FSME Procedure Approval

Reviewing the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program SA-109

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NOTE
These procedures were formerly issued by the Office of State and Tribal Programs (STP). Any changes to the procedure are the responsibility of the FSME Procedure Contact as of October 1, 2006. Copies of FSME procedures are available through the NRC web site.

I. INTRODUCTION

This document describes the procedure for conducting reviews of Agreement State Low-Level Radioactive Waste (LLRW) programs using the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program [NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program* (IMPEP)].

II. OBJECTIVES

A. The generic objective is to determine if an Agreement State's LLRW disposal program is adequate to protect public health and safety. Five sub-elements are used to make this determination: (1) Technical Staffing and Training; (2) Status of the LLRW Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

1. To confirm that qualified and trained technical staff are available to license, regulate, control, inspect, and assess the operation and performance of the LLRW disposal facility. Depending on the life cycle of the facility, qualified technical staff, and/or consultants, should be available as needed to conduct/overview LLRW activities within a reasonable time period during the pre-licensing, construction, operation, closure, and post-closure phases of the facility. For example, qualified staff should be available to conduct an acceptance review of LLRW disposal facility license application within 15 months during the pre-licensing phase. The evaluation of staffing and training needs is generally assessed according to Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training*, and this procedure.

2. To confirm that the LLRW facility is inspected at prescribed frequencies and to verify that statistical data on the status of the inspection program are maintained and can be retrieved, as generally assessed according to FSME Procedure SA-101, *Reviewing the Common Performance Indicator, Status of Materials Inspection Program*, and this procedure.

   When reviewing the Agreement State status of LLRW inspection, the reviewer(s) should consider the specific phase of the LLRW facility life cycle. Therefore the Agreement State inspections may be conducted during one or more of the following phases: (a) the pre-licensing and construction phase; (b) the pre-operation phase; (c) the operation phase; (d) the closure phase; and (e) the post-closure phase. Examples of inspections corresponding to these phases are: (a) inspection of performance assessment approaches, methods, and computations for compliance with the performance criteria of the LLRW facility; (b) inspections of compliance with the technical specifications or the required performance criteria of the engineering systems, components, and/or structures (e.g., liners, concrete barriers, and/or

pre-operational environmental monitoring inspections); (c) inspection of LLRW facility management and operational controls (e.g., inspection of licensee operational procedures; workers' exposure and ALARA records; quality assurance records; waste classification, waste-form, and waste characterization data; waste shipments' manifests, packages, and labeling; operator qualifications and training; compliance with disposal site license conditions; and inspection of operational effluent releases and environmental monitoring records); (d) site closure plans, inspection of covers, maintenance of barriers or structures, and/or closeout inspection surveys; and (e) inspection of long-term environmental monitoring.

3. To confirm that the technical quality of LLRW inspections is adequate, as generally assessed according to FSME Procedure SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections*, and this procedure.

   The technical quality of inspection is typically conducted through NRC staff accompanying and observing an Agreement State inspection of the LLRW facility. The quality of inspection is also evaluated through an on-site review of completed inspection reports, QA/QC assessment, and evaluation of inspector(s) regarding use of appropriate methods and calibrated instruments. Agreement State management overview and involvement in inspections as well as evaluation of actions for timely follow-up on inspection findings are also used in evaluation of this subelement.

4. To confirm that the technical quality of licensing action is adequate, as generally assessed according to FSME Procedure SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions*, and this procedure.

   LLRW licensing action reviews may include compliance with the State licensing and regulatory requirements for: type of waste products and volumes, site and waste characteristics, performance assessment criteria, operational procedures, financial qualifications and assurances, and actions related to license renewal and amendments. The basis for major licensing decisions should be fully documented in a safety evaluation report. Specific licensing actions and decisions are largely dependent on the life cycle (e.g., phases) of the licensed LLRW disposal facility. Evaluation of the technical quality of licensing actions should include a review of the safety evaluation reports pertaining to these actions. Evaluation of the quality of licensing actions should also include an assessment of ongoing requests and supporting documents for amendment, modifications, and/or renewal of the LLRW license. LLRW facility license renewal may require detailed performance assessment evaluations, safety analysis, and public and stake holders involvement in the renewal decision process. Under certain circumstances, the State may decide to prepare an environmental impact statement (EIS) and use the National Environmental Policy Act (NEPA) process. In general, the reviewer should focus on licensing actions and decisions that may have long-term or short-term implications to the health and safety of workers, the public, or the environment.

5. To confirm that the response to incidents and allegations is adequate, as generally assessed according to FSME Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities*.

B. The review should consider the unique needs of the LLRW disposal program, while conducting a performance-based evaluation, considering risk information when possible. For example, the unique needs for developing an effective LLRW disposal site performance assessment process and measures should consider the following performance aspects: (a) consideration of future site conditions, processes, and events; (b) performance of engineering barriers; (c) the time-frame for LLRW site performance assessment; (d) treatment of sensitivity and uncertainty in LLRW performance assessment; and (e) role of performance assessment during operational and closure periods. The unique needs of the LLRW performance assessment methodology may require a modular approach to enable assessment and modeling of the disposal system components and processes. These components and processes may include: (a) source terms; (b) disposal cell design and engineering barriers; (c) LLRW disposal operations; (d) potential radionuclide transport via surface water infiltration, groundwater, and air; and (e) assessment of potential dose impacts and exposures to the public and workers. Considering the unique needs of the LLRW disposal program, it is preferable to use a modular approach and subsequent integration of specific inspection modules to achieve an overall assessment of the performance of the disposal facility.

III. BACKGROUND

The ability to conduct effective licensing and inspection of LLRW program depends primarily on having a sufficient number of experienced, knowledgeable, and well-trained technical personnel. Therefore, qualitative as well as quantitative measures of staff needs, skills, and training must be considered. For example, apparent trends in staffing, staff qualifications compared with designated activities or positions, and staff completed training should be used as qualitative and quantitative measures to gauge the status of technical staffing and training. Staff interviews and review of staff qualification journals, in consideration of established Agreement State training plans, should be used in evaluation of staffing and training.

Agreement State periodic inspections of licensed LLRW disposal facilities are essentially conducted to ensure that LLRW activities comply with regulatory requirements and are consistent with good safety practices. Inspection frequency, determined by a priority designation, should be based on the potential radiation hazard of each module of the licensee's program; for example, a module presenting the greatest risk to workers and to public health and safety and the environment would be inspected most frequently. LLRW inspections are typically conducted in segments or modules to ensure adequate and timely inspection. Information regarding the number of overdue inspections for each module is a significant measure of the status of LLRW inspection program. In this context, an inspection program must be capable of maintaining and retrieving statistical data on the status of the program or a module of the program.

The quality of a LLRW inspection program must be adequate for ensuring protection of workers and the public and compliance with license and regulatory requirements, particularly those requirements associated with the health and safety and protection of the environment. For example, the following factors may be used to assess the quality of

inspections: (a) use of proper instrumentation for inspection; (b) use of monitoring data and exposure records as well as adequate analysis and proper interpretation of data; (c) quality and adequacy of inspection reports; (d) promptness in communication of inspection findings and follow-up actions; and (e) inspection accompaniments of State inspectors by managers.

The following components of the licensing program must be evaluated to determine whether they may have an adverse impact on public health and safety: (a) review of license requirements and conditions; (b) licensing actions; (c) safety and environmental reports supporting licensing actions; (d) security of handled radioactive materials; (e) release of contaminated vehicles, waste containers, and equipment; (f) placement of liners and covers; (g) cleanup and decommissioning actions; (h) financial surety reviews; (i) notifications; and (j) examination of any actions that have been pending for a significant amount of time.

In addition to the above components, responses to incidents and allegations must be conducted correctly and in a timely manner to protect health and safety of workers and the public, and minimize environmental impacts, as well as maintain public trust.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader

1. Determines which team member is assigned the lead review responsibility for this non-common performance indicator. The principal reviewer(s) should meet the appropriate requirements specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members.*

2. Assists in developing a plan to conduct further review or to identify root causes for any potential health, safety, or environmental protection issues identified by the review.

B. Principal Reviewer

1. Selects and reviews relevant documentation related to the LLRW program review.

2. Conducts an inspection accompaniment of a LLRW facility before the on-site portion of the review.

3. Conducts staff discussions, evaluates the quality of the LLRW program, and maintains a summary of the review for this indicator.

V. GUIDANCE

A. Scope

1. This procedure applies only to review of the status of the LLRW program and related activities common to Agreement States. In particular, the procedure applies to activities involving licensing, control, management, operation, inspection, closure,

and/or post-closure of radioactive waste disposal under NRC's 10 CFR Part 61 and/or equivalent State regulations.

2. This procedure evaluates the Agreement State's quantitative and qualitative performance over the period of time since the last IMPEP review. This time frame is defined as the review period.

3. The review details in Subsection D are examples of evaluation elements and are not requirements.

B. Evaluation Procedures

1. The principal reviewer should specifically refer to MD 5.6, Part II (*Performance Indicators*) and Part III (*Evaluation Criteria*) of Non-Common Performance Indicator 3 – "Low-Level Radioactive Waste Disposal Program." These criteria should apply to program data for the entire review period.

2. Evaluation for each sub-indicator for this non-common indicator should be conducted in the same general manner as outlined in the respective IMPEP performance indicator procedures (SA-103, SA-101, SA-102, SA-104, or SA-105).

3. In applying the criteria, the review team should take into account the current status of the program regarding the life cycle of the LLRW disposal facility during the review period. Any mitigating factors that may have affected the performance should be reviewed. The team should evaluate the State inspections and licensing actions pertaining to each module or segment of the facility. The review team should integrate these segments or modules to achieve an overall evaluation of the status and quality of inspection and licensing actions.

C. Review Guidelines

1. The responses generated by the Agreement State, relevant to LLRW questions in the IMPEP questionnaire, should be used to focus the IMPEP review on potential LLRW issues.

2. The principal reviewer coordinates with the team leader, the NRC Region, and the Agreement State to accompany State inspectors during an inspection of the LLRW disposal facility before the on-site portion of the IMPEP review. The principal reviewer observes inspections and reviews inspection procedures and reports usually available on site, with emphasis on inspection approaches, measurements, and related health and safety issues.

3. The reviewer should be familiar with the following documents:
   - NRC Inspection Manual Chapter (IMC) 2401, *Near Surface Low-Level Radioactive Waste Facility Inspection Program*;
   - IMC 2410, *Conduct of Observation Audits*;

- NRC's Inspection Procedure (IP) 84100, *Special Nuclear Material Inspections at Near Surface Low-Level Waste Disposal Facilities in Agreement States*;
- IP 84101, *Radioactive Waste Management*;
- IP 84521, *Radwaste Startup*;
- IP 84750, *Radioactive Waste Treatment, and Effluent and Environmental Monitoring*;
- IP 84850, *Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR 20 and 10 CFR 61*;
- IP 84900, *Low-Level Radioactive Waste Storage*;
- IMC 2602, *Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees*; and
- IMC 2604, *Licensee Performance Review*.

4. The reviewer should be familiar with the basic regulatory guides involving LLRW disposal siting, licensing, environmental impacts, performance assessment, waste characterization, and waste averaging. These guidance documents include, but are not limited to, the following:
   - NUREG-1200, *Standard Review Plan for the Review of a License Application for a Low-Level Waste Disposal Facility*;
   - NUREG-1199, *Standard Format and Content Guide for a License Application for a Low-Level Waste Disposal Facility*;
   - NUREG-1300, *Environmental Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility*;
   - NUREG-0945, *Final Environmental Impact Statement on 10 CFR Part 61: Licensing Requirements for Land Disposal of Radioactive Waste*;
   - Technical Position (on "Concentration Averaging and Encapsulation," January 17, 1995);
   - Branch Technical Position (on "Waste Form," Rev.1, January 24, 1991);
   - Regulatory Guide 4.19, *Guidance for Selecting Sites for Near Surface Disposal of Low-Level Radioactive Waste*;
   - *Federal Register*, Vol. 60, No. 158, August 16, 1995, pp. 4262-42630 ("Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" [Final Policy Statement]; and
   - NUREG-1573, *A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities*.

5. When reviewing State inspections of a LLRW disposal facilities and/or LLRW storage activities, the reviewer should be familiar with pertinent procedures. Examples of these procedures include, but are not limited to:
   - IP 84850, Radioactive Waste Management - *Inspection of Waste Generator Requirements of 10 CFR Part 20 and Part 61*;
   - IP 30703, *Management Entrance/Exit Interviews*;
   - IP 83822, *Radiation Protection*;
   - IP 83890, *Closeout Inspection and Survey*;
   - IP 84900, *Low-Level Radioactive Waste Storage*;
   - IP 84101, *Radioactive Waste Management*;

- IP 86750, *Solid Waste Management & Transportation of Radioactive Material*;
- IP 88045, *Effluent Control and Environmental Protection*;
- IP 87102, *Maintaining Effluents from Material Facilities As Low As Is Reasonably Achievable (ALARA)*;
- IP 86750, *Solid Radioactive Waste Management and Transportation of Radioactive Materials*;
- IP 86740, *Inspection of Transportation Activities*;
- IP 88005, *Management Organization and Controls*;
- IP 88010, *Operator Training/Retraining*;
- IP 88035, *Radioactive Waste Management*;
- IP 88050, *Emergency Preparedness*;
- IP 88045, *Effluent Control and Environmental Protection*;
- IP 92701, *Follow-up*;
- IP 92702, *Follow-up on Corrective Actions for Violations and /Deviations*;
- IP 92703, *Follow-up of Confirmatory Action Letters*;
- IP 93001, *OSHA Interface Activities*; and
- IP 94702, *Participation in Licensee Meeting*.

6. Technical quality of licensing is evaluated based on assessment of the quality and promptness of licensing actions, completed licensing activities, and licensing corrective actions to ensure health and safety of workers, of the public, and protection of the environment. Examples of significant licensing actions include: approval of variations in waste characteristics, waste concentration averaging, procedures in waste handling and processing, liners and cover properties, and disposal cell design. The review team should review documents supporting significant licensing actions focusing on health and safety issues associated with these actions.

7. Any issues identified in the last IMPEP review that remain open should be resolved in accordance with Section V.H.4 of FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.

D. Review Details

1. Technical Staffing and Training

   The review details presented in FSME Procedure SA-103 should be evaluated before this detailed review. The following specific review details apply, as well, to the LLRW program reviews:

   a. It is recommended that all managers and technical staff involved in LLRW receive a generic training course in radiation safety and health physics to ensure understanding of potential risks and self protection from potential radiation exposure. Technical staff involved in the inspection of LLRW facilities for environmental monitoring should have additional training courses in the area of radiation exposures and radiological environmental transport monitoring and analysis. Inspection staff should be familiar with NRC's

Inspection Procedure 88010, *Operator Training/Retraining*. List of NRC sponsored courses for State staff are listed in Attachment A of FSME Procedure SA-600, "Training Criteria for Agreement State Personnel." The State should develop and document a training program for its staff, including required core (or basic) training; specialized training; supplemental (or advanced) training; and refresher training, as required, for staff designated position and/or assigned duties. The NRC/Organization of Agreement States (OAS) Training Working Group report entitled: "Recommendations for Agreement State Training Programs (October 1997)" should be used as a guide to develop staff training needs for the LLRW program.

b. Staff (or access to staff in other divisions/departments, or to consultants) should be available with expertise in materials licensing and/or inspection; health physics and radiation protection; radioactive materials' transportation and inspection; civil (geotechnical) and mechanical engineering; geology/geochemistry, surface water and groundwater hydrology; chemical safety; and environmental science. The principal reviewer may conduct interviews with staff to evaluate program staffing qualifications and potential needs.

c. The LLRW program should have plans and schedules for development and implementation of a training program for the staff. The program should keep records of staff training and qualification journals and include refresher training for important skills and training specific to LLRW management, including radiation protection, transportation, treatment, storage, and disposal of radioactive waste, as well as environmental monitoring aspects and associated chemical and industrial hazards.

d. Staff should receive some training in risk and performance assessment, and should be made aware of the NUREG-1573 ("A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities"). Staff should also be aware of NRC's risk informed performance-based approaches and probabilistic risk assessment methods.

2. Status of the LLRW Inspection Program

The review details presented in the FSME Procedure SA-101 should be evaluated. NRC's MC 2401 describes the specific radiological safety inspection program for near surface LLRW disposal facilities and defines specific inspection requirements. The primary reviewer should evaluate the current phase(s) of the program activity (e.g., pre-licensing/construction, pre-operation, operation, closure, and post-closure). The reviewer(s) should consider that the primary purpose of the inspection program is to verify if the LLRW facilities are operated and managed throughout their entire life cycle in a manner that provides protection from radioactivity to employees, members of the public, and the environment. The State typically conducts routine and non-routine LLRW inspections. Depending on whether the regulatory program chooses to maintain an onsite inspector at the LLRW facility, inspections may be conducted on a daily, weekly, or monthly basis.

Routine inspections may include the following LLRW aspects: waste shipments; waste manifest; waste characteristics and volumes; shipment vehicle surveys and records; waste packages; marking, labeling, and placarding; emergency response information; and general shipping inspections for compliance with regulatory requirements by DOT, NRC, and/or Agreement State.

Site security, trenches, disposal cells, and site boundary inspections should be conducted on a routine basis. Non-routine inspections are typically more extensive and conducted in modules or segments on an annual basis. Non-routine inspection may include the following modules or segments: personnel exposures and dosimetry (e.g., internal, bioassay, and external dosimetry); personnel qualifications and training; radiological control for air monitoring; radiological control surveys; surface water and groundwater monitoring; emergency response plans and drills; waste receiving, treatment, storage, and disposal operations; instruments calibrations and check sources; posting; respiratory protections, ALARA records; and records of incidents and allegations. In general, the following specific review details may apply to the LLRW program reviews:

a. The LLRW program review team should conduct an inspection accompaniment before conducting an on-site IMPEP review. The purposes of the inspection accompaniment are to: (a) observe current status of LLRW facility safety and security; (b) observe on-site inspection to become familiar with inspection modules and procedures; (c) evaluate adequacy of inspection tools and equipment used; (d) evaluate completeness of onsite inspection; and (e) examine inspection reports, inspection records, and findings.

b. The review team should be aware that LLRW facility inspections are typically conducted in routine and non-routine fashion and may be conducted in segments, modules, or through an on-site inspector, as explained above. Each module or segment should be conducted annually at the site. Breaking the inspection into modules or segments is more efficient, effective, and timely. Nevertheless, for evaluation of the overall inspection status, all inspection modules or segments should be considered and integrated. Further consideration, should also be given if an onsite inspector is stationed at the facility.

c. Evaluate routine inspections and assess adequacy and frequency needed for safety, security, and to demonstrate compliance with regulatory requirements and license conditions. Evaluate non-routine inspections through identification of each inspection module or segments and an evaluation of any missed or late inspections (>25 percent of the frequency) for each module or segment during the IMPEP review period. In this regard, the reviewer should review the license, license conditions and amendments, and current LLRW activities. The reviewer should evaluate the need for any additional inspection areas or modules taking into consideration new activities and the current life cycle of the facility.

d. Include a qualitative evaluation that examines the justifications for an Agreement State revision of its internal inspection frequencies.

e. When reviewing an Agreement State program, use inspection data provided by the State from the IMPEP questionnaire and information provided during the on-site review. The State should not be penalized for failing to meet internally developed inspection schedules that are more aggressive than those specified in current NRC policy. In addition, the reviewer should ensure that overdue inspections are tallied in a consistent fashion, based on the frequency specified in NRC IMC 2401 and 2602.

3. Technical Quality of LLRW Inspections

The review details presented in FSME Procedure SA-102 should be evaluated. The reviewer should consider the life cycle of the inspected LLRW facilities and address completeness of the inspection to cover all necessary modules or segments of LLRW activities. The quality of the modular inspection can be evaluated by examining each module inspection report for timeliness, completeness, and follow-up on inspection findings. For example, during an inspection accompaniment, LLRW IMPEP reviewers should observe State inspector(s) and evaluate inspection methods, adequacy of instruments used, survey of vehicles and waste packages. A reviewer should also examine routine inspection records and files and evaluate completeness of the inspection reports, inspection findings, and follow-up actions for mitigation measures. The reviewer should also examine the quality of Agreement State inspection records for staff dosimetry and exposure records, and follow-up actions to reduce exposures below action levels. State inspection of environmental monitoring activities and review of inspection reports for completeness and adequacy is another indicator of the quality of inspection. The following specific review details may apply to the LLRW program reviews:

a. The risk significance of radiological and chemical hazards at an LLRW facility should be considered during an inspection. The reviewer should determine whether the inspector used proper and calibrated instruments or tools to detect radioactivity and potential radiation exposure. The reviewer should determine whether the inspector has access to chemical safety experts and/or to consultants if a chemical safety issue is noticed on an inspection. In addition to potential radiological hazards, the team should determine whether the inspector understands the regulatory authority and relationships between agencies in regulating waste shipment, potential chemical hazards, and potential environmental releases at LLRW disposal facility including waste storage and treatment facilities (e.g., Occupational Safety and Health Administration (OSHA) ,Mine Safety and Health Administration (MSHA), U.S. Environmental Protection Agency (EPA), U.S. Department of Transportation (DOT), and State agencies).

b. The team should evaluate records of each module, or segment, of the LLRW program for completeness and follow-up actions. The team should also determine whether inspection findings, including violations, are communicated to the licensee in a timely fashion and whether licensee responses are evaluated and documented by the State LLRW regulatory program

c. The team should determine if the Agreement State's inspection of clean-up and

decommissioning projects (within the facility), or release of equipment, vehicles, or cars, after offloading of waste shipments, are inspected in accordance with a written inspection procedure to confirm the safety of decommissioning and the safety in release of equipment. Inspections should focus on radiological safety aspects, implementation of safety procedures, potential effluent releases to the environment, public and worker's exposure, and suitability of decontaminated areas, equipment, and structures for release.

d. There should be a review of workers exposure records and ALARA records, to minimize radiological exposure levels.

e. There should be a review of the quality and adequacy of environmental monitoring data (air, soil, surface-water, and/or groundwater) and evaluation of data analysis for potential radionuclide releases, on-site/off-site, above threshold limits.

f. There should be a review of inspection data regarding the quality and performance of liners and/or covers placed at the LLRW disposal facility, to ensure compliance with the required standards.

g. There should be reviews of inspection records for waste shipments, to ensure that radiological and physical/chemical characteristics of the waste are consistent with license requirements and NRC's and DOT's regulations and guidance.

h. Decommissioning recordkeeping [see 10 CFR 40.36(f)] should be periodically checked for completeness, especially before commencement of decommissioning.

i. There should be sufficient radiological monitoring and surveys, given the potential extent of any on-site/off-site residual contamination, conducted before license termination and site closure. Licensee's survey results should be validated through a close-out inspection or confirmatory survey.

4. Technical Quality of Licensing Actions

The review details presented in the FSME Procedure SA-104 should be evaluated. The reviewer should determine the current life cycle of the licensed facility (e.g., pre-licensing/construction, pre-operation, operational, a closure, or post-closure phase). Each phase of the LLRW disposal facility may require different licensing actions. For example, the pre-licensing/construction phase may require an extensive review of licensing actions regarding site selection, site performance assessment, disposal cell designs, license conditions, and technical specifications of liners and engineering barriers. The pre-operational phase may require examination of State licensing actions regarding each component of the LLRW engineering system and planned disposal operations or processes. The operational phase may require modifications of license conditions, expansion of LLRW disposal activities, mitigation measures, site security, modification of cell design, and/or LLRW management controls. The closure and post-closure phase licensing actions may involve on-site,

buffer zone, and off-site environmental monitoring activities, mitigation and clean-up measures, and financial assurance and institutional control issues. In addition, the following specific review details may apply to the LLRW program reviews:

a. A sample of licensing actions that are representative based on the number and type of actions performed during the review period should be reviewed, including a cross-section of as many different technical reviewers and categories as practical.

b. The selected licensing actions should be reviewed for technical correctness and quality, including adequacy, accuracy, completeness, clarity, specificity, and consistency. Licensing actions supporting technical documents (e.g., safety evaluation reports and/or environmental impact statement) should be examined.

c. The selected licensing actions should conform to applicable regulations and license conditions in all aspects, based on regulatory guidance, checklists, and policy memoranda, to ensure consistency with current accepted practice and standards.

d. Records that document deficiencies in licensee supporting information, including significant errors, omissions, or missing information, should be examined. Such records include letters, file notes of a telephone conversation, and other documents.

e. The reviewer should examine how well the decision-making process is documented, including any significant deficiencies related to health and safety. The reviewer should determine if decisions are made under a proper signature by an authorized official.

f. If the initial review suggests a weakness in the program, or problems regarding one or more aspects of the technical review in support of licensing actions, additional samples should be reviewed to determine the extent of the problem or identify a systematic weakness. The finding, if any, should be documented in the report.

g. In reviewing licensing actions against the criteria, the reviewer may exercise flexibility in assessing the performance for this subelement. The reviewer should take into account the current status of the program and any mitigating factors that may have prohibited the program from completing needed technical review which is customarily a requisite for supporting licensing action. If management took appropriate steps to address the licensing issues an unsatisfactory rating may not be appropriate.

h. Justifications for the Agreement State to grant an exception or exemption from an applicable rule, regulatory guide, or industry standard, should be checked and verified.

i. It should be determined whether adequate financial assurance for the decommissioning and site closure has been established in accordance with regulatory requirements and applicable guidance. It should be determined whether financial assurance mechanisms are reviewed and maintained to ensure that they will be executable and provide sufficient funding for decommissioning and closure, if the licensee liquidates or is otherwise unable to pay for remedial actions or decommissioning.

j. It should be determined during the on-site review if the Agreement State has made a special effort to develop or identify local regulatory guidance and how such guidance may be uniquely applied to the LLRW disposal facility.

5. Technical Quality of Incident and Allegation Activities

The review details presented in FSME Procedure SA-105 should be evaluated. In addition, the following specific review details may apply to the LLRW program reviews:

a. Coordination should be made with the FSME and Regional Allegation Coordinators to obtain a listing of the LLRW concerns and allegations submitted to NRC's through the concerned Region.

b. There should be a review of State response regarding incidents and allegations.

c. A representative number of incidents and allegations filed at the State should be evaluated from the entire review period. If possible, all incidents and allegations should be reviewed.

d. When selected, incidents and allegations can be reviewed. The review should focus on: (a) risk significant aspects; (b) discernment of root causes; (c) confidentiality and protection of alleger's identity; (d) conformance to applicable specific rules, guides, license conditions, or general guidance provided in Section V, SA-105, and (e) follow-up actions for closure of allegations.

e. The review should include all pertinent event records entered in the Nuclear Material Events Database (NMED). The reviewer should verify whether event actions and notifications are conducted as specified in SA-300, "*Reporting Material Events*," and comparable Regional guidance. If there are any issues or questions with the event data, then the NMED project manager in NMSS should be consulted before the on-site review.

6. IMPEP Review of LLRW Disposal Facility During Closure/Post-Closure Phase

The term "closure" is typically used to encompass LLRW activities that must be carried out to allow issuance of a license amendment for the disposal-site closure. The LLRW disposal-site closure is followed by a period of "post-closure" for observation of performance, environmental monitoring, and maintenance. The post-closure period is followed by an institutional control period of 100 years

(see 10 CFR 61.7(b)(4) and 10 CFR 61.59(b)). Where LLRW disposal sites are operating under Agreement State regulation it is anticipated that responsibility for regulation and inspection of closure and post-closure activities will continue to reside with the Agreement States. The licensee develops a closure plan for review and approval of the State.

The IMPEP reviewer of LLRW disposal facilities during the Closure/Post-closure phases should focus on review of the site-closure plan approved by the Agreement State and implementation activities associated with any portion of the plan. The IMPEP review during site-closure/post-closure phases is generally conducted to evaluate conformance with applicable regulations under 10 CFR Part 20 (Standards for Protection against Radiation) and 10 CFR Part 61 (Licensing Requirements for Land Disposal of Radioactive Waste). Conformance with license conditions and applicable regulations to these phases (e.g., 10 CFR §§ 61.26-61.31 or Agreement State compatible regulations) must be evaluated. The reviewer should be aware that it is likely to implement a portion of the closure plan while LLRW active operations continue elsewhere onsite. The closure plan itself, as amended during site operation should be reviewed to assess adequacy of the procedural or scheduling modifications. The Agreement State inspection during the closure phase should be evaluated to ensure that the licensee has implemented all elements of the closure plan and the State has approved initiation of the post-closure observation and maintenance.

The IMPEP review during the post-closure phase encompass Agreement State LLRW activities such as: (a) LLRW disposal-site record keeping; (b) review of site safety and security; (c) review of environmental monitoring data and records and followup;as appropriate based on trend analysis (d) review of disposal site performance records for conformance with the safety criteria in 10 CFR Part 20 and 10 CFR Part 61; (e) review of site repair and maintenance activities and records; and (e) review of financial assurance records and activities pertaining to license transfer, termination, and institutional controls.

For details, the IMPEP reviewer is referred to the LLRW closure-phase Inspection Procedures (IP) listed in Inspection Manual Chapter 2401. These procedures include: IP-30703, IP-83822; IP-83890, IP-86750, IP-88005, IP-88025, IP-88035, IP -88045, IP-88050, and generic procedures identified in Inspection Manual Chapter 2401, as appropriate.

It should be noted that the IMPEP review guidance in SA-109 (e.g., Sections I through V) applies, as well, to LLRW disposal sites during the closure and post-closure phases as practicable. The information provided in Section V Item 6 is additional supplementary information pertaining to LLRW sites during the closure and post-closure phases.

VI. REFERENCES

1. FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP).*

2. FSME Procedure SA-101, *Reviewing the Common Performance Indicator, Status of Materials Inspection Program.*

3. FSME Procedure SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections.*

4. FSME Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training.*

5. FSME Procedure SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions.*

6. FSME Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities.*

7. FSME Procedure SA 300, *Reporting Material Events*.

8. FSME Procedure SA-600, *Training Criteria for Agreement States Personnel.*

9. NRC Inspection Manual, Inspection Manual Chapter 2401, *Near-Surface Low-Level Radioactive Waste Disposal Facility Inspection Program* (Issue date: 11/27/01).

10. NRC Inspection Manual, Inspection Manual Chapter 2410, *Conduct of Observation Audits* (Issue date: 7/12/00).

11. NRC Inspection Manual, Inspection Manual Chapter (IMC) 2602, *Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees* (Issue date: 7/29/08)

12. NRC Inspection Manual, Inspection Manual Chapter (IMC) 2604, *Licensee Performance Review*.

13. NRC's Inspection Procedure (IP) 30703, *Management Entrance/Exit Interviews*.

14. NRC's Inspection Procedure (IP) 83822, *Radiation Protection*.

15. NRC's Inspection Procedure (IP) 83890, *Closeout Inspection and Survey*.

16. NRC's Inspection Procedure (IP) 84100, *Special Nuclear Material Inspections at Near Surface Low-Level Waste Disposal Facilities in Agreement States.*

17. NRC's Inspection Procedure (IP) 84101, *Radioactive Waste Management.*

18. NRC's Inspection Procedure (IP) 84521, *Radwaste Startup.*

19. NRC's Inspection Procedure (IP) 84750, *Radioactive Waste Treatment, and Effluent and Environmental Monitoring*

20. NRC's Inspection Procedure (IP) 84850, *Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR 20 and 10 CFR 61*.

21. NRC's Inspection Procedure (IP) 84900, *Low-Level Radioactive Waste Storage.*

22. NRC's Inspection Procedure (IP) 86750, *Solid Waste Management & Transportation of Radioactive Material*.

23. NRC's Inspection Procedure (IP) 87102, *Maintaining Effluents from Material Facilities as Low as Is Reasonably Achievable (ALARA)*.

24. NRC's Inspection Procedure (IP) 88005, *Management Organization and Controls*.

25. NRC's Inspection Procedure (IP) 88010, *Operator Training/Retraining.*

26. NRC's Inspection Procedure (IP) 88035, *Radioactive Waste Management*.

27. NRC's Inspection Procedure (IP) 88045, Effluent Control and *Environmental Protection*.

28. NRC's Inspection Procedure (IP) 88050, *Emergency Preparedness*.

29. NRC's Inspection Procedure (IP) 92701, *Follow-up.*

30. NRC's Inspection Procedure (IP) 92702, *Follow- up on Corrective Actions for Violations and Deviations.*

31. NRC's Inspection Procedure (IP) 92703, *Follow-up of Confirmatory Action Letters*;

32. NRC's Inspection Procedure (IP) 93001, *OSHA Interface Activities*.

33. NRC's Inspection Procedure (IP) 94702, *Participation in Licensee Meeting.*

34. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

35. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members.*

36. Regulatory Guide 4.19, *Guidance for Selecting Sites for Near Surface Disposal of Low-Level Radioactive Waste*; *Federal Register*, Vol. 60, No. 158, August 16, 1995, pp. 4262-42630 ("Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" [Final Policy Statement].

37. U.S. Nuclear Regulatory Commission NUREG-0945, *Final Environmental Impact Statement on 10 CFR Part 61: Licensing Requirements for Land Disposal of Radioactive Waste*; Technical Position.

38. U.S. Nuclear Regulatory Commission NUREG-1199, *Standard Format and Content Guide for a License Application for a Low-Level Waste Disposal Facility*.

39. U.S. Nuclear Regulatory Commission NUREG-1200, *Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility* (Rev. 2), Office of Nuclear Material Safety and Safeguards, January 1994.

40. U.S. Nuclear Regulatory Commission NUREG-1300, *Environmental Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility*.

41. U.S. Nuclear Regulatory Commission NUREG-1573, *A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities,* Published October 2000.

42. U.S. Nuclear Regulatory Commission, "*Regulating the Disposal of Low-Level radioactive Waste: A Guide to the Nuclear Regulatory Commission's 10 CFR Part 61,"* Office of Nuclear Material Safety and Safeguards, 1989.

VII. ADAMS REFERENCE DOCUMENTS

For knowledge management purposes, all previous revisions of this procedure, as well as associated correspondence with stakeholders that have been entered into NRC's Agencywide Documents Access and Management System (ADAMS) are listed below.

No.	Date	Document Title/Description	Accession Number
1	7/2/2004	STP-04-047, Opportunity for Comments on Draft of Two New IMPEP Procedures Regarding Review of Uranium Recovery Programs and Low-Level Waste Programs	ML041880157
2	6/20/05	STP Procedures SA-109, Reviewing the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program (Redline/Strikeout Version)	ML061640294
3	6/20/05	Summary of Comments on SA-109	ML061640301
4	5/16/06	STP Procedures SA-109, Reviewing the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program	ML061640290
5	6/30/05	STP-05-050, Final STP Procedure SA-109	ML051810484
6	7/14/09	FSME-09-051, Opportunity to Comment on Draft Revisions to SA-108 and SA-109	ML091330602
7	7/14/09	FSME Procedure SA-109 Draft Revision	ML091330114