UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 10, 2016

Hiram C. Polk, Jr., MD
Commissioner
Department for Public Health
Cabinet for Health and Family Services
275 East Main Street, HS1C-A
Frankfort, KY 40621-0001

Dear Dr. Polk:

On October 20, 2016, a Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Kentucky Agreement State Program. The MRB found the Kentucky program adequate to protect public health and safety, but not compatible with the NRC's program.

The enclosed final report contains a summary of the IMPEP team's findings and recommendations (Section 5.0). The MRB acknowledges the significant improvement Kentucky has made since 2012 concerning the timely performance of inspections. Kentucky improved from an unsatisfactory rating to a satisfactory rating for this indicator.

For the 2016 review, the review team identified some performance issues in the indicators of Compatibility Requirements and Low-Level Waste Disposal. With regard to Compatibility Requirements, the review team did not make a specific recommendation for Kentucky to implement because Kentucky is pursuing a process which would allow NRC regulations to be adopted by reference. If Kentucky is successful in this effort, the issue of timely adoption of regulations will be resolved. The review team did make a specific recommendation concerning the Maxey Flats Disposal Site (MFDS). The MRB noted that without timely issuance of inspection reports, public visibility of Kentucky's oversight responsibilities for MFDS is lacking. To ensure openness and transparency with respect to Kentucky's monitoring and oversight activities involving MFDS, the review team recommended that Kentucky's Radiological Health Branch ensure timely and consistent issuance of licensing actions and inspection results for the MFDS.

Based on the results of the current IMPEP review, the next full review of the Kentucky Agreement State Program will take place, as regularly scheduled, in approximately 4 years with a periodic meeting in 2 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Marc L. Dapas, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Kentucky Final IMPEP Report

cc: Matthew W. McKinley, Administrator
Radiation Health Program

BJ Smith, MS
Organization of Agreement States
Liaison to the MRB

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Letter to Hiram Polk from Marc Dapas, dated November 10, 2016

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE KENTUCKY AGREEMENT STATE PROGRAM

July 25–29, 2016

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Kentucky Agreement State Program. The review was conducted during the period of July 25–29, 2016, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Tennessee, and the Commonwealth of Pennsylvania.

Based on the results of this review, Kentucky's performance was found satisfactory for seven of the eight performance indicators reviewed: Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incident and Allegation Activities, Sealed Source and Device Evaluation Program, and Low-Level Radioactive Waste Disposal Program. Performance with respect to the Compatibility Requirements performance indicator was determined to be unsatisfactory.

The finding for the Status of Materials Inspection Program indicator significantly improved from unsatisfactory to fully satisfactory since the previous IMPEP review. The finding for the Compatibility Requirements indicator was downgraded to an unsatisfactory rating as the backlog of required regulation adoptions increased since the last IMPEP review. Kentucky is pursuing a process which would allow NRC regulations to be adopted by reference. Several regulations, including Title 10 of the *Code of Federal Regulations* Part 37, were adopted in this manner. If Kentucky is successful in this effort, the issue of timely regulation adoption would be resolved. The unsatisfactory finding results in Kentucky being not compatible with the NRC's program.

The review team considered recommending that Kentucky be placed on monitoring until the regulation adoption problem is resolved, but since actions are currently underway to use the adoption by reference process, this action was deemed unnecessary.

The review team made one recommendation, regarding the Low-Level Radioactive Waste Disposal Program, (see Section 5.0) and determined that the recommendation from the 2012 IMPEP review, regarding a self-assessment of the inspection program, should be closed (see Section 2.0).

Accordingly, the review team recommended, and the Management Review Board (MRB) agreed, that the Kentucky Agreement State Program is adequate to protect public health and safety, but is not compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place, as regularly scheduled, in approximately 4 years with a periodic meeting in 2 years.

1.0 INTRODUCTION

This report presents the results of the review of the Kentucky Agreement State Program. The review was conducted during the period of July 25–29, 2016, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Tennessee, and the Commonwealth of Pennsylvania. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of June 16, 2012, to July 29, 2016, were discussed with Kentucky managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to Kentucky on December 10, 2015. Kentucky provided its response to the questionnaire on July 11, 2016. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16194A002.

A draft of this report was issued to Kentucky on August 31, 2016, for factual comment. Kentucky responded to the findings and conclusions of the review by electronic mail dated October 3, 2016. A copy of Kentucky's response is available in ADAMS (Accession Number ML16281A199). The Management Review Board (MRB) met on, October 20, 2016, to consider the proposed final report. The MRB found the Kentucky Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The Kentucky Agreement State Program is administered by the Radiation Health Branch (Branch) which is located within the Department for Public Health (Department). The Department is part of the Cabinet for Health and Family Services (Cabinet). The Branch is comprised of three sections: the Radioactive Materials Section (Section), the Radiation Producing Machines Section, and the Radiation/Environmental Monitoring Section. The Radioactive Materials Section implements the elements of the Agreement State Program. Organization charts for Kentucky are available in ADAMS (Accession Number ML16194A003).

At the time of the review, the Kentucky Agreement State Program regulated 364 specific licenses authorizing possession and use of radioactive materials. Kentucky also regulates the closed Maxey Flats low-level radioactive waste disposal site. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Kentucky.

The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators and made a preliminary assessment of the Kentucky Agreement State Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on June 15, 2012. The final report is available in ADAMS (Accession Number ML12264A598). The results of the 2012 review and the status of the recommendation are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Unsatisfactory

Recommendation: The MRB recommended that the Branch perform a self-assessment to determine the effectiveness of its oversight of the inspection program and that the results of this self-assessment be reviewed as part of the IMPEP periodic meeting.

Status: Kentucky submitted its self-assessment and the resulting programmatic changes to the NRC and these items were evaluated during the July 9, 2014, periodic meeting. The changes adopted by Kentucky allow managers to be aware of potential inspection backlogs. A new inspection tracking database allows for simplified tracking of inspection metrics. The review team determined that these efforts were effective in Kentucky's oversight of the materials inspection program. The review team recommended, and the MRB agreed, that this recommendation be closed.

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

Compatibility Requirements: Satisfactory, but needs improvement
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Low-Level Radioactive Waste Disposal Program: Not reviewed during the 2012 IMPEP

Overall finding in 2012: Adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program.

The 2012 MRB directed that Kentucky remain on monitoring to provide continued assurance that the Agreement State Program maintained sustained performance in the area of timely inspections and promulgation of the required regulations. NOTE: The period of monitoring was discontinued after the July 2014 periodic meeting. At that time, Kentucky had no current overdue inspections and only one inspection was overdue in the 2 years since the last IMPEP review. Six regulations were overdue for adoption.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, and well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires a consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The review team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Kentucky's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Branch is comprised of a manager, a supervisor, and seven staff members which equals approximately 8.2 full-time equivalents for the radioactive materials program. Additional technical assistance for oversight of the Maxey Flats Disposal Site (MFDS) is provided by a staff member from the Radiation/Environmental Monitoring Section.

Currently, there are no vacancies, and the Branch is fully staffed. During the review period, one of the staff members left the program and three staff members were hired, filling vacant positions. One staff member was deployed on active duty for approximately 2 ½ years during the review period. All of the staff members are fully

qualified in licensing and inspection for either medical or industrial programs. Several staff members are undergoing qualifications for full qualification of all license types. Kentucky has a training and qualification manual compatible to IMC 1248.

c. Evaluation

The team determined that, during the review period, the Kentucky program met the performance indicator objectives listed in Section 3.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The review team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of Materials Inspection Program," and evaluated Kentucky's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Kentucky performed 203 Priority 1, 2, 3, and initial inspections during the review period. Kentucky conducted two percent of Priority 1, 2, 3, and initial inspections overdue. Three priority 1, 2, or 3 inspections, and one initial inspection were conducted overdue.

The team's evaluation of 29 inspection reports indicated that one of the inspection reports was communicated to a licensee beyond Kentucky's goal of 30 days after the inspection exit.

In 2016, the Branch performed a self-assessment and determined that it was incorrectly prioritizing service providers requesting reciprocity. A recalculation of reciprocity frequencies indicated that Kentucky performed only 13 percent of candidate reciprocity inspections in 2012, but had an inspection percentage above 20 percent for each of the last 3 years.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of a program's inspection capability.

a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Kentucky's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.

- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 29 materials inspections conducted during the review period. The casework reviewed included inspections conducted by nine current and former inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses.

Review team members accompanied eight program inspectors in April and June 2016. The inspectors were adequately prepared and conducted performance-based inspections. The inspector accompaniments are identified in Appendix B. The review team noted the Branch performed annual supervisory accompaniments for each of the inspectors throughout the review period.

Over the past two IMPEP review periods, Kentucky developed a robust General License (GL) program for certain types of generally licensed devices, particularly fixed gauges. The GL program incorporates a tracking database, inspections, and fees. Inspections are performed at 5-year intervals. Kentucky has validated this program out of concern for lost and orphaned sources, particularly in the coal industry, and sees the GL program as a significant benefit to Kentucky.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 3.3.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, and security. An assessment of licensing procedures, actual implementation of these procedures, and documentation of communications and associated actions between the Kentucky licensing staff and regulated community will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and

evaluated Kentucky's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements meet current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Kentucky performed 2,856 radioactive materials licensing actions. The review team evaluated 27 of these actions. The licensing actions selected for review included six new applications, nine amendments, seven renewals (amendments in entirety), four terminations, and one bankruptcy filing. The review team evaluated casework which included the following license types and actions: broad scope academic, broad scope medical, medical diagnostic and therapy, other manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, self-shielded irradiators, well-logging, service providers, and bankruptcy. The casework sample represented work from nine license reviewers, including one former license reviewer. Terminated licensing actions were well documented, showing transfer to authorized recipients and final status surveys, as appropriate.

All licensing actions undergo a peer review and management review by the Section Supervisor. The Branch Manager subsequently signs all of the materials licenses.

During the previous IMPEP review period, it was reported that due to staff turnover and license backlog issues, processing of amendments in entirety were delayed. During this review period, the team noted that the amendments in entirety were again being processed. Currently, no amendments in entirety are backlogged.

The Branch performed a self-assessment of the pre-licensing program in response to the NRC's publication of Radiation Control Program Directors (RCPD)-15-010 in October 2015, entitled "The Importance of Using Pre-Licensing Guidance and Site Visits During

the Licensing Process." The RCPD letter requested that the Agreement States conduct a self-assessment or audit of those licenses in which pre-licensing guidance was used and required.

The results of the self-assessment indicated that the pre-licensing forms were being utilized, but the section of the form related to the basis for making the determination that licensed materials would be used as intended was not complete, and the basis for making that determination was not thoroughly documented. It was noted that many of the staff had not thoroughly reviewed the directions at the end of the form nor understood completely what each question was asking. In addition, in those cases where a solid determination of material use as intended could not be made, the staff was not performing adequate assurance screening. Therefore, based on these results, the Section Supervisor held several training sessions with the staff to review the pre-licensing policy and the pre-licensing forms contained therein. After the self-assessment, Kentucky performed a retroactive review of all pre-licensing actions to ensure that appropriate determinations had been made, in spite of the weaknesses identified in the process. Kentucky's pre-licensing review methods now incorporate the essential elements of the NRC's pre-licensing guidance to verify that an applicant will use requested radioactive materials as intended.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 3.4.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky*'s* performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup procedures and actions, will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Kentucky's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.

- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or the NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, Kentucky reported 25 incidents to the NRC. The review team evaluated 17 radioactive materials incidents which included 11 medical events and 6 damaged equipment events. The review team also evaluated one potential overexposure event which Kentucky determined not to be an overexposure. The review team determined that the potential overexposure was correctly categorized by the Branch as non-reportable. Kentucky dispatched inspectors for onsite followup for nine of the cases reviewed. For the incidents that did not receive an onsite followup inspection, the review team determined that Kentucky conducted appropriate followup activities via telephone and/or e-mail to ensure that public health and safety were protected.

Kentucky received six allegations during the review period. The review team evaluated all six allegations, including two allegations that the NRC referred to Kentucky during the review period. The review team evaluated the completed casework and determined that the Branch took prompt and appropriate action in response to the concerns raised. The concerned individuals were notified of the findings. The team found that the Branch adequately protected the concerned individuals' identity.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 3.5.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery (UR) Program. The NRC's Agreement with Kentucky does not relinquish regulatory authority for a UR program; therefore, only the remaining three non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Kentucky's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC website at the following address: https://scp.nrc.gov/regtoolbox.html.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200, that have been designated as necessary for maintenance of an adequate and compatible program have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

Kentucky became an Agreement State on March 26, 1962. The Kentucky Agreement State Program's current effective statutory authority is contained in the Kentucky Revised Statutes 13B.170, 194A.050, 211.090, 211.842 to 211.852, 211.859, 211.990(4), and 211.861 to 211.869. The Branch is designated as Kentucky's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

Kentucky's administrative rulemaking process takes approximately 19 months from drafting to finalizing a rule. The public, NRC, other agencies, and potentially impacted licensees and registrants, are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved. The review team noted that Kentucky's rules and regulations are not subject to "sunset" laws.

During the review period, Kentucky submitted 2 final regulation amendments and 12 revised final regulation amendments to the NRC for a compatibility review. One of the two final regulation amendments was overdue for adoption by Kentucky at the time of submission.

At the time of this review, the following 12 amendments were overdue:

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," Title 10 of the *Code of Federal* Regulations (10 CFR) Parts 30, 31 and 32 amendment (65 FR 79162), that was due for Agreement State adoption by February 16, 2004 (10 CFR Parts 30 and 31 only).

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that was due for Agreement State adoption by October 29, 2010.

- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that was due for Agreement State adoption by December 17, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that was due for Agreement State adoption by November 30, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that was due for Agreement State adoption by February 15, 2011.

- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that was due for Agreement State adoption by September 28, 2012.

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512), that was due for Agreement State adoption by December 17, 2015.

- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendment (76 FR 56951), that was due for Agreement State adoption by November 14, 2014.

- "Change of Compatibility of 10 CFR 31.5 and 31.6," 10 CFR Part 31 amendment (77 FR 3640), that was due for Agreement State adoption by January 25, 2015.

- "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), that was due for Agreement State adoption by August 10, 2015.

- "Technical Corrections," 10 CFR Parts 30, 34, 40, and 71 amendment (77 FR 39899), that was due for Agreement State adoption by August 6, 2015.

- "Requirements for Distribution of Byproduct Material," 10 CFR Parts 30, 31, 32, 40, and 70 amendment (77 FR 43666), that was due for Agreement State adoption by October 23, 2015.

The review team had several discussions with Kentucky management to determine their path forward in addressing the overdue regulation amendments. This included access to a dedicated Regulation Coordinator in the Cabinet and adoption of the NRC regulations by reference. Previously, regulations were drafted by Branch staff who were already tasked with other duties such as licensing and inspection activities.

Kentucky started adoption by reference with 10 CFR Part 37 which was adopted timely and as a final regulation in February 2016. At the time of the team's review, Kentucky was in the process of adopting by reference specific tables from 10 CFR Parts 20 and 30. These regulations were finalized on August 17, 2016. The Branch intends to adopt all applicable NRC regulations by reference by June of 2018. The plan was shared with the review team at the time of their review. The Branch provided the plan in writing just prior to the October 20 MRB meeting. The MRB acknowledged the Branch's significant action to address the regulation backlog that has been accruing over time. The Branch's plan is available in ADAMS (Accession Number ML16298A199).

c. Evaluation

The review team determined that during the review period, Kentucky did not meet all of the performance indicator objectives listed in Section 4.1.a. Specifically, Kentucky had not adopted final regulations for 12 NRC amendments within the required 3-year timeframe. This represents an increase of seven overdue amendments since the 2012 IMPEP review. The review team considered making a formal recommendation to Kentucky for addressing the overdue regulations; however, because Kentucky has already developed a written plan and implemented a path forward to adopt all applicable NRC regulations by reference, the review team did not make a recommendation for this indicator.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for review teams. Under this guidance, three sub-elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The review team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated Kentucky's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3, Revision 2.

Evaluation of Defects and Incidents Regarding SS&Ds

- SS&D incidents are reviewed to identify possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

The Branch has two SS&D reviewers previously qualified and two new SS&D reviewers who are qualified to perform safety evaluations of SS&D registrations. Kentucky has a training program compatible with the NRC training requirements listed in IMC 1248, Appendix D. All reviewers have degrees in a physical science or engineering discipline and have attended the NRC's SS&D Workshop or the Branch's contracted training course. The reviewers also have attended the G-108 "Licensing and Inspection Course," G-109 "Licensing Practice and Procedure Course," or have equivalent training. The review team interviewed all of the SS&D reviewers and determined that they were familiar with the procedures used in the evaluation of a device or source and had access to applicable reference documents.

Technical Quality of the Product Evaluation Program

Kentucky currently has one device manufacturer who has 11 active SS&D registrations. Registrations clearly summarize the product evaluations and provide license reviewers with adequate information to license the possession and use of the products. Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. Overall, the review team determined that the product evaluations were thorough, complete, consistent, of acceptable quality, and adequately addressed the integrity of the product during use and under accident conditions.

The review team evaluated the only two amendment actions issued during the review period, and discussed the one pending action in process at the time of the review.

Analysis of the casework and interviews with the SS&D reviewers confirmed that the Branch follows the recommended guidance from the NRC SS&D Workshop and NUREG-1556, Volume 3, Revision 2. The review team confirmed that all applicable and pertinent American National Standards Institute NUREG-1556 Series guides, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews. The Branch follows a documented internal process when performing an SS&D review that includes communication via email with the licensee and the use of the evaluation checklist as recommended in NUREG-1556.

Evaluation of Defects and Incidents Regarding Sealed Source and Devices

Utilizing NMED, the review team examined reported incidents involving devices regulated by Kentucky. There were 31 events reported nationally over the review period for Kentucky's one device manufacturer. The review team determined that the Branch analyzed the events, reviewed the issues, and followed up on the incidents with the manufacturer, as appropriate. None of the events were related to manufacturing or design of the product.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 4.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed, that Kentucky's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

The objective is to determine if Kentucky'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 LLRW Inspection, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities. This program was not evaluated during the 2012 IMPEP review.

a. Scope

The review team used the guidance in State Agreements procedure SA-109, "Reviewing the Non-Common Performance Indicator: Low-Level Radioactive Waste Disposal Program," and evaluated Kentucky's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- Qualified and trained technical staff are available to license, regulate, and inspect the operation and performance of the LLRW disposal facility.
- Qualification criteria for new LLRW technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing the LLRW licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing LLRW licensing and inspection activities are adequately qualified and trained to perform their duties.
- LLRW license reviewers and inspectors are trained and qualified in a reasonable period of time.

Status of LLRW Inspection

- The LLRW facility is inspected at prescribed frequencies.
- Statistical data on the status of the inspection program is maintained and can be retrieved.
- Deviations from inspection schedules are coordinated between LLRW technical staff and management.
- There is a plan to reschedule any missed or deferred inspections or a basis has been established for not rescheduling any missed inspections.
- Inspection findings are communicated to licensees in a timely manner.

Technical Quality of Inspections

- Inspections of LLRW licensed activities focus on health, safety, and security for the public, as well as, the environment.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors conduct annual accompaniments of each LLRW inspector to assess performance and assure consistent application of inspection policies.
- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection (sampling and monitoring) program.

Technical Quality of Licensing Actions

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Applicable LLRW guidance documents are available to reviewers and are followed (e.g., pre-licensing guidance, regulatory guides, etc.).
- LLRW license reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License tie-down conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of amendments in their entirety demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

Technical Quality of Incident and Allegation Activities

- LLRW incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or the NRC.
- Incidents are reported to the NMED.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

The MFDS is a closed LLRW site in its Final Closure Period. The Cabinet for Health and Family Services is responsible for oversight for the protection of the public health, safety, and welfare. The Branch performs licensing and inspection functions at the MFDS. Kentucky's Energy and Environment Cabinet is the licensee listed on the MFDS radioactive materials license.

The MFDS operated as a commercial LLRW disposal facility authorized by Kentucky from 1963 through 1977. The waste was dumped into unlined trenches, resulting in some containers laying on their sides, upside-down, and in a variety of configurations. Approximately 4 to 6 million cubic feet of radioactive waste was received and buried at MFDS in 40 unlined trenches.

Between 1977 and 1986, a vapor barrier was placed over approximately 30 acres of the trenched area for stabilization. However, water continued to collect in the trenches and leach radioactive material into the surrounding environment. Based on the chemicals and radioactive materials in the trenches, MFDS was listed on the National Priorities List in 1986, and a Record of Decision (ROD) was issued in September 1991, by the U.S. Environmental Protection Agency (EPA) under its Comprehensive Environmental Response, Compensation, and Liability Act authority. The ROD describes a remedy of natural stabilization, which also includes installing and monitoring a landfill cap made of a synthetic liner, replacing the landfill cap after 20 years, and installing a final landfill cap after 35 to 100 years. Construction of the interim cap was completed in 2003, and MFDS entered the "Interim Maintenance Period" of operation. The plan to replace the interim cap approximately every 25 years would have allowed the trenches to stabilize and allowed further decay of the shorter half-life radionuclides. Although natural stabilization was estimated to require 35 to 100 years, the EPA elected to proceed to the Final Closure Period, which would require a final cap. In 2012, EPA, in its Five Year Review, indicated that 35 years had passed since the termination of authorized disposal (1977-2012), and the Cabinet and EPA agreed to place a final cap in 2012.

In November 2012, MFDS was placed into the Final Closure Period which includes an installation of a vegetative cap, surface water control features, and surface monuments to identify the location of buried waste. Once the Final Closure Period is completed, MFDS will enter into the Custodial Maintenance Period. The first 100 years of the Custodial Maintenance Period is defined as the Institutional Control Period which will include fencing and other activities to control access to the MFDS; periodic surveillance; custodial care; and filing of notices, survey plats, and deed restrictions with the appropriate authorities. This Institutional Control Period will accomplish the goal of preventing inadvertent intrusion onto the MFDS and providing of custodial care in perpetuity.

Technical Staffing and Training

LLRW activities are handled by Kentucky's staff, under the direction of the Branch Manager. The basic qualifications for the LLRW program staff are the same as for the radioactive materials program staff, as described in Section 3.1, and are commensurate with IMC 1248.

Status of LLRW Disposal Inspection

The Branch conducts site visits at least once a month to acquire water samples from multiple locations, and performs inspections every 2 years. NRC guidance in IMC 2401 "Near Surface Low-Level Radioactive Waste Disposal Facility Inspection Program," IMC 2602 "Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees," and IMC 2800, allows for inspections to be performed as needed based on the licensee's activities at the site.

There were not any areas of non-compliance identified as a result of inspections conducted in 2012. A finding from the 2014 inspection was verbally communicated to the licensee. A formal report was withheld at the direction of previous Cabinet management. A review of the documentation indicated that there was a non-compliance regarding failure to continue monitoring the trench sump levels, as the sumps had been removed. The 2016 inspection was not performed prior to the onsite IMPEP review. However, the Branch reported to the MRB that the 2016 inspection was conducted in October.

Technical Quality of Inspections

On June 22, 2016, the review team accompanied three representatives from the Branch at the MFDS. The inspectors were adequately prepared and performed performance based inspections. Site security, environmental monitoring stations, and facility postings were observed.

The review team evaluated three inspections, an independent third party site assessment, and the Branch's annual monitoring reports based on the water samples collected and analyzed.

On July 27, 2016, the review team toured the Branch laboratory and observed equipment capable of analyzing the types of radionuclides that are present at the MFDS. The Branch collected and analyzed surface water and ground water samples. The review team evaluated the Branch's MFDS monitoring reports and determined that all radionuclide measurements did not exceed the annual drinking water standards at any of the sample locations. However, the review team noted tritium mobility from the unlined trenches at MFDS based on measurements taken during the construction of the north wall cutoff drain and nearby creeks. The Branch has been compiling the water quality data and performing trend analysis. The Branch has identified an upward trend in uranium and plutonium concentrations and more recently, cesium-137, at one sample location inside the owner controlled area. This data will assist the Branch in identifying releases from the MFDS and allow the Branch to develop remedies to address potential issues. The Branch's water sampling and analysis of water quality results support the conclusion that the public health and safety have been maintained. The reports were thorough, complete, consistent, and had sufficient documentation to ensure that licensee performance with respect to health and safety was acceptable.

Technical Quality of Licensing Actions

The review team examined two LLRW licensing actions which included one denial and one pending amendment to renew the MFDS license in its entirety. In December 2013, the licensee submitted an amendment to renew the license in its entirety. The action to

renew the license was halted by Cabinet management. The licensee subsequently submitted a request to terminate the license. In July 2014, the Branch officially denied the licensee's request to terminate the license. At the time of the onsite review, the license had not been amended in its entirety.

Technical Quality of Incident and Allegation Activities

There were no incidents or allegations pertaining to the LLRW program during the review period.

c. Evaluation

The review team noted that the MFDS is a closed radioactive waste burial facility and the Final Closure Period is nearing completion. This performance indicator is based on oversight of open and active disposal sites, so not all of the performance criteria are relevant for the MFDS. The review team determined that, during the review period, the Commonwealth met the relevant performance indicator objectives listed in Section 4.3.a.

The review team discussed a rating of satisfactory versus satisfactory, but needs improvement for the indicator. The review team noted that the Branch has shared the July 2014 inspection findings with the licensee, but has delayed issuance of the inspection report. In addition the Branch has not issued the renewal (amendment in its entirely) for the MFDS license. The review team determined that this indicator should be found satisfactory with a recommendation. The Cabinet is responsible for regulatory oversight of MFDS and the oversight is implemented by the Branch. The MRB noted that without issuance of inspection reports, there is no public visibility with respect to the results of the Branch's execution of its oversight responsibilities for MFDS in accordance with Kentucky's requirements. To ensure openness and transparency regarding the Branch's monitoring and oversight of MFDS, the team recommended, and the MRB agreed, that the Branch ensure timely and consistent issuance of licensing actions and inspection results for the MFDS.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended, and the MRB agreed that Kentucky's performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Kentucky's performance was found satisfactory for seven out of eight performance indicators reviewed and unsatisfactory for the Compatibility Requirements performance indicator. The failure by Kentucky to adopt regulations, or other legally binding requirements, in a timely manner, creates a gap in the collective national effort to regulate radioactive materials, which led to the not compatible finding. The review team made one recommendation regarding program performance by Kentucky and determined that the recommendation from the 2012 IMPEP review should be closed.

With the unsatisfactory finding in the Compatibility Requirements indicator, the review team considered recommending that Kentucky be placed on monitoring until the

regulation adoption problem is resolved, but since actions are currently underway to use the adoption by reference process, this action was deemed unnecessary.

Accordingly, the review team recommended, and the MRB agreed, that the Kentucky Agreement State Program is adequate to protect public health and safety, but is not compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place, as regularly scheduled, in approximately 4 years with a periodic meeting in 2 years.

Below is the review team's recommendation, as mentioned in the report, for evaluation and implementation by Kentucky:

> To ensure openness and transparency regarding the Branch's monitoring and oversight of the Maxey Flats Disposal Site (MFDS), the review team recommends that the Branch ensure timely and consistent issuance of licensing actions and inspection results for the MFDS. (Section 4.3.c.)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Jim Lynch, Region III	Team Leader Technical Staffing and Training Inspection Accompaniments
Donna Janda, Region I	Technical Quality of Incident and Allegation Activities Compatibility Requirements
Dwight Shearer, Pennsylvania	Status of Materials Inspection Program Technical Quality of Inspections
Jackie Cook, Region IV	Technical Quality of Licensing Actions
Ron Parsons, Tennessee	Sealed Source and Device Evaluation Program Technical Quality of Licensing Actions
Kathy Modes, NMSS	Low-Level Radioactive Waste Disposal Program Inspection Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1	License No.: 201-168-05
License Type: Industrial Radiography	Priority: 1
Inspection Date: 4/25/16	Inspector: EP

Accompaniment No.: 2	License No.: 201-798-05
License Type: Industrial Radiography	Priority: 1
Inspection Date: 4/26/16	Inspector: CK

Accompaniment No.: 3	License No.: 201-768-96
License Type: Irradiators	Priority: 5
Inspection Date: 4/27/16	Inspector: AB

Accompaniment No.: 4	License No.: 202-352-27
License Type: Medical Therapy	Priority: 2
Inspection Date: 4/28/16	Inspector: MV

Accompaniment No.: 5	License No.: 202-433-25
License Type: Medical	Priority: 3
Inspection Date: 6/23/16	Inspector: JM

Accompaniment No.: 6	License No.: 206-002-03
License Type: Low-Level Radioactive Waste Site	Priority: 2
Inspection Date: 6/22/16	Inspectors: MM, AB, NG