

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

March 13, 2017

Lisa Morris, MSSW Director Division of Public Health Services Department of Health and Human Services 29 Hazen Drive Concord, NH 03301

Dear Ms. Morris:

On February 14, 2017, a Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New Hampshire Agreement State Program. The MRB found the New Hampshire program adequate to protect public health and safety, and compatible with the NRC's program.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0). Based on the results of the current IMPEP review, the next full review of the New Hampshire Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for February 2018.

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

Sincerely,

# /RA/

Scott W. Moore, Deputy Director Office of Nuclear Material Safety and Safeguards

Enclosure: Final IMPEP Report

cc: Michael Dumond, Chief Bureau of Public Health Protection

Perry Plummer, Acting Director Department of Safety

Jay Hyland, ME Organization of Agreement States Liaison to the MRB



Protecting People and the Environment

# INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE NEW HAMPSHIRE AGREEMENT STATE PROGRAM

November 14-18, 2016

FINAL REPORT

Enclosure

## **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the New Hampshire Agreement State Program. The review was conducted during the period of November 14–18, 2016, by a team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Virginia.

Based on the results of this review, New Hampshire's performance was found satisfactory for all performance indicators. The finding for the Compatibility Requirements indicator has been upgraded from unsatisfactory to satisfactory due to New Hampshire's adoption of all previously overdue regulation amendments. Due to the significant progress New Hampshire has made since the last IMPEP review in regulation adoption, the team is recommending that the period of monitoring be discontinued.

The team did not make any new recommendations and determined that the one recommendation from the 2012 IMPEP review, regarding regulation adoption timeliness, be closed. Upon deliberation, the Management Review Board (MRB) issued two recommendations to New Hampshire. One concerns the Program's inspection frequency of licensees authorized for High Dose Rate Remote Afterloaders, and the second concerns a retrospective review of the amendments that added Radiation Safety Officers to medical licenses whose qualifications did not meet the Program's regulatory requirements at the time of issuance. (Sections 3.2 and 3.4.)

Overall, the team recommended, and the MRB agreed, that the New Hampshire Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The team recommended, and the MRB agreed, that the next IMPEP review take place in approximately 4 years. The MRB directed that a periodic meeting be held in 1 year. Further the team recommended, and the MRB agreed, that the period of monitoring be discontinued.

# 1.0 INTRODUCTION

This report presents the results of the review of the New Hampshire Agreement State Program. The review was conducted during the period of November 14–18, 2016, by a team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Virginia. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of October 6, 2012 to November 18, 2016, were discussed with New Hampshire managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to New Hampshire on July 26, 2016. New Hampshire provided its response to the questionnaire on October 28, 2016. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16307A132.

A draft of this report was issued to New Hampshire on December 19, 2016, for factual comment. New Hampshire responded to the findings and conclusions of the review by electronic mail dated January 23, 2017. A copy of New Hampshire's response is available in ADAMS (Accession Number ML17023A154). New Hampshire did not have any comments or request any changes to the IMPEP report.

The New Hampshire Agreement State Program is administered by the Radiological Health Section (the Section) which is located within the Bureau of Public Health Protection (Bureau), Division of Public Health Services (the Division). The Division is part of the Department of Health and Human Services (the Department). Organization charts for New Hampshire are available in ADAMS (Accession Number ML16305A211).

At the time of the review, the New Hampshire Agreement State Program regulated 84 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of New Hampshire.

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

# 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on October 5, 2012. The final report is available in ADAMS (Accession Number ML12354A183). The results of the previous review and the status of the recommendation are as follows:

Technical Staffing and Training: Satisfactory Recommendation: None

Status of Materials Inspection Program: Satisfactory Recommendation: None

Technical Quality of Inspections: Satisfactory Recommendation: None

Technical Quality of Licensing Actions: Satisfactory Recommendation: None

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

Compatibility Requirements: Unsatisfactory Recommendation: "The team recommends that the State develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility." (Held open from the 2008 IMPEP review.)

Status: In a letter dated January 29, 2013, New Hampshire submitted its action plan to adopt regulations in accordance with the NRC's policy on adequacy and compatibility (ML13044A096). This plan included the formation of a Rulemaking Committee to oversee and monitor New Hampshire's progress in timely adoption of regulation amendments. A "working plan" was developed with milestones for the associated steps of the regulation adoption process. In the event that a rule cannot be adopted in a timely manner due to actions outside of the control of the Rulemaking Committee, steps would be taken to use other legally binding requirements to meet the required adoption date.

Since the 2012 IMPEP review, New Hampshire has adopted as final regulations all overdue amendments that were identified in the 2012 IMPEP report (Section 4.1). The team recommended, and the MRB agreed, that this recommendation be closed.

Sealed Source and Device Program: Satisfactory Recommendation: None

Overall finding: Adequate to protect health and safety and not Compatible. New Hampshire was placed on monitoring to address the ten overdue regulations.

#### 3.0 COMMON PERFORMANCE INDICATORS

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

# 3.1 <u>Technical Staffing and Training</u>

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

# a. <u>Scope</u>

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

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

## b. Discussion

The New Hampshire Agreement State Program is composed of six staff members with a total of 4.05 full-time equivalents (FTE) for the radioactive materials program including, 3.05 FTE technical staff, 0.1 FTE Section Administrator/Rulemaking, and 0.9 FTE administrative staff. At the time of the review, 0.5 FTE technical staff was vacant. During the review period, two technical staff members left the program and one technical staff member was hired. The one technical position that was filled was vacant for 2 days. The other technical position that was unfilled at the time of the review has been vacant for 5 months. New Hampshire has a training and qualification manual compatible with the NRC's IMC 1248.

c. Evaluation

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

d. Results

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

#### 3.2 Status of Materials Inspection Program

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

# a. <u>Scope</u>

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

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

# b. Discussion

New Hampshire's inspection frequency is the same for similar license types in IMC 2800. The Section performed 52 Priority 1, 2, 3 and initial inspections during the review period. The Section conducted 5.8 percent of Priority 1, 2, 3, and initial inspections overdue. Specifically, New Hampshire performed three Priority 2 inspections overdue. The overdue inspections were all of High Dose Rate (HDR) afterloader brachytherapy programs at three medical licensees. The team determined that these three medical licensees were the only licensees regulated by the Section that authorized HDR therapy.

The inspection frequency for HDR therapy is 2 years. The licenses for this therapy also include other licensed activities with different priority codes, i.e. medical-written directive required and prostate brachytherapy, both of which have a 3-year inspection frequency, and medical-no written directive required which has a 5-year inspection frequency. The team discovered that the Section did not always inspect the HDR brachytherapy program during each 2-year inspection of the facility. As a result, the HDR brachytherapy inspections were performed overdue, i.e., ranging from 3 to 7 years overdue. When questioned about inspection frequency, the Section management indicated that it was not a requirement to inspect every modality on each inspection. The team explained that IMC 2800 states, "...with licenses that have multiple priority codes, each part of the program shall be inspected in accordance with its assigned priority."

# c. Evaluation

The team determined that during the review period, New Hampshire did not meet the performance indicator objectives listed in Section 3.2.a. Specifically, New Hampshire did not perform three Priority 2 inspections at the frequency prescribed in IMC 2800.

While the percentage of overdue inspections meets a satisfactory performance of conducting less than 10 percent of inspections overdue, the team considered a finding of satisfactory versus satisfactory, but needs improvement based on the risk-significance of HDR therapy. However, the team determined that a finding of satisfactory is acceptable because less than 10 percent of inspections were conducted overdue and there were no health and safety issues identified by the Section during subsequent inspections of these HDR therapy programs. Upon deliberation, the MRB determined that a recommendation should be issued to address the Section's misinterpretation of IMC 2800 and the prescribed inspection frequencies for those licensees with more than one program code. The MRB recommended that Section management implement a mechanism to ensure that licensees with more than one program code authorized by the license are inspected at the required frequency assigned to each program code.

# d. Results

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

# 3.3 <u>Technical Quality of Inspections</u>

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

# a. <u>Scope</u>

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated New Hampshire'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.

- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

# b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 20 materials inspections conducted during the review period. The casework reviewed included inspections conducted by four of New Hampshire's inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses.

A team member accompanied two program inspectors on September 22 and September 23, 2016. The inspectors were adequately prepared and performed performance-based inspections. The inspector accompaniments are identified in Appendix B. The team noted that the Section supervisor performed annual supervisory accompaniments for each inspector throughout the review period.

# c. Evaluation

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

# d. <u>Results</u>

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

#### 3.4 <u>Technical Quality of Licensing Actions</u>

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the New Hampshire licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

# a. <u>Scope</u>

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated New Hampshire's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.

- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

# b. Discussion

During the review period, New Hampshire performed approximately 670 licensing actions. The team reviewed 33 licensing actions including 2 initials, 1 termination, 3 rejections, 24 amendments, and 3 renewals representing work from five license reviewers. These actions included a variety of license types including medical broad scope, research and development broad scope, industrial radiography, academic broad scope, mobile medical service, diagnostic medical, medical therapy, veterinary science, service provider, portable gauges, and self-shielded irradiator.

The team determined that licensees were evaluated for meeting the additional security requirements and license conditions to implement Title 10 of the *Code of Federal Regulations* Part 37 by reference. All reviews were of a high quality, using a thorough, concise and easily understood process.

The team discovered that the Section issued three amendments for the approval of a Radiation Safety Officer (RSO) during the review period who did not meet requirements of New Hampshire regulations that were in place at the time the licensing actions were issued. These amendments were for medical licenses. At the time the amendments were issued, the New Hampshire regulations allowed licensees to use another materials license (NRC, New Hampshire or other Agreement State) to add RSOs to a license. With these three RSO amendments, the individuals were not authorized users on another New Hampshire, Agreement State or NRC license for all the medical modalities listed on the license for which the RSO was authorized. In discussions with Section management, the team found that the Section approved these individuals to be listed as RSOs because the licensee confirmed in writing that other Authorized Users (physicians, consultants) would be available to assist the RSO, if necessary. The team discussed with the Section the need to review and determine corrective actions needed for any of the three individuals approved as RSOs who do not meet the current medical regulations in New Hampshire.

Due to New Hampshire's commitment to adhere to its regulatory requirements to prevent future occurrence, and because the three licensees had committed in writing that an Authorized User was available to support the RSO, the team determined that a finding of satisfactory for this indicator was appropriate. Upon deliberation, the MRB determined that a recommendation should be issued to address the Section's licensing of these three medical RSO's. The MRB recommended that Section management review the qualifications of the aforementioned RSOs, and implement a mechanism to ensure the named RSOs on these and all medical licenses meet New Hampshire's regulatory requirements.

# c. Evaluation

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

d. <u>Results</u>

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

# 3.5 <u>Technical Quality of Incident and Allegation Activities</u>

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

# a. <u>Scope</u>

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

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

During the review period, 50 incidents,<sup>1</sup> including 4 allegations, were reported to New Hampshire. Thirty of these incidents involved patient waste from hospitals which triggered alarms at waste/scrap facilities; the remaining incidents included those for aircraft gauges, smoke detectors, contaminated cat litter found at waste facilities, and the report of missing check sources. None of the 50 incidents met the NRC reporting criteria and therefore, were not reported to NRC. The team evaluated six of the incidents involving patient waste and confirmed that none of the incidents met the NRC event reporting requirements. New Hampshire dispatched inspectors for onsite

<sup>&</sup>lt;sup>1</sup> New Hampshire considers any type of notification from a licensee as an "incident."

followup for all of the cases reviewed. New Hampshire dispatches inspectors for onsite followup whenever the possibility of radioactive material exists in the public domain.

During the review period, four allegations were received by New Hampshire. The team evaluated all four allegations. The NRC did not refer any allegations to the State during the reporting period. The team evaluated the completed casework and determined the Section took prompt appropriate action in response to the concerns raised. The concerned individuals were notified of the findings. The team found that the Section adequately protected the concerned individual's identity.

c. Evaluation

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

# d. <u>Results</u>

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

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

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

#### 4.1 <u>Compatibility Requirements</u>

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. 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, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by an Agreement State within 6 months following NRC designation.

# a. <u>Scope</u>

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated New Hampshire'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: <u>https://scp.nrc.gov/regtoolbox.html</u>.

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

#### b. Discussion

New Hampshire became an Agreement State on May 16, 1966. The New Hampshire Agreement State Program's current effective statutory authority is contained in the New Hampshire Revised Statutes Annotated, 1990, Title 125. The Section is designated as the State's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

New Hampshire's administrative rulemaking process takes approximately 20 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 New Hampshire Rulemaking Committee. The team noted that New Hampshire's rules and regulations are subject to "sunset" laws. Regulations whose initial filing dates occurred prior to September 11, 2011, expire 10 years after the rule's effective date. New Hampshire has a system in place to track rules that are subject to expiration to begin the renewal process.

During the review period, New Hampshire submitted 13 final regulation amendments, 13 proposed regulation amendments and 1 legally binding license condition to the NRC for a compatibility review. Seventeen of the amendments (13 final and 4 proposed) were overdue for State adoption at the time of submission to the NRC. At the time of the review, New Hampshire had adopted as final regulations all previous overdue amendments. New Hampshire is currently in the process of making editorial corrections (e.g., reference numbers) to nine adopted amendments before submitting them for the NRC's review as final regulations.

# c. Evaluation

The team determined that during the review period New Hampshire met the performance indicator objectives listed in Section 4.1.a. Based on the progress of the program in addressing all overdue regulation amendments, the team is recommending that the previous recommendation for this indicator be closed.

# d. <u>Results</u>

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

# 4.2 <u>Sealed Source and Device (SS&D) Evaluation Program</u>

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for teams. 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. <u>Scope</u>

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated New Hampshire'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 that qualification criteria will be established if new staff members are hired.
- Any vacancies are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

# Technical Quality of the Product Evaluation Program

• SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with NUREG 1556, Volume 3.

# Evaluation of Defects and Incidents

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

# b. Discussion

#### Technical Staffing and Training

New Hampshire has two staff qualified to perform SS&D reviews. The Section has no current plans to train another staff member. New Hampshire has a training and qualification program equivalent to NRC training requirements listed in IMC 1248, Appendix D.

#### Technical Quality of the Product Evaluation

New Hampshire has two SS&D licensees. There were no registry actions for either SS&D licensee over the review period. The Section does provide SS&D registry review support to the Maine Agreement State program. The team evaluated two new SS&D registrations processed by the Section during the review period for Maine. At the conclusion of the process, the certificates were provided to the Maine program and entered into the SS&D Registry as Maine certificates.

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

No incidents involving SS&D registered products occurred during the review period. Incident procedures are in place should a SS&D related incident occur. The team found that the Section is aware of the need to review SS&D-related incidents including those related to SS&D defects as potentially generic in nature with possible wide-ranging effects.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended, and the MRB agreed, that New Hampshire's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

# 4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Although the New Hampshire Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in New Hampshire. Accordingly, the team did not review this indicator.

# 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, New Hampshire's performance was found satisfactory for all performance indicators reviewed. The team did not make any recommendations, and determined that the recommendation from the 2012 IMPEP review regarding timely adoption of regulation amendments, should be closed. The MRB issued two recommendations to New Hampshire under the indicators Status of Materials Inspection Program and Technical Quality of Licensing Actions (Sections 3.2 and 3.4).

Accordingly, the team recommended, and the MRB agreed, that the New Hampshire Agreement State Program be found adequate to protect public health and safety, and compatible with the NRC's program. Based on the results of the current IMPEP review, the team recommended, and the MRB agreed, that the next full IMPEP review be conducted in approximately 4 years. The MRB directed that a periodic meeting be held in one year. Based on the significant progress made by New Hampshire in the adoption of overdue regulations, the team recommended, and the MRB agreed, that the period of monitoring be discontinued.

Below are the recommendations, as mentioned in the report, for evaluation and implementation by New Hampshire:

#### RECOMMENDATIONS

- 1. The MRB recommended that Section management implement a mechanism to ensure that licensees with more than one program code authorized by the license are inspected at the required frequency assigned to each program code (Section 3.2).
- 2. The MRB recommended that Section management review the qualifications of the aforementioned RSOs, and implement a mechanism to ensure the named RSOs on these and all medical licenses meet New Hampshire's regulatory requirements (Section 3.4).

# LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Inspection Accompaniments

# APPENDIX A

# IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility	
Michelle Beardsley, NMSS	Team Leader Status of Materials Inspection Program Technical Staffing and Training Compatibility Requirements	
Donna Janda, Region I	Technical Quality of Inspections Inspection Accompaniments Technical Quality of Incidents and Allegations	
Beth Schilke, VA	Technical Quality of Licensing Actions	
Stephen Poy, NMSS	Sealed Source and Device Evaluation Program	

# APPENDIX B

# INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 491R
License Type: Industrial Radiography	Priority: 1
Inspection Date: 09/22/16	Inspector: TL

Accompaniment No.: 2	License No.: 308R
License Type: Limited Medical Institution, WD Required	Priority: 3
Inspection Date: 09/23/16	Inspector: DS