



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

May 1, 2020

Steven Stack, MD, Commissioner
Department for Public Health
Cabinet for Health and Family Services
275 East Main Street, HS1C-A
Frankfort, KY 40621-0001

Dear Dr. Stack:

On April 14, 2020, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States MRB member, met to consider the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Kentucky Agreement State Program. The MRB found the Kentucky program adequate to protect public health and safety and compatible with the NRC's program.

The enclosed final report documents the IMPEP team's findings and summarizes the results of the MRB meeting (Section 5.0). Based on the results of the current IMPEP review, the next full review of the Kentucky Agreement State Program will take place in approximately 4 years, with a periodic meeting in approximately 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,

John W. Lubinski, Director
Office of Nuclear Material Security
and Safeguards

Enclosure:
Kentucky Final IMPEP Report

cc: B. Smith, Director
Organization of Agreement States
Representative to the MRB

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW
OF THE KENTUCKY PROGRAM – DATED: May 1, 2020

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE KENTUCKY AGREEMENT STATE PROGRAM

January 13-17, 2020

FINAL REPORT

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Kentucky Agreement State Program (the Program) are discussed in this report. The review was conducted during the period of January 13-17, 2020, by a team composed of technical members from the U.S. Nuclear Regulatory Commission (NRC), and the State of Minnesota.

Based on the results of this review, Kentucky's performance was found satisfactory, for six indicators: *Technical Staffing and Training*, *Status of Materials Program*, *Technical Quality of Inspections*, *Technical Quality of Licensing*, *Technical Quality of Incidents and Allegations*, and *Sealed Source and Device Evaluation Program*, and satisfactory, but needs improvement for the *Legislation, Regulations, and Other Program Elements* performance indicator. The finding for the *Legislation, Regulations, and Other Program Elements* indicator improved from unsatisfactory during the previous IMPEP review to satisfactory but needs improvement during this review.

The team did not make any recommendations. The team determined, and the Management Review Board (MRB) Chair agreed, that the recommendation from the 2016 IMPEP review regarding timely issuance of licensing actions and inspection results for the Maxey Flats Disposal Site, should be closed (see Section 2.0).

Accordingly, the team recommended, and the MRB Chair agreed, that the Kentucky Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team also recommended, and the MRB Chair agreed, that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

1.0 INTRODUCTION

The Kentucky Agreement State Program review was conducted during the period of January 13-17, 2020, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* (FR) on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated July 24, 2019. Preliminary results of the review, which covered the period of July 30, 2016, to January 17, 2020, were discussed with Kentucky managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to Kentucky on November 19, 2019. Kentucky provided its response to the questionnaire on December 23, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19365A118.

A draft of this report was issued to Kentucky on February 27, 2020, for factual review and opportunity to comment (ADAMS Accession Number ML20052E638). Kentucky responded to the draft report by electronic mail dated April 2, 2020, from Matthew McKinley, Administrator, Radiation Health Program, Kentucky Cabinet for Health and Family Services (ADAMS Accession Number ML20093J141). The Management Review Board (MRB) was convened on April 14, 2020, to discuss the team's findings and recommendations.

The Kentucky Agreement State Program is administered by the Radiation Health Branch (the Branch) which is located within the Department for Public Health (the Department). The Department is part of the Cabinet of Health and Family Services (the Cabinet). The Branch is comprised of three sections: the Radioactive Materials Section (the Section), the Radiation Producing Machine Section, and the Radiation/Environmental Monitoring Section. The Radioactive Materials Section implements the Agreement State Program. Organization charts for Kentucky are available in ADAMS (Accession Number ML19365A108).

At the time of the review, Kentucky regulated 350 specific licenses authorizing possession and use of radioactive materials. The review focused on the radiation control program as it is carried out under Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Kentucky.

The 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 July 29, 2016. The final report is available in ADAMS (Accession Number ML16299A197). The results of the review and the status of the associated recommendations are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None
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 (now Legislation, Regulations and Other Program Elements): Unsatisfactory
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Low-Level Radioactive Waste Program: Satisfactory
Recommendation: 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 MFDS.

Status: The team reviewed one licensing action and one inspection that was performed during the review period. The licensing action was a renewal action and it was completed and issued in a timely manner. In addition, the results of the sole inspection during the review period were issued in a timely manner, after the conclusion of the inspection.

This recommendation is closed.

Overall finding: Adequate to protect public health and safety and not compatible with the NRC's program.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC and Agreement State radiation control 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, 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 assessed. Review of staffing also requires 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 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.
- 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.
- 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 followed, or qualification criteria will be established if new staff members are hired.
- 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

Kentucky's Radioactive Materials Section is comprised of eight staff members (e.g., one director, one supervisor, and six staff members) which equals 7.2 full-time equivalent (FTE) when fully staffed. This is one FTE less than the Section had at the time of the 2016 IMPEP review. During the review period, seven staff members left the program and five staff members were hired. One of the staff positions (1 FTE) was transferred to the Radiation Producing Machines Section during this review period. Another individual was hired and left the program within the review period. The positions were vacant from 4 to 10 months with most of the positions vacant for 4 to 5 months. However, the Section hired highly qualified individuals with experience in certain modalities, such as medical (e.g., nuclear medicine technicians). At the time of the review, the Section was comprised of one director, one supervisor, five staff members, and one vacancy. This position has been vacant for 9 months. An individual fully qualified in licensing and inspection was selected for the position in December 2019 and will start once human resources finalizes the hire. It is worth noting, that three of the staff remained constant throughout the review period.

In December 2017, the Section supervisor left the program. The individual who was hired for this position in May 2018, was reassigned in October 2018 to another area

within the Section. The individual currently filling the position was hired in August 2019 and has prior experience in radiation control programs.

The team noted the supervisory position was intermittently vacant for a total of 15 months of the review period, with three different individuals filling this position during the review period. This supervisory turnover had an impact on issuing timely inspection reports, as further discussed in Section 3.2. Notwithstanding, the staff-level positions were generally filled in a timely manner and the turnover rate did not negatively impact any other aspects of their work in implementing the Agreement State Program.

Kentucky has a training and qualification program compatible with the NRC's IMC 1248. The Section uses a combination of on the job training along with the NRC sponsored courses as part of its qualification process. Staff is fully qualified in a modality before they can perform licensing and inspection tasks independently. Staff is considered fully qualified when they are qualified in all modalities. At the time of the review, three staff members were undergoing the qualification process.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommended that Kentucky's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, 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 and security practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and type of radioactive 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 team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the 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.
- 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.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 2800, and other applicable guidance or compatible Agreement State Procedure.
- 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 138 Priority 1, 2, 3, and initial inspections during the review period. One Priority 3 inspection (less than 1 percent) was performed overdue during the review period. The inspection was overdue because it was entered to the database as a Priority 5 instead of a Priority 3. The database error was identified during the following inspection. All initial inspections of new licenses were performed within 12 months of license issuance. The team determined that the Program's inspection frequencies are the same for similar license types found in IMC 2800. Additionally, the team determined that in each year of the review period, the Section performed 20 percent of candidate reciprocity inspections.

A sampling of 21 inspection reports indicated that 5 of the inspection findings were communicated to the licensee beyond Kentucky's goal of 30 days after the inspection exit. A more detailed review of the Section's database showed that out of the Priority 1,2,3, and initial inspections completed, 81 of the inspection findings were communicated to the licensees beyond 30 days after the inspection exit. These findings were issued between 31 to 123 days after the inspection exit. Most of the late inspection reports were clear inspections. Sixteen of the 81 instances of late inspection correspondence involved an item of non-compliance.

The team determined, through interviews with inspectors and through the performance of inspection accompaniments, that inspectors consistently communicated the results of the inspection to the licensee prior to leaving the site.

c. Evaluation

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

- Inspection findings were not communicated to licensees within 30 days, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports."

The team determined that the root cause of the timeliness of inspection findings was due to the vacancy in the supervisory position. As mentioned in Section 3.1 of this report, that position was unfilled for approximately 15 months throughout the review period which delayed the reports from being issued within 30 days. The team noted that although the position was filled for 5 months at one time, reports continued to be issued beyond the 30-day goal during that time. The team noted that 80 percent of the reports issued beyond the 30-day goal were clear inspections. The team was able to confirm

through observations during the inspection accompaniments that the outcome of the inspections was being verbally communicated to the licensee at the inspection exit meeting. In addition, the team did not identify any health, safety, or security impacts due to the late issuance of the inspection reports. It is worth noting that since the supervisory position was filled in August 2019, all inspection findings have been issued timely.

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide reasonable 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 an inspection program.

a. Scope

The 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, or senior staff as appropriate, 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.
- Inspection guides are compatible with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors involved in 21 materials inspections conducted during the review period. The casework reviewed included inspections conducted by six of Kentucky's inspectors (current and former) and covered medical, industrial, commercial, academic, research,

and service provider licenses. The casework also included initial security, temporary job sites, and reciprocity inspections.

A team member accompanied three inspectors on December 3-5, 2019. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared, thorough, and assessed the impact of licensed activities on health, safety, and security. The inspectors clearly communicated the inspection findings to licensees at the exit meeting. The inspector accompaniments are identified in Appendix B.

The team identified that the Section's inspection results were well documented with respect to health, safety, and security. The Section conducts unannounced, performance-based inspections. Violations were well supported by appropriate Commonwealth regulations. The Section has procedures in place for documenting violations and items of non-compliance. Inspection reports are reviewed and signed by the Section supervisor. Ultimately, the Section manager signs all letters of compliance, notices of violation, and return to compliance before being sent to the licensee.

With two exceptions, supervisory accompaniments were performed of each qualified inspector for each year in the review period. In 2017, one qualified inspector was not accompanied and in 2018, another qualified inspector was not accompanied.

The team determined that the Section has an ample supply of radiation survey instruments such as Geiger-Mueller meters, scintillation detectors, ion chambers, and micro-R meters to support its inspection program.

Each inspector is assigned instruments commensurate with the type of inspections they perform. The survey instruments used during the inspector accompaniments were operational and calibrated.

c. Evaluation

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

- Supervisors, or senior staff as appropriate, did not conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.

Two of the Section's qualified inspectors were not accompanied during the review period, one in 2017 and another in 2018. The inspectors were not accompanied due to management oversight. However, the inspectors had been accompanied every other year of the review period.

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, 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, as well as security. An assessment of licensing procedures, implementation of those procedures, and documentation of communications and associated actions between the Kentucky licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The 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 are consistent with current regulatory guidance (e.g., pre-licensing guidance, Title 10 of the *Code of Federal Regulations* (CFR) Part 37, financial assurance, etc.).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- 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 the physical protection of Category 1 and Category 2 quantities of radioactive material (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Kentucky performed 761 radioactive materials licensing actions. The team evaluated 27 of those licensing actions. The licensing actions selected for review included 3 new applications, 16 amendments, 3 renewals (amendments in entirety), 3 terminations, 1 bankruptcy, and 1 change of control. The team evaluated casework which included the following license types and actions: medical broad scope, medical diagnostic and therapy, medical academic, mobile medical, industrial radiography, nuclear pharmacy, fixed and portable gauges, well-logging, service providers, decommissioning actions, financial assurance, and bankruptcies. The casework sample represented work from 6 former and 4 current license reviewers.

Licensing actions were well documented and properly address health, safety, and security issues. All documentation for each licensing action is found in paper files, with security licenses locked in a cabinet when not in use. The team determined that

documents containing sensitive security information were marked and handled in accordance with applicable Section procedures.

The team noted that Kentucky requires license renewals to be submitted every 5 years. However, the team noted that the Section does not have a mechanism to identify and track licenses that are required to have a comprehensive technical review to support license renewal because the Section's database used to track renewal actions was compromised during the review period. The Section is in the process of rebuilding the database to identify, track, and perform comprehensive technical reviews of renewals. As an interim measure, the staff reviews licensing files as amendment requests are received and/or during the preparation for inspections to determine whether a renewal is warranted.

The staff then notifies the licensee if it is determined that the license is due for renewal. The team confirmed that the staff continues to process renewal requests as they are received. At the time of the review, no renewals were pending for review.

The team evaluated the implementation of the Pre-Licensing Guidance (PLG) and Risk Significant Radioactive Materials (RSRM) checklist. Kentucky conducted pre-licensing site visits for all unknown entities in accordance with the checklist, and properly implemented the PLG. For applications with RSRM, Kentucky issues a license after completing the checklist and performing an on-site security review. In addition, for applications requesting to possess radioactive material equal to or exceeding Category 2 quantities, Kentucky ensures all increased security requirements are in place prior to license issuance.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 3.4.a. Based on the criteria in MD 5.6, the team recommended that Kentucky's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, 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, safety, and security. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, timely incident reporting, and investigative and follow-up actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The 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, 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 follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center (HOC) for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED) and closed when all required information has been obtained.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified within 30 days, of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 24 radioactive materials incidents were reported to Kentucky. The team evaluated 13 of these incidents, including 4 concerning lost, stolen, or abandoned radioactive materials; 2 concerning damaged equipment; 3 medical events; and 4 equipment or procedure failures. The Section dispatched inspectors for onsite follow-up for five of the reviewed incidents, and three incidents were reviewed at the next routine inspection.

The team found that Kentucky properly evaluated each incident, interviewed involved individuals, and documented its findings. When an incident was reported to the Commonwealth, staff worked with management to evaluate the information received to determine its health and safety significance and then decide on the appropriate response. That response ranged from an immediate onsite response to reviewing the event during the next routine inspection. The team determined that Kentucky responded to incidents in accordance with its established procedure.

The team determined that, in general, incidents were reported timely to the NRC. However, one medical event had not been reported to the NRC Headquarters Operations Officer (HOO) though it was reported to NMED. Initial review of a reported medical event seemed to show that it did not meet the definition of a medical event and was thus not reportable, but further review by the staff showed that it was reportable. However, due to an oversight, staff did not report the event to the HOO once it was recognized as a medical event. The Section contacted the HOO by telephone while the team was on-site to provide the required notification for completion purposes only. The team determined this was an isolated incident because other medical events reviewed by the team were reported timely.

During the review period, six allegations were received by Kentucky. The team evaluated all six allegations, including three allegations that the NRC referred to the Commonwealth, and found that Kentucky took prompt and appropriate action to the concerns raised. Each allegation was appropriately closed, concerned individuals were notified of the actions taken as appropriate, and allegeders' identities were protected.

c. Evaluation

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

- One notification was not made to the NRC HOC for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.

The team determined that this was due to staff oversight of the original review of the medical event. The team determined that this was an isolated case since other medical events were properly and timely communicated to the HOO and NMED, as applicable.

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

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Legislation, Regulations, and Other Program Elements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery Program. The NRC retains regulatory authority for the uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

4.1 Legislation, Regulations, and Other Program Elements

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 State's agreement with the NRC. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of adequate 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. The 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 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 Program Element Table indicating the Compatibility Categories for those program elements other than regulations can be found on the Office of Nuclear Material Safety and Safeguards (NMSS) website/Regulation Toolbox at <https://scp.nrc.gov/regtoolbox.html>.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Legislation, Regulations, and Other Program Elements," 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 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 with the NRC and does not create gaps or conflicts in the National Materials Program due to compatibility or health and safety discrepancies.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- State statutes are consistent with Federal statutes, as appropriate.
- The State has legally enforceable measures, such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health, safety, and security in the regulation of agreement material.
- The State has compatible legally binding requirements, regulations, and other program elements in accordance with MD 5.9, and NMSS procedures SA-200, SA-201, and SA-107.
- NRC 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 such designation and issuance by the NRC.
- Sunset requirements, if any, do not negatively impact the effectiveness of 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 (KRS) 13A.3102 and 3104, 13B.17, 194A.050, 211.090, 211.842 to 211.852, 211.859, 211.990(4), and 211.861 to 211.869. The Cabinet is designated as the Commonwealth's radiation control agency.

Two statutes affecting the radiation control program were passed during the review period. These statutes (KRS 13A.3102 and 3104) involve expiration of administrative regulations and are described further below.

Kentucky's administrative rulemaking process takes approximately 18 months from drafting to finalizing a rule. The public, the 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 team noted that during this review period Kentucky's rules and regulations became subject to "sunset" laws. This requirement is described in KRS 13A.3102 which became effective June 29, 2017. The statute states in part that "(1) An ordinary administrative regulation with a last effective date on or after July 1, 2012, shall expire seven (7) years after its last effective date, except as provided by the certification process in KRS 13A.3104; (2) An ordinary administrative regulation with a last effective date before July 1, 2012, shall expire on July 1, 2019, except as provided by the certification process in KRS 13A.3104." The team determined that no regulations involving the agreement state program have expired since the statute became effective.

During the review period, Kentucky submitted 25 proposed regulation amendments and 33 final regulation amendments to the NRC for a compatibility review. Of the 33 final regulation amendments submitted, 12 were overdue for Commonwealth adoption at the time of submission.

In the 2016 final IMPEP report, the team determined that Kentucky had 12 amendments overdue for adoption at the time of the review. Ten of the 12 regulations that were overdue for Commonwealth adoption at the time of submission, as noted in the paragraph above, were ones identified as being overdue in the 2016 final IMPEP report.

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

- "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. (Unresolved from the 2016 IMPEP report).
- "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. (Unresolved from the 2016 IMPEP report).
- "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions," 10 CFR Parts 30, 40, and 70 amendment (78 FR 32310), that was due for Agreement State adoption by August 27, 2016.

The team noted that Kentucky is in the process of adopting NRC regulations identified as a matter of compatibility or health and safety by reference. Since the last IMPEP review, Kentucky has adopted regulations associated with 10 CFR Parts 33, 34, 35, 37, 39, and 71 by reference. Additionally, Kentucky is in the process of adopting 10 CFR Parts 20, 30, 31, 32, 40, 70, and 150 by reference. In a letter dated January 10, 2020, Kentucky submitted draft regulations adopting by reference 10 CFR Parts 20, 30, 31, 32, 40, 70, and 150 and, adopting draft rule language to adopt rule changes made to address outstanding comments on regulations associated with 10 CFR Part 19 to the NRC for a compatibility review.

The team reviewed guidance documents that Kentucky uses to meet the requirements of other program elements (e.g., Pre-Licensing Guidance, Inspection Procedures, etc.) that the NRC has designated as necessary for the maintenance of an adequate and compatible program. All changes to these documents were made within 6 months of the NRC's changes and were determined to be compatible.

c. Evaluation

The team determined that, except as noted below, during the review period Kentucky met the performance indicator objectives listed in Section 4.1.a.:

- Regulations were not adopted by the Agreement State for purposes of compatibility or health and safety within 3 years after the effective date of the NRC regulation.

The team determined that Kentucky adopted 12 regulation amendments overdue during the review period, 10 of which were adopted as a result of being identified as overdue during the 2016 IMPEP review, and 3 regulation amendments were overdue for adoption at the time of the review.

The team considered a finding of satisfactory but needs improvement and unsatisfactory for this performance indicator. In reviewing MD 5.6, the team noted that Kentucky met four of the seven conditions (conditions (a), (b), (c), (g)) for a finding of satisfactory; two of the seven conditions (conditions (d) and (e)) for a finding of satisfactory, but needs improvement; and one of seven conditions listed for a finding of unsatisfactory (condition (f)). The MD states that "Consideration should be given to a finding of "unsatisfactory" when a review demonstrates the presence of one or more of the following conditions," therefore the team discussed the impact of the unsatisfactory condition to the overall indicator.

During its deliberation, the team took into consideration the significance of the overdue regulations and the amount of work Kentucky did over the review period to bring regulations identified during the 2016 IMPEP review as being overdue, up-to-date, along with the work that Kentucky has done and is currently doing to adopt NRC regulations by reference. The team also considered the fact that although several regulation amendments were adopted in a time frame greater than 3 years, an example could not be found of where the late adoption had an adverse effect on the protection of public health and safety. Therefore, the team concluded that a finding of unsatisfactory is not warranted for this indicator. Additionally, the team does not believe a recommendation is necessary to improve program performance in this indicator since Kentucky has proactively started adoption of NRC regulations by reference without tying them to a specific date so that this performance issue will be eliminated in future IMPEP reviews.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Kentucky's performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found satisfactory, but needs improvement.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, satisfactory, but needs improvement.

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 the SS&D reviews and establishes useful guidance for teams. In accordance with MD 5.6, 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 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, especially senior-level positions, 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.

Evaluation of Defects and Incidents

- 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 the NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

Kentucky has two staff qualified to perform SS&D reviews. At the time of the review, the Section is in the process of training a current staff member to be fully qualified to perform SS&D evaluations to replace one staff member who left the program in 2019. The team determined that the Section is appropriately staffed and trained to carry out the SS&D program.

Kentucky has a training program for SS&D reviewers equivalent to the NRC training requirements listed in the NRC's IMC 1248, Appendix D. The team interviewed staff involved in SS&D reviews and determined that they were familiar with the procedures used in the evaluation of sources and devices and had access to applicable reference documents. Both of the Section's qualified reviewers with full signature authority have at least a BS degree in physical or life sciences.

Technical Quality of the Product Evaluation

Kentucky has one device manufacturer who has 11 active SS&D registrations. There were no SS&D actions that occurred during the review period.

The team verified that SS&D reviewers had access to the guidance from the NRC's SS&D workshop; NUREG-1556, Volume 3, Revision 1; and applicable American National Standards Institute standards.

Kentucky is committed to going outside of the program, as necessary, to seek expertise in any areas that it needs while conducting SS&D evaluations. This includes working with engineering programs at the University of Kentucky in Lexington, other SS&D programs in neighboring Agreement States like Ohio, or the NRC SS&D program at NRC Headquarters.

Evaluation of Defects and Incidents Regarding SS&Ds

There were 33 incidents related to SS&D defects involving devices registered by the Commonwealth of Kentucky reported during the review period. Incident procedures are in place for such SS&D-related incidents. The Section is currently reviewing 22 incidents related to 2 specific devices involved in these incidents. The Section is working to determine if there is a generic issue with regard to a defect in these devices. The Section will coordinate with the NRC if it is determined that there is a generic issue. The other 11 incidents were reviewed and determined not to be related to any kind of generic issue.

c. Evaluation

The team determined that, during the review period, Kentucky met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommended that Kentucky's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Kentucky's performance with respect to this indicator, satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

The Kentucky Agreement State Program's LLRW disposal program consists of the oversight of the Maxey Flats Disposal Site (MFDS), located in eastern Kentucky. Maxey Flats Disposal Site operated as a commercial LLRW disposal facility from May 1963 through December 1977. The site was listed on the National Priority list in 1986, and a Record of Decision was issued in September 1991, by the Environmental Protection Agency under its Comprehensive Environmental Response, Compensation, and Liability Act authority to stabilize the site and treat contaminated leachate (mainly tritium) from tanks and trenches. Currently, MFDS is a closed LLRW site in its Final Closure Period. In accordance with SA-109, "Reviewing the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program," the team leader in coordination with NRC headquarters management and the Regional Agreement State Officer determined that this indicator did not need to be reviewed during this review period because there were no changes or issues in the closure phase and status of MFDS since the last IMPEP review that would impact safety.

The team reviewed the elements of the recommendation from the 2016 IMPEP report as detailed in Section 2 of this report. The Cabinet is responsible for the oversight of the protection of the public health and safety, and the oversight is implemented by the Section. During the 2016 IMPEP review, the team noted the issuance of the renewal to the MFDS license was delayed. In addition, while inspection findings from a 2014 inspection were verbally communicated to the licensee, a formal inspection report was never issued. The 2016 MRB noted that without issuance of inspection reports, there is no public visibility with respect to the results of the Section's execution of its oversight responsibilities for MFDS in accordance with Kentucky's requirements. To ensure openness and transparency regarding the Section'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. During the review period, the Section received one licensing action and performed one inspection. The team reviewed both actions and determined that the licensing action and inspection report were completed and communicated timely.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Kentucky's performance was found to be satisfactory for six out of seven performance indicators reviewed and satisfactory, but needs improvement, for the indicator Legislation Regulations, and Other Program Elements. The team did not make any recommendations. The team determined, and the MRB Chair agreed that the recommendation from the 2016 IMPEP review should be closed regarding the timeliness of licensing actions and issuance of inspection reports of the MFDS.

Accordingly, the team recommended, and the MRB Chair agreed, that Kentucky be found adequate to protect public health and safety, and compatible with the NRC's program. Based on the results of the current IMPEP review, the team recommended,

and the MRB Chair agreed, that the next full IMPEP review take place in approximately 4 years, with a periodic meeting in approximately 2 years.

LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Lizette Roldan-Otero, Ph.D., NMSS	Team Leader Technical Staffing and Training Inspector Accompaniments
Geoffrey Warren, Region III	Team Leader in Training Technical Quality of Incidents and Allegations
Sherrie Flaherty, Minnesota	Technical Quality of Licensing
Monica Ford, Region I	Legislations, Regulations, and Other Program Elements
Farrah Gaskins, Region I	Status of Materials Inspection Program Technical Quality of Inspections
Stephen Poy, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 201-798-05
License Type: <i>e.g., Industrial Radiography</i>	Priority: 1
Inspection Date: 12/3/19	Inspector: AB

Accompaniment No.: 2	License No.:202-029-22
License Type: <i>e.g., Medical Institution Broad Scope</i>	Priority: 2
Inspection Date: 12/4/19	Inspector: RH

Accompaniment No.: 3	License No.: 202-029-22
License Type: <i>e.g., Medical Institution Broad Scope</i>	Priority: 2
Inspection Date: 12/5/19	Inspector: AW