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

June 7, 2019

Amy Acton, M.D., M.P.H., Director
Ohio Department of Health
246 North High Street
Columbus, OH 43215

Dear Dr. Acton:

On May 16, 2019, the 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 Ohio Agreement State Program. The MRB found the Ohio Agreement State Program adequate to protect public health and safety and compatible with the NRC's program.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0). The team did not make any recommendations regarding the performance of the Ohio Agreement State Program during this review. Since this was the second consecutive IMPEP review with all performance indicators being found satisfactory, the team recommended, and the MRB agreed, that the next full IMPEP review will take place in approximately 5 years, with a periodic meeting in approximately 2.5 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 respective organizations continuing to work cooperatively in the future.

Sincerely,

/RA/

John W. Lubinski
Director Office of Nuclear Material Safety
and Safeguards

Enclosure:
Ohio Final IMPEP Report

cc: Eva S. Nair, Program Manager
Radiological Health Program
Maryland Department of Health
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE OHIO AGREEMENT STATE PROGRAM

February 25 – March 1, 2019

FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Ohio Agreement State Program. The review was conducted during the period of February 25 – March 1, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Tennessee, and the Commonwealth of Massachusetts.

Based on the results of this review, the Ohio Agreement State Program's performance was found satisfactory for all indicators reviewed. The team noted that the Ohio Agreement State Program has had five IMPEP reviews since becoming an Agreement State and in each review all indicators reviewed were given a rating of satisfactory.

The team did not make any recommendations and there were no recommendations from the previous review for the team to consider. The team identified one good practice related to the incorporation of revision histories into Sealed Source and Device Registry Sheets.

Accordingly, the team recommended, and the Management Review Board (MRB) agreed, that the Ohio Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 5 years and that a periodic meeting be held in approximately 2.5 years.

1.0 INTRODUCTION

This report presents the results of the review of the Ohio Agreement State Program (the Program). The review was conducted during the period of February 25 – March 1, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Tennessee, and the Commonwealth of Massachusetts. 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* on October 18, 2017 (82 FR 48535), and the NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of December 14, 2013 to March 1, 2019, were discussed with program 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 Ohio on October 5, 2018. Ohio provided its response to the questionnaire on February 11, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19042A376.

A draft of this report was issued to Ohio on March 29, 2019, for factual comment (ADAMS Accession Number ML19084A279). Ohio responded to the draft report by letter dated April 18, 2019, from W. Gene Phillips, Chief, Bureau of Environmental Health and Radiation Protection, (ADAMS Accession Number ML19123A153). The MRB convened on May 16, 2019, to discuss the team's findings.

The Program is administered by the Bureau of Environmental Health and Radiation Protection which is located within the Ohio Department of Health (the Department). Organization charts are available in ADAMS (Accession Number ML19042A310).

At the time of the review, the Program regulated 553 specific licenses authorizing possession and use of radioactive materials. 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 State of Ohio.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on December 13, 2013. The final report is available in ADAMS (Accession Number ML14055A239). The results of the review 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: Satisfactory
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Low-Level Radioactive Waste Disposal Program: Not Reviewed

Uranium Recovery Program: Not Reviewed

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program.

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, 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 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 Ohio’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 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 team determined that the Program has sufficient staff to carry out the responsibilities of the Agreement and a good balance between licensing and inspection staffing levels. The Program is comprised of a Bureau Chief, an Assistant Bureau Chief, a Program Administrator, three Supervisors, and 20 technical staff members. Eleven of the 26 technical staff and managers use only a portion of their time to support the Agreement State Program. In total, when fully staffed, 18.20 full time equivalents (FTE) are utilized to implement the Program. At the time of the review, there were two technical staff vacancies. The two technical staff positions originally became vacant in January 2017 and January 2018, respectively. The positions were posted and both were filled in October 2018 through promotion of two internal staff, creating two new vacancies in the Program. The Program management anticipates filling these vacancies in the near future.

During the review period, five staff left the Program, including a Program Administrator, two Supervisors, and two technical staff; one technical staff transferred to a new position within the Agreement State Program; and three staff members were hired during the review period. The longest time any position was vacant was approximately 21 months. The vacancies had no impact on program performance.

The team reviewed the Program's training and qualification manual and determined that the training and qualification program is compatible with the NRC's IMC 1248. The team determined that all qualified license reviewers and inspectors met the required 24 hours of refresher training every 24 months.

c. Evaluation

The team determined that, during the review period, Ohio met the performance indicator objectives listed in Section 3.1.a., and, based on the criteria in MD 5.6, recommended that Ohio's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be 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 team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Ohio'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

The Program performed 525 Priority 1, 2, 3, and initial inspections during the review period. No Priority 1, 2, or 3 inspections were performed overdue during the review period. 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 Program performed greater than 20 percent of candidate reciprocity inspections.

A sampling of 88 inspection reports indicated that 19 of the inspection findings were communicated to the licensees beyond 30 days after the inspection exit. These findings were issued between 31 to 51 days after the inspection exit. Eight of the 19 instances of late inspection correspondence involved either a violation or a documented 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. Additionally, the Program performed a review of all 525 Priority 1, 2, 3, and initial inspections performed during the review period and determined that 24 of the 525 (or 4.5 percent) of the inspection findings were communicated to licensees beyond 30 days after the inspection exit. The team determined that the Program met the criteria in Management Directive 5.6 as a large majority of inspection findings were issued within 30 days and the causes of the delays were justified (e.g., inspections with violations, inspections of large institutions, and several instances related to the availability of State personnel).

c. Evaluation

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

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be 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 an Agreement State's 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 Ohio'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 consistent 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 27 materials inspections conducted during the review period. The casework reviewed included inspections conducted by 13 of Ohio's inspectors (current and former) and covered medical, industrial, commercial, academic, research, and service provider licenses.

A team member accompanied four inspectors on November 26-29, 2018. 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 inspector accompaniments are identified in Appendix B.

The team identified that the Program's inspection results were well documented with respect to health, safety, and security. The Program conducts unannounced, performance based inspections. Violations were well supported by appropriate State regulations. The Program has procedures in place for documenting violations and items of non-compliance. Inspection reports are signed by either the medical or industrial supervisor before being sent via e-mail as an attachment to the licensee. Supervisors performed accompaniments of each qualified inspector for each year of the review period.

The team determined that five of the inspections reviewed had health and safety inspection documents containing security-related information that were not marked in a similar manner as the security inspection documents containing the same security-related information. Specifically, the health and safety inspection documentation listed the types and quantities of materials authorized on the license in addition to the licensee's address, instead of stating "as authorized in license number X, amendment X." The Program agreed with the team's finding and immediately sent a notification to all inspectors that going forward, inspection documentation should not list materials and quantities but should instead refer to the license and appropriate amendment. The team found the Program's corrective action acceptable and determined that a recommendation was not needed to correct this finding.

The team determined that the Program 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, Ohio met the performance indicator objectives listed in Section 3.3.a., and based on the IMPEP evaluation criteria in MD 5.6, recommended that Ohio's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be 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, actual implementation of those procedures, and documentation of communications and associated actions between the Ohio 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 Ohio'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., 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 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 increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

The Program completed 2,337 radioactive materials licensing actions during the review period. The team evaluated 23 of those licensing actions. The licensing actions selected for review included five new applications, nine amendments, six renewals, and three terminations. The team evaluated casework which included the following license types and actions: medical broad scope, medical diagnostic and therapy, medical academic, commercial manufacturing and distribution, industrial radiography, research and development, fixed and portable gauges, self-shielded irradiators and decommissioning actions. The casework sample represented work from 13 former and current license reviewers.

The Program is split into two licensing groups, Medical & Decommissioning and Industrial. As licensing actions come in, the respective Supervisor assigns the action to staff qualified to perform the review. All licensing actions are recorded in a digital database system. Forms, applications, formal letters and electronic letters are scanned and entered into the database by the reviewer. Once complete, each action undergoes supervisory review and approval before being signed by the Bureau Chief. The team found licensing actions to be thorough, complete, consistent and of acceptable technical quality to assure protection of health, safety, and security.

The team evaluated the pre-licensing guidance and the pre-licensing site visit aspect of the new license application process. The team determined that the Program has implemented the essential elements of the NRC's pre-licensing guidance revised August 9, 2018, and transmitted to the Agreements States via Radiation Control Program Director (RCPD) Letter RCPD-18-005, "Request to Implement the Revised Pre-Licensing Guidance, Notification of Upcoming Webinar Training, and Discontinuance of a Licensing Practice." Based on the files reviewed, the team determined that the assigned license reviewer used the pre-licensing guidance appropriately prior to the issuance of the license. In addition, the Program is also appropriately implementing the checklist for Risk-Significant Radioactive Materials, which was revised on June 30, 2017.

c. Evaluation

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

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be 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 actions, are significant indicators 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 Ohio'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 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, the Program received reports for 311 incidents, of which 63 required reporting to the NRC. The team selected 10 incidents to evaluate. The casework included two events involving lost/stolen radioactive materials, two events involving potential overexposures, three medical events, two events involving damaged equipment, and one event involving equipment failure.

When an event is reported to the Program, staff and management collectively evaluate the information received to determine its health and safety significance and then decide on the appropriate response. That response can range anywhere from responding immediately to reviewing the event during the next inspection. For each incident that the Program determined to have potential health and safety significance, the Program responded immediately. The team also found that the Program responded to events in accordance with their established procedure. The team evaluated the Program's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case evaluated where HOO notification was required, the Program

reported all events within the required timeframe. The team determined that inspectors properly evaluated each event, interviewed involved individuals, and thoroughly documented their findings. Enforcement actions were taken where appropriate.

During the review period, 18 allegations were received by the Program. The team evaluated eight allegations, including four allegations that the NRC referred to the State during the review period. The team found that the Program took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed, concerned individuals were notified of the actions taken, and allegers' identities were protected whenever possible in accordance with State law.

c. Evaluation

The team determined that, during the review period, Ohio met the performance indicator objectives listed in Section 3.5.a., and, based on the criteria in MD 5.6, recommended that Ohio's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be 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 Program. All four 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 team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Ohio'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.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

Ohio became the 31st Agreement State on August 31, 1999. The Program's current effective statutory authority is contained in the Ohio Revised Code, Section 3748.03. The Department is designated as the State's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

Ohio's administrative rulemaking process takes approximately 6 to 8 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 by the Radiation Advisory Council. The team noted that the State's rules and regulations are subject to "sunset" laws. Rules adopted pursuant to Chapter 119 (Ohio Administrative Procedures Act) are subject to review every five years. In that five year review period, the adopting agency evaluates whether to modify the rule or maintain the rule as written. There are 11 chapters of Ohio Administrative Code rules that pertain to radioactive material. The expiration date of each rule is based on the date that it was adopted. The team determined that all rules pertaining to radioactive material regulated by the Program contained in the Ohio Administrative Code have been reviewed within the five year sunset requirement and are current.

During the review period, the Program submitted nine final regulation amendments, eight proposed regulation amendments and two revised final regulation amendments. All required regulations have been adopted. At the time of this review, no amendments required for adoption were overdue.

One regulation amendment "Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40, and 70," (77 FR 43666) due for adoption October 23, 2015, was adopted 13 days overdue.

c. Evaluation

The team determined that, during the review period, Ohio met the performance indicator objectives listed in Section 4.1.a., and based on the criteria in MD 5.6, recommended that Ohio's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be satisfactory.

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, Revision 2, "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 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 team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated Ohio'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, Revision 2.

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

At the time of the IMPEP review, the Program had two fully qualified staff that perform SS&D reviews, one staff member going through the qualification process to become an SS&D reviewer, and no vacancies. The team noted that the Program has plans to qualify two additional reviewers in the future for succession planning purposes and to increase reviewer capacity in the event that one of the Program's two fully qualified staff leaves the Program.

During the review period, one fully qualified SS&D reviewer left the program and one staff member was trained as an SS&D reviewer. The position was vacant for less than 6 months. The team determined that the Program has a training and qualification program equivalent to the training requirements identified in Appendix D of the NRC's IMC 1248.

Technical Quality of the Product Evaluation

The Program has 17 active SS&D registrants. The team evaluated 12 of 46 SS&D actions processed during the review period. These actions included five amendments, six new applications, and one inactivation. Based on the information reviewed, the team determined that the technical evaluation of the applications was adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3, Revision 2.

The Program maintains all SS&D records in its electronic database. The team found that the Program references records that provide a readily accessible historical overview of all the current, as well as the previous, actions on the SS&D registration. Addition of the

revision history to the SS&D sheets makes it easier for license reviewers to understand how a device has changed over time. It is worth noting that this concept was included in NUREG-1556, Volume 3, Revision 2, issued in September 2015, based on a suggestion from a working group member from the State of Ohio. Since this occurred during the review period the team is recommending that this effort be identified as a good practice.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated 5 of the 88 Incidents involving SS&D registered products that occurred during the review period. None of the five incidents reviewed were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered in the State of Ohio. The Program reviews NMED on a quarterly basis for root cause and trend analysis. Documentation is well maintained.

c. Evaluation

The team determined that, during the review period, Ohio met the performance indicator objectives listed in Section 4.2.a. and, based on the criteria in MD 5.6, recommended that Ohio's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Ohio's performance with respect to this indicator to be satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

Although the Ohio Agreement State Program has authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a commercial LLRW disposal facility in Ohio. Accordingly, the team did not review this indicator.

4.4 Uranium Recovery Program

Although the Ohio Agreement State Program has authority to regulate uranium recovery activities, the NRC has not required States to have a program for licensing a uranium recovery facility until such time as the State has such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a uranium recovery facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible uranium recovery program. There are no plans for a uranium recovery facility in Ohio. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Ohio's performance was found to be satisfactory for all performance indicators reviewed. The team did not make any recommendations and there were no recommendations from the previous review for the team to consider. The team identified one good practice which is described in Section 4.2.

Accordingly, the team recommended, and the MRB agreed, that the Ohio Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Since this was the second consecutive IMPEP with all performance indicators being found satisfactory, the team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Monica Ford, Region I	Team Leader Technical Quality of Incident and Allegation Activities
Jackie Cook, Region IV	Team Leader in Training Status of Materials Inspection Program Compatibility Requirements
Darren Piccirillo, Region III	Technical Staffing and Training (lead for training purposes)
Farrah Gaskins, Region I	Technical Quality of Inspections Inspector Accompaniments
Kenath Traegde, MA	Technical Quality of Licensing
Ronald Parsons, TN	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.: 02230220000
License Type: *High Dose Rate Remote After loader*	Priority: 2
Inspection Date: 11/26/18	Inspector: JW

Accompaniment No.: 2	License No.: 02120780000
License Type: *Medical Institution Written Directive Required (Gamma Knife Only)*	Priority: 3
Inspection Date: 11/27/18	Inspector: DC

Accompaniment No.: 3	License No.: 03320530004
License Type: *Industrial Radiography*	Priority: 1
Inspection Date: 11/28/18	Inspector: SD

Accompaniment No.: 4	License No.: 11300180001
License Type: *Source Material Other >150kg*	Priority: 5
Inspection Date: 11/29/18	Inspector: CL