manuals furnished by the packaging manufacturers). Tests should typically include the following considerations: • structural integrity • leak-tightness (on containment vessel as well as auxiliary equipment and shield tanks) • component performance for valves, gaskets, and fluid transport devices	Section B.8.a states that "A test control program is established and implemented to demonstrate that items will perform satisfactorily in service." Section B.8.b states that "Criteria are defined that specify when testing is required." Section B.8.c states that "The test control program includes, as appropriate, proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests." Section B.8.d states that "Test procedures are developed that include: instructions and prerequisites to perform the test, use of proper test equipment, acceptance criteria, and mandatory inspections as required." Section B.8.e states that "Test results are evaluated to assure that test objectives and inspection requirements have been satisfied." Section B.8.f states that "Unacceptable test results shall be evaluated." For 10 CFR 71 licensed Type B packages used for waste shipments offsite, tests are conducted in accordance with the NRC packaging Certificate Holder's procedures and processes. In the case of the 10 CFR 72 licensed storage packages at the ISFSI, the testing required for acceptance has already been completed during the fuel transfer project. The implementation of any Important to Safety work at the ISFSI in the future would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review. Any appropriate test guidance would be included in the Work Order to verify acceptability of Important to Safety items. Future Greater Than Class C (GTCC) waste requiring packaging for storage and or transportation will be performed in a manner that satisfies the applicable regulatory requirements for Important to Safety SSCs (10 CFR 71 and or 10 CFR 72) as determined by the packaging material selected and associated licensing strategy. Procedure V-EN-AD-103, "Document Control and Records Management Programs" identifies the types of records considered QA records, and establishes the retention periods for each.

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• shielding integrity • thermal integrity 11.4. Maintenance Tests The QA program user should establish maintenance test programs to ensure that packages remain usable and free of excessive radiation and contamination. These test programs should include measures to ensure that qualified and responsible individuals document, evaluate, and assess the acceptability of all test results. 11.5. Results The QA program user should establish measures to ensure that test results are documented, evaluated, and maintained as QA records. These records should be readily available if questions arise concerning operational aspects of the packages. In addition, a qualified individual or group should determine the acceptability of the records.	
12. GUIDANCE ON §71.125, "CONTROL OF MEASURING AND TEST EQUIPMENT" 12.1. Calibration Control The QA program user should establish guidelines to ensure that measurement and test equipment (e.g., gauges, fixtures, and devices used to measure product characteristics) is calibrated, adjusted, and maintained at prescribed intervals or before use. Such equipment should be labeled or tagged to indicate the planned date of its next calibration. Calibration records should be identified, traceable, and maintained as QA records. The QA program user should also establish measures to ensure that in-house reference or transfer standards used in calibrating measuring and test equipment are traceable to nationally recognized standards. Calibrating standards should have known valid relationships to nationally recognized	Section B.9.a states that "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." Section B.9.b states that "The types of equipment covered by the program (e.g., instruments, tools, gauges, and reference and transfer standards) are defined in procedures." Section B.9.c states that "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

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standards. If no known recognized standard exists, the QA program user should document the basis for calibration. 12.2. Out-Of-Calibration Equipment When test and measuring equipment is found to be out of calibration, the QA program user should take measures to validate previous inspection and test results up to the time of previous calibration. In addition, the QA program user should repair or replace any measuring equipment that is consistently out of calibration.	and other conditions affecting its performance." Section B.9.d states that "Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data." Section B.9.e states that "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." Section B.9.f states that "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." Section B.9.g states that "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." The implementation of any Important to Safety work at the ISFSI in the future would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review. Provisions for use of any M&TE in accordance with all requirements would be included in the Work Order for any M&TE used to verify acceptability of Important to Safety items.
13. GUIDANCE ON §71.127, "HANDLING, STORAGE, AND SHIPPING CONTROL" 13.1. Preservation The QA program user should establish measures to ensure that cleaning, handling, storage, and shipping are accomplished in accordance with design requirements to preclude damage or deterioration by environmental conditions such as temperature and humidity. When necessary, the QA program user also should establish provisions for the use of special handling, lifting, or storage devices (e.g., cranes, shock absorbers, or special markings) to	Section B.7.a states that "A program is established and implemented to control the handling, storage, shipping, cleaning, and preserving of items to ensure the items maintain acceptable quality." Section B.7.b states that "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." Section B.7.c states that "Specific procedures are developed and used for cleaning, handling, storage, packaging, shipping, and preserving items when

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adequately identify and preserve packaging components or assemblies. In addition, the QA program user should ensure that conditions identified in the CoC are adhered to when unloading packaging. 13.2. Preparation, Release, and Delivery to Purchaser The QA program user should establish measures to ensure that a final pre-release review has been completed. This review should ensure that the packaging (1) is prepared for delivery to the purchaser in accordance with NRC-approved drawings, specifications, and government regulations, (2) has passed all applicable inspections and tests, (3) is properly identified by physical markings or tags, and (4) contains operating manuals, maintenance manuals, and generic procedures relating to its use. In addition, the QA program user should establish measures to ensure that the following requirements are fulfilled: • Cavities within gas-cooled package containments have been adequately dried, and cavities within liquid-cooled packages have been drained to allow adequate void space. • All conditions (including specified operations, inspections, and tests) have been completed before delivery to a carrier. • All NRC and DOT requirements have been satisfied before delivery to a carrier. • All necessary shipping papers have been prepared as required and reviewed by qualified personnel to verify completeness and accuracy.	required to maintain acceptable quality." Section B.7.a states that "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." Transportation cask handling and operation shall conform to the handling and operating procedure for each licensed cask. Prior to the shipment of radioactive material, applicable conditions of the NRC's Certificate of Compliance (specifications, tests, and inspections) shall be satisfied. Required shipping papers shall be prepared and shall accompany the shipment in accordance with regulatory requirements and approved procedures. For 10 CFR 71 licensed Type B packages used for waste shipments offsite, tests are conducted in accordance with the NRC packaging Certificate Holder's procedures and processes. In the case of the 10 CFR 72 licensed storage packages at the ISFSI, the testing required for acceptance has already been completed during the fuel transfer project. The implementation of any Important to Safety work at the ISFSI in the future would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review. Any appropriate test guidance would be included in the Work Order to verify acceptability of Important to Safety items. Future Greater Than Class C (GTCC) waste requiring packaging for storage and or transportation will be performed in a manner that satisfies the applicable regulatory requirements for Important to Safety SSCs (10 CFR 71 and or 10 CFR 72) as determined by the packaging material selected and associated licensing strategy. Procedure V-EN-AD-103, "Document Control and Records Management Programs" identifies the types of records considered QA records, and establishes the retention periods for each. Procedure V-EN-MP-125, "Warehousing" includes guidance to ensure handling, storage and shipping are adequately addressed for any Important To Safety items in storage prior to release to the field or prior to shipping offsite.

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14. GUIDANCE ON §71.129, "INSPECTION, TEST, AND OPERATING STATUS" The QA program user should establish measures to ensure that the status of inspections, tests, and operating conditions (including maintenance of items) is known by organizations responsible for ensuring quality. The QA program user should also establish measures to control the application and removal of status indicators (e.g., tags, markings, stamps) and to ensure that bypassing a required inspection or test or any other required operation is procedurally controlled under the cognizance of the QA organization.	Section B.10.a states that "The status of required inspections and tests and the operating status of items are 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." Section B.10.b states that "The application and removal of inspection, test, and operating status indicators are controlled in accordance with procedures." The implementation of any Important to Safety work at the ISFSI in the future would invoke the use of Procedure MTAP-10084, "Work Management Process" and the generation of a Work Order subject to Quality Assurance review.
15. GUIDANCE ON §71.131,"NONCONFORMING MATERIALS, PARTS, OR COMPONENTS" An acceptable program for controlling nonconforming items should include the following principal elements: • proper identification • segregation of discrepant or nonconforming items • evaluation of the nonconforming items • disposition of the nonconforming items	Section A.6.d states that "Non-conforming items are properly controlled to prevent their inadvertent test, installation, or use. They are reviewed and either accepted, rejected, repaired, or reworked."
16. GUIDANCE ON §71.133,"CORRECTIVE ACTION" 16.1. Reporting The QA program user should establish measures to ensure that the causes of conditions detrimental to quality (e.g., those resulting from failures, malfunctions, deficiencies, deviations, or defective material and equipment) are identified promptly and reported to appropriate levels of management. In addition, the QA program user should establish measures to obtain corrective actions from suppliers and ensure that followup actions are documented to verify that the corrective actions were implemented and effective. 16.2. Closeout, Retrieval, and Disposition of Records The QA program user should establish measures to ensure that corrective actions designated by cognizant individuals have been	Section A.6.a states that "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." Section A.6.b states that "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." The approved QAPM guidance shall be used rather than the specific guidance provided within Regulatory Guide 7.10 Section A.6.c states that "Specific responsibilities within the corrective action program may be delegated, but VY maintains responsibility for the program's effectiveness."

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implemented to preclude recurrence. In addition, the QA program user should identify (by function or position) the individuals or organizations responsible for closing out corrective actions and documenting their resolution.	Section A.6.d states that "Non-conforming items are properly controlled to prevent their inadvertent test, installation, or use. They are reviewed and either accepted, rejected, repaired, or reworked." Section A.6.e states that "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." Section B.13.a states that "Procedures shall provide for identification, evaluation, and resolution of conditions adverse to quality." Section B.13.b states that "Reworked, repaired, and replacement items are to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives." Procedure V-EN-MP-101, "Procurement" includes guidance to ensure the requirements for corrective actions are applied to suppliers for Important To Safety scope.
17. GUIDANCE ON §71.135, "QUALITY ASSURANCE RECORDS" 17.1. General QA records should furnish documentary evidence of the activities that affect quality and should provide sufficient information to allow each record to be identified with the items or activities to which it applies. In accordance with 10 CFR 71.135, QA records shall be retained for 3 years beyond the date when the QA program user last engaged in the activity for which the QA program was developed. If any portion of the written procedures or instructions is superseded, the QA program user shall retain the superseded material for 3 years after it is superseded. As a minimum, QA records should include the following information: • design, procurement, manufacturing, and installation records • supplier evaluations • nonconformance reports	Section B.15.a states that "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." Section B.15.b states that "The program provides provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of records." Section B.15.c states that "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." Procedure V-EN-AD-103, "Document Control and Records Management Programs" identifies the types of records considered QA records, and establishes the retention periods for each. The full range of records required to be retained and the retention periods, including those required by 10 CFR

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• results of inspections and tests • failure analyses • as-built drawings and specifications • qualification of personnel, procedures, and equipment • calibration procedures • training and retraining records • corrective action reports • records demonstrating evidence of operational capability • records verifying repair, rework, and replacement • audit plans, audit reports, and corrective actions • records that are used as a baseline for maintenance • maintain records documenting changes to the QA program as required by 10 CFR 71.106 In addition, the QA program user should retain records that show evidence of package delivery to a carrier and proof that all NRC and DOT requirements have been satisfied (with their retention times identified). Where applicable, inspection and test records should contain the following information: • a description of the observation • evidence of completion of the inspection or test operation • results of inspections or tests with appropriate data • conditions detrimental to quality • names of inspectors, testers, or data recorders • evidence of acceptability	71.135. The procedure establishes the various types of acceptable storage media. Records are processed by VY into an electronic records system for indexing, storage and retrieval in accordance with approved procedures. Procedure V-EN-AD-103, "Document Control and Records Management Programs" establishes the overall guidance for the management of QA records. In addition, retention periods specified in various governing codes and standards (e.g. 10 CFR 71 & 10 CFR 72) are included in the retention requirements established in approved procedures for QA records.

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17.2. Generating Records The QA program user should establish measures to ensure that methods employed to generate and manage documents that are designated as QA records result in information that is retrievable, intelligible, and reliable. Such records should reflect the work accomplished and should be stored in a manner that avoids unnecessary delay when access to the record is needed. In addition, procedures for generating QA records should address both hard copy records and electronic information. 17.3. Indexing and Classification of Records The QA program user should classify QA records as either "lifetime" or "nonpermanent": • Lifetime records include those pertaining to package fabrication and those associated with a particular item while it is installed in the packaging or stored for future use. These records (1) demonstrate the capability for safe operation, provide evidence of repair, rework, replacement, or modification, (3) aid in determining the cause of an accident or malfunction of an item, and (4) provide a baseline for inservice inspection. • Nonpermanent records are those that show evidence that an activity has been performed but do not meet the criteria for lifetime records. Records pertaining to use of a package should be retained for a period of 3 years after each shipment. 17.4. Receipt, Retrieval, and Disposition of Records The QA program user should establish measures to provide a receipt control system, including identification of functions or positions in each organization responsible for receiving records and assessing the current status of records in their possession. The QA program user should also establish measures to ensure that records maintained in- house or at other locations are identifiable and retrievable, and are not disposed of until prescribed conditions are satisfied. For electronic records, the software systems used to	

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image and store information should be compatible with new hardware as current technologies are implemented. In addition, the QA program user should have a procedure in place before installing any new hardware systems to ensure that the new systems can reliably store and retrieve information from existing software systems. 17.5. Storage, Preservation, and Safekeeping The QA program user should establish measures to ensure that the following outcomes are fulfilled: • Facilities used to store records should be constructed to minimize the risk from damage or destruction by severe natural conditions, such as wind, flood, fire, temperature, humidity, mold, or infestation by insects or rodents. • Records should be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets. • Electronic records should be maintained in facilities that minimize or eliminate the potential for destruction of information as a result of demagnetization (Ref. 12). • Electronic records should be backed up daily to eliminate the potential for loss of information as a result of equipment failure or human error (Ref. 12). • If dual storage facilities are used to ensure the record integrity, the storage facilities should be sufficiently remote from each other to preclude a single event (such as a fire or flood) from damaging both facilities. • The QA program user should take measures to protect special records • (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature.	

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• The QA program user should take measures to prevent unauthorized personnel from entering record storage areas. • Electronic information storage systems should be accessible only through security measures such as passwords, and the number of personnel who have authorized access should be limited. In addition, personnel who have authorized access should have identified privileges, such as "read only" or "read and add only." • The QA program user should establish measures to ensure prompt replacement of lost or damaged records.	
18. GUIDANCE ON §71.137, "AUDITS" 18.1. Elements of an Audit Program A comprehensive audit program should include the following elements: • assurance of the authority and organizational independence of the auditors • a commitment to adequate manpower, funding, and facilities to implement the audit • identification of audit personnel and their qualifications • provisions for reasonable and timely access of audit personnel to facilities, documents, and qualified personnel necessary for performing audits • use of established procedures and checklists • methods for reporting audit findings to responsible management of both the audited and auditing organizations • provisions for the audit team to gain access to levels of management that have responsibility and authority for corrective action • methods for verifying that effective corrective action has been	Section C.1.a states that "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." Section C.1.b states that "Organizations performing audits are to be technically and performance oriented commensurate with the activity being reviewed." Section C.1.c states that "Personnel performing audits have no direct responsibilities in the area they are assessing." Section C.1.d states that "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. Section C.2.a states that "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 technical areas are audited at the

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accomplished on a timely basis • The QA program user also should establish and maintain a list to reflect the current status of the activities important to safety that are to be audited and the frequency at which each quality criterion is to be audited. The frequency of audits should be based on each activity's importance to safety; however, each quality criterion should be audited at least once each year. • The QA program user also should establish measures to ensure that packaging manufacturers are audited to assess the extent of their compliance with purchase orders and to verify that their work is controlled under an NRC-approved QA program. In addition, the QA program user also should identify (by function or position) the individuals or groups that have the responsibility and authority to ensure that corrective actions resulting from audit findings are accomplished on a timely basis. The QA program user should re-audit deficient areas on a timely basis to verify implementation of corrective actions. 18.2. Scheduling of Audits • The QA program user should establish schedules for internal audits, external audits, and audits performed by management. These schedules should ensure that key activities of the QA program (e.g., design, fabrication) receive priority consideration. • For audits performed by management, the schedules should identify the level of management (usually from the corporate office or another division) designated to assess the overall effectiveness of the implementation of the described in-house QA program. The QA program user should also identify the activities important to safety (e.g., procurement, training of personnel) that should be included in the audit program. Management audits should be conducted at least once every 12 months. • For internal audits, the schedules should ensure that applicable	QAPM indicated frequencies, or more frequently as performance dictates. Note that these are the frequencies used to comply with the QAPM rather than the specific guidance provided within Regulatory Guide 7.10. Section C.2.b states that "Audits shall provide an objective evaluation of quality related practices, procedures, instructions, activities, and items and a review of documents and records, as applicable." Section C.2.c states that "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." Section C.2.d states that "Scheduling and resource allocation are based on the status and safety importance of the activity or process being assessed." Section C.2.e states that "Scheduling is dynamic and resources are supplemented when the effectiveness of the quality assurance program is in doubt." Section C.2.f states that "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." Section C.2.g states that "Implementation of delegated portions of the quality assurance program is assessed." Section C.2.h states that "Audits are conducted using predetermined acceptance criteria." Audit Team Leaders (ATL) will continue to be qualified under our current approved ATL training program and not under NQA-1a-2009 as recommended in RG 7.10. The approved program is based on requirements contained in ANSI N45.2.23 and outline in V-EN-QV-117 Oversight Training Program. Additional guidance and requirements for audit team selection, including the use of technical specialists is contained in Implementing Procedure V-EN-QV-

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elements of the QA program are audited annually or at least once within the life of the activity, whichever is shorter. • For external audits, the schedules should ensure that all elements of a major supplier's (or major contractor's) QA program are audited on a triennial basis. The 3-year period should begin with performance of an audit when sufficient work is in progress to demonstrate implementation of a QA program that has the required scope for purchases placed during the 3-year period. 18.3. Team Selection • The QA program user should establish the qualifications of the lead auditor and audit team members and specify their respective responsibilities for evaluating and issuing audit reports. The auditing organizations should be responsible for establishing qualifications for prospective audit personnel and the requirements for the use of technical specialists to accomplish auditing activities that are important to safety. The QA program user should select the lead auditor and audit team members from personnel who do not have direct responsibility in the areas being audited. • Specific guidance for determining qualifications for the lead auditor and individual audit team members may be obtained from ANSI/ASME NQA-1- 2008 with the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications (QA)" (Ref. 2). 18.4. Pre-Audit Conference Before an audit, the QA program user should specify the nature and scope of the pre-audit conference between management of the organizations being audited and the team conducting the audit. The purpose of the pre-audit conference should be to (1) meet counterparts, confirm the audit scope and dates, (3) establish channels of communication, (4) discuss the sequence and duration of	109, "Audit Process." Implementing Procedure V-EN-QV-109 provides guidance on the conduct of audits, including development of audit plans, the conduct of audits, the conduct and purpose of audit exit meetings, the generation and transmittal or reports, the interface with corrective actions processes, and the required follow-up actions.

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the audit, (5) prepare an agreed-upon agenda for the audit, and (6) set the time for the post-audit conference. 18.5. Post-Audit Conference The QA program user should establish measures to conduct a post-audit conference between management of the organizations being audited and the team conducting the audit to present the results and clarify any questions that may arise. 18.6. Reporting and Response The QA program user should establish measures to identify time constraints imposed for issuing audit reports and the requested date for a corrective action response by the audited organization. The response should clearly state the corrective action taken to prevent recurrence of nonconformances. If corrective action cannot be taken immediately, the response of the audited organization should include scheduled dates for initiation and completion of the corrective action. 18.7. Followup Action The audit team leader should verify that (1) the audited organization provides a timely response to the audit report, (2) the response is adequate, and (3) the corrective action has been accomplished within the prescribed schedule.	

Table 1

10 CFR 71 Criterion	Key Implementing Procedure No. and Title
71.103 Quality assurance organization	V-EN-PL-100, "Nuclear Excellence Model" V-EN-QV-100, "Conduct of Nuclear Independent Oversight at Vermont Yankee"
71.105 Quality assurance program	Various Quality Procedures
71.107 Design control	V-EN-DC series of procedures
71.109 Procurement document control	V-EN-MP-101, "Procurement"
71.111 Instructions, procedures, and drawings	AP-0096, "Control of Procedures"
71.113 Document control	V-EN-AD-103, "Document Control and Records Management Programs"
71.115 Control of purchased material, equipment, and services	V-EN-MP-101, "Procurement" V-EN-MP-120, "Quality Receipt Inspection" V-EN-MP-125, "Warehousing" V-EN-QV-109, "Audit Process" V-EN-QV-201, "Quality Control Inspection Program"
71.117 Identification and control of materials, parts, and components	V-EN-MP-120, "Quality Receipt Inspection" V-EN-MP-125, "Warehousing"
71.119 Control of special processes	MTAP-10084, "Work Management Process"
71.121 Internal inspection	MTAP-10084, "Work Management Process" V-EN-QV-201, "Quality Control Inspection Program"
71.123 Test control	MTAP-10084, "Work Management Process" EF-1, ISFSI Engineering Evaluations and Design Control Program OP-2, ISFSI Surveillance and Inspections Program OP-4, VCC and ISFSI Pad Inspection Program
71.125 Control of measuring and test equipment	MTAP-10084, "Work Management Process" AD-16, Requisitioning Material, Equipment & Services
71.127 Handling, storage, and shipping control	AD-16, Requisitioning Material, Equipment & Services AD-17, Receipt Inspection, Storage and Control of Purchased Equipment, Material & Services
71.129 Inspection, test, and operating status	MTAP-10084, "Work Management Process" AD-17, Receipt Inspection, Storage and Control of Purchased Equipment, Material & Services
71.131 Nonconforming materials, parts, or components	AD-21, Nonconformance Reporting AD-15, Evaluation of Component or Equipment Failure or Deviation for 10CFR21 Reportability
71.133 Corrective action	V-EN-LI-102, "Corrective Action Program"
71.135 Quality assurance records	V-EN-AD-103, "Document Control and Records Management Programs"
71.137 Audits	V-EN-QV-109, "Audit Process"

ATTACHMENT 2

Vermont Yankee Nuclear Power Station

Summary of Proposed Changes to the VY QAPM

SUMMARY OF PROPOSED CHANGES TO THE ENTERGY VERMONT YANKEE QUALITY ASSURANCE PROGRAM MANUAL (VY QAPM)

Purpose

The purpose of this summary is to characterize the proposed changes to be included in the VY QAPM Revision 7. The proposed revision is a substantial revision to the QAPM and will replace the previous revision in its entirety. Several substantial changes are described, along with the justifications for those changes. In addition, the various minor editorial and administrative changes are discussed in a summary form.

Background

The revision reflects a simplification of the QAPM that is based on the decommissioning status of the VY facility with all spent nuclear fuel in dry storage on the VY Independent Spent Fuel Storage Installation (ISFSI) and the long-term passive operational status of the ISFSI. VY is currently undergoing a campaign to transfer all spent nuclear fuel from the spent fuel pool to dry storage. The campaign is expected to be completed by late 2018 (Reference 1)

Once the transfer of all spent nuclear fuel to the ISFSI is complete and the ISFSI transitions to long term passive operations, the radiological risk factors associated with decommissioning activities will have been significantly reduced. Additionally, although radioactive waste remains to be shipped offsite for disposal, the QAPM still applies to the applicable activities for shipping of radioactive material within shipping packages and activities as described by the VY QAPM.

QAPM Revision 7 applies to all activities associated with structures, systems and components (SSCs) which are classified as Important-to-Safety (ITS) under 10 CFR 72. The QAPM also applies to transportation packages and activities licensed by the NRC under 10 CFR 71 and designated as ITS. For other ISFSI and decommissioning activities, administrative programs and procedures ensure compliance with governing regulations and include appropriate controls for activities under the radiological control and monitoring programs previously contained in the Technical Specifications and relocated to Appendix D of the QAPM in Revision 6.

The proposed Revision 7 to the QAPM is appropriate for the remaining decommissioning activities and to support ISFSI operations. All safety-related SSCs will have been removed from service and/or have been reclassified. The ISFSI will have transitioned to long-term passive operations. The spent fuel storage system is inherently safe by design. The main function of the ISFSI organization is to monitor the environment in a way that demonstrates the integrity of the system. Maintaining appropriate quality standards that preserve the passive functionality of the system continues to be important, and can be accomplished satisfactorily through conformance to the guidance provided in Regulatory Guide 7.10, Revision 3.

The proposed revision will continue to satisfy the criteria of 10 CFR 50, Appendix B and the Quality Assurance (QA) requirements of 10 CFR 71, Subpart H and 10 CFR 72, Subpart G.

Change 1 – Substantial Changes:

***Change 1A**:* The program basis was changed from ANSI/ANS standards to use primarily Regulatory Guide 7.10 "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material", Revision 3 as a guidance document. This was previously included in Appendix C as an additional guidance document. The highest level of safety significance items and activities remaining at the VY facility are designated as Important-to Safety (ITS) under 10 CFR 71 and 10 CFR 72 as defined in Appendix A. There will be no systems, structure or components (SSCs), items or activities remaining at the VY site that are classified as safety-related as defined in 10 CFR 50 Appendix B. The NRC Quality Assurance Program guidance for ITS activities under 10 CFR 71 and 10 CFR 72 is included in Regulatory Guide 7.10. The change in base guidance documents is a reduction in commitment to the previously approved QA Program, but it is acceptable due to the current state of decommissioning at the VY facility and the passive operational status of the VY ISFSI.

***Change 1B**:* The Safety Review Committee (SRC) is replaced with the Independent Management Assessment (IMA) function as defined in Section A.3.f. IMAs are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is effectively implemented. IMAs are performed by individual(s) who: are designated by the chief nuclear officer, are independent of activities assessed; and provide the appropriate level of expertise in the activities assessed. The IMA results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the chief nuclear officer. These IMAs will ensure that independent oversight of activities being performed at the VY facility will continue during fuel storage at the ISFSI and decommissioning.

Specific changes are summarized as follows:

- Currently, the SRC is required to be composed of at least two (2) members plus a Chairman. The IMA will not be required to be performed by a committee.
- An IMA may be conducted by as few as one person appointed by the chief nuclear officer.
- The SRC is required, collectively, to have experience and competence in a number of technical areas. This revision does not specify qualification, experience, or competency requirements for personnel performing IMAs.
- There is no requirement for a minimum number of meetings per year as there is no committee to meet. IMAs will be performed periodically as directed by the chief nuclear officer.
- The IMAs will be governed by implementing procedure and will include implementation of the QAPM with focus on the safe storage of spent nuclear fuel, but can include other activities as directed by the chief nuclear officer.

The requirements for an independent review function was based on ANSI N18.7-1976 as endorsed by Regulatory Guide 1.33, Revision 2 and were satisfied by the SRC. The composition and function of the SRC as described in the previous QAPM revision follows the guidance provided in ANSI N18.7-1976, Section 4.3.1, with exceptions previously approved by the NRC. The program described therein was intended for operating nuclear power plants. 10 CFR 50, Appendix B, does not specifically require an independent review function (as described in ANSI N18.7) as part of its quality assurance program requirements. Appendix B, 10 CFR 50, Criterion II states in

part: “The applicant shall regularly review the status and adequacy of the quality assurance program.”

Change 1C: Modified Fire Protection Audit requirements based on all spent nuclear fuel being moved from the spent fuel pool to the ISFSI. There continues to be a requirement to perform Fire Protection Program Audits once every 24 months; however, the fire protection and loss prevention program inspection and fire protection and loss prevention program inspection audits have been eliminated.

Change 2 – Editorial / Administrative Improvements and Clarifications:

A number of editorial changes were made for consistency, clarity and to improve readability were made. The types of changes of this nature are as follows:

Editorial Changes Type 1: Eliminate discussion of safety-related items and activities.

Editorial Changes Type 2: Modified some organizational titles, responsibilities and positions to reflect the completion of the movement of spent fuel from the spent fuel pool to the ISFSI.

Editorial Changes Type 3: Modified Appendix A to reflect that there are no longer any safety-related SSCs at the facility.

Editorial Changes Type 4: Modified the exceptions to ANSI/ANS 3.1-1978 to reflect the transfer of all spent nuclear fuel from the spent fuel pool to the ISFSI.

Editorial Changes Type 5: Moved remaining information from Appendix D to Appendix C and modified information slightly to reflect that all spent nuclear fuel has been relocated from the Spent Fuel Pool to the ISFSI. The change with the SRC was previously described.

In summary, these types of changes are considered editorial and do not alter the intent or purpose of the QAPM and continue to satisfy the criteria of Appendix B to 10 CFR 50 and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

Overall Evaluation:

This revision is a substantial change to the QAPM. It includes editing to ensure consistency with the major changes being implemented, along with providing modifications to reflect a decommissioning nuclear facility that has moved all spent nuclear fuel from the spent fuel pool to an ISFSI. This editing, however, did not alter the effectiveness of the QAPM.

The changes were evaluated and determined to be acceptable based on the proposed state of decommissioning at the VY site required for implementation and the passive operational status of the VY ISFSI. The proposed revision continues to satisfy the criteria of Appendix B to 10 CFR 50 and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

References:

1. Letter, Entergy Nuclear Operations, Inc. to USNRC, “Notification of Schedule Change for Dry Fuel Loading Campaign,” BVY 17-013, dated April 12, 2017 (ML17104A050)

CNRO-2017-00017
BVY 17-023
Docket Nos. 50-271, 72-59 and 71-0907

ATTACHMENT 3

Vermont Yankee Nuclear Power Station

VY QAPM Proposed Revision 7

Vermont Yankee Nuclear Power Station

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

Quality Assurance Program Manual

Effective: (DATE)

Proposed Revision 7

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 results of ~~off-site safety~~Independent Management Assessments are ~~review committee~~ report~~eds~~ 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.

A. 2. (continued)

b. VY Site Organization

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

1. The VY ~~executive~~ top level management position ~~(senior manager)~~ 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. A~~The~~ manage ment position~~r~~ that~~is~~ is 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~~ independent safety review function reports to the manager responsible for facility operations.

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

4. A manage~~r~~ment position that is 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).

A. 2.b. (continued)

5. A management position that is~~r~~ 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~~ top level management position. The site personnel organizationally report to an executive (supply chain – offsite) who has a functional interface with the VY ~~executive~~ top level management position.

~~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.~~6. A management position that is~~r~~ 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~~independent ~~and off-site~~ safety review function and Independent Management Assessments independently review~~s~~ activities to provide additional assurance that VY is maintained in accordance with the Operating License and applicable regulations that address nuclear safety. The~~se~~ independent safety review function~~s~~ ~~are~~ is described in Appendix D. The Independent Management Assessment function is described in A.3.f.

3. Responsibility

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

b. VY may delegate all or part of the activities of planning, establishing, and implementing the quality assurance program to others, but retains the responsibility for the program's effectiveness.

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

d. Individual 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.

A 3. (continued)

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

f. The Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is effectively implemented. This Independent Management Assessment is performed by individual(s) designated by the chief nuclear officer, independent of activities assessed and who provide the appropriate level of expertise in the activities assessed. The Independent Management Assessment results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the chief nuclear officer.

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.

A 6. (continued)

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

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

d. Non-conforming items are properly controlled to prevent their inadvertent test, installation, or use. They are reviewed and either accepted, rejected, repaired, or reworked.

e. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to the appropriate level of management.

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

A 7. (continued)

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 is 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 ~~B~~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 2. (continued)

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

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

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

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

f. Changes to final designs (including field changes and modifications) and dispositions of non-conforming items to either use-as-is or repair are to be subjected to design control measures commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designee.

g. Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs are defined in procedures.

h. Design documentation and records, which provide evidence that the design and design verification process was performed in accordance with this program, shall be collected, stored, and maintained in accordance with documented procedures. This documentation includes final design documents, such as drawings and specifications, and revisions thereto and documentation which identifies the important steps, including sources of design inputs that support the final design.

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

B. 3. (continued)

c. When a test program is used to verify the acceptability of a specific design feature, the test program is to demonstrate acceptable performance under conditions that simulate the most adverse design conditions that are expected to be encountered.

d. Independent design verification is to be completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is to be identified and controlled. In all cases, the design verification is to be completed before relying on the item to perform its function.

e. Individuals or groups responsible for design reviews or other verification activities shall be identified in procedures and their authority and responsibility shall be defined and controlled. Design verification shall be performed by any competent individuals or groups other than those who performed the original design but who may be from the same organization. The designer's immediate supervisor may perform the design verification provided:

1. the supervisor is the only technically qualified individual capable of performing the verification,

2. the need is individually documented and approved in advance by the supervisor's management, and

3. the frequency and effectiveness of the supervisor's use as a design verifier are independently verified to guard against abuse.

f. Design verification procedures are to be established and implemented to ensure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, the verification is satisfactorily accomplished, and the results are properly recorded.

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

B. 4. (continued)

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

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

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

f. The program includes provisions for ensuring that documented evidence of an item's conformance to procurement requirements is available at the site before the item is placed in service or used unless otherwise specified in procedures.

g. The program includes provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used unless otherwise specified in procedures.

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

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

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

B. 9. (continued)

e. Measuring and test equipment is calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that ensures the equipment being calibrated will be within the required tolerance.

f. If nationally recognized standards exist, calibration standards are to be traceable to them. Except where calibration standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.

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

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

B. 11.b (continued)

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

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

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

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
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.

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.~~g. 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.~~

C. 2. (continued)

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

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

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

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

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

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

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

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

h. Audits are conducted using predetermined acceptance criteria.

i. Additional details concerning audits may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Appendix B ~~(e.g., Regulatory Guides 1.33 and 1.144)~~.

D. INDEPENDENT SAFETY REVIEW

1. Description

a. The ~~i~~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 Section A.2.c and 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-SAFTY 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.
ISFSI Pad	C	VY
Lifting Yoke	A	Holtec Intl.
Damaged Fuel Container	C	Holtec Intl.

Appendix A

~~SAFETY RELATED AND~~ IMPORTANT-TO-SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

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

SSC	Quality Category	Design/License Responsible
Multipurpose Canister and Fuel Basket Assembly	A	Holtec Intl.
Damaged Fuel Container	C	Holtec Intl.
Transportable Storage Canister and Basket Assembly For GTCC Waste Containers	A	TBD
Transport Cask	A	Holtec Intl.

C. Radioactive Material Transport Packages (10 CFR 71)

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

NOTES:

1. There are no longer any safety related SSCs at the VY facility.

~~1.~~2. See Holtec Intl. Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information. Holtec defines the classification of the SSCs and VY reflects this information in Appendix A for those SSCs described.

~~2.~~3. See Holtec Transport Cask Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information.

~~3.~~4. For the definition of Quality Categories A, B, and C refer to NUREG/CR-6407.

~~5~~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.
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)

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

Appendix B
Regulatory Commitments

~~B. Regulatory Guide 1.30, dated August 1972~~

		~~Clarification/Exception~~
~~1.~~	~~ANSI N45.2.4 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 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 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 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 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 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 Section 4.3.2.3	Deleted

~~Appendix B~~
~~Regulatory Commitments~~

~~C. Regulatory Guide 1.33 (continued)~~

		~~Clarification/Exception~~
~~6.~~	~~ANSI N18.7 Section 4.3.4.(1) & (2)~~	~~Deleted~~
~~7.~~	~~ANSI N18.7 Section 4.3.4(2)~~	~~Deleted~~
~~8.~~	~~ANSI N18.7 Section 4.3.4(3)~~	~~Deleted~~
~~9.~~	~~ANSI N18.7 Section 4.3.4(4)~~	~~Deleted~~
~~10.~~	~~ANSI N18.7 Section 4.3.4(5)~~	~~Deleted~~
~~11.~~	~~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.~~
~~12.~~	~~ANSI N18.7 Section 4.5~~	~~Deleted~~

~~Appendix B~~
~~Regulatory Commitments~~

~~C. Regulatory Guide 1.33 (continued)~~

		~~Clarification/Exception~~
~~13.~~	~~ANSI N18.7 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.~~
~~14.~~	~~ANSI N18.7 Section 5.2.2~~	~~The person who approves a temporary change to a procedure is not required to be in charge of the shift.~~
~~15.~~	~~ANSI N18.7 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.~~
~~16.~~	~~ANSI N18.7 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.~~
~~17.~~	~~ANSI N18.7 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.~~
~~18.~~	~~ANSI N18.7 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 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 Section 5.2.9~~	~~The requirements of the Physical Security Plan shall be implemented in place of these general requirements.~~
~~21.~~	~~ANSI N18.7 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 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 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 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 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 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~~
~~1.~~	~~General~~	~~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.~~
~~2.~~	~~Section C.3~~	~~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.~~
~~3.~~	~~Section C.4~~	~~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.~~
~~4.~~	~~ANSI N45.2.1 Section 5~~	~~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~~
~~1.~~	~~ANSI N45.2.2 Section 3.2~~	~~Storage of an item in a higher-level storage area meets the lower level storage requirements.~~
~~2.~~	~~ANSI N45.2.2 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 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 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 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 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
7.	ANSI N45.2.2 Section 5.2.2	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). 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.
8.	ANSI N45.2.2 Section 5.2.3	The "Special Inspection" procedure is not required to be attached to the item or container but shall be readily available to inspection personnel.
9.	ANSI N45.2.2 Section 6.2.1	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.
10.	ANSI N45.2.2 Section 6.2.4	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."

~~Appendix B~~
~~Regulatory Commitments~~

~~E. Regulatory Guide 1.38 (continued)~~

		~~Clarification/Exception~~
~~11.~~	~~ANSI N45.2.2 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."~~
~~12.~~	~~ANSI N45.2.2 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."~~
~~13.~~	~~ANSI N45.2.2 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."~~
~~14.~~	~~ANSI N45.2.2 Section 6.5~~	~~The last sentence of this section is not applicable to the operations phase.~~
~~15.~~	~~ANSI N45.2.2 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
16.	ANSI N45.2.2 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.
17.	ANSI N45.2.2 Appendix (A-3) 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."
18.	ANSI N45.2.2 Appendix (A-3) 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.
19.	ANSI N45.2.2 Appendix (A-3) 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.
20.	ANSI N45.2.2 Appendix (A-3) 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~~
~~21.~~	~~ANSI N45.2.2 Appendix (A-3) 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.~~
~~22.~~	~~ANSI N45.2.2 Appendix (A-3) 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.~~
~~23.~~	~~ANSI N45.2.2, Appendix (A-3) 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.~~
~~24.~~	~~ANSI N45.2.2, Appendix (A-3) 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.~~
~~25.~~	~~ANSI N45.2.2 Appendix (A-3) 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.~~

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~~F. Regulatory Guide 1.39 Revision 2, dated September 1977~~

		~~Clarification/Exception~~
~~1.~~	~~ANSI N45.2.3 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 Section 3.1~~	~~This section is not applicable.~~
~~3.~~	~~ANSI N45.2.3 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 Section 3.3~~	~~The first paragraph is not applicable to the operations phase.~~
~~5.~~	~~ANSI N45.2.3 Section 3.4~~	~~This section is not applicable.~~
~~6.~~	~~ANSI N45.2.3 Section 3.5~~	~~Subparagraph (1) is not applicable to the operations phase; (2), (3), and (4) will be implemented.~~

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~~G. Regulatory Guide 1.58 Revision 1, dated September 1980~~

		~~Clarification/Exception~~
~~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 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 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 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 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 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 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.~~

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~~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~~
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~~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.~~

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~~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.~~

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~~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.~~

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~~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.~~

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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~~
~~5.~~	~~ANSI N45.2.5 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.~~
~~6.~~	~~ANSI N45.2.5 Section 5.5~~	~~VY will comply with inspection requirements of the applicable welding codes and any exceptions instead of this section.~~

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~~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.~~

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~~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.~~

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M. Regulatory Guide 1.123 (continued)

		Clarification/Exception
5a.	ANSI N45.2.13 Section 3.2	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: • The accreditation is to ANSI/ISO/IEC 17025. • The accrediting body is either NVLAP A2LA. • The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. • The purchase documents require calibration/report to include identification of the laboratory equipment/standards used. • The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
6.	ANSI N45.2.13 Section 3.4	The requirements of the QAPM will be implemented instead of this section.
7.	ANSI N45.2.13 Section 4.2	Supplier evaluations may be performed any time prior to placing the purchased item in service.
8.	ANSI N45.2.13 Section 8.2 Item b	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.

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~~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."~~

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~~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
4a.	RG 1.144 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: • The accreditation is to ANSI/ISO/IEC 17025. • The accrediting body is either NVLAP A2LA. • The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
5.	ANSI N45.2.12 Section 4.3.1	Pre-audit and post-audit conferences may be fulfilled by a variety of communications, such as telephone conversation.
6.	ANSI N45.2.12 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.
7.	ANSI N45.2.12 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~~
~~8.~~	~~ANSI N45.2.12 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.~~
~~9.~~	~~ANSI N45.2.12 Section 4.3.3~~	~~Pre-audit and post-audit conferences may be fulfilled by a variety of communications, such as telephone conversation.~~
~~10.~~	~~ANSI N45.2.12 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.~~
~~11.~~	~~ANSI N45.2.12 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.~~

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

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

Appendix C

Other General Guidance Documents

~~Regulatory Guide 7.10, Revision 2 (3/05), "Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material."~~Documents Deleted-not currently used

~~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.

23.0 ADMINISTRATIVE CONTROLS RELOCATED FROM TECHNICAL SPECIFICATIONS

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

32.1 RESPONSIBILITY

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

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

23.2 ORGANIZATION

A. Onsite and Offsite Organizations

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

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

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

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

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

B. Facility Staff Qualifications

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

~~23~~.3 PROCEDURES

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

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

B. Actions to be taken to correct specific and foreseen potential malfunctions of systems or components needed for the safe storage of nuclear fuel.

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

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

E. Surveillance and testing requirements.

F. Fire protection program implementation.

G. Process Control Program in-plant implementation.

H. Off-Site Dose Calculation Manual implementation

~~3~~2.4 REPORTING REQUIREMENTS

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

A. Radioactive Effluent Release Report

The Radioactive Effluent Release Report covering the operation of the facility shall be submitted by May 15 of each year and in accordance with 10 CFR 50.36a. The report shall include a summary of the quantities of radioactive liquid and gaseous effluents and solid waste released from the facility. The material provided shall be consistent with the objectives outlined in the ~~Offsite Dose Calculation Manual (~~ODCM~~)~~ and Process Control Program and in conformance with 10 CFR 50.36a and 10 CFR 50, Appendix I, Section IV.B.1.

B. Annual Radiological Environmental Operating Report

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

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

~~2~~3.5 PROGRAMS AND MANUALS

The following programs shall be established, implemented and maintained:

A. OFF-SITE DOSE CALCULATION MANUAL (ODCM)

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

The ODCM shall also contain the radioactive effluent controls and radiological environmental monitoring activities and descriptions of the information that should be included in the Radioactive Effluent Release Report and the Annual Radiological Environmental Operating Report required by QAPM Section 3.4.A and QAPM Section 3.4.B., respectively.

1. Licensee initiated changes to the ODCM:

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

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

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

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

   c. Shall be submitted to the Commission in the form of a legible copy of the affected pages of the ODCM as a part of or concurrent with the Radioactive Effluent Release Report for the period of the report in which any change to the ODCM was made. Each change shall be identified by markings in the margin of the affected pages, clearly indicating the area of the page that was changed, and shall indicate the date (e.g., month/year) the change was implemented.

B. Radioactive Effluent Controls Program

This program conforming to 10 CFR 50.36a provides for the control of radioactive effluents and for maintaining the doses to members of the public from radioactive effluents as low as reasonably achievable. The program shall be contained in the ODCM, shall be implemented by operating procedures, and shall include remedial actions to be taken whenever the program limits are exceeded. The program shall include the following elements:

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

b. Limitations on the concentrations of radioactive material released in

liquid effluents from the site to unrestricted areas, conforming to 10 times the concentration values in Appendix B, Table 2, Column 2, to 10 CFR 20.1001 - 20.2402;

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

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

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

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

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

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

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

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