NEI 07-10A [Revision 0]

Generic FSAR Template Guidance for Process Control Program (PCP)

March 2009

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Nuclear Energy Institute

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March 2009

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ACKNOWLEDGEMENTS

This program description document, *Generic FSAR Template Guidance for Process Control Program (PCP),* NEI 07-10A, Revision 0, was developed by the NEI New Plant Radiation Protection and Radioactive Waste Task Force. We appreciate the time, efforts and expertise of the individuals who contributed to the development of this guideline.

NOTICE

EXECUTIVE SUMMARY

NEI 07-10A, *Generic FSAR Template Guidance for Process Control Program (PCP)*, Revision 0, provides a complete generic program description for use in developing construction and operating license (COL) applications. The document reflects contemporary Nuclear Regulatory Commission (NRC) guidance, including Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants," and industry-NRC discussions regarding the applicable standard review plan section. A main objective of this program description is to assist in expediting NRC review and issuance of the combined license.

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GENERIC FSAR TEMPLATE GUIDANCE FOR PROCESS CONTROL PROGRAM (PCP)

1 INTRODUCTION

This Process Control Program (PCP) Description identifies the administrative and operational controls for waste processing, process parameters, and surveillance requirements which assure that the final waste product meets the requirements of applicable Federal, State and Disposal Site waste form requirements for burial at a 10 CFR 61 licensed Low Level Waste (LLW) disposal site. The mobile radioactive waste processing system conforms to applicable requirements in Regulatory Guide 1.143 and Generic Letters applicable to wet solid waste. The PCP complies with 10 CFR 61.55 and 10CFR 61.56 for wet solid wastes. The PCP presents the methods by which liquid, and wet waste are processed and disposed in accordance with 10 CFR Part 61 and packaged and transported in accordance with 10 CFR Part 20,10 CFR Part 71 and 49 CFR Parts 171-180.

The PCP implementation of process methods considers the plants efforts to minimize the quantity of radioactive waste produced (volume and/or activity).

The users of this template should review the reference section for additional information related to NRC regulatory requirements and guidance. This template describes the elements of the PCP at the functional level consistent with 10 CFR 52.79 and if these programs are implemented as described, they do not require implementation of inspections, tests, analyses and acceptance criteria in the COL application.

2 APPLICABILITY AND CONTROLS

2.1 PROCESS CONTROL PROGRAM

2.1.1 The Solid Waste Management System shall be operated in accordance with the requirements given in the PCP for the solidification or dewatering and packaging of radioactive wastes in order to comply with the requirements of 10 CFR Part 20 and of 10 CFR Part 71 prior to shipment of radioactive wastes from the site (Reference 5.2.1).

2.1.2 The PCP is applicable to the Solid Waste Management System in the solidification of liquid or wet radioactive wastes or the dewatering of wet radioactive wastes to be shipped for direct burial to a 10 CFR Part 61 licensed disposal site.

Radioactive wastes shipped off-site for processing are not required to be solidified or dewatered to meet disposal requirements and are not subject to the solidification or dewatering requirements of the PCP (Reference 5.2.1).

2.1.3 The above controls of 2.1.1 and 2.1.2 are applicable at all times. If the packaging requirements of 10 CFR Part 20, 10 CFR Part 61 or burial site requirements and/or 10 CFR Part 71 are not satisfied, shipments of defectively packaged solid waste from the site will be suspended. The PCP will include surveillance checks necessary to demonstrate compliance with the above controls (Reference 5.2.21/5.2.22).

2.1.4 The PCP is only applicable to Mixed Waste when it is solidified for disposal at a 10 CFR Part 61 disposal site. Waste streams with the potential for having the presence of hazardous chemicals and radioactive materials, mixed waste, will be identified, processed and disposed in accordance with applicable Federal, State and local regulations (Reference 5.1.1).

2.1.5 The PCP confirms that incidental levels of waste petroleum-based oil contained in radioactive waste meets the disposal site requirement for shipment.

2.1.6 The PCP identifies required implementing procedures for radioactive waste interim storage of liquid or wet waste to meet the current final waste form requirements for free standing liquids.

2.1.7 The interface between plant processing equipment (permanent or non-permanent) and equipment used for solidification and/or dewatering of wet solid radioactive waste will be controlled in site procedures (Reference 5.2.5).

2.1.8 Samples will be obtained and analyzed for a batch of waste in accordance with site procedures for waste to be processed in the PCP. Analysis will be performed to ensure that the waste falls within the acceptable parameters for solidification/dewatering/drying (Reference 5.2.3).

3 PROCESS DESCRIPTION GUIDLINES

3.1 RESPONSIBILITIES

Each licensee will designate a site organization to be the owner, sponsor and administrator for the PCP. Examples of the organization's PCP responsibilities include review and approval of revisions; document administration; PCP technical content; and supporting the site compliance with the PCP.

3.2 ADMINISTRATION OF THE PCP AND SUPPORT DOCUMENTS

Any changes to the PCP or implementing procedures require a review to assure that the requirements of the SRP Sections 11.4 and 11.5, BTP 11-3, 10 CFR 20, 61, and 71, 49 CFR 171-180, state regulations, disposal and process facility waste acceptance criteria, and other requirements governing the disposal of solid radioactive waste (contained in the

references to this plan), are met. PCP changes will be sent to the NRC in the site's Annual Radioactive Effluent Report for the period in which the changes were implemented.

Implementing procedures are developed, approved, and maintained for performing the activities in support of the PCP. Examples of functions included in site specific implementation procedures are:

- Sampling, analysis, scaling of difficult to measure radionuclides, and waste classification of waste type and waste form,
- Process controls and parameters for processing "wet wastes" for land disposal and for processing Waste Class B and C wastes,
- Processing and disposal of "mixed waste" which is a waste containing both radioactive material and hazardous material,
- Control and acceptance of vendor waste processing equipment and processes for site and offsite processing of radioactive waste,
- Verification of compliance with disposal and processor site acceptance criteria,
- Mobile system conformance to Regulatory Guide 1.143 and Generic Letters 80-009 and 81-039.

In addition to the implementing procedures for PCP activities, site procedures will be developed that describe the following activities associated with packaging and shipping radioactive wastes:

- Preparing radioactive material for shipment, preparation of the uniform radioactive waste manifests, preparation of shipping papers, notifications, and shipment security,
- Container specifications and inspections, vehicle inspections, proper loading and shoring of shipments,
- Radioactive survey requirements and limitations for radioactive material shipments,
- Maintaining waste disposal records as required by 10 CFR 20.2108 and reporting information on radioactive waste disposal.

3.3 Approval Process For QA Approved Suppliers

Any supplier providing PCP services will be reviewed and approved prior to providing those services. The site identifies the criteria that the waste processor will meet for the services provided. Examples of criteria include the vendor PCP Topical Reports or equivalent, radioactive material license, state licensing, compliance with DOT regulations for packaging, shipment, packages, transportation, and 10 CFR Part 61 disposal requirements.

3.4 PCP Requirements For Vendor Processes and Services

The vendor-supplied processes for solidification or dewatering will have a Topical Report or other certification documenting appropriate approval of the process and associated containers used. The vendor approved for solidification or dewatering services will have NRC or appropriate regulatory certification documenting compliance with waste form

requirements of the final product. The vendor Topical Report or equivalent certifies that the final product conforms to the appropriate waste form for Class A, B, or C waste.

Any vendor-supplied high integrity containers (HIC's) will have an NRC or appropriate regulatory approved report documenting compliance with waste form requirements.

Each container of processed waste will be classified as Class A, B or C waste using a site specific 10 CFR Part 61 Waste Form, Waste Classification and Waste Characterization Implementation Program(Reference 5.3).

Vendors providing PCP services on-site will meet the applicable requirements of the PCP and quality assurance requirements identified by the site contract. The vendor equipment will meet the design, construction, operation and quality assurance provisions of NRC BTP 11-3 (Reference 5.2.3) and Regulatory Guide 1.143 (Reference 5.2.5).

Vendors providing PCP services offsite will meet the requirements of their PCP process and applicable quality assurance requirements.

3.5 WASTE TYPES

There are various types of radioactive waste expected to be generated at the plant site that will require processing, including solidification, or dewatering, or drying, or offsite processing prior to burial. These radwaste types can be categorized based on their chemical and physical properties. Typical waste types generated at a plant site may include but are not limited to; bead resin, powdered resin, demineralizer sludge/slurries, filter cartridges, oily waste, and dry active waste.

Dry wastes do not normally require stabilization processing and are treated as radioactively contaminated solids and packaged for disposal or offsite processing in accordance with applicable Federal/ State regulations and burial site criteria.

3.6 PCP SOLIDIFICATION PROCESS DESCRIPTION

Waste solidification will be performed to approved procedures that ensure all applicable regulatory and disposal site criteria are met. The specific waste processing technology and method and process parameters used to process waste are described in site procedures. The parameters should include (depending on the type of waste):

- waste pH;
- water content;
- oil content;
- waste density;
- content of chelating agents;
- ratio of stabilization agent to chemical additives by types of wastes;
- waste form;
- mixer speed; mixing time; curing time;

- pre-solidification hazardous waste characterization;
- specific activity and gamma analysis.

The minimum solidification acceptance criteria will include free standing liquid criteria; physical criteria and chemical criteria based on the disposal site. A representative sample of the waste to be solidified will be obtained for bench scale testing based on a frequency identified by the disposal site. The process parameters should include any of the above parameters that are applicable.

3.7 PCP Dewatering Process Description

The methods used for removal of liquid from wet waste for final disposal will comply with the specific disposal site requirements where the waste is being disposed. Dewatering/drying of wet wastes will be performed in a manner equivalent to the process guidelines described below using approved procedures with enough detail to implement applicable requirements. Examples of dewatering/drying process parameters include:

- Settling time
- Drain time
- Pumping time
- Dewatering pump suction vacuum (inches Hg)
- Drying time
- Additional dewatering/drying cycles

Mechanical filters (e.g., cartridge, bag, membrane) are dewatered so that accumulation of free standing liquid in the disposal container does not exceed disposal site limits. The method of dewatering is in accordance with a previously defined, evaluated and documented process.

Dewatering of "slurried" wet wastes (e.g., resin, carbon, Zeolite, filter precoat, filter backwash, sludge) removes the interstitial liquid from solids such that the disposal container meets the applicable regulatory and burial free standing liquid criteria for disposal.

Wet wastes may also be dewatered using a drying process that adds an absorber material resulting in a product with no free standing liquid (e.g. a monolithic salt block in a storage drum). This method of dewatering by drying will be in accordance with a previously defined, evaluated and documented process.

3.8 Acceptability

The solidification and dewatering/drying process product is verified and documented to meet the PCP Acceptance Criteria requirements for that process. Verification may include bench scale test, full scale test, verification of PCP process compliance, or verification that the amount of free-standing liquid is within disposal site criteria for the container and the standing water requirements of 10 CFR Part 61.

Product verification failures will be documented, reported if required, investigated and remedial actions taken. Any misuse, mishaps, or failure of a waste form or container will be reported to responsible site personnel for action.

3.9 WASTE CLASSIFICATION, CHARACTERIZATION AND MANIFEST

All waste will be classified in accordance with the requirements of 10 CFR 61.55 as implemented by site procedures. Analysis will be performed on the waste streams at least annually (biannually for Class A waste), to determine the isotopic abundance of non-gamma emitting isotopes in the waste streams. Scaling factors, for the non-gamma emitting and transuranic constituents, will be developed from these analyses (Reference 5.2.8 and 5.2.18).

All wastes shall meet the waste characteristics requirements of 10 CFR 61.56 as applicable and waste packages will be marked to identify the waste-class as required by 10 CFR 61.57. The manifesting requirements of 10 CFR 20.2006 and Appendix G to 10 CFR Part 20 will be implemented by site shipping instructions (Reference 5.2.23).

3.10 QUALITY ASSURANCE

Quality related activities for the PCP will be implemented as described in site procedures to meet the applicable requirements of Regulatory Guide 1.143 and/or ANSI 55.6 (Reference 5.2.5 and 5.2.9). The activities include verification that all solid radioactive waste meets applicable State and Federal regulations and burial site criteria.

4 DEFINITIONS

4.1 FREE STANDING LIQUID (FSL)

Liquid that is in a disposal container but is not bound by the waste in the container is called a free-standing liquid (FSL). FSL is the liquid available for release if disposal container integrity is lost. The amount of FSL in a radioactive waste disposal container is less than a specified amount to meet 10 CFR Part 61, state regulations, and disposal site criteria.

4.2 SOLIDIFICATION

Solidification is a process that converts radioactive waste into a product meeting 10 CFR Part 61, state, and disposal site requirements for waste-form stability and FSL. Solidification is accomplished by mixing measured amounts of liquid or wet radioactive waste, binder and required additives that, after sufficient curing time, produce a solid homogeneous, freestanding monolith. At the end of the curing period, the absence of

excessive FSL is verified by confirmation that the PCP was followed or by physical verification/testing.

4.3 DEWATERING

Dewatering removes the loosely bound liquid from a wet radioactive waste such that accumulation of Free Standing Liquid in disposal container is unlikely to approach the disposal limit threshold values defined by applicable regulations and disposal site criteria. NRC regulations require that the process used to dewater radioactive wastes to meet disposal criteria shall be governed by a PCP.

4.4 PROCESS PARAMETERS

Those conditions measured or observed during a solidification or dewatering process to ensure an acceptable product are the process parameters. These are determined for each waste type and are specific to the process method used.

4.5 PCP ACCEPTANCE CRITERIA

The PCP acceptance criteria are the bounding numerical values for the solidification process parameters that produce an acceptable product or the bounding numerical values for the dewatering process parameters that ensure free standing liquid requirements are met.

5 REFERENCES

5.1 REGULATORY REQUIREMENTS

5.1.1 10 CFR 20.2006, 20.2007, 20.2108 and Appendix G of 10 CFR Part 20

5.1.2 10 CFR Part 50, Appendix A, General Design Criterion 60, "Control of Releases of Radioactive Materials to the Environment." General Design Criterion 64, "Monitoring Radioactivity Releases."

5.1.3 10 CFR 61.55, 61.56, 61.57, "Licensing Requirements for Land Disposal of Radioactive Waste."

5.1.4 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

5.1.5 40 CFR Part 266" Storage, Treatment, Transportation, and Disposal of Mixed Waste"

5.1.6 49 CFR Parts 171-180 "Hazardous Materials Regulations"

5.1.7 Licensed radioactive waste burial site

5.1.8 State hazardous waste regulations

5.2 REGULATORY GUIDANCE

5.2.1 NUREG-0133, "Preparation of Radiological Effluent Technical Specifications for Nuclear Power Plants.

5.2.2 NUREG-0800, SRP 11.4, "Solid Waste Management Systems"

5.2.3 NUREG-0800, Branch Technical Position 11-3 "Design Guidance for Solid Radioactive Waste Management Systems Installed in Light-Water-Cooled Nuclear Power Reactor Plants"

5.2.4 Generic Letter 89-01, "Guidance for the Implementation of Programmatic Controls For RETS in The Administrative Controls Section of Technical Specifications and the Relocation of Procedural Details of Current RETS to the Offsite Dose Calculation Manual or Process Control Program"

5.2.5 Regulatory Guide 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants."

5.2.6 USNRC, Branch Technical Position, "Technical Position on Waste Form", Rev. 1, January, 1991 and HPPOS-290, "Waste Form Technical Position, Revision 1"

5.2.7 Issuance of Final Technical Position on Concentration Averaging and Encapsulation, Revision in Part to Waste Classification Technical Position January 17, 1995

5.2.8 "Final Waste Classification and Waste Form Technical Position Papers" dated May 11, 1983

5.2.9 ANSI 55.6, "Liquid Radioactive Waste Processing Systems for Pressurized Water Reactor Plants"

5.2.10 ANSI/ANS 40.37-1993, "Mobile Radioactive Waste Processing Systems"

5.2.11 Regulatory Guide 8.8, "Information Relevant to Ensuring That Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable."

5.2.12 Generic Letter 80-009, "Low Level Radioactive Waste Disposal."

5.2.13 Generic Letter 81-038, "Storage of Low Level Radioactive Wastes at Power Reactor Sites."

5.2.14 Generic Letter 81-039, "NRC Volume Reduction Policy"

5.2.15 Information Notice 87-07, "Quality Control of Onsite Dewatering / Solidification Operations By Outside Contractors"

5.2.16 IE Bulletin 79-19, "Packaging, Transport and Burial of Low-Level Radioactive Waste"

5.2.17 Information Notice 90-31, "Update on Waste Form and High Integrity Containers Topical Report Review Status, Identification of Problems with Cement Solidification, and Reporting of Waste Mishaps"

5.2.18 Information Notice 86-020, "Low-Level Radioactive Waste Scaling Factors, 10 CFR Part 61"

5.2.19 Information Notice 84-072, "clarification of Conditions For Waste Shipments Subject To Hydrogen Gas Generation"

5.2.20 Information Notice 85-092, "Surveys of Wastes Before Disposal from Nuclear Reactor Facilities"

5.2.21 NUREG-1301 "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors."

5.2.22 NUREG-1302 "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Boiling Water Reactors."

5.2.23 NUREG/BR-0204 "Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest"

5.3 PROGRAMMATIC REFERENCES –SITE SPECIFIC

5.3.1 Technical Specifications 5.0 Administrative Controls

5.3.2 Site Specific Licensee Commitments

5.3.3 Site Specific FSAR

5.3.4 Site Quality Assurance Program

5.3.5 Vendor Quality Assurance Program

5.3.6 Plant PCP Procedures for Specific Waste Processing Methods such as Dewatering, Solidification, or HIC Integrity Verification.

5.3.7 Plant implementation procedures on 10 CFR Part 61 waste form, waste classification and waste characterization.

5.3.8 Plant procedures on the requirements for interim storage for processed waste.

APPENDIX A
FINAL SAFETY EVALUATION REPORT

January 8, 2009

Mr. Russell J. Bell, Director
New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, DC 20006-3708

SUBJECT: FINAL SAFETY EVALUATION FOR TOPICAL REPORT NEI 07-10, "GENERIC FINAL SAFETY ANALYSIS REVIEW TEMPLATE GUIDANCE FOR PROCESS CONTROL PROGRAM," REVISION 3 (TAC NO. Q00159)

Dear Mr. Bell:

By letter dated September 27, 2007, the Nuclear Energy Institute (NEI) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review it's proposed Topical Report, NEI 07-10, "Generic Final Safety Analysis Review Template Guidance for Process Control Program," Revision 0. Based on comments and input from NRC staff, NEI submitted Revision 1 of the Process Control Program (PCP) generic template on October 18, 2007 and Revision 2 on February 28, 2008.

In response to the NRC staff's May 6, 2008, request for additional information (RAI), NEI submitted NEI 07-10, Revision 3 on May 30, 2008.

Enclosed is the staff's safety evaluation (SE) which defines the basis for acceptance of NEI 07-10, Revision 3. The NRC staff finds that for combined license applications (COLAs), NEI 07-10, Revision 3, provides an acceptable template for assuring that the administrative and operational controls for waste processing, process parameters, and surveillance requirements within the scope of the PCP will meet the requirements of Title 10 of the *Code of Federal Regulations*, Section 52.79.

Our acceptance applies only to material provided in NEI 07-10, Revision 3. We do not intend to repeat our review of the acceptable material described in the NEI 07-10, Revision 3. When the NEI 07-10, Revision 3 appears as a reference in COLAs, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from NEI 07-10, Revision 3, will be subject to a plant-specific or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that NEI publish the accepted version of NEI 07-10, Revision 3 within 3 months of receipt of this letter. The accepted version should incorporate this letter and the enclosed SE after the title page. The accepted version should also contain historical review information, including NRC RAIs and your responses. The accepted versions shall include a "-A" (designating accepted) following the report identification symbol.

If future changes to the NRC's regulatory requirements affect the acceptability of NEI 07-10, Revision 3, NEI will be expected to revise NEI 07-10 appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Sheryl A. Burrows at (301) 415-6086 or via email at Sheryl.Burrows@nrc.gov.

Sincerely,

/RA/

William D. Reckley, Chief
Rulemaking, Guidance, and
Advanced Reactor Branch
Division of New Reactor Licensing
Office of New Reactors

Project No. 689

Enclosure:
Safety Evaluation

cc w/encl: See next page

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Sincerely,

/RA/

William D. Reckley, Chief
Rulemaking, Guidance, and
Advanced Reactor Branch
Division of New Reactor Licensing
Office of New Reactors

Project No. 689

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Safety Evaluation

cc w/encl: See next page

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SAFETY EVALUATION

FINAL SAFETY EVALUATION FOR THE NUCLEAR ENERGY INSTITUTE'S TECHNICAL REPORT NEI 07-10, "GENERIC FINAL SAFETY ANALYSIS REVIEW TEMPLATE GUIDANCE FOR PROCESS CONTROL PROGRAM," REVISION 3 (TAC NO. Q00159)

1.0 BACKGROUND

On September 27, 2007, the Nuclear Energy Institute (NEI) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review its proposed Topical Report, NEI 07-10, "Generic Final Safety Analysis Report Template Guidance for Process Control Program" Revision 0 [Agencywide Documents Access Management System (ADAMS) accession no. ML072740309]. NEI-07-10 was developed by the NEI to assist in expediting NRC review and approval of combined licenses (COLs). Based on comments and input distributed at a series of public meetings in the intervening period, NEI submitted Revision 1 of the Process Control Program (PCP) template on October 18, 2007 [ADAMS accession no. ML072840029] and Revision 2 on February 28, 2008 [ADAMS accession no. ML080640463]. The staff determined that additional information was necessary to complete its review, and on April 1, 2008, an email of a request for additional information (RAI) was transmitted to NEI staff, with follow-up letter dated May 6, 2008 [ADAMS accession no. ML080940250]. On May 31, 2008, the NEI formally responded to the RAI by submission of Revision 3 of the Technical Report [ADAMS accession no. ML081720166]. The Technical Report provides a generic PCP description for use with combined license applications (COLAs). NEI-07-10 is not applicable to the review and issuance of construction permits or operating licenses under Title of the *Code of Federal Regulations*, Part 50 (10 CFR Part 50).

2.0 REGULATORY EVALUATION

The NRC staff verified that NEI-07-10, Revision 3 complies with the following regulations, regulatory guidance, and NUREGs:

- 10 CFR Part 20, "Standards for protection against radiation."
- 10 CFR Part 21, "Reporting of defects and noncompliance."
- 10 CFR Part 50, "Domestic licensing of production and utilization facilities."
- 10 CFR Part 52, "Licenses, certifications, and approvals for nuclear power plants; Subpart A, Subpart B, Subpart C."
- 10 CFR Part 61, "Licensing requirements for land disposal of radioactive waste."
- 10 CFR Part 71, "Packaging and transportation of radioactive material."
- Regulatory Guide (RG) 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants."

Enclosure

- NUREG-0800, Standard Review Plan (SRP), Section 11.4, Revision 3, "Solid Waste Management System."
- NUREG-0800, SRP, Branch Technical Position (BTP) 11-3, Revision 3, "Design Guidance for Solid Radioactive Waste Management Systems Installed in Light-Water-Cooled Nuclear Power Reactor Plants."

3.0 TECHNICAL EVALUATION

The staff's review concentrated on the proposed PCP as one element of the Process and Effluent Monitoring and Sampling Program. The staff also reviewed the template to ensure that the generic PCP addressed those items pertaining to the Process and Effluent Monitoring and Sampling Program, and proposed milestones were included under the requirements of Section 13.4 of the final safety analysis review (FSAR). In evaluating the adequacy of the program, the staff followed the guidance of the SRP (NUREG-0800), Section 11.4, "Solid Waste Management System."

To satisfy Section 13.4 of each FSAR application, Operational Program Procedures under NEI 07-10 are to be developed, but will not necessarily all be implemented, prior to fuel load. Under the requirements of a license condition, a COL holder is required to make available to the NRC a plant-specific PCP. The plant–specific PCP developed under the requirements of the license condition will be verified by the NRC through inspection and shall replace and supersede the generic NEI 07-10 Template. Accordingly, NEI 07-10 fulfills licensing requirements starting with the submission of a COLA, and ending with the fulfillment of the license condition specifying the availability of and verification by the NRC of a plant-specific PCP prior to fuel load. Finally, in accordance with SECY 05-0197, the implementation of operational programs identified in NEI 07-10 does not necessitate inspections, tests, analyses, and acceptance criteria (ITAAC) in a design certification (DC) or COLA.

NEI-07-10 is organized into guidelines for responsibilities and administration of the program, approval process for quality assurance (QA) approved suppliers, waste types, solidification, dewatering, acceptability, waste characterization, waste classification, shipment manifests, and QA for the program itself. The safety evaluation (SE) follows the organization of the PCP.

3.1 Responsibilities and Administration

The "Responsibilities" and "Administration" sections of NEI-07-10 describes the basic organizational responsibilities and controls over the administration of the program to assure that NRC guidance will be followed and requirements will be met. The program includes a commitment to develop procedures and practices to achieve the program objectives.

NEI-07-10 does not specifically include a timeline for development of the complete program. The PCP does outline the procedures that will be developed, and which will be required to be developed and inspected after issuance of the license but prior to fuel load.

Based on the staff's review of the "Responsibilities" and "Administration" sections of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, these aspects of the PCP to enable a reasonable assurance finding of

acceptability for issuance of a COL with verification of the PCP after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.2 Approval Process for (QA) Approved Suppliers, PCP Requirements for Vendor Processes and Services

The "Approval Process for (QA) Approved Suppliers" and "PCP Requirements for Vendor Processes and Services" sections of NEI-07-10 indicate that suppliers will be evaluated and approved prior to providing related services, and vendor processes will ensure that processed materials will conform to waste class, form, and content stipulated by regulations and contract specifications. The PCP also requires that containers used for shipment offsite be designed and/or certified consistent with regulatory approvals such as certificates of compliance or design specifications. Vendor equipment used on site is required to meet design, construction, operation, and quality assurance provisions of NUREG-0800, SRP, BTP 11-3, "Design Guidance for Solid Radioactive Waste Management Systems Installed in Light-Water-Cooled Nuclear Power Reactor Plants," which includes provisions for collection of spilled materials (curbing/collection), connection of temporary and portable systems, corrosion prevention, leak and spill minimization, and prevention of cross-connection with, or contamination of, non-radioactive systems.

Based on the staff's review of the "Approval Process for (QA) Approved Suppliers" and "PCP Requirements for Vendor Processes and Services" sections of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, these aspects of the PCP to enable a reasonable assurance finding of acceptability for issuance of a COL with verification of these program elements after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.3 Waste Types

The "Waste Types" section of NEI-07-10 describes in general terms the variety of waste types typically encountered from operations, and addresses categorization based on chemical and physical properties as required by NRC regulation. Stabilization of wastes is briefly addressed. Processing of the various waste types, and programs and processes to address waste types not specifically listed, are addressed throughout the PCP template.

Based on the staff's review of the "Waste Types" section of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, waste types sufficient to enable a reasonable assurance finding of acceptability for issuance of a COL with verification of these program elements after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.4 PCP Solidification/Dewatering Process Descriptions

The "PCP Solidification Process Description" and "PCP Dewatering Process Description" sections of NEI-07-10 addresses approved procedures for solidification and dewatering of liquid and wet solid wastes. Parameters relevant to determination of the appropriate process are addressed, such as chemical and physical forms, hazardous waste characterization, media, and

minimum acceptance criteria. Limitations on free standing liquids, slurried or other heterogeneous wastes containing liquids, and removal of interstitial liquids are also addressed.

Based on the staff's review of the "PCP Solidification Process Description" and "PCP Dewatering Process Description" sections of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, solidification and dewatering processes sufficient to make a reasonable assurance finding of acceptability for issuance of a COL with verification of these program elements after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.5 Acceptability

The "Acceptability" section of NEI-07-10 describes in general terms the verification process to ensure that wastes are acceptable for disposal consistent with the requirements of the disposal facility and land disposal regulations. Verification procedures, compensatory action upon failure of solidification or dewatering processes, and mishaps or unsuccessful processes are briefly addressed.

The template provides for acceptability of materials for interim storage awaiting disposal through development of site-specific procedures, consistent with NRC guidance. The template does not require that radioactive materials be stored in containers suitable for transportation under Department of Transportation regulations, but does require that storage be according to procedures developed under the template and subject to site-specific NRC inspection and verification. With regard to storage, the template is consistent with NRC Generic Letter (GL) 81-038. Due to site-specific differences in availability of disposal capacities and variations in the need for storage capacity pending disposal, COL applicants will need to provide information on a case-by-case basis with respect to long-term management and storage of solid wastes using the guidance of RG 1.206 and SRP Section 11.4, Revision 3 (NUREG-0800).

Based on the staff's review of the "Acceptability" section of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, acceptability of process controls sufficient to enable a reasonable assurance finding of acceptability for issuance of a COL with verification of these program elements after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.6 Waste Characterization, Classification, and Manifests

The "Waste Characterization, Classification, and Manifests" section of NEI-07-10 describes that waste classification will be implemented by site-specific procedures in accordance with 10 CFR 61.55, "Waste classification." The section requires at least annual waste stream assessment through analysis (biannually for Class A waste) for radionuclide distribution and concentrations, and addresses non-gamma emitters, transuranics, and scaling factors. The section requires waste characteristics to be consistent with 10 CFR 61.56, "Waste characteristics." The section also refers to identification of waste class as required by 10 CFR 61.57, "Labeling," and indicates that site shipping instructions be developed consistent with NUREG/BR-0204, "Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest", 10 CFR 20.2006, "Transfer for disposal and manifests", and 10 CFR Part 20,

Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

Based on the staff's review of the "Waste Characterization, Classification, and Manifests" section of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, acceptability of waste characterization, classification, and manifests, sufficient to make a reasonable assurance finding of acceptability for issuance of a COL with verification of these program elements after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.7 QA Programs

The "QA Programs" section of NEI-07-10 indicates that site procedures will be implemented consistent with RG 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants" and/or American National Standards Institute 55.6, "Liquid Radioactive Waste Processing Systems for Pressurized Water Reactor Plants."

Based on the staff's review of the "QA Programs" section of NEI-07-10 outlined above, the staff concludes that NEI-07-10 sufficiently describes, in terms of scope and level of detail, acceptability of QA programs, sufficient to enable a reasonable assurance finding of acceptability for issuance of a COL, with verification of these program elements after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition.

3.8. NRC Post Combined License Activities

Before the implementation of a plant specific PCP, the NRC staff will inspect the elements of the PCP in accordance with the NRC Construction Inspection Program as outlined in the NRC Inspection Manual Chapter 2504. The objectives of these inspections are to determine the readiness of the PCP program in performing its intended objectives. The inspection will confirm that solid waste management systems (SWMS) equipment, administrative programs, and operational procedures implementing the functional elements of the PCP are consistent with the DC, supplemental information or departures described in the COL; regulatory requirements of 10 CFR Part 20, 10 CFR Part 61, 10 CFR Part 71, 49 CFR Parts 171-180; GL 89-01; NUREG-1301 for PWR Plants or NUREG-1302 for BWR plants and NUREG-0133 for either plant; RGs 1.21 and 1.33, and applicable NRC and industry guidance, as listed in NEI 07-10.

The NRC inspection will confirm that the COL holder has successfully completed all applicable ITAACs for those portions of the liquid waste management systems (LWMS) and SWMS used to process solid and wet wastes under the PCP. The ITAACs are described in DCD Tier 1 of DCs and Section 14.3 of the FSAR of COL applications. The staff will confirm whether the COL holder has addressed all relevant ITAACs for liquid and solid waste processing systems, including confirming their descriptions, functional arrangements, and operating characteristics. The ITAACs, once performed by the COL holder and meeting their respective acceptance criteria, provide reasonable assurance that a plant that incorporates the features described in its DC, and operates in accordance with the DC and PCP, will meet the provisions of NRC regulations.

4.0 CONCLUSION

Construction Health Physics Branch (CHPB) staff used the acceptance criteria of SRP Section 11.4, "Solid Waste Management System," and BTP 11-3, "Design Guidance for Solid Radioactive Waste Management Systems Installed in Light-Water-Cooled Nuclear Power Reactor Plants," as the basis for evaluating the acceptability of NEI-07-10, "Generic FSAR Template Guidance for Process Control Program," Revision 3. The CHPB staff has determined that NEI-07-10 Revision 3 is consistent with the requirements, guidance, and industry standards for a PCP as outlined in Section 2.0 of this evaluation with verification of the program after completing the construction inspection program in implementing the plant-specific PCP under the requirements of a license condition. Any processing, storage, or handling of wastes offsite are required to be consistent with onsite controls, and are to be addressed by applicants as site-specific information.

The PCP described in NEI-07-10 incorporates standards and guidance that allow an applicant to operate and maintain the facility, in a safe manner, during normal operation and anticipated operational occurrences. The PCP will be developed and maintained in compliance with the facility license and applicable regulations. The PCP calls for processes to be periodically evaluated and revised to reflect industry experience; to incorporate changes to the facility, procedures, regulations, and quality assurance requirements; and to support facility management in determining the overall program effectiveness as well as compliance with NRC regulations and state agency disposal site regulations. The template requires that the storage of waste pending disposal be developed under site-specific NRC review and verification by inspection, such as addressed in NRC GL 81-038. Due to site-specific differences in availability of disposal capacities and variations in the need for storage capacity pending disposal, applicants will need to provide information on a case-by-case basis with respect to long-term management and storage of solid wastes using the guidance of RG 1.206 and SRP Section 11.4, Revision 3 (NUREG-0800).

The final PCP prepared under a license condition will be further described in site and/or operating procedures as specified in the PCP template. Sufficient records will be maintained and kept available for NRC inspection during construction to verify adequacy of the program.

On the basis of its review, the staff concludes that NEI-07-10, "Generic FSAR Template Guidance for Process Control Program," Revision 3 adequately provides guidance for establishing the PCP. Accordingly, NRC staff concludes that NEI-07-10 Revision 3 complies with the applicable NRC regulations, guidance, and industry standards and can be utilized by applicants for COLAs.

5. REFERENCES

5.1 Bell, R. J., NEI, to the U.S. NRC, "Response to NRC April 28 Request for Additional Information on NEI 07-09 and May 6 Request for Additional Information on NEI 07-10," May 30, 2008.

5.2 NUREG-0800, SRP, Section 11.4, Revision 3, "Solid Waste Management System," March 2007.

5.3 NUREG-0800, SRP, BTP 11-3, Revision 3, "Design Guidance for Solid Radioactive Waste Management Systems Installed in Light-Water-Cooled Nuclear Power Reactor Plants," March 2007.

5.4 RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)" Section C.I.11, "Radioactive Waste Management," June 2007.

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APPENDIX B
NRC REQUEST FOR ADDITIONAL INFORMATION

May 6, 2008

Mr. Russell J. Bell, Director
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Washington, DC 20006-3708

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING NUCLEAR ENERGY INSTITUTE TOPICAL REPORT 07-10, GENERIC FINAL SAFETY ANALYSIS REPORT TEMPLATE GUIDANCE FOR PROCESS CONTROL PROGRAM, REVISION 2 (PROJECT NO. 689; TAC MD6860)

Dear Mr. Bell:

By letter dated September 27, 2007, the Nuclear Energy Institute (NEI) submitted for U.S. Nuclear Regulatory Commission staff review its proposed topical report, NEI 07-10, "Generic Final Safety Analysis Report Template Guidance for Process Control Program (PCP)" Revision 0. Based on comments and input distributed at public meetings, NEI submitted Revision 1 of the PCP template in October 2007 and Revision 2 in February 2008. The staff has determined that additional information is necessary to complete its review. On April 1, 2008, an electronic copy of the enclosed request for additional information (RAI) was transmitted to Ralph Andersen of NEI. Although this RAI has already been provided to you electronically, we will not expect a response until 30 days following the date of issuance of this letter; therefore, please let me know if you will not be able to provide your written reply within that time period.

If you have any questions or comments regarding this matter, please contact Ms. Sheryl A. Burrows by telephone at (301) 415-6086 or by e-mail at Sheryl.Burrows@nrc.gov.

Sincerely,

/RA/

William D. Reckley, Chief
Rulemaking, Guidance and
Advanced Reactor Branch
Division of New Reactor Licensing
Office of New Reactors

Project No. 689

Enclosure:
As stated

cc: See next page

May 6, 2008

Mr. Russell J. Bell, Director
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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING NUCLEAR ENERGY INSTITUTE TOPICAL REPORT 07-10, GENERIC FINAL SAFETY ANALYSIS REPORT TEMPLATE GUIDANCE FOR PROCESS CONTROL PROGRAM, REVISION 2 (PROJECT NO. 689; TAC MD6860)

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Project No. 689

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ADAMS ACCESSION NO.: ML080940250

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DATE	04/03/08	04/03/08	04/09/08	05/06/08

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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING NUCLEAR ENERGY INSTITUTE TOPICAL REPORT 07-10, GENERIC FINAL SAFETY ANALYSIS REPORT TEMPLATE GUIDANCE FOR PROCESS CONTROL PROGRAM (PCP), REVISION 2 (PROJECT NO. 689; TAC MD6860)

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Request for Additional Information
Generic FSAR Template Guidance for Process Control Program
NEI 07-10 Rev. 2, February 2008

Consistent with Regulatory Guide 1.206, Section C.IV.1, and 10 CFR 52.79, a Combined License (COL) Application must contain a Final Safety Analysis Report (FSAR) that includes information "at a level sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved . . . before issuance of a COL." The following is a request for additional information (RAI) on the Nuclear Energy Institute's (NEI's) Template No. NEI 07-10, titled "Generic FSAR Template Guidance for Process Control Program (PCP)," Revision 2, dated February 2008, which is contemplated to be incorporated by reference by applicants as a sufficient program description consistent with the above.

The listed item addresses technical and regulatory clarifications remaining to be resolved in order to develop a safety evaluation of the generic program, based on the staff's review of the template against U.S. Nuclear Regulatory Commission (NRC) regulatory and technical requirements and guidance. The RAI is tied to a specific section of the NEI template, and includes a suggested modification to the existing text for the purpose of addressing the technical issue identified by NRC staff. The staff recognizes other approaches may be used in achieving the same objectives. The recommendation is presented for the purpose of attaining a mutual understanding of issues identified by the staff and facilitate NEI's effort in revising the template. The comment does not address editorial or typographic topics the authors may wish to review prior to finalization for NRC staff evaluation.

1. Executive Summary / Section 1, Introduction

The Executive Summary on page i, or a third paragraph in Section 1 on page 1, should be edited to include statements that users should review the reference section for additional information related to NRC regulatory requirements and guidance, that the template describes the elements of the PCP at the functional level consistent with 10 CFR 52.79, and that if these programs are implemented as described, they do not require implementation of inspections, tests, analyses and acceptance criteria in the COL application.

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