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Vermont Yankee Nuclear Power Station
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10 CFR 50.54(a)(3)
10 CFR 71.106(b)
10 CFR 72.140(d)

BVY 22-012

April 12, 2022

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

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

REFERENCE: Letter, NorthStar Nuclear Decommissioning Co., LLC to USNRC "Biennial
report for Quality Assurance Program Manual changes under
10 CFR 50.54(a)(3), 10 CFR 71.106, and 10 CFR 72.140(d)," (BVY 20-014),
dated April 30, 2020 (ML20143A098)

Dear Sir or Madam:

NorthStar Nuclear Commissioning Co., LLC, is submitting the Vermont Yankee Quality Assurance Program Manual (VY QAPM) in accordance with 10 CFR 50.54(a)(3), 10 CFR 72.140(d) and 10 CFR 71.106(b). The last submittal, dated April 30, 2020, encompassed the VY QAPM thru Revision 8 (Reference). Since that date, Revision 9 to the VY QAPM has been issued to ensure consistency with the advanced stages of decommissioning at Vermont Yankee and to reflect the most current industry document approved by the NRC.

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

A synopsis of the changes associated with Revision 9 is provided as Enclosure 1. The VY QAPM Revision 9 remains in effect and is included as Enclosure 2.

This letter contains no new regulatory commitments.

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

I state under penalty of perjury that the forgoing is true and correct. Executed on April 12, 2022.

Sincerely,

A handwritten signature in blue ink, appearing to be "BER/tbs", written in a cursive style.

BER/tbs

Enclosures:

1. Synopsis of VY QAPM Revision 9 Changes.
2. VY QAPM Revision 9.

cc: Mr. David C. Lew
Regional Administrator, Region 1
U.S. Nuclear Regulatory Commission
475 Allendale Road, Suite 102
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Commissioner
Vermont Department of Public Service
112 State Street – Drawer 20
Montpelier, Vermont 05602-2601

Enclosure 1

Vermont Yankee Nuclear Power Station

Synopsis of VY QAPM Revision 9 Changes
(2 pages excluding this cover sheet)

VERMONT YANKEE NUCLEAR POWER STATION

Synopsis of VY QAPM Revision 9 Changes

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

VY QAPM Revision 9:

This change to the Vermont Yankee Nuclear Power Station (VY) Quality Assurance Program Manual (QAPM) established a program that is consistent with the advanced stages of decommissioning at VY and reflects the most current industry document approved by the NRC. The information contained within Revision 9 to the VY QAPM is similar in content to the information contained in the NRC approved San Onofre Nuclear Generating Station (SONGS) Decommissioning Quality Assurance Program (DQAP) that was approved with an SER based on all fuel being transferred to an ISFSI. The unique site specific aspects of the VY QAPM (Rev 9) remain similar to the previously approved QAPM (Rev 8) including the majority of the organizational section, although some changes were made to better reflect the current organizational structure. The majority of the information in the appendices remained the same since they were unique to VY and contained within the approved QAPM. The limited changes to Appendix A, B and D were either considered administrative or were based on the NRC approved SONGS DQAP. Since the majority of the content of the SONGS DQAP was based on the information contained within the current VY QAPM, many of the changes within this revision are primarily impacted by the reformatting of the document. Since the majority of the changes were made utilizing a currently NRC approved quality assurance program (QAP) with an accompanying SER and utilizes the same conditional basis, the change was allowed to be made without prior NRC approval utilizing the guidance contained within 10 CFR 50.54.a(3). Some other minor editorial and administrative corrections were made in various portions of the document as well and are not all specifically discussed in the details provided below. The following are a discussion of the major changes by section that were made to the VY QAPM Revision 8 and the basis for the changes being acceptable:

Policy Statement – Added an additional discussion to describe how the associated process controls described within the QAPM are also applied to decommissioning activities in a graded approach. These process controls are administrative changes that does not contain any commitments and does not change the applicability of the QAPM, but rather describes how some of the controls are also applied to decommissioning activities.

Table of Contents – Updated to reflect the changes made to the documents and associated page numbers – These were administrative changes.

Section A – Renamed to Section 1, Organization and nonapplicable information was removed since the content was captured in other sections of the QAPM, such as personnel training and qualifications and corrective action. Several additional changes were made to organizational positions to better describe the current organizational structure rather than relying solely on the allowances due to generic titles, including the addition of the following specific language: “site management positions describe the typical site QAPM functional responsibilities, which may be delegated to others as established in this document.” This change was made based on a QAP that was previously approved by the NRC with an accompanying SER that includes the same approval basis. There were also some administrative changes.

Section B – Completely reformatted to cover the applicable criterion, including subdividing into 18 sections with a format that is consistent with 10 CFR 50 Appendix B, 10 CFR 71 Subpart H and 10 CFR 72 Subpart G. This format reflects that contained within the NRC approved SONGS DQAP, which includes similar language to that contained in the current VY QAPM Section B. It is reformatted and subdivided into more sections. This change was made based on a QAP that was previously approved by the NRC with an accompanying SER that includes the same approval basis.

Section C – Renamed to Section 18.0 and was completely rewritten to be consistent with the content contained within the SONGS DQAP. This change was made based on a QAPM that was previously approved by the NRC with an accompanying SER that includes the same approval basis. There were also some administrative changes.

Section D – Deleted the section since this information is already provided within Section 1.0 and Appendix D and only provided a reference to those sections discussing the independent safety review function. This was an administrative change.

Appendix A – Provides some minor editorial comments and updates the description of greater than class C (GTCC) waste container in several areas since the specific approach to packaging this waste has yet to be finalized. These were administrative changes.

Appendix B – Provides some corresponding changes to those made with Appendix D and adds a specific alternative that was previously approved by the NRC with an associated SER and was incorporated into the SONGS DQAP. This change was made based on a QAPM that was previously approved by the NRC with an accompanying SER that includes the same approval basis. There were also some administrative changes.

Appendix C – No changes were made to this appendix.

Appendix D – Several changes were made to this appendix. A change was made to Section 2.2.B for Facility Staff Qualification. More specific language previously approved by the NRC for the SONGS DQAP was added to this section, although ANSI/ANS 3.1 continues to be the applicable VYNPS standard. Some administrative changes were made to Section 2.3 to clarify applicability. Two (2) new sections were added to Section 2.5. The Sealed Source Control Program and the Process Control Program had been previously included as license basis conditions with the historical Technical Requirements Manual. These requirements were relocated to a licensee controlled procedure and are also being added to the VY QAPM. Item one was made based on a change previously approved by the NRC with an SER with the same approval basis. The other changes are considered administrative since they are only adding information that was previously included in another site License Basis Document.

In summary, the QAPM changes associated with transitioning from Revision 8 to Revision 9 did not constitute a reduction in commitments to the QAPM previously accepted by the NRC.

Enclosure 2

Vermont Yankee Nuclear Power Station

VY QAPM Revision 9
(26 pages excluding this cover sheet)



Vermont Yankee Nuclear Power Station

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

Quality Assurance Program Manual

VY QUALITY ASSURANCE PROGRAM MANUAL

POLICY STATEMENT

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

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

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

The QAPM is applicable to site activities that support ITS SSCs and associated activities. With the transfer of all spent nuclear fuel to the Independent Spent Fuel Storage Installation (ISFSI) a significant change to the facility license basis occurred. This change to the license basis resulted in the reduction of number of SSCs and activities controlled under QAPM requirements. The only remaining SSCs and activities that continue to be designated as ITS are those directly associated with the storage of spent nuclear fuel at the ISFSI and for selected radioactive material transportation packages controlled under 10 CFR 71 (i.e., Type B Packages). These radioactive material transportation package license basis requirements are applicable to both ISFSI and decommissioning activities. The fuel is stored in canisters that are approved for storage under 10 CFR 72 and will be used for transportation under 10 CFR 71. Type B Packages will be also be needed to transport some selected radioactive material. The applicable QAPM controls for these services are applied in a graded approach based on their importance to safety. Although not a commitment, some QAPM controls which are developed to implement ITS activities are also applied in a graded approach to facility decommissioning activities, such as those for organization, document control, procedures, corrective action and records. This strategy is utilized to ensure quality considerations are applied to decommissioning of the facility.

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

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Organization

1.0 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. These functional responsibilities include other responsibilities that are not directly related to ITS activities but are necessary to support the decommissioning of the facility. The authority to accomplish the quality assurance functions described is delegated to the incumbent's staff as necessary to fulfill the identified responsibility.

a. Corporate Organization

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

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

b. VY Site Organization

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

1. A management position that is responsible for overall spent fuel safety operational activities is accountable for maintaining the facility within the constraints of applicable regulatory requirements and the operating license, including training. Different aspects of these responsibilities may be fulfilled by separate management positions. This management position is responsible for operation of the ISFSI. Examples of this position's responsibilities includes 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. The independent safety review function reports to this management position.

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2. A management position that is responsible for plant side activities including those aspects of ITS implementing activities performed in support of decommissioning.
3. The management position that is responsible for quality assurance has overall authority and responsibility for establishing, controlling, and verifying the implementation and adequacy of the quality assurance program as described in this QAPM. This position has the authority and responsibility to escalate matters directly to the nuclear executive, if necessary.
4. A management position that is responsible for materials, purchasing, and contracts is responsible for procurement, services, receipt, storage, and issue of materials, parts, and components. Different aspects of these responsibilities may be fulfilled by separate site managers.
5. A management position that is responsible for radiation protection and chemistry activities. This management position is responsible for the implementation of the Radiation Protection Program, Radiological Environmental Monitoring Program, Radiological Effluent Controls Program, radioactive waste shipping and Process Control Program activities.

c. Independent Review

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

d. Responsibility

1. VY has the responsibility for the scope and implementation of an effective quality assurance program.
2. 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.
3. 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.
4. Individual management positions are to ensure that personnel working under their management cognizance are provided the necessary training and resources to accomplish their assigned tasks within the scope of the QAPM.

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5. Procedures that implement the QAPM are approved by the management responsible for the applicable quality function as defined in procedures. These procedures are to reflect the QAPM and work is to be accomplished in accordance with them.
6. The Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPM and that the QAPM is effectively implemented. This Independent Management Assessment is performed by individual(s) designated by the nuclear executive, independent of activities assessed and who provide the appropriate level of expertise in the activities assessed. The Independent Management Assessment results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the nuclear executive.

e. Authority

1. 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.
2. The management position responsible for quality assurance has the responsibility and the authority to stop unsatisfactory work and control further processing, delivery, installation, or use of non-conforming items or services. Cost and schedule considerations will not override safety considerations.

Quality Assurance Program

2.0 Quality Assurance Program

The Quality Assurance Program (QAP) for VY is described in the QAPM. This QAPM provides control over ITS and selected decommissioning related activities to an extent consistent with their importance to ensure safety and compliance as defined in procedures. The QAPM includes specific monitoring activities which are measured against acceptance criteria in a manner sufficient to provide VY management assurance that the ITS activities are performed in an acceptable manner. The VY QAPM requirements apply to SSCs designated as ITS defined in Appendix A. Additional administrative requirements associated the facility programs are defined in Appendix D. The QAPM is applicable to site activities that support ITS SSCs and associated activities.

The QAPM satisfies the requirements of 10 CFR 50 Appendix B Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants, 10 CFR 71, Subpart H, Quality Assurance for Packaging and Transportation of Radioactive Material, and 10 CFR 72, Subpart G, Quality Assurance for Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste. Additional regulatory commitments are listed within Appendix A of the QAPM. Implementation of the VY QAPM is controlled through separately issued procedures, instructions and drawings. Each organization is responsible for the establishment and implementation of procedures and instructions prescribing the ITS activities for which they are responsible.

Important to safety activities shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all

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prerequisites for the given activity have been satisfied. The QAPM takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

The only remaining SSCs and activities that continue to be designated as ITS are those directly associated with the storage of spent nuclear fuel at the ISFSI and for selected radioactive material transportation packages controlled under 10 CFR 71 (i.e., Type B Packages). These radioactive material transportation package license basis requirements are applicable to both ISFSI and decommissioning activities. The fuel is stored in canisters that are approved for storage under 10 CFR 72 and will be used for transportation under 10 CFR 71. Type B Packages will be also be needed to transport some selected radioactive material. The applicable QAPM controls for these services are applied in a graded approach based on their importance to safety. Although not a commitment, some QAPM controls which are developed to implement ITS activities are also applied in a graded approach to facility decommissioning activities, such as those for organization, document control, procedures, corrective action and records. This strategy is utilized to ensure quality considerations are applied to decommissioning of the facility.

Changes to the QAPM will be implemented in accordance with 10 CFR 50.54(a) and 10 CFR 71.106.

a. Program Control and Authority

The manager responsible for quality assurance is responsible for ensuring that the applicable portions of the QAPM are properly documented approved and implemented (with trained staff, necessary materials and approved procedures available) before an activity within the scope of the QAPM is executed. Disputes arising between departments or organizations on any QA matter that cannot be resolved at a lower level of management will be referred to the nuclear executive.

Additional requirements for specific programs are described in Appendix D, Administrative Controls.

b. Personnel Training and Qualifications

Individual managers are responsible for ensuring that personnel working under their cognizance are provided with the necessary indoctrination training and resources to accomplish assigned activities which fall under the scope of the QAPM.

Members of the VY staff (including audit and inspection personnel) shall have the appropriate qualifications necessary to perform their assigned duties defined in implementing procedures. These implementing procedures provide the criteria utilized for determining and assessing appropriate staff qualification. Additionally, Appendices B and D cites references that stipulate the use of specific industry standards addressing qualifications. 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 approved procedures.

QA Lead Auditors are qualified and certified by the manager responsible for quality assurance in accordance with approved procedures. Training methods, minimum experience requirements, and certification practices are in accordance with established

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procedures and based on criteria set forth in QA implementing procedures. Proficiency evaluations are performed and documented as defined in approved procedures.

Records of the implementation for staff indoctrination and training, as well as records for audit and inspection personnel qualification shall be maintained in accordance with approved procedures and show the appropriate documentary evidence of training completion.

c. Performance/Verification

1. Personnel performing work activities such as design, engineering, procurement, installation, maintenance, modification, operation, and decommissioning are responsible for achieving acceptable quality.
2. Personnel performing independent verification activities are responsible for verifying the achievement of acceptable quality and are different personnel than those who performed the work.
3. 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.
4. Criteria that define acceptable quality are specified, and quality is verified against these criteria.

Design Control

3.0 Design Control

The program will ensure that the activities associated with the design of ITS structures, systems and components and modifications thereto, are executed in a planned, controlled, and orderly manner.

The program utilizes the guidance of NUREG/CR-6407 to classify structures, systems and components such that appropriate quality requirements are identified and documented on drawings, component lists, or procurement documents, as applicable.

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

Design inputs (e.g., performance, conditions of the facility license, quality, and quality verification requirements) shall be correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions).

The final design output shall relate to the design input in sufficient detail to permit verification. The design process shall ensure that materials, parts, equipment and processes are selected and independently verified consistent with their importance to safety to ensure they are suitable for their intended application.

Changes to final designs (including field changes and modifications) and dispositions of non-conforming items to either use-as-is or repair shall be subjected to design control measures

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commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designee. The original design organizations for the VY ISFSI are identified in Appendix A. Subsequent changes to the original design can be made by VY as defined in the design control process.

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

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

Design Verification

The program will verify the acceptability of design activities and documents for the design of items. The selection and incorporation of design inputs and processes, outputs and changes are verified.

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.

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

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

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 or manager may perform the design verification and controls for this are defined in approved procedures.

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

Procurement Document Control

4.0 Procurement Document Control

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The program will ensure that purchased items and services are of acceptable quality.

The program includes provisions for evaluating prospective suppliers and ensuring that selected suppliers continue to provide acceptable products and services.

The program includes provisions for taking corrective action with suppliers (qualified or otherwise) whose products and services are not considered acceptable.

The program includes provisions for source verification (inspection, audit, etc.) for accepting purchased items and services identified as ITS when determined necessary.

The program includes provisions for invoking applicable technical, regulatory, administrative, and reporting requirements (e.g., specification, codes, standards, tests, inspections, special processes, records, certifications, 10 CFR 21) applicable to the procurement to be specified in procurements documents.

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.

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.

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

The program includes provisions for the identification of critical characteristics and methods of acceptance for the dedication of a commercial grade item or service for its use in an ITS function(s).

Instructions, Procedures and Drawings

5.0 Instructions, Procedures and Drawings

Measures are established to assure that quality activities are prescribed by and performed in accordance with documented instructions, procedures, or drawings. These instructions, procedures, and drawings include, as appropriate, quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. Controls are established which ensure that instructions, procedures, and drawings are current and accurately reflect the facility design and regulatory requirements.

Changes or deviations from established instructions, procedures or drawings for SSCs and other quality activities that have current ITS functions, require the same review and approval as the original document. Instructions, procedures and drawings, including changes and deviations subject to the VY QAPM, shall be maintained as required by administrative procedures.

Administrative controls may be established that provide the methods by which temporary changes can be made to procedures which are approved, including the designation of persons authorized to approve such changes.

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Document Control

6.0 Document Control

The program will control the development, review, approval, issue, use, and revision of documents.

The scope of the document control program includes, but is not limited to:

- a. Safety Analysis Report(s);
- b. NRC License Documents, including Defueled Technical Specifications;
- c. Design Documents and Drawings;
- d. Procurement Documents;
- e. Procedures, Manuals, Plans, Directives, Policies, Instructions, etc.;
- f. Corrective Action Documents; and
- g. Other documents as defined in procedures.

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.

Copies of controlled documents are distributed to and used by the person performing the activity.

The distribution of new and revised controlled documents is in accordance with procedures. Superseded documents are controlled to prevent inadvertent use.

Control of Purchased Materials, Equipment and Services

7.0 Control of Purchased Materials, Equipment and Services

The program will verify the quality of purchased items and services at intervals and to a depth consistent with the item's or service's importance to safety, complexity and quality of the item or service. Control of items and services for ITS applications are clearly and adequately specified in procurement documents.

The program is executed in all phases of procurement. As necessary, this may require verification of activities of suppliers below the primary supplier of the item or service.

Procedures shall describe each organization's responsibilities for the control of purchased material, equipment and services including the interfaces between all affected organizations.

Controls for the audits or surveys of suppliers providing ITS items and services are provided for in Section 18.

Controls for the inspection (source verification/surveillance/inspection) of suppliers providing ITS items and services are provided for in Section 10.

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Identification and Control of Materials, Parts and Components

8.0 Identification and Control of Materials, Parts and Components

The program will identify and control ITS items to prevent the use of incorrect or defective items.

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.

Control of Special Processes

9.0 Control of Special Processes

This program will ensure that special processes identified as ITS are properly controlled.

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

- a. Welding;
- b. Heat treating;
- c. NDE (Non-Destructive Examination);
- d. Chemical cleaning; and
- e. Unique fabricating or test processes which require in-process controls.

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

Inspection

10.0 Inspection

The program will ensure inspections of ITS activities are planned, executed and documented in order to verify conformance with instructions, procedures and drawings for accomplishing the activity.

Provisions to ensure inspection planning is properly accomplished are to be established. Planning activities shall identify the characteristics and activities to be inspected, the inspection techniques, the acceptance criteria, and the organization responsible for performing the inspections.

Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organizations are to be defined.

Inspection results are to be documented by the inspector and reviewed by qualified personnel.

Unacceptable inspection results shall be evaluated and resolved in accordance with procedures.

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Inspections are performed by qualified personnel other than those who performed or directly supervised the work being inspected. While performing the inspection activity, inspectors functionally report to the nuclear safety manager.

Test Control

11.0 Test Control

The program will demonstrate that items will perform satisfactorily in service using approved test procedures.

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

Test procedures shall be developed which include:

- a. Instructions and prerequisites to perform the test;
- b. Use of proper test equipment;
- c. Acceptance criteria; and
- d. Mandatory inspections, as required.

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

Unacceptable test results shall be evaluated and documented for impact on safety and reportability.

Control of Measuring and Test Equipment

12.0 Control of Measuring and Test Equipment

The program will control the calibration, maintenance and use of measuring and test equipment consistent with activities ITS to ensure accuracy.

Calibration reference standards shall be based on traceability to nationally recognized standards. Where national standards do not exist, M&TE is calibrated against standards that have an accuracy of at least four (4) 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. Special calibration and control measures are not required when normal commercial practices provide adequate accuracy (e.g. rulers, tape measures, level, and other such devices).

The types of equipment covered by the program (e.g., instruments, tools, gages, and reference and transfer standards) are defined in procedures.

Measuring and test equipment is calibrated at specified intervals or immediately before use on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics and other conditions affecting its performance.

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

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

Handling, Storage and Shipping

13.0 Handling, Storage and Shipping

The program will control the handling, storage, shipping, cleaning, and preserving of items to ensure the items maintain acceptable quality.

Special protective measures (e.g., containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels, etc.) are specified and provided when required to maintain acceptable quality.

Specific procedures shall be developed and used for cleaning, handling, storage, packaging, shipping and preserving items when required to maintain acceptable quality.

Items are marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and identify the need for any special controls.

Inspection, Test and Operating Status

14.0 Inspection, Test and Operating Status

The program will ensure that required inspections and tests and the operating status of items ITS 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. Operating status is identified by the use of tags, markings, stamps, or other suitable means.

Items whose required inspections and tests are incomplete or inconclusive may be released for further processing. Controls are provided in procedures for establishing limitations on the release, applying status indications and documenting the basis for the conditional release of the item and any limitations.

The application and removal of inspection, test, and operating status indicators are controlled in accordance with procedures.

Non-conforming Materials, Parts or Components

15.0 Nonconforming Materials, Parts or Components

VY establishes measures to control ITS materials, parts and components which do not conform to requirements. The measures used to control nonconforming materials, parts and components are described by approved procedures.

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Management at all levels and each individual working at the facility is responsible for promptly identifying and reporting the identification of nonconforming materials, parts and components.

The corrective action program will be used to ensure the prompt identification, documentation, and correction of nonconforming materials, parts and components as described in Section 16.0.

Nonconforming items are properly controlled by approved procedures describing the identification, documentation, segregation requirements disposition and notification to the affected organizations to prevent their inadvertent installation or use. Nonconforming items are reviewed and either accepted, rejected, repaired, or reworked in accordance with approved procedures.

Corrective Action

16.0 Corrective Action

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

Significant conditions adverse to quality shall require cause determination, a corrective action that should prevent recurrence, and be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify effective implementation of the required corrective actions to prevent recurrence and to verify that they are effectively implemented.

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

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

Quality Assurance Records

17.0 Quality Assurance Records

The program will ensure that sufficient records of ITS items and activities affecting quality (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 the completed work. Controls for the administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of records are provided in procedures.

Management of the electronic storage of records will utilize the guidance provided in the 1998 NIRMA standards as defined in approved procedures.

Records generated for SSCs that were once classified as safety-related or quality-related but no longer have a safety function do not need to be retained for purposes of the QAPM (but may need to be retained for other purposes, such as compliance with 10 CFR 50.75(g), other

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regulations, or for business reasons). As defined in Partial Exemptions from the Requirements of 10 CFR Part 50, Appendix B, Criterion XVII; 10 CFR 50.59(d)(3); and 10 CFR 50.71(c), NVEY 15-103, December 22, 2015 (NRC ADAMS Accession No. ML15344A243).

Audits

18.0 Audits

VY establishes measures for a system of planned and documented audits in order to verify compliance with all aspects of the QAPM and determines the effective implementation of programs covered by the QAPM. QA internal and supplier audits are planned and performed by qualified auditors utilizing approved written procedures and/or checklists. External audits by licensees / utilities, Contractors, or Consultants acting for VY to satisfy VY audit requirements shall have the results evaluated by VY to ensure acceptability.

Lead Auditors shall have experience, training or qualifications commensurate with the scope and complexity of their audit responsibility. Individuals performing audits shall not have direct responsibilities in the areas being audited.

Scheduling, preparation, personnel selection, performance, reporting, response, follow-up, and records management for audits are performed in accordance with written procedures. Audit scopes and schedules are based upon the status of work progress, ITS activities being performed, and regulatory requirements. Internal audits for the VY QAPM shall continue on a 24-month cycle with a 90 day grace period. Grace periods are not intended to be used repetitively, merely as an administrative convenience to extend audit intervals. Therefore, the next performance due date is based on the originally scheduled date.

When specific audits are identified as requiring a more frequent periodicity, the shortest periodicity will be adhered to for activities covered by those specific regulatory requirements. The frequency of internal audits will be prescribed by the site implementing procedures which govern the conduct of QA audits.

External audits of suppliers providing ITS materials, parts, equipment or services are scheduled and performed based on the importance of the activity and to confirm implementation of the supplier's QAP at a frequency of not less than three (3) years with a 90 day grace period. The supplier audit requirement shall not apply to standard off-the-shelf items and bulk commodities where required quality can adequately be determined by receipt inspection or post-installation test.

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

Results of audits are reviewed with the management of the organization audited. Responsible management in the areas audited shall implement the necessary corrective actions required to address deficiencies. These actions are documented and reviewed periodically and, if needed, re-examined during re-audits of the subject area to verify deficient areas have completed corrective actions.

Audit records shall be retained in accordance with approved implementing procedures.

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Appendix A IMPORTANT-TO-SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

The pertinent quality assurance requirements of 10 CFR 50 Appendix B, 10 CFR 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 an NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel Storage (10 CFR 72).

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

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

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

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

A. Dry Spent Fuel Storage (10 CFR 72)

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

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Appendix A IMPORTANT-TO-SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

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

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

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 QAPM.

NOTES:

1. No safety related SSCs remain at the VY facility.
2. See Holtec Intl. Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information. Holtec defines the classification of the SSCs and VY reflects this information in Appendix A for those SSCs described.
3. See Holtec Intl. Transport Cask Safety Analysis Report (SAR) and associated Holtec specifications for additional classification information.
4. For the definition of Quality Categories A, B, and C refer to NUREG/CR-6407.
5. VY engineering documentation defines the safety classification assigned to the ISFSI pads.

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 ANSI/ANS 3.1-2014 (Section 4.3.3, Radiation Protection).
2. General
The following qualifications may be considered equivalent to a bachelor's degree:
 - 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.
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.

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Appendix B Regulatory Commitments

5. ANSI/ANS 3.1 Section 5 VY will maintain a training program for the associated unit staff as defined in Appendix D, Section 2.2.B, that meets the applicable regulations and meets the standards of section 5 of ANSI/ANS 3.1-1978.
- 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, (2/96) “Classification of Transportation Packaging and Dry Fuel Storage System Components According to Important to Safety” is used as a guidance document.**

Alternatives

Suppliers providing commercial grade calibration and testing services, who are accredited by a nationally recognized accrediting body, as described in Nuclear Energy Institute (NEI) 14-05, Revision 1, (8/14) guidelines, may be used without additional qualification, provided the conditions of the associated NRC Safety Evaluation are met. Controls shall be established in applicable procedures to ensure the requirements of the NRC Safety Evaluation are satisfied prior to acceptance.

Appendix C Other General Guidance Documents

None

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

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overall operational activities (or designee) shall document the appointment of Independent Safety Reviewers.

3. The following subjects shall be independently reviewed by a qualified Independent Safety Reviewer:
 - a) Evaluations for changes to the facility as described in the Defueled Safety Analysis Report (DSAR). Changes to procedures as described in the DSAR and tests or equipment not described in the DSAR to verify that such actions do not involve a change to the Technical Specifications or will not require prior NRC approval as defined in 10 CFR 50.59 or 10 CFR 72.48, and
 - b) Proposed changes to the programs required by the QAPM Appendix D to verify that such changes do not involve a change to the Technical Specifications or will not require prior NRC approval as defined in 10 CFR 50.59 or 10 CFR 72.48.

2.0 ADMINISTRATIVE CONTROLS RELOCATED FROM TECHNICAL SPECIFICATIONS

The following information was administrative controls relocated from the defueled Technical Specifications or from the historical Technical Requirements Manual.

2.1 RESPONSIBILITY

- A. The management position responsible for overall operational activities shall delegate in writing the succession to this responsibility during absences.
- B. The management position responsible for overall operational activities or designee shall approve, prior to implementation, each proposed test, experiment, or modification to systems or equipment that affect nuclear safety.

2.2 ORGANIZATION

A. Onsite and Offsite Organizations

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

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

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shall have control over those on-site activities necessary for safe storage and maintenance of the nuclear fuel.

3. A specified corporate officer (nuclear executive) shall have corporate responsibility for overall site nuclear safety and shall take any measures needed to ensure acceptable performance of the staff in operating, maintaining, and providing technical support to the facility to ensure safe management of nuclear fuel.
4. The individuals who carry out health physics or perform quality assurance functions may report to the appropriate on-site management position; however, these individuals shall have sufficient organizational freedom to ensure their ability to perform their assigned functions.

B. Facility Staff Qualifications

1. Each member of the facility staff responsible for the safe storage of nuclear fuel and radiation protection personnel, including those performing final status survey activities 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).

2.3 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 as described in the approved Emergency Plan.
- D. Preventative and corrective maintenance operations which could have an effect on the safety of the nuclear fuel.
- E. Surveillance and testing requirements needed for the safe storage of nuclear fuel.
- F. Fire protection program implementation.
- G. Process Control Program in-plant implementation.
- H. Off-Site Dose Calculation Manual implementation.

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2.4 REPORTING REQUIREMENTS

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

A. Radioactive Effluent Release Report

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

B. Annual Radiological Environmental Operating Report

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

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

2.5 PROGRAMS AND MANUALS

The following programs shall be established, implemented and maintained:

A. OFF-SITE DOSE CALCULATION MANUAL (ODCM)

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

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

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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 50, and do not adversely impact the accuracy or reliability of effluent dose or setpoint calculations.
 - b. Shall become effective upon approval by the manager responsible for overall operational activities.
 - c. Shall be submitted to the Commission in the form of a legible copy of the affected pages of the ODCM as a part of or concurrent with the Radioactive Effluent Release Report for the period of the report in which any change to the ODCM was made. Each change shall be identified by markings in the margin of the affected pages, clearly indicating the area of the page that was changed, and shall indicate the date (e.g., month/year) the change was implemented.

B. Radioactive Effluent Controls Program

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

- a. Limitations on the functional capability of radioactive liquid and gaseous monitoring instrumentation, including surveillance tests and setpoint determination in accordance with the methodology in the ODCM;
- b. Limitations on the concentrations of radioactive material released in liquid effluents from the site to unrestricted areas, conforming to 10 times the concentration values in Appendix B, Table 2, Column 2, to 10 CFR 20.1001 - 20.2402;
- c. Monitoring, sampling, and analysis of radioactive liquid and gaseous effluents pursuant to 10 CFR 20.1302 and with the methodology and parameters in the ODCM;

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- 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.

C. Sealed Source Control Program

Licensed radioactive sealed sources shall be leak tested for contamination. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an agreement state as follows:

- 1. Each licensed sealed source, except startup sources previously subjected to core flux, containing radioactive materials, other than Hydrogen-3, with half-life greater than thirty days and in any form, other than gas, shall be tested for leakage and/or contamination at intervals not to exceed six months.
- 2. The periodic leak test required does not apply to sealed sources that are stored and are not being used. The sources exempted from this test shall be tested for leakage prior to any use or transfer to another user unless they have been leak tested within six months prior to the date of use or transfer.

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In the absence of a certificate from a transferrer indicating that a leak test has been made within six months prior to the transfer, sealed sources shall not be put into use until tested.

The leakage test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, it shall immediately be withdrawn from use, decontaminated, and repaired or be disposed of in accordance with Commission regulations.

Notwithstanding, the periodic leak test required by this section for any licensed sealed source, any licensed sealed source is exempt from such leak test when the source contains 100 microcuries or less of beta and/or gamma emitting material or 5 microcuries or less of alpha emitting material.

A special report shall be prepared and submitted to the Commission within 90 days if source leakage tests reveal the presence of ≥ 0.005 microcuries of removable contamination.

D. Process Control Program

A process control program shall contain the sampling, analysis, tests, and determinations by which wet radioactive waste from liquid systems is assured to be converted to a form suitable for off-site disposal.

1. Licensee initiated changes to the PCP:

- a. Shall be submitted to the Commission in the Annual Radioactive Effluent Release Report for the period in which the change(s) was made. This submittal shall contain:
 - i. Sufficiently detailed information to support the rationale for the change without benefit of additional or supplemental information.
 - ii. A determination that the change did not reduce the overall conformance of the dewatered spent resins/filter media waste product to meet existing criteria for solid waste shipments and disposal.
 - iii. Documentation of the fact that the change has received an Independent Safety Review (ISR) and has been approved by the manager responsible for overall operational activities.
- b. Shall become effective following completion of an ISR and approval by the manager responsible for overall operational activities