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

July 28, 2023

Clark Eldredge, Interim Bureau Chief
Bureau of Radiation Control
Division of Emergency Preparedness
and Community Support
Department of Health
4052 Bald Cypress Way, SE, Bin C21
Tallahassee, FL 32399-1741

Dear Mr. Eldredge:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the review of Agreement State and NRC radiation control programs. Enclosed is the draft IMPEP report, which documents the results of the Florida Agreement State review conducted on June 12-16, 2023. The team's preliminary findings were discussed with you and your staff on the last day of the review. The team's proposed recommendations are that the Florida Agreement State Program be found adequate to protect public health and safety and not compatible with the NRC's program.

The NRC conducts periodic reviews of radiation control programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The IMPEP process uses a team comprised of Agreement State and NRC staff to perform the reviews. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy and compatibility of each program, based on the team's report, is made by the Chair of the Management Review Board (MRB) after receiving input from the MRB members. The MRB is composed of NRC senior managers and an Agreement State program manager.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter.

The team will review the response, make any necessary changes to the report, and issue it to the MRB. The MRB meeting is scheduled to be conducted on October 5, 2023, at 1:00 ET in Rockville, Maryland. The NRC will also provide you with Microsoft Teams connection information prior to the meeting. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland.

If you have any questions regarding the enclosed report, please contact me at 301-415-0324 or Randy Erickson at (817) 676-4024.

Thank you for your cooperation.

Sincerely,


Signed by Giantelli, Adelaide
on 07/28/23

Adelaide S. Giantelli, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Enclosure: 2023 FL Draft IMPEP Report

cc:
Kevin Kunder, Environmental Administrator
Radioactive Materials
Division of Emergency Preparedness
and Community Support
Department of Health

SUBJECT: FLORIDA FY2023 DRAFT IMPEP REPORT DATE July 28, 2023

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

JUNE 12-16, 2023

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Florida Agreement State Program (Florida) are discussed in this report. The review was conducted June 12-16, 2023, in Tallahassee, FL. In-person inspector accompaniments were conducted between February and May 2023.

The team found Florida's performance satisfactory for the performance indicators Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incidents and Allegation Activities, and Sealed Source and Device Evaluation. The team found Florida's performance unsatisfactory for the performance indicator Legislation, Regulations, and other Program Elements.

The team proposed closing the three recommendations from the 2019 IMPEP review, and opening a new recommendation related to the Legislation, Regulations, and other Program Elements performance indicator.

Accordingly, the team recommends that the Florida Agreement State Program be found adequate to protect public health and safety and not compatible with the NRC's program. The team also recommends that a periodic meeting take place in approximately 2 years with the next IMPEP review taking place in approximately 4 years.

1.0 INTRODUCTION

The Florida Agreement State Program review was conducted from June 12-16, 2023, by a team of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the states of Arizona, Illinois, and Louisiana. Team members are identified in Appendix A. The team completed twenty in-person materials inspector accompaniments between February and May of 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 June 29, 2019, to June 16, 2023, were discussed with Florida 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 Florida on May 8, 2023. Florida provided its response to the questionnaire on May 26, 2023. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML23151A354.

The Florida Agreement State Program is administered by the Bureau of Radiation Control (the Bureau), which is designated as the State's radiation control agency. The Bureau is in the Division of Emergency Preparedness and Community Support in the Department of Health. Organization charts for Florida are available in ADAMS ML23151A309.

At the time of the review, the Bureau regulated 1521 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 Florida.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on June 28, 2019. The final report is available in ADAMS ML19262D631. 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, but needs improvement
Recommendation 1: The outcome of previously identified inspection open items and violations be documented and communicated formally to the licensee.

Status of Recommendation 1: The team is proposing that this recommendation be closed. Details related to the work performed by Florida to address this recommendation

and the 2023 IMPEP team's evaluation of that effort can be found in Section 3.3 of this report.

Technical Quality of Licensing Actions: Satisfactory
Recommendation 2: The Program consistently document the training completed by license reviewers, including the license types for which each reviewer has obtained signature authority.

Status of Recommendation 2: The team is proposing that this recommendation be closed. Details related to the work performed by Florida to address this recommendation and the 2023 IMPEP team's evaluation of that effort can be found in Section 3.4 of this report.

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

Legislation, Regulations, and Other Program Elements (formerly Compatibility Requirements): Unsatisfactory
Recommendation 3: The team recommends that a plan be developed and implemented to address the overdue regulations, including how rules should be prioritized. The plan should also address instituting a knowledge management program for the staff involved in the rulemaking process.

Status of Recommendation 3: The team is proposing that this recommendation be closed based on the progress made, and that a new recommendation be opened to address the remaining scope of work. Details related to the work performed by Florida to address this recommendation and the 2023 IMPEP team's evaluation of that effort can be found in Section 4.1 of this report.

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

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

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

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

a. Scope

The team used the guidance in State Agreements (SA) procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Florida'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

Florida is composed of 50 technical staff members, which includes 24 full-time equivalent (FTE) for the radiation control program when fully staffed. During the review period, 23 of the staff members left the program and 21 staff members were hired. Currently, there are two vacancies. Staff members left the Program for reasons including retirement, better paying jobs, and personal reasons. The positions were vacant from 60 to 120 days, except for one, which remained open for approximately 160 days. Florida assigned resources from other areas of the Bureau to supplement staffing demands. Senior level positions were filled in a timely manner. As a result, licensing and inspection work was still completed successfully, as described below.

In addition, Florida has initiated steps to be more successful in recruiting and retaining staff. The Environmental Specialist II (ESII) positions were upgraded to Environmental Specialist III (ESIII) positions, which included a pay increase. Future staff will be hired in at an ESIII position.

Florida has a training and qualification program that is compatible with the NRC's IMC 1248. Four of the 21 employees hired during the review period had a master's degree in science, 10 had a bachelor's degree in science, six had associate degrees in nuclear medicine or radiation technology and one had completed Navy Nuclear Power School. Florida uses a combination of in-house training, NRC sponsored training, and on the job training for its license reviewers and inspectors. New inspectors are on probation for a year and are expected to demonstrate proficiency in performing nuclear gauge and nuclear medicine (no written directive required) inspections to successfully complete the probationary period.

c. Evaluation

The team determined that, during the review period, Florida met the performance indicator objectives listed in Section 3.1.a. Based on the criteria in MD 5.6, the team

recommends that Florida's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

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

The final report will present the MRB Chair's determination regarding this indicator.

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 Florida'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

Florida performed 1,207 Priority 1, 2, 3, and initial inspections during the review period. No Priority 1, 2, 3 or initial inspections were conducted overdue during the review period. Florida's inspection frequencies are the same, or in some cases more frequent, than frequencies listed in IMC 2800 for similar license types in Florida.

A sampling of 36 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond Florida's goal of 30 days after the inspection exit or 45 days after the team inspection exit.

Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 2800 and other applicable guidance. For each year of the review period, Florida performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

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

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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 Florida'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 34 inspection reports, reviewed enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by 31 current and former Florida inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses.

The team completed 20 in-person materials inspector accompaniments between February 2023 and May 2023. The team found that the inspectors were well-prepared, thorough in their evaluation of each licensee, and assessed the impact of licensed activities on health, safety, and security. During interviews of licensee staff, inspectors used open-ended questions, and were able to develop 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. All findings and conclusions were well-founded and appropriately documented. The inspector accompaniments are identified in Appendix B.

The team noted that supervisory accompaniments were performed annually for most of the qualified inspectors in each year of the review period. Florida's high staff turnover rate made it difficult to complete all the required accompaniments in a timely manner. Missing some of the inspector accompaniments did not affect Florida's ability to protect public health and safety.

The team identified that Florida's inspection results were well documented, and violations were well supported. Florida followed its own documented inspection and enforcement procedures. The team reviewed the Florida inspection procedures and found them to be compatible with NRC inspection procedures.

As a result of the 2019 IMPEP review, the team made one recommendation related to Florida's performance on the Technical Quality of Inspection performance indicator.

Recommendation 1: The outcome of previously identified inspection open items and violations be documented and communicated formally to the licensee.

The team identified that in all inspection reports reviewed, the program had adequately identified all open inspection items and violations and communicated them formally to the licensee. Therefore, the team proposing this recommendation be closed.

The team verified that Florida maintained an adequate supply of appropriate and calibrated survey instruments to support the inspection program and to respond to radioactive materials incidents.

c. Evaluation

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

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

The team conducted 20 inspector accompaniments of the 29 fully or partially qualified inspectors and found that all inspectors were well-prepared, thorough in their evaluation of each licensee, and adequately assessed the impact of licensed activities on health, safety, and security. Therefore, the team determined that missing some of the supervisory accompaniments did not affect Florida's ability to protect public health and safety.

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

c. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.4 Technical Quality of Licensing Actions

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

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Florida'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 Regulation* (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, Florida performed 7,877 radioactive materials licensing actions. The team evaluated 27 of those licensing actions. The licensing actions selected for review included 6 new applications, 14 amendments, 5 renewals, and 2 terminations. The team also reviewed 2 licensing actions that included security requirements and 2 that involved financial assurance. The team evaluated casework which included the following license types: broad scope, medical diagnostic and therapeutic, mobile medical, industrial radiography, veterinary, research and development, academic, nuclear pharmacy, portable and fixed gauges, panoramic and self-shielded irradiators, service provider, waste processor, and decommissioning licensees. The casework sample represented work from 13 current and former license reviewers.

Florida had 12 qualified license reviewers. Florida successfully processed a very large number of licensing actions in a timely manner. License reviewers benefitted from comprehensive license application checklists developed based on the NUREG-1556 series, and emerging technologies guidance. These checklists also provide guidance to

Florida's licensees on the necessary elements of a successful license application, thus reducing the need for requests for additional information.

Florida also benefitted from the expertise of long-term staff who were highly qualified, using them to review actions performed by newer staff who had yet to obtain broad qualification. Florida implemented the RSRM and Pre-Licensing Guidance checklists for new licenses, and 100 percent of new license applicants receive pre-licensing visits. The team found that all documents containing sensitive security related or protected information were properly marked and secured in accordance with their procedures for controlling sensitive information.

The team reviewed decommissioning activities at two legacy decommissioning sites. These legacy sites contained laboratory hazardous and radioactive wastes. Decommissioning at the Tallahassee site was completed during this review period. Decommissioning at the Apalachicola National Forest legacy site was nearing completion at the time of the review. The team noted that the licensee was currently working with a contractor to ensure proper disposal of the waste. The team also determined that the two legacy sites will continue to be listed on the license until decommissioning is completed.

As a result of the 2019 IMPEP review, the team made a recommendation related to Florida's performance on the Technical Quality of Licensing Actions performance indicator.

Recommendation 2: Florida consistently document the training completed by license reviewers, including the license types for which each reviewer has obtained signature authority.

To assess Florida's work related to this recommendation, the team reviewed license reviewer qualification journals and found that each license reviewer had a qualification journal that documented what type of license reviews they were qualified to perform independently. Therefore, the team proposes closing this recommendation.

c. Evaluation

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

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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 Florida'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, 85 events were reported to the NMED database by Florida. The team evaluated 18 radioactive materials events, which included 7 medical events, 5 events involving lost or stolen radioactive materials, 1 event involving an industrial radiography source disconnect, 1 fire event involving radioactive materials, 1 event involving medical waste setting off an alarm, 2 auto accidents involving radiopharmaceuticals, and 1 security event involving a delivery driver inadvertently attempting to enter an incorrect door. Florida dispatched inspectors for on-site follow-up for all cases reviewed.

When an event is reported to Florida, management evaluates it and determines its health and safety significance and then decides on the appropriate response. That response can range anywhere from responding immediately to reviewing the event during the next inspection. For each incident Florida staff determined to have potential health and safety significance, Florida responded immediately. Responses were appropriate, well-coordinated and timely. The team found that inspectors properly evaluated each event, interviewed involved individuals, and thoroughly documented their findings. Enforcement actions were taken where appropriate. The team also found that Florida responded to events in accordance with their established procedure.

The team evaluated Florida's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case evaluated where HOO notification was required, Florida reported all events within the required timeframe.

During the review period, 18 allegations were received directly by Florida with 6 additional allegations referred by the NRC. The team evaluated 10 of the allegations and found that Florida took prompt and appropriate action in response to each of the concerns raised. The team determined that all allegations reviewed were appropriately closed, concerned individuals were notified timely of the actions taken, and allegers' identities were protected whenever possible in accordance with State law. The team also found that Florida responded to allegations in accordance with their established procedure.

c. Evaluation

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

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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) Uranium Recovery Program. The NRC retains regulatory authority for Uranium Recovery Program; therefore, only the first three non-common performance indicators applied to this review.

4.1 Legislation, Regulations, and Other Program Elements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the State's agreement with the NRC. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of adequate protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. The NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by an Agreement State within 6 months following NRC designation. A Program Element Table indicating the Compatibility Categories for those program elements other than regulations can be found on the 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 Florida's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC website at the following address: https://scp.nrc.gov/regtoolbox.html.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.

- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

Florida became an Agreement State on July 1, 1964. Florida 's current effective statutory authority is contained in the Florida Radiation Protection Act in Title XXIX, Chapter 404, of the State of Florida Statutes. The Bureau is designated as the State's radiation control agency. The Bureau is in the Division of Emergency Preparedness and Community Support in the Department of Health. No legislation affecting the radiation control program was passed during the review period.

Florida's administrative rulemaking process takes approximately 12-18 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 Governor. The State's rules and regulations are not subject to "sunset" laws.

During the review period, Florida submitted one proposed regulation amendment, no final regulation amendments, and two license conditions to the NRC for a compatibility review. The proposed regulation amendment, RATS ID 2015-3, was submitted overdue for State adoption at the time of submission. Florida also used one license condition to adopt regulations set forth in 10 CFR Part 37 and another to do was to adopt regulations set forth in 10 CFR Part 71.

At the time of the review, the following six amendments were overdue and had not been submitted to the NRC for review:

- "Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements Part 71 (80 FR 33987), that was due for Agreement State adoption on August 15, 2020.
- "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments", 10 CFR Parts 30, 32 and 35, that was due for Agreement State adoption on January 14, 2022.
- "Miscellaneous Corrections – Organizational Changes" 10 CFR Parts 37,40.70, and 71, that was due for Agreement State adoption on December 21, 2021.
- "Miscellaneous Corrections", 10 CFR Part Parts 1, 2, 34, 37, 50, 71, 73, and 140, that was due for Agreement state adoption, July 30, 2022.
- "Miscellaneous Corrections", 10 CFR Parts 2, 21, 37, 50, 52, 73, and 110, that was due for Agreement State adoption on December 18, 2022
- "Organizational Changes and Conforming Amendments", 10 CFR Parts 1, 2, 37, 40, 50, 51, 52, 55, 71, 72, 73, 74, 100, 140, and 150, that was due for Agreement State adoption on December 30, 2022.

In addition, “Individual Monitoring Devices,” 10 CFR Parts 34, 36, and 39, was not overdue at the time of the review but had not been submitted to the NRC for review. It became overdue on June 16, 2023, after the review period.

As a result of the 2019 IMPEP review, the team made one recommendation related to Florida’s performance on the Legislation, Regulations, and Other Program Elements performance indicator.

Recommendation 3: The team recommended that a plan be developed and implemented to address the overdue regulations, including how rules should be prioritized. The plan should also address instituting a knowledge management program for the staff involved in the rulemaking process.

The team noted that Florida developed and implemented a plan to address the overdue regulations which included several members of the staff. Staff met periodically to address the status of overdue regulations. Although the plan had been established and included knowledge management, not all overdue regulations were adopted, and additional regulation amendments became overdue during this review period. The team recommends closing the 2019 recommendation because Florida developed and implemented a plan and addressed knowledge management. However, the implementation of the plan was not fully successful, as described below.

To begin rule promulgation, Florida submits a Notice to Develop Rulemaking to the Department of Health (Department). The Department will then send the notice to the Office of Program Policy Analysis and Government Accountability (OFARR) in the Governor’s Office for review and approval. Once permission is given, the Department publishes a Notice to Develop Rulemaking in the Florida Administrative Register (FAR) for a period of 21 days offering to hold a rule development workshop. If a workshop is requested, it is published in the FAR at least seven days prior to the workshop. The Notice of Proposed Rulemaking must be published within one year from the Notice of Rule Development. If the notice is not published within one year, Florida is required to refile the notice. Because of process delays, Florida filed the Notice for Rule Development in 2021 and had to file again in 2022. The filing included the overdue regulations amendments mentioned previously.

After the Notice was filed, the proposed regulations were reviewed by the Department’s Office of General Counsel (OGC). During the pandemic, OGC focused their review of proposed rules to those concerning emergency response to the pandemic, which caused a delay in reviewing Florida’s rules. OGC also added levels of management review, extending the time required for OGC to complete their review.

The team found that a detailed, realistic timeline of regulation promulgation was not established and monitored by senior Division of Emergency Preparedness and Community Support management in the Department of Health. These actions would help to avoid cross-organizational challenges and support meeting the 3-year implementation deadline. To address challenges with promulgating regulations, the team proposes opening a new recommendation to have Florida:

- Manage implementation of the compatibility plan to establish realistic timelines and leverage senior Division of Emergency Preparedness and Community Support management engagement to ensure timely adoption of current and future regulations.

The team also reviewed other program elements designated as necessary for the maintenance of an adequate and compatible program. The other program elements included, licensing guidance, inspection guidance, and new or revised medical guidance. Program elements require adoption by Florida within 6 months of NRC issuance. The team determined that Florida implemented these program elements, as required.

c. Evaluation

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

- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted later than 3 years after the effective date of the NRC regulation.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Florida's performance with respect to the indicator, Legislation, Regulations, and Other Program Elements, be found unsatisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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 Florida'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

Florida has two qualified SS&D reviewers with two additional staff being trained. At the time of the review there were no vacancies. During the review period, no SS&D reviewers left the program and none were hired. Florida's training program is equivalent to NRC's IMC 1248, Appendix D.

Technical Quality of the Product Evaluation

Florida has eight SS&D licensees. The team evaluated all seven SS&D actions processed during the review period. These actions included six amendments and one new application. These actions were thorough, adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents Regarding SS&Ds

The team reviewed NMED for incidents involving SS&D registered products during the review period. The team did not identify any incidents related to manufacturing or design of the sources or devices manufactured or distributed by a licensee with a SS&D registered by Florida.

c. Evaluation

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

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

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

5.0 SUMMARY

The team found Florida’s performance satisfactory for the performance indicators Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incidents and Allegation Activities, and SS&D Evaluation Program. The team found Florida’s performance unsatisfactory for the performance indicator Legislation, Regulations and other Program Elements.

The team proposes closing the three 2019 IMPEP review recommendations. The team also proposes opening a new recommendation to have Florida:

- Manage implementation of the compatibility plan to establish realistic timelines and leverage senior management engagement to ensure timely adoption of current and future regulations.

Accordingly, the team recommends that the Florida Agreement State Program be found adequate to protect public health and safety, and not compatible with the NRC’s program. The team recommends that the next periodic meeting take place in approximately 2 years and the next IMPEP review take place in approximately 4 years.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Randy Erickson, Region IV	Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Darren Piccirillo, Region III	Team Leader in Training
David Stradinger, North Dakota	Technical Staffing and Training
Robin Muzzalupo, Illinois	Status of the Materials Inspection Program Inspector Accompaniments
Brian Goretzki, Arizona	Technical Quality of Inspections Inspector Accompaniments
Robin Elliott, Region I	Technical Quality of Licensing Actions
Farrah Gaskins, Region I	Legislation, Regulations, and Other Program Elements
James Pate, Louisiana	Sealed Source and Device Evaluation Program
Miranda Ross, NMSS	Observer
Trisha Gupta Sarma, NMSS	Observer

APPENDIX B

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 4723-8
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 2/6/2023	Inspector's initials: BC

Accompaniment No.: 2	License No.: 3111-4
License Type: Gamma Knife	Priority: 2
Inspection Date: 2/7/2023	Inspector's initials: MC

Accompaniment No.: 3	License No.: 0014-6
License Type: Gamma Knife	Priority: 2
Inspection Date: 2/27/2023	Inspector's initials: KM

Accompaniment No.: 4	License No.: 4472-2
License Type: Industrial Radiography	Priority: 1
Inspection Date: 2/28/2023	Inspector's initials: WG

Accompaniment No.: 5	License No.: 2612-2
License Type: Industrial Radiography	Priority: 1
Inspection Date: 3/2/2023	Inspector's initials: MV

Accompaniment No.: 6	License No.: 3157-1
License Type: Medical – Written Directive (WD) required	Priority: 3
Inspection Date: 3/3/2023	Inspector's initials: AC

Accompaniment No.: 7	License No.: 1042-1
License Type: Medical – WD required	Priority: 3
Inspection Date: 4/4/2023	Inspector's initials: RL

Accompaniment No.: 8	License No.: 1099-1
License Type: Medical WD required	Priority: 3
Inspection Date: 4/3/23	Inspector's initials: DG

Accompaniment No.: 9	License No.: 3955-4
License Type: Industrial Radiography	Priority: 1
Inspection Date: 4/4/23	Inspector's initials: NP

Accompaniment No.: 10	License No.: 0993-1
License Type: Medical WD required	Priority: 3
Inspection Date: 4/5/23	Inspector’s initials: EK

Accompaniment No.: 11	License No.: 4239-1
License Type: Medical No WD required	Priority: 5
Inspection Date: 4/6/23	Inspector’s initials: ML

Accompaniment No.: 12	License No.: 4764-5
License Type: High Dose-Rate Afterloader Brachytherapy Device	Priority: 2
Inspection Date: 4/7/23	Inspector’s initials: FN

Accompaniment No.: 13	License No.: 2476-1
License Type: Medical – WD required	Priority: 3
Inspection Date: 4/5/2023	Inspector’s initials: LB

Accompaniment No.: 14	License No.: 4388-1
License Type: Medical – No WD required	Priority: 5
Inspection Date: 4/6/2023	Inspector’s initials: JA

Accompaniment No.: 15	License No.: 4203-4
License Type: Medical – No WD required	Priority: 5
Inspection Date: 4/7/2023	Inspector’s initials: RC

Accompaniment No.: 16	License No.: 4104-1
License Type: Brachytherapy	Priority: 3
Inspection Date: 5/22/2023	Inspector’s initials: CC

Accompaniment No.: 17	License No.: 4430-1
License Type: Pool Irradiator	Priority: 2
Inspection Date: 5/23/2023	Inspector’s initials: AO

Accompaniment No.: 18	License No.: 0387-1
License Type: Medical – WD required	Priority: 3
Inspection Date: 5/24/2023	Inspector’s initials: CH

Accompaniment No.: 19	License No.: 0549-3
License Type: High Dose-Rate Afterloader Brachytherapy Device	Priority: 2
Inspection Date: 5/25/2023	Inspector’s initials: SR

Accompaniment No.: 20	License No.: 3887-4
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 5/26/2023	Inspector’s initials: AH