



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

July 22, 2024

Bruce Vanderhoff, M.D.  
Ohio Department of Health  
246 North High Street  
Columbus, OH 43215

SUBJECT: OHIO FY2024 FINAL IMPEP REPORT

Dear Dr. Vanderhoff:

On July 2, 2024, the Management Review Board (MRB) met, which consisted of the U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Ohio Agreement State Program. The MRB Chair found the Ohio program adequate to protect public health and safety, and compatible with the NRC program.

The enclosed final report documents the IMPEP team's findings and summarizes the results of the MRB meeting. Based on the results of the current IMPEP review, the next periodic meeting will take place in approximately 2.5 years with the next IMPEP review taking place in approximately 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 agencies continuing to work cooperatively in the future.

Sincerely,

A handwritten signature in black ink, appearing to be "J. Lubinski".

Signed by Lubinski, John  
on 07/22/24

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

Enclosure:

1. 2024 Ohio IMPEP Report
2. 2024 Ohio MRB Meeting Participants

cc:

Mary DiOrio, M.D., Medical Director

Deborah Kroninger, Deputy Medical  
Director

Gene Phillips, Chief  
Bureau of Environmental, Health and  
Radiation Protection

Mary Shaffer, Assistant Chief, Bureau of  
Environmental Health and Radiation  
Protection

Stephen James, Health Physics  
Administrator  
Agreement State Program

Michael Rubadue, Health Physics  
Supervisor



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

March 11 – 15, 2024

**FINAL REPORT**

## EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Ohio Agreement State Program (Ohio) are discussed in this report. The review was conducted in-person from March 11-15, 2024. Inspector accompaniments were conducted from November 13 - 17, 2023.

Ohio's performance was found satisfactory for all seven indicators reviewed. There were no open recommendations and the team made one new recommendation that:

- Ohio perform an extent of condition evaluation of their financial assurance tracking for all active licenses to ensure: that all licenses authorizing possession of radioactive material in excess of quantities requiring financial assurance provide financial assurance in approved amounts; that financial assurance license conditions be consistent with possession limits authorized on the license; that the financial assurance review is documented at the last license action requiring it; that responsibilities for documenting the financial assurance review are clearly assigned to staff; and that staff are trained on updated financial assurance processes.

Accordingly, the Management Review Board (MRB) Chair found the Ohio radiation control program adequate to protect public health and safety and compatible with the NRC's program. Since this is Ohio's sixth consecutive IMPEP review in which they were found to be satisfactory for all performance indicators, the MRB Chair determined that the next periodic meeting should take place in approximately 2.5 years with the next IMPEP review taking place in approximately 5 years.

## 1.0 INTRODUCTION

The Ohio Agreement State Program (Ohio) Integrated Materials Performance Evaluation Program (IMPEP) review was conducted from March 11 – 15, 2024, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), and the Agreement State members from Wisconsin, Iowa, Virginia, and Louisiana. Team members are identified in Appendix A. Inspector accompaniments were conducted from November 13 - 17, 2023. The inspector accompaniments are identified in Appendix B. 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 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 March 2, 2019, to March 15, 2024, were discussed with Ohio 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 January 30, 2024. Ohio provided its response to the questionnaire on February 23, 2024. A copy of the questionnaire response is available in the NRC’s Agencywide Documents Access and Management System Accession Number [ML24064A162](#).

The team issued a draft report to Ohio on April 23, 2024, for factual comment available in [ML24094A031](#). Ohio identified a few minor editorial comments and responded to the draft report by email dated June 3, 2024, from Stephen James, Health Physics Administrator, in the Ohio Bureau of Environmental, Health and Radiation Protection available in [ML24169A425](#).

The Ohio Agreement State Program is administered by the Bureau of Environmental Health and Radiation Protection which is located within the Ohio Department of Health. Organization charts for Ohio are available in [ML24064A159](#).

At the time of the review, Ohio regulated 495 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 State of Ohio.

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

## 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on March 1, 2019. The final report is available in [ML19141A224](#). 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

Legislation, Regulations and Other Program Elements: Satisfactory  
Recommendation: None

Sealed Source and Device (SS&D) Evaluation Program: Satisfactory  
Recommendation: None

Low-Level Radioactive Waste (LLRW) Disposal Program: No Reviewed

Uranium Recovery (UR) Program: Not Reviewed

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the 2019 Ohio IMPEP review, the team recommended and the MRB agreed, that a periodic meeting be held within 2.5 years and that the next IMPEP review take place in approximately 5 years.

### **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 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) [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.
- 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](#), "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.

b. Discussion

Ohio is comprised of 18 total staff members equaling approximately 13.5 full-time equivalents (FTE) for the radiation control program when fully staffed. Of the 13.5 FTE, Ohio currently has eight health physicists, who are responsible for both licensing and inspection activities. The health physicists are equally divided amongst the Medical and Decommissioning Group and the Industrial Group. The most recently hired health physicist was hired in October 2020 at the height of the pandemic, and this individual has nearly completed the formal qualification process.

Ohio experienced three vacancies that included the Assistant Bureau Chief and a health physicist position which were both filled during the current review period. The third vacancy occurred due to the retirement of the Health Physics Administrator on July 31, 2023. In December of 2023, the former Industrial Supervisor was promoted to this position, leaving the Industrial Supervisor position as the program's only vacancy. Ohio expressed its intention to fill the remaining position soon and reported that most positions were typically vacant between 6 to 12 months prior to filling. The program had two health physicist vacancies at the conclusion of the 2019 IMPEP review. These positions have since been eliminated and were excluded from this report.

Ohio implemented a training and qualification program consistent with NRC's IMC 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs." Management was committed to ensuring that all staff were trained and qualified in accordance with Ohio's established training procedure. Ohio tracks continuing education requirements to ensure that staff receive a minimum of 24 hours of retraining during each 24-month cycle and provided an abundance of opportunities for staff to fulfill this requirement.

The team noted that although the pandemic reduced the number of in-person training opportunities, Ohio's sole staff member seeking formal qualification during the pandemic continued to enroll in NRC classes either virtually or in-person, when available. The Program also took advantage of NRC on-line training classes, which the Organization of Agreement States worked with NRC to provide. Overall, there were no impacts noted from the pandemic.

c. Evaluation

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

d. Management Review Board (MRB) Discussion and Chair's Determination

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

### 3.2 Status of Materials Inspection Program

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 [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 prescribed frequencies (<https://www.nrc.gov/materials/miau/mat-toolkits.html>).
- 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

During the review period, Ohio completed a total of 400 Priority 1, 2, and 3, and 44 Initial inspections. Ohio conducted one priority 1, 2, or 3 inspection overdue accounting for just 0.2% and there were no initial inspections conducted overdue. Ohio's inspection frequencies were equivalent with similar license types listed in NRC's IMC 2800.

Although Ohio inspections were not impacted by the pandemic, the review team noted that the Director of the Department of Health issued a letter on March 31, 2020, that permitted Ohio to defer routine radioactive material and radiation generating equipment inspections of hospitals. The letter was issued due to the stress the pandemic placed on hospitals, to free up hospital staff to focus on their response to the pandemic, and to prevent Program staff from unnecessarily being exposed to potentially infected patients. The letter was rescinded on July 7, 2021.

The team reviewed 26 inspection reports and found that 5 inspections were communicated outside of the 30-day goal and ranged between 1 and 38 days in excess. Two of the five instances of late inspection correspondence involved a violation, and three of the five instances were issued one or two days past the 30-day goal. The team did not identify an impact to health, safety and security since Ohio verbally disclosed inspection findings to the licensee in advance of issuing the formal correspondence. Subsequent to the MRB, Ohio reported that it tracked compliance with reporting requirements and determined that 90.5% of reports were issued in a timely manner during the review period.

The team noted that Ohio updated its reciprocity procedure during the 2019 IMPEP review to implement the new Risk Informed Performance-Based Analysis contained in the new IMC 2800. Ohio inspected approximately 16.7 percent of eligible reciprocity candidates in 2019, 42.1 percent in 2020, 27.3 percent in 2021, 35.3 percent in 2022, and 31.6 percent in 2023.

c. Evaluation

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

d. Management Review Board (MRB) Discussion and Chair's Determination

The MRB Chair agreed with the team's recommendation and found Ohio'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 [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 compatible with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated 26 inspection reports and associated enforcement documentation, and interviewed inspectors involved in radioactive materials inspections that were conducted throughout the review period. The team reviewed casework for inspections conducted by

nine of Ohio's inspectors and covered medical, industrial, commercial, academic, research and development and service provider licensees.

The team completed in-person accompaniments of five inspectors between November 13-17, 2023. The team found that each of the inspectors was well-prepared, thorough in their evaluation of each licensee, and that each assessed the impact of licensed activities on health, safety, and security. Inspectors observed the use of radioactive materials whenever possible. During interviews of licensee staff, inspectors posed open-ended questions, and developed a basis of confidence that radioactive materials were being used safely and securely. Any findings observed were brought to the licensee staff member's attention at the time of the inspection and again to the licensee's management during the inspection closeout. All findings and conclusions were well-founded and appropriately documented. The inspector accompaniments are identified in Appendix B.

The team verified that Ohio's inspection results were well documented with respect to health, safety, and security. Ohio conducted both unannounced and announced performance-based inspections and implemented procedures for documenting violations identified during inspections. Violations were well supported by appropriate Ohio regulations and license conditions and were signed by either the medical or industrial supervisor before being emailed to each licensee. All Notice of Violations were signed by the Director of Health and mailed to the licensee, via certified mail.

During the review period, all inspectors were accompanied by a supervisor on an annual basis, until 2020. As a result of the pandemic and in accordance with Temporary Instruction TI-003, "Evaluating the Impacts of the COVID-19 Public Health Emergency as Part of the Integrated Materials Performance Evaluation Program (IMPEP)," Ohio paused annual supervisory accompaniments to prevent further spread of the virus from 2020 through 2022. Annual inspector accompaniments resumed in 2023. Since the team concluded that Ohio continued to maintain public health, safety, and security during the pandemic, the suspended inspector accompaniments were not considered by the team in establishing the overall rating for this performance indicator.

The team confirmed that Ohio maintained an adequate supply of radiation survey instrumentation to support its radioactive materials inspection program. Each inspector was assigned instruments commensurate with the type of inspections performed. Furthermore, survey instruments utilized during inspector accompaniments were operational and properly calibrated.

c. Evaluation

The team determined that, during the review period, Ohio met the performance indicator objectives listed in Section 3.3.a. Based on the criteria in MD 5.6, the team recommends that Ohio's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Discussion and Chair's Determination

The MRB Chair agreed with the team's recommendation and found Ohio'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 Ohio's 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 [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., pre-licensing guidance, Title 10 of the *Code of Federal Regulations* (10 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 (RSRM) are appropriately implemented including the physical protection of Category 1 and Category 2 quantities of radioactive material (10 CFR Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

#### b. Discussion

During the review period, Ohio performed 2,022 radioactive materials licensing actions. The team evaluated 24 of the licensing actions including 4 new applications, 12 amendments, 7 renewals, and 1 termination. The team evaluated casework from 10 license reviewers encompassing licensing actions of broad scope, diagnostic and therapeutic medical, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, service providers, decommissioning, financial assurance, and change of ownership. Ohio had no licensing action backlog at the time of the review and was very timely in processing requests, including renewals.

The team observed that the respective supervisor assigned licensing actions to staff qualified to perform each review. Licensing actions were recorded in a digital database where forms, applications, formal letters, and electronic letters were also uploaded. After completion, the actions were reviewed and approved by the supervisor and signed by the Bureau Chief. Ohio utilizes NUREG-1556 series as the technical basis for reviewing license actions. Overall, the licensing actions reviewed were thorough, complete, consistent and of an acceptable technical quality to assure protection of health, safety, and security with the exception of inconsistencies identified in the tracking and managing of financial assurance.

During the review period, Ohio evaluated incoming licensing requests to determine if a financial assurance review was required. The Ohio licensing process required that a financial assurance review be completed for new license applications, license renewals, and amendments for increases in possession limits. Ohio's administrative code further stipulated that decommissioning funding plans be submitted at license renewal and at intervals not exceeding three years. Licensing actions requiring a financial assurance review were assigned to Ohio's Decommissioning Group for the financial assurance review and the balance of the request was reviewed and processed in parallel by another license reviewer. The team noted that the peer review process did not ensure that the financial assurance review and documentation were in place prior to issuing a license action. Specific examples of inconsistencies include:

- The team identified four instances where the financial assurance review was not documented during the renewal of a licensee with financial assurance on file. Furthermore, the team identified one instance of a documented financial assurance review that incorrectly concluded financial assurance was not required.
- Two of the licensing actions reviewed required financial assurance based upon the isotopes and activities approved but were issued by Ohio prior to having the financial assurance in place. While Ohio identified that financial assurance was required and approved the dollar amounts proposed in the licensees' decommissioning cost estimates in September of 2023, the financial assurance had not yet been finalized at the time of the evaluation by the review team.
- The review team identified two Ohio licensees who posted financial assurance. Ohio approved isotopes in quantities requiring financial assurance but retained a standard license condition in the license that prohibited possession of licensed material in quantities that required financial assurance.

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. 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. Ohio also appropriately implemented the checklist for RSRM.

#### c. Evaluation

The team determined that, during the review period, Ohio met the performance indicator objectives listed in Section 3.4.a, except for:

- Financial assurance practices were not consistent with current regulatory guidance.

The team identified two cases where license conditions regarding financial assurance conflicted with authorized possession limits and submitted financial assurance. In addition, the team identified two licenses whose authorized isotopes required financial assurance, yet Ohio had not received financial assurance. Inconsistencies in the performance of financial assurance reviews and use of financial assurance license conditions presented a potential decommissioning vulnerability for Ohio.

The team made one new recommendation that:

- Ohio perform an extent of condition evaluation of their financial assurance tracking for all active licenses to ensure that: all licenses authorizing possession of radioactive material in excess of quantities requiring financial assurance provide financial assurance in approved amounts; financial assurance license conditions be consistent with possession limits authorized on the license; the financial assurance review is documented at the last license action requiring it; responsibilities for documenting the financial assurance review are clearly assigned to staff; and staff are trained on updated financial assurance processes.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Ohio's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Discussion and Chair's Determination

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

### 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 [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 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 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, 58 events were reported to Ohio. The team evaluated 14 radioactive materials events, which included 7 medical events, 4 events involving lost or stolen radioactive materials, 1 event involving contaminated radiopharmaceutical transport cases, 1 event involving a fixed nuclear gauge shutter failure, and 1 event involving an air emissions release that exceeded the public dose limit. Ohio dispatched inspectors for on-site follow-up for 40 of the 58 events reviewed.

During the review period, Ohio management evaluated each event that was reported to determine the health, safety and security risk significance and an appropriate response. The team observed that Ohio's responses to reportable events ranged from an immediate response to reviewing the event during the next inspection. Qualified staff led appropriate, well-coordinated, and timely event investigations. The inspectors properly evaluated each event, interviewed pertinent individuals, and thoroughly documented investigation findings. The team found that Ohio reported all events within the required time frames, responded to events in accordance with its established procedure and observed no change to incident response during the pandemic.

During the review period, Ohio received a total of six allegations including two referred by the NRC. The team evaluated all of them. Ohio took prompt and appropriate action in response to each concern raised. The team verified that all allegations were appropriately closed, concerned individuals were notified timely of the actions taken, and alleged identities were adequately protected whenever possible in accordance with State law. Ohio responded to allegations in accordance with its established procedure and no changes to allegation response during the pandemic were identified.

## c. Evaluation

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

## d. MRB Discussion and Chair's Determination

The MRB Chair agreed with the team's recommendation and found Ohio'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) SS&D Evaluation Program; (3) LLRW Disposal Program; and (4) UR Program. While Ohio has the authority to have a licensing and inspection program for LLRW and UR facilities, the LLRW Disposal Program and UR Program indicators were not reviewed as there were no active facilities and no active regulatory program in place at the time of the 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 NRC Web site at the following address: <https://scp.nrc.gov/regtoolbox.html>.

a. Scope

The team used the guidance in [SA-107](#), "Reviewing the Non-Common Performance Indicator: Legislation, Regulations, and Other Program Elements," 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 of 1954, 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 31<sup>st</sup> Agreement State on August 31, 1999. The Program's effective statutory authority is contained in the Ohio Revised Code, Section 3748.03. The Ohio Department of Health is designated as the State's radioactive materials program. Ohio'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. The following legislation affecting the Program had been passed since the IMPEP review:

- Chapter 3748 of the Ohio Revised Code (overall legislation for the program)
- Chapter 3747 of the Ohio Revised Code (LLRW act)
- Chapter 119 of the Ohio Revised Code (due process following license denial)

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. 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.

During the review period, Ohio submitted eight proposed regulation amendments, eight final regulation amendments, and zero legally binding requirements or license conditions to the NRC for a compatibility review. One of the amendments was overdue for State adoption at the time of submission.

- Miscellaneous Corrections: 10 CFR Parts 1, 2, 34, 37, 50, 71, 73, and 140), that was due for Agreement State adoption by July 30, 2022.

At the time of the review, Regulation Amendment Tracking System (RATS) 2018-3 was 19 months overdue since it was due for adoption on July 30, 2022. This amendment simply contains corrections, and its late adoption is not expected to impact public health, safety, and security. During the review period, the State finalized regulatory amendments and received NRC correspondence stating “No Comments” for RATS 2018-1, 2018-2, 2019-1, 2019-2, 2020-1, 2020-2, and 2020-3. There are three regulatory amendments coming due for adoption: RATS 2021-1 due September 8, 2024, RATS 2021-2 due December 30, 2024, and RATS 2023-1 due September 25, 2026. Work by the Program is ongoing to provide NRC with proposed amendments ahead of schedule.

The team also reviewed other program elements that fall within this non-common performance indicator. The other program elements include the use of compatible procedures such as the RSRM checklist, pre-licensing guidance, IMC 1248, NUREG-1556, and NRC inspection procedures, and license conditions.

#### 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, Legislation, Regulations, and Other Program Elements, be found satisfactory.

#### d. MRB Discussion and Chair’s Determination

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

## 4.2 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 [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.

## 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

Ohio had two staff qualified to perform SS&D reviews with no vacancies at the close of the review. During the review period, no Ohio SS&D reviewers left the program and there were no new staff hired. Ohio has a training program equivalent to NRC training requirements listed in the NRC's IMC 1248, Appendix D.

## Technical Quality of the Product Evaluation

Ohio had a total of 21 SS&D licensees. The team evaluated each of the 56 SS&D actions processed by Ohio during the review period. The actions included 36 amendments, 7 new applications, 2 transfers from another state, and 10 inactivation's. Each evaluation was found to be of an acceptable technical quality.

## Evaluation of Defects and Incidents Regarding SS&amp;Ds

The team evaluated 70 of the 99 total incidents involving SS&D registered products during the review period. None of the incidents were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered by Ohio.

Ohio tracked NMED events that related to their SS&D program in visual charts indicating causes of events, especially life cycle of devices being exceeded that led to an NMED reportable event. During the review period, approximately 25 reportable NMED events that were related to life cycle.

c. Evaluation

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

d. MRB Discussion and Chair's Determination

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

## 5.0 SUMMARY

The team found Ohio's performance to be satisfactory for all seven performance indicators reviewed.

The MRB Chair agreed with the new recommendation that:

- Ohio perform an extent of condition evaluation of their financial assurance tracking for all active licenses to ensure: that all licenses authorizing possession of radioactive material in excess of quantities requiring financial assurance provide financial assurance in approved amounts; that financial assurance license conditions be consistent with possession limits authorized on the license; that the financial assurance review is documented at the last license action requiring it; that responsibilities for documenting the financial assurance review are clearly assigned to staff; and that staff are trained on updated financial assurance processes.

Accordingly, the MRB Chair found Ohio's radioactive materials program adequate to protect public health and safety and compatible with the NRC's program. Since this is Ohio's sixth consecutive IMPEP review in which they were found to be satisfactory for all performance indicators, the MRB Chair determined that the next periodic meeting should take place in approximately 2.5 years with the next IMPEP review taking place in approximately 5 years.

## LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspector Accompaniments

## APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

<b>Name</b>	<b>Areas of Responsibility</b>
Randy Erickson, RIV DRSS	Team Leader Technical Staffing and Training Inspector Accompaniments
Lisa A. Forney, RI DRSS	Team Leader in Training
Darren Piccirillo, RIII DRSS	Status of Materials Inspection Program Legislation, Regulations, and Other Program Elements
Stuart Jordan, Iowa	Technical Quality of Inspections
Megan Shober, Wisconsin	Technical Quality of Licensing Actions
Sheila Nelson, Virginia	Technical Quality of Incident and Allegation Activities
James Pate, Louisiana	Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 02500180000
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 11/13/23	Inspector's initials: JW

Accompaniment No.: 2	License No.: 03320990002
License Type: Industrial Radiography TJS	Priority: 1
Inspection Date: 11/14/23	Inspector's initials: CS

Accompaniment No.: 3	License No.: 02120250071
License Type: Medical W/D Required	Priority: 3
Inspection Date: 11/15/23	Inspector's initials: PW

Accompaniment No.: 4	License No.: 02230120000
License Type: HDR	Priority: 2
Inspection Date: 11/16/23	Inspector's initials: AC

Accompaniment No.: 5	License No.: 03310580001
License Type: Industrial Radiography Fixed Facility	Priority: 1
Inspection Date: 11/17/23	Inspector's initials: PB

**OHIO MANAGEMENT REVIEW BOARD ATTENDANCE**  
**July 27, 2024, 1:00 p.m. – 3:33 p.m. EST, via Microsoft Teams**

**Management Review Board:**

- John Lubinski, Director, Office of Nuclear Material Safety and Safeguards (NMSS), Acting MRB Chair;
- Jessica Bielecki, Assistant General Counsel for Rulemaking, Agreement States and Fee Policy;
- Rob Lewis, Deputy Director, NMSS;
- Ray Lorson, Regional Administrator, NRC Region I; and
- Lea Anna Perlas, Organization of Agreement States representative to the MRB, from the Commonwealth of Virginia.

**Ohio Program Management (via Teams):**

- Gene Phillips, Chief, Bureau of Environmental, Health and Radiation Protection;
- Mary Shaffer, Ass. Chief, Bureau of Environmental, Health and Radiation Protection; and
- Stephen James, Health Physics Administrator.

**IMPEP Team:**

- Randy Erickson, Team Leader, NRC Region IV;
- Lisa Forney, Team Leader in Training, NRC Region I;
- Darren Piccirillo, RSAO, NRC Region III;
- Stuart Jordan, State of Iowa;
- Sheila Nelson, Commonwealth of Virginia;
- James Pate, State of Louisiana; and
- Megan Shoher, State of Wisconsin.

**NRC and OTHER MEMBERS OF THE PUBLIC:**

- Adelaide Giantelli, NMSS;
- Robert Johnson, NMSS
- Jackie Cook; NMSS;
- Shawn Seeley, NRC Region I;
- Karen Meyer, NMSS;
- Morgan Tawney, State of North Carolina;
- Sangita Desai, Ohio Department of Health; and
- Perry Wagner, Ohio Department of Health;
- Joshua Wagner, Ohio Department of Health;
- Douglas Cosner, Ohio Department of Health.
- Sherrie Flaherty, NMSS.
- Farrah Gaskins, NRC Region I;
- Connie Kline, Member of the public from the State of Ohio.

OHIO FY2024 DRAFT IMPEP REPORT DATE July 22, 2024

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DATE	Jul 12, 2024	Jul 15, 2024	Jul 12, 2024	Jul 17, 2024
OFFICE	NMSS/MSST	NMSS		
NAME	KWilliams <i>KW</i>	JLubinski <i>JL</i>		
DATE	Jul 17, 2024	Jul 22, 2024		

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