



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

April 12, 2022

Daniel Huff, Assistant Commissioner  
Minnesota Department of Health  
Health Protection Bureau  
625 Robert Street N  
P.O. Box 64975  
St. Paul, MN 55164-0975

Dear Mr. Huff:

On March 17, 2022, 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 Minnesota Agreement State Program. The MRB Chair in consultation with the MRB found the Minnesota Agreement State 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. Based on the results of the current IMPEP review, the MRB directed that the next periodic meeting take place in approximately 2 years and the next IMPEP review take place in approximately 4 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 cursive script that reads "Catherine Haney".

Signed by Haney, Cathy  
on 04/12/22

Catherine Haney  
Deputy Executive Director for Materials, Waste,  
Research, State, Tribal, Compliance, Administration,  
and Human Capital Programs  
Office of the Executive Director for Operations

Enclosure:  
Final Minnesota Agreement State Program  
IMPEP Report

cc: Tom Hogan, Director  
Environmental Health Division  
Mary Navara, Manager  
Indoor Environments & Radiation Section  
Sherrie Flaherty, Supervisor  
Radioactive Materials Unit

SUBJECT: FINAL MINNESOTA AGREEMENT STATE PROGRAM INTEGRATED  
MATERIALS PERFORMANCE EVALUATION PROGRAM REPORT  
DATE APRIL 12, 2022

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**ADAMS Accession No.: ML22083A236**

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

December 13-17, 2021

**FINAL REPORT**

## EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Minnesota Agreement State Program are discussed in this report. The review was conducted in-person from December 13-17, 2021. In-person inspector accompaniments were conducted November 16-18, 2021.

The team found Minnesota's performance to be satisfactory for all performance indicators:

- Technical Staffing and Training;
- Status of Materials Inspection Program;
- Technical Quality of Inspections;
- Technical Quality of Licensing Actions;
- Technical Quality of Incident and Allegation Activities; and
- Legislation, Regulations, and Other Program Elements.

The team did not make any recommendations.

In accordance with the U.S. Nuclear Regulatory Commission's (NRC's) Management Directive 5.6 "Integrated Materials Performance Evaluation Program (IMPEP)," the team recommended and the Management Review Board (MRB) agreed that the Minnesota Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team also recommended that a periodic meeting take place in approximately 2 years and the next IMPEP review take place in approximately 4 years. The MRB members discussed whether Minnesota should receive or not receive, the 1-year extension granted to programs when two or more consecutive IMPEP reviews achieve all satisfactory findings, and ultimately agreed with the team's recommendation that the next IMPEP review take place in 4 years and a periodic meeting take place in 2 years.

## 1.0 INTRODUCTION

The Minnesota Agreement State Program (Minnesota) review was conducted in-person from December 13-17, 2021, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky. Team members are identified in Appendix A. In-person inspector accompaniments were conducted November 16-18, 2021. 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. In addition, the team considered IMPEP Temporary Instruction TI-003, "Evaluating the Impacts of the COVID-19 Public Health Emergency as Part of Integrated Materials Performance Evaluation Program (IMPEP)," dated October 21, 2020, to evaluate the impact of the pandemic on the Program. Preliminary results of the review, which covered the period of October 8, 2016, to December 17, 2021, were discussed with Minnesota 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 Minnesota on September 3, 2021. Minnesota provided its response to the questionnaire on October 27, 2021. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number [ML21319A203](#).

The Agreement State Program is administered by the Radioactive Materials Unit, which is located within the Indoor Environments and Radiation Section of the Division of Environmental Health (the Division). The Division is part of the Health Protection Bureau which is one of four bureaus in the Minnesota Department of Health. Organization charts are available in ADAMS (Accession Number [ML21319A149](#)).

The team issued a draft report to Minnesota on January 31, 2021, for factual comment (ADAMS Accession Number [ML22019A274](#)). Minnesota responded to the draft report by e-mail dated February 16, 2022, from Ms. Mary Navara, Manager, Indoor Environments and Radiation Section of the Minnesota Environmental Health Division (ADAMS Accession Number [ML22055A463](#)). Minnesota had one specific comment related to reporting requirements which was on the draft report were discussed during the Management Review Board (MRB) which convened on March 17, 2022. As a result of the discussions, the MRB determined no changes to the report were warranted.

At the time of the review, Minnesota regulated 148 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 Minnesota. 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 State's performance.

## 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on October 7, 2016. The final report is available in ADAMS (Accession Number [ML17009A338](#)). The results of that 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

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 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 SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Minnesota'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

Minnesota is comprised of five technical staff and one supervisor which equals 4.5 full-time equivalent for the Radioactive Materials Unit when fully staffed. At the beginning of the review period all five technical staff positions were filled. Currently, there are two vacant technical staff positions. One position has been vacant since June 2018, and the second position has been vacant since August 2020 (3 years, 6 months, and 16 months respectively). During the review period, one technical staff person was hired and three technical staff members left the program. Minnesota stated in its questionnaire response that the program has been unable to post these positions due to a lack of revenue. Statutory changes were approved in 2021 and provided an increase in fees and appropriations for the program. Additionally, after the start of the COVID-19 pandemic (pandemic), the State of Minnesota imposed a hiring freeze and only positions related to pandemic response were allowed to be posted. Minnesota anticipates being allowed to post at least one of the open positions once the hiring freeze is lifted. During the MRB Meeting Minnesota management indicated that they had received approval to post both of these positions.

Minnesota has a training and qualification program for both license reviewers and inspectors that is compatible with NRC's IMC 1248. The three technical staff members in the program are fully qualified and perform both inspection and licensing activities. The team determined that all qualified staff are completing at least 24 hours of refresher training every 24 months.

The team noted that Minnesota experienced impacts on this indicator related to the pandemic. Temporary Instruction TI-003, "Evaluating the Impacts of the Coronavirus Disease 2019 Public Health Emergency as part of the Integrated Materials Performance Evaluation Program (IMPEP)," states, in part, that impacts outside of a Program's control that under normal circumstances could impact the overall performance indicator rating should not be considered by the team for certain performance indicator objectives. One objective for consideration is vacancies at the technical staff or management level may not be filled in a timely manner. Throughout the pandemic, staff have been reassigned to support pandemic response activities within the Department of Health. However, Minnesota management ensured that one technical staff member was allowed to stay fully focused on the Agreement State Program to ensure programmatic consistency is

maintained during the pandemic. The pandemic also prevented posting of positions not related to pandemic response such that the two vacancies within the program are currently unable to be filled. As a result, the team did not consider the length of time each position was vacant in the overall finding for this indicator.

c. Evaluation

The team determined that, during the review period, Minnesota met the performance indicator objectives listed in Section 3.1.a except for:

- Two vacant positions have not been filled in a timely manner.

Specifically, Minnesota has had two positions vacant within the program for 16 months and 3 years-6 months respectively. Although Minnesota was able to hire one individual in August 2018, this individual left in August 2020 to seek work outside of State government. Additionally, Minnesota has been unable to fund the longstanding vacancy due to a lack of revenue. Statutory changes were approved in 2021 which provided an increase in fees and appropriations. However, at this time there is a hiring freeze in place related to the pandemic. Once the freeze is lifted Minnesota anticipates being allowed to post at least one of the positions for hire now that the revenue issues have been resolved. During the MRB Meeting Minnesota management indicated that they had received approval to post both of these positions.

Based on the team's findings, the team discussed ratings of satisfactory and satisfactory but needs improvement for this indicator. Specifically, the team noted that MD 5.6 states in Section III.B.2 that "Consideration should be given to a finding of satisfactory but needs improvement when a review demonstrates the presence of one or more of the following conditions." The team determined that, as discussed above, Minnesota met the following condition under this section during this review period:

(c) Staffing trends that could have an adverse impact on the quality of the program are not consistently tracked, analyzed, or addressed by program management in a timely manner.

The team discussed with program management the potential that exists for downgraded performance in the next IMPEP review if any of the current staff were to leave the program or if the vacancies were not addressed. The team noted that Minnesota was aware of this potential and that steps were being taken to address the staffing issues. Specifically, Minnesota was able to raise its fees in 2021 to adjust for the lack of revenue.

The team reviewed the rating criteria in MD 5.6 and determined that Minnesota met the intent of a finding of satisfactory. Minnesota was able to raise fees to support both vacancies. However, filling these vacancies was delayed due to the pandemic-related hiring freeze. Therefore, the team recommended that Minnesota's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.



d. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Minnesota'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 Minnesota'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

Minnesota performed 182 Priority 1, 2, and 3 inspections, and 9 initial inspections during the review period. Prior to the start of the pandemic, Minnesota conducted no Priority 1, 2, 3, or initial inspections overdue. However, in April 2020, at the onset of the pandemic, Minnesota suspended all routine inspection activities. This suspension of routine inspection activities did not impact Minnesota's ability to respond to incidents or other emergent notifications it received. In September 2020, Minnesota instituted a temporary inspection policy to maintain public health, safety, and security while ensuring protection of staff, which allowed inspectors to perform remote inspections, as appropriate. As a result, in-person and remote inspections were able to resume in October 2020. The 6 month suspension of inspection activities caused 19 Priority 1, 2, and 3 inspections to be performed overdue during the review period. No Priority 1 inspections were overdue at the time of the IMPEP review. No initial inspections were overdue at the time of the IMPEP review. Six Priority 2 and 3 inspections were overdue at the time of the IMPEP

review and were still not completed at the time of the MRB meeting. During the MRB meeting, Minnesota indicated that they planned to complete these six inspections by the end of October 2022.

The team noted that Temporary Instruction TI-003, "Evaluating the Impacts of the Coronavirus Disease 2019 Public Health Emergency as part of the Integrated Materials Performance Evaluation Program (IMPEP)," states, in part, that for inspections that exceed the scheduling window with overdue dates falling inside the defined timeframe of the pandemic, the number of overdue inspections should be noted in the report but should not be counted in the calculation of overdue inspections described in SA-101, "Reviewing the Common Performance Indicator: Status of Materials Inspection Program," Appendix A, provided that the State continues to maintain health, safety, and security. Of the overdue inspections noted above, all are due to impacts related to the pandemic. Therefore, the team did not include these inspections when performing the calculation.

Minnesota's inspection frequencies are the same for similar license types as described in the NRC's program. A sampling of 26 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond Minnesota's goal of 30 days after the inspection exit.

The team determined that for the first part of the review period Minnesota implemented a reciprocity inspection procedure equivalent to the NRC's IMC 1220. Then in 2019, Minnesota implemented a revised reciprocity inspection procedure as discussed in the recent revision to the NRC's IMC 2800. Per State and Tribal Communications Letter 20-082, "The IMPEP review team should evaluate the Agreement State's reciprocity inspection program for the entire review period based on the procedure (IMC 1220 or revised IMC 2800) implemented with the least restrictive criteria." The team reviewed both of the reciprocity procedures and determined that the procedure implemented by Minnesota in 2019 was the less restrictive of the two. Therefore, the team reviewed the reciprocity inspections completed throughout the review period against the process as described in the procedure implemented in 2019. This process allows Minnesota staff to answer questions about a reciprocity applicant and dependent on the answers provided, a value is assigned based on perceived risk. If the total value for the applicant is seven or higher, the applicant becomes a candidate for inspection in that calendar year. Minnesota's goal is to inspect 20 percent of those applicants who score 7 or higher each calendar year. Minnesota met this goal in calendar years 2017, 2018, and 2019. Minnesota did not meet its goal of inspecting 20 percent of candidate applicants in calendar years 2020 and 2021 due to limitations relating to the pandemic. In 2020 Minnesota inspected 9 percent and to date in 2021 inspected 5 percent of reciprocity candidate licensees.

c. Evaluation

The team determined that, during the review period, Minnesota met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommended that Minnesota'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 Minnesota'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 Minnesota'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 enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by six of Minnesota's current and former inspectors and covered medical, industrial, academic, and research licenses.

A team member accompanied three inspectors on November 16-18, 2021. The inspector accompaniments were conducted in-person. The inspector accompaniments are identified in Appendix B. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared and thorough, assessed the impact of licensed activities on health, safety, and security, and followed documented inspection procedures during the inspections.

The team noted that Minnesota maintained sufficient instrumentation for inspectors to conduct independent and/or confirmatory measurements that were calibrated at appropriate intervals and were appropriate for the types of licensed activities inspected.

Supervisory accompaniments of qualified inspectors were performed in all years of the review period except for 2020, in which no supervisory accompaniments occurred. This was due to the suspension of inspections and limited staff availability during the pandemic. Supervisory accompaniments resumed in 2021 and all qualified inspectors were accompanied. The team noted that Temporary Instruction TI-003, "Evaluating the Impacts of the Coronavirus Disease 2019 Public Health Emergency as part of the Integrated Materials Performance Evaluation Program (IMPEP)," states, in part, that if these impacts to supervisory accompaniments were outside of the Program's control, they should not be considered by the IMPEP team while establishing the overall indicator rating. Therefore, the team did not consider the absence of supervisory accompaniments in 2020 when establishing the overall indicator rating.

### Evaluation

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

#### c. MRB Chair's Determination

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

### 3.4 Technical Quality of Licensing Actions

The team used the guidance in SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Minnesota'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 *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 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.

a. Discussion

During the review period, Minnesota performed 570 radioactive materials licensing actions. The team evaluated 30 of those licensing actions: 9 new applications, 12 amendments, 4 renewals, 3 terminations, and 2 Transfers of Control. The team evaluated casework which included the following license types: Type A medical broad scope, medical diagnostic, mobile medical, emerging medical technology, radiopharmacy, industrial radiography, research and development, academic institutions, fixed gauges, veterinary medicine, service providers, and financial assurance. The casework sample represented work from six current and former license reviewers.

Licensing actions were well documented and properly addressed health, safety, and security issues. Renewal applications demonstrated a thorough analysis of the licensee's inspection and enforcement history. Each completed action included administrative peer review and a final supervisory review. All final actions are signed by each reviewer in the process.

The team evaluated the pre-licensing guidance and the pre-licensing site visit aspect of the new license application process. The team determined Minnesota conducted pre-licensing site visits for all unknown entities in accordance with the checklist, and properly implemented the guidance.

The team evaluated Minnesota's use of the Risk Significant Radioactive Materials Checklist (RSRM). The team determined that although Minnesota is using the most current version of the RSRM, it is not using the checklist for all applicable actions. Specifically, Minnesota does not use the checklist when staff believe RSRM limits will not be reached. This is contrary to the guidance which states that the checklist must be completed if an applicant is requesting a license authorizing possession of a Category 1 or Category 2 quantity of material, or if a licensee is requesting to add and/or remove a radionuclide or increase or reduce the possession limit of a radionuclide listed in the RSRM table. Even though the checklist was not used consistently, the team found no RSRM omissions in risk-significant licenses reviewed. The team discussed this issue with Program management, who committed to using the checklist as stated in the guidance.

All documentation for each licensing action is processed electronically using Web-Based Licensing, with financial surety instruments maintained in a secure file. No impacts related to the pandemic were seen related to this indicator. However, the team noted that two licensing variances were issued to licensees related to the pandemic. The team reviewed both variances and found them to be acceptable.

b. Evaluation

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

c. MRB Chair's Determination

The MRB Chair agreed with the team's recommendation and found Minnesota'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 SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Minnesota'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, Minnesota received 22 reportable incidents which included 10 lost or stolen radioactive materials, 2 potential overexposures, 4 medical events, 3 damaged equipment, 1 leaking source, and 2 radiography source disconnects. The team evaluated all of the incidents.

When notified of an incident, Minnesota management and staff discuss the incident and determine the appropriate level of response, which can range from an immediate response to a review of the incident during the next routine inspection. Those determinations are made based on both the circumstances and the health and safety significance of the incident. The team determined that Minnesota dispatched inspectors for on-site follow-up, as appropriate. The team found that Minnesota's evaluation of incident notifications and its response to those incidents was thorough, complete, and comprehensive.

The team also evaluated Minnesota's reporting of incidents to the NRC's HOC and NMED, as well as the timeliness of those reports. The team determined that 18 incidents required reporting to the HOC and of those 18, 6 were not reported in the manner required. Additionally, the team looked at the timeliness of reporting for all 22 incidents and determined that 9 incidents were reported late.

The team noted that the six incidents that were not reported in the correct manner were not reported to the NRC's HOC but instead were submitted directly to NMED. Four of the six incidents that were not reported to the HOC fell under 10 CFR 20.2201(a)(1)(ii). Minnesota staff stated that SA-300, "Reporting Material Events" led them to conclude that these incidents only required a written report and did not require reporting to the HOC. The team informed Minnesota staff that the text of the regulation states that these incidents are required to be called into the HOC within 30 days after the occurrence becomes known. However, the team noted that this issue had been seen in previous IMPEP reviews and recognized that SA-300 identifies this incident as falling into the 5 to 60 days reporting category. Further, the team noted that pages 19 and 30 of SA-300 state that any incident requiring reporting between 5 and 60 days can be sent straight to NMED. Minnesota questioned whether the expectation to report to the HOC was applicable to a State. The team explained to Minnesota staff that in this instance, a report required within this timeframe is required to be sent into the HOC. Minnesota management stated it would update its procedure to ensure incidents meeting this criteria were sent to the HOC in the future. A forthcoming revision to SA-300 will clarify the issues described above. For the other two incidents that were not submitted to the HOC, one involved a general license device which Minnesota did not realize required reporting to the HOC; the other incident involved a quantity of lost material that Minnesota thought fell under the greater than 10 times 10 CFR Part 20 Appendix C quantity (10 CFR 20.2201(a)(1)(ii)). The actual quantity, however, was greater than 1000 times the quantity in 10 CFR Part 20 Appendix C (10 CFR 20.2201(a)(1)(i)) which the State understands requires a 24-hour report to the NRC's HOC. All six incidents were reported to the HOC on December 16, 2021, for completeness.

The team found that 9 of the 22 reportable incidents received by Minnesota during the review period were reported to the NRC in a timeframe greater than prescribed. Six of the nine are discussed above and are considered late as a result of not being reported to the HOC. For two of the nine incidents, reported 1 day and 2 weeks late respectively, the team determined there was no root cause to the late reporting. For the remaining incident, the team noted that it was reported 1 day late as a result of the impacts from the pandemic. Specifically, Minnesota staff were busy supporting the pandemic response and recognized the following day that the incident had not been submitted to the NRC. Once Minnesota staff realized the incident had not been reported, it was immediately reported to the HOC.

In Minnesota's response to the draft report, they expressed a concern about the team's application of State Agreements (SA) procedure SA-300, particularly the reporting requirements for low-risk significant incidents of lost material, and requested that the related discussion be removed from this section of the IMPEP report. During the MRB meeting Minnesota, the team, and the MRB discussed whether the reporting requirement was applicable. Based on the discussion, the MRB agreed with the teams position and concluded no changes to the report should be made relative to Minnesota's comment on the draft report (ADAMS Accession Number [ML22055A463](#)).

During the review period, three allegations were received by Minnesota. The team evaluated each of these allegations, including two allegations that the NRC referred to Minnesota, during the review period. The team determined that the allegations were investigated promptly and that concerned individuals were informed of the results of the investigation and their identities were protected as allowed by law. Other than the one late incident report noted above, the team did not identify other pandemic-related impacts for this indicator.

c. Evaluation

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

- Notifications for six incidents requiring notification to the NRC's HOC were not made during the review period and were therefore reported late, and notification for an additional three incidents requiring reporting to the HOC and to NMED were reported in the correct manner, however, were reported late.

Specifically, Minnesota reported a total of nine incidents late to the NRC. Six of those incidents were not reported to the NRC's HOC as required. The other three were reported in the correct manner, but in a time frame greater than prescribed.

Based on the team's findings, the team discussed ratings of satisfactory and satisfactory but needs improvement for this indicator. Specifically, the team noted that MD 5.6 states in Section III.F.2 that "Consideration should be given to a finding of satisfactory but needs improvement when a review demonstrates the presence of one or more of the following conditions." The team determined that, as discussed above, Minnesota met the following condition under Section III.F.2 during this review period:

(h) Notifications to the NRC Headquarters Operations Center, with follow-up to NMED, as necessary, are not performed in accordance with the time frames established in NMSS procedure SA-300 or compatible Agreement State procedure, in more than a few, but less than most, of the cases reviewed.

Minnesota, the team, and the MRB discussed whether the requirement was applicable to a State. The team determined that Minnesota's evaluation, response, and follow-up to events to be comprehensive, well-coordinated, and timely. The team viewed the deficiency of reporting some of the events received late as administrative and not significant from a health and safety perspective. The team also determined that solely meeting bullet (h) under a finding of satisfactory, but needs improvement was not enough to lower the overall rating of the indicator. Therefore, in order to be consistent with recent IMPEP reviews the team determined that a finding of satisfactory but needs improvement was not warranted. Therefore, based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Minnesota'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 Minnesota'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 (LLRW) Disposal Program, and (4) Uranium Recovery Program. The NRC retains regulatory authority for SS&D Evaluation, LLRW Disposal, and Uranium Recovery Programs; therefore, only the first non-common performance indicator applied to this review.

##### 4.1 Legislation, Regulations, and Other Program Elements

State of Minnesota 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 Minnesota's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site 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

The State of Minnesota became an Agreement State on March 31, 2006. The statutory authority for Minnesota's Agreement State activities is primarily found in Minnesota's Statutes, Sections 144.12 through 144.1205. The Minnesota Department of Health is designated as the State's radiation control agency. One legislative change occurred during the review period and became effective July 1, 2021. This change resulted in the raising and restructuring of Minnesota's fees to their licensees.

The State's administrative rulemaking process typically takes approximately 18 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 State of Minnesota's Office of Administrative Hearings. The team noted that the Minnesota's rules and regulations are not subject to "sunset" laws.

During the review period, Minnesota submitted eight proposed regulation amendments, six final regulation amendments, and no legally binding requirements or license condition to the NRC for a compatibility review. Three of the amendments were overdue for State adoption at the time of submission.

- Regulation Amendment Tracking Sheet (RATS) 2015-1. "Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments," Part 70, 79 FR 57721, and 80 FR 143" (due for State adoption by January 26, 2018);
- RATS 2015-4. "Safeguards Information - Modified Handling Categorization, Change for Materials Facilities," Parts 30, 37, 73, and 150, 79 FR 58664, 80 FR 3865 (due for State adoption by September 2, 2018); and
- RATS 2015-5. "Miscellaneous Corrections," 10 CFR Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150, 80 FR 74974 (due for State adoption by December 31, 2018).

The regulations that were overdue for adoption were submitted anywhere from 9 to 20 months overdue. Specifically, the cause of delays in regulation implementation were due to staff turnover (i.e., retirements and attrition) in the Legal Unit. In addition, there were competing priorities for rules development resources within the Division, and other agencies within the State of Minnesota. At the time Minnesota was promulgating these rule changes, there was one individual performing rule reviews for the entire the Division, which resulted in the delay in rule promulgation. The section has since hired a rules analyst who assists the staff in ensuring timely adoption. The team did not identify pandemic-related impacts for this indicator.

c. Evaluation

The team determined that, during the review period, Minnesota met the performance indicator objectives listed in Section 4.1.a except for:

- Three regulation amendments adopted by Minnesota for purposes of compatibility or

health and safety were adopted in a time frame greater than 3 years after the effective date of the NRC regulation.

The team looked at the three regulation amendments overdue for adoption and determined that the rule changes for all three amendments involved minor clarifications that did not impact the overall regulatory framework. Additionally, the team determined that Minnesota adopted three regulation amendments overdue during the review period, anywhere from 9 to 20 months, due to a lengthy internal review process and legal staffing challenges within the Minnesota Department of Health.

Therefore, based on the criteria in MD 5.6, the team recommended that Minnesota's performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found satisfactory.

d. MRB Chair's Determination

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

## 5.0 SUMMARY

The team found Minnesota's performance to be satisfactory for all performance indicators reviewed:

- Technical Staffing and Training;
- Status of Materials Inspection Program;
- Technical Quality of Inspections;
- Technical Quality of Licensing Actions;
- Technical Quality of Incident and Allegation Activities; and
- Legislation, Regulations, and Other Program Elements.

The team did not make any recommendations.

Therefore, the team recommended that Minnesota be found adequate to protect public health and safety, and compatible with the NRC's program. Additionally, the team recommended that Minnesota's next IMPEP review be held in 4 years and that a periodic meeting take place in 2 years. The team recognized that Minnesota had achieved all satisfactory findings for two or more consecutive IMPEP reviews making them eligible to receive a 1-year extension to the 4-year IMPEP review period. However, because of the potential consideration for satisfactory but needs improvement findings as discussed in Section 3.1 and 3.5 of this report, the team did not believe a 1-year extension was warranted. The MRB members discussed whether Minnesota should receive, or not receive, the 1-year extension during the MRB meeting and ultimately agreed with the team's recommendation that the next full IMPEP review take place in 4 years, with a periodic meeting in 2 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>
Monica Ford, Region I	Team Leader Technical Quality of Incident and Allegation Activities Status of Materials Inspection Program
Ryan Craffey, Region III	Team Leader in Training Technical Quality of Inspections Inspector Accompaniments
Darren Piccirillo, Region III	Technical Staffing and Training Legislation, Regulations, and Other Program Elements
Angela Wilbers, Commonwealth of Kentucky	Technical Quality of Licensing Actions

## APPENDIX B

### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 1192
License Type: Industrial Radiography	Priority: 1
Inspection Date: 11/16/21	Inspector's initials: TK

Accompaniment No.: 2	License No.: 1036
License Type: Medical Institution Limited Scope	Priority: 3
Inspection Date: 11/17/21	Inspector's initials: LF

Accompaniment No.: 3	License No.: 1086
License Type: Self-Shielded Irradiator	Priority: 2
Inspection Date: 11/18/21	Inspector's initials: BJ