



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

October 9, 2019

Doug Woodlief, Program Director
Division of Emergency Preparedness
and Community Support
Department of Health
4052 Bald Cypress Way, Bin C21
Tallahassee, FL 32399-1741

Dear Mr. Woodlief:

On September 17, 2019, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Florida Agreement State Program. The MRB found the Florida program adequate to protect public health and safety, but needs improvement, and not compatible with the NRC program.

The enclosed final report documents the IMPEP team's findings and recommendations and summarizes the results of the MRB meeting (Section 5.0). Based on the results of the current IMPEP review, the next full review of the Florida Agreement State Program will take place in approximately 4 years, with two periodic meetings in approximately 1 and 3 years, respectively.

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/

K. Steven West
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosure:
Florida Final IMPEP Report

cc: Sherrie Flaherty, Supervisor
Radioactive Materials Unit
Minnesota Department of Health
Organization of Agreement States
Liaison to the MRB

SUBJECT: FLORIDA FY2019 FINAL INTEGRATED MATERIALS PERFORMANCE
 EVALUATION PROGRAM DATED: October 9, 2019

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE FLORIDA PROGRAM

JUNE 24-28, 2019

FINAL 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 during the period of June 24-28, 2019, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Arizona and the Commonwealth of Virginia.

Based on the results of this review, Florida's performance was found satisfactory for five indicators: Technical Staffing and Training, Status of Materials Program, Technical Quality of Licensing, Technical Quality of Incidents and Allegations, and Sealed Source and Device Evaluation; satisfactory, but needs improvement for Technical Quality of Inspections; and unsatisfactory for the Compatibility Requirements performance indicator.

There were no recommendations for the team to consider and the team made three recommendations (see Section 5.0).

The team determined that the declining performance was mainly due to staff with institutional knowledge leaving the program, and training issues. Although, Florida hired staff in a timely manner, the lack of knowledge transfer affected the areas of inspections, reporting of incidents to the Nuclear Material Events Database, and the promulgation to regulations required for compatibility.

Accordingly, the team recommended, and the MRB agreed that Florida be found adequate to protect public health and safety, but needs improvement and not compatible with the NRC's program. The team recommended that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years. The MRB agreed with the team that the next IMPEP review take place in 4 years but determined that two periodic meetings should be conducted in approximately 1 and 3 years, respectively. Based on the findings at the time of the review, the team also recommended that Florida initiate a period of Monitoring. However, the MRB took into consideration actions taken by the Program subsequent to the review, which the team was able to confirm, and determined not to implement a period of Monitoring.

1.0 INTRODUCTION

The Florida Agreement State Program (Florida) review was conducted during the period of June 24-28, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the State of Arizona, and the Commonwealth of Virginia. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of March 14, 2015, to June 28, 2019, 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 the applicable non-common performance indicators was sent to Florida on November 14, 2018. Florida provided its response to the questionnaire on June 11, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using Accession Number ML19169A094.

A draft of this report was issued to Florida on July 21, 2019, for factual comment (ADAMS Accession Number ML19210C558). Florida responded to the draft report by letter dated August 26, 2019, from Doug Woodlief, Division Director, Division of Emergency Preparedness and Community Support, (ADAMS Accession Number ML19241A323). The Management Review Board (MRB) convened on September 17, 2019, to discuss the team's findings and recommendation.

Florida is administered by the Bureau of Radiation Control (the Bureau) which is located within the Division of Emergency Preparedness and Community Support (the Division). The Division is part of the Department of Health (the Department). Organization charts for Florida are available in ADAMS using Accession Number ML19169A089.

At the time of the review, Florida regulated 1,636 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials 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 the applicable non-common performance indicators and made a preliminary assessment of Florida's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on March 13, 2015. The final report is available in ADAMS using Accession Number ML15159B035. The results of the review are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

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

Compatibility Requirements: Satisfactory
Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

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

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

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

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated 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.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed, or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

Florida is comprised of 59 staff members which contribute 30 Full Time Equivalent (FTE) for the radioactive materials program when fully staffed. Currently, there are four vacancies. One of the vacancies has been unfilled for 211 days. Two lead candidates declined to accept the position and another candidate was selected and resigned after a few weeks for a better paying position. During the review period, 18 staff members left the program and 11 staff members were hired. Eight employees left the program to retire, eight employees left for better paying jobs, and the other two left for personal reasons. The positions were vacant from 60 to 120 days with the majority of the positions vacant for closer to 60 days. Florida assigned resources from other areas of the Bureau to supplement staffing demands. Senior level positions were filled in a timely manner. However, the loss of the institutional knowledge from these senior level positions had impacts on Florida's performance. The staffing impact due to the loss of institutional knowledge is further described in Sections 3.5 and 4.1. Additional details about staffing in the Sealed Source and Device Evaluation program is discussed in Section 4.2.

Florida has a training and qualification program that is compatible with the NRC's IMC 1248. Eight of the 11 employees hired during the review period had a bachelor's degree in science and the other three had associate degrees in nuclear medicine or radiation technology. Florida uses a combination of in-house training, NRC sponsored training, and on the job training for its license reviewers and inspectors. Deficiencies in certain parts of Florida's in-house training related to enhanced materials security and sealed sources in medical therapy are discussed in Section 3.3. 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 recommended that Florida's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

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

3.2 Status of Materials Inspection Program

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

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated 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 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

Florida performed 1,275 Priority 1, 2, 3, and 68 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 more frequent for similar license types in IMC 2800.

A sampling of 55 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. For each year of the review period, Florida performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

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

d. MRB Decision

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

3.3 Technical Quality of Inspections

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

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated 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 consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors involved in 62 materials inspections conducted during the review period. The casework reviewed included inspections conducted by 30 of Florida's inspectors and covered medical, industrial, commercial, academic, research, and service licenses.

Florida's communication of inspection findings with its licensees was found to be exemplary. For instance, Notice of Violations are expeditiously prepared, usually within a couple of days, and clearly identify areas of concern.

During the inspection accompaniments, the team observed inspectors review previously identified open items and violations, and addressed them accordingly (e.g., closing an open item or violation). The inspector verbally communicated to the licensee the status of the open item or violation at the end of the inspection. However, the outcome was not documented and formally submitted to the licensee.

Except for 2017, supervisory accompaniments were conducted annually for all inspectors. Most of the 2017 supervisory accompaniments were not completed. This was due to a shortage of inspector supervisors, with the Miami supervisor position vacant and coverage being provided from other field offices. All accompaniments for 2018 were conducted as required. No performance issues were identified related to the missed accompaniments.

During the review, the team noted that there were inconsistencies in the communication between license reviewers and inspectors. Florida has a mechanism in place for license reviewers to communicate the need for a pre-licensing site visit or an on-site security review to the inspectors. Florida also has a mechanism in place for inspectors to relay required licensing actions to license reviewers. However, in one instance, the team identified an inspection where the inspector determined the need for a license amendment and this information did not get communicated to the licensing staff for follow-up. In addition, the licensee did not submit a request to trigger the license amendment. A licensing action was initiated after it was identified by the team.

An adequate supply of calibrated survey instruments is available to support the program and are calibrated at the required frequency. All field offices have access to calibrated instruments.

Team members accompanied 14 program inspectors in April and May of 2019. The inspector accompaniments are identified in Appendix B. Inspections of licensed activities, in many areas, adequately focused on health, safety, and security. However, the team identified several instances of gaps in knowledge for certain modalities.

The team identified deficiencies in 5 out of the 14 inspection accompaniments in the areas of enhanced security requirements, and for safety requirements in therapy facilities using a high dose-rate remote afterloader (HDR) and/or gamma stereotactic radiosurgery device (GSR). For instance, during the security portion of a GSR inspection, the inspector did not adequately identify issues with the licensee's implementation of both the access authorization program and the security program requirements. Moreover, a review of the previous inspection report indicated that the security program requirement deficiencies were also not identified by the previous inspector. The team also observed that inspectors had knowledge gaps regarding identification of security zones, verification of alarm systems, and the requirements for licensees to detect unauthorized removal of radioactive material from the security zone. In the area of health and safety, the team observed that the adequacy of spot checks, full calibration tests, written directive delivery (e.g., treatment plans), and shielding with the source exposed (e.g., at the console, at the interlock door) was not evaluated by some of the inspectors that accompanied. Discussions with additional inspection staff and a review of inspector records confirmed these weaknesses. In addition, the team identified a regulation that was not being evaluated by the inspectors because it was not added to the checklist used by the inspectors to perform security related inspections. Florida updated the security checklist as soon as the team made them aware of the omission.

The team determined that the root cause for the deficiencies identified in the accompaniments were due to insufficient training. In discussions with the accompanied inspectors, several inspectors stated their in-house training did not address the evaluation of the adequacy of the spot checks and full calibration test. The team noted that during the review period, Florida staff could not travel out of state and therefore, were unable to attend the NRC course for medical therapy where full calibration tests and spot-checks are discussed. However, the ban on out of state travel has been lifted and staff can now attend NRC training. The two inspectors observed with knowledge deficiencies in the security area had received NRC training on security inspections. To address the concerns noted in the accompaniments, Florida immediately sent two inspectors to the NRC security course and has plans to send more. In addition, Florida has reached out to a licensee to support additional training for inspectors and license reviewers for HDR/GSR spot-checks, full calibrations, shielding, and surveys. Florida expects this training to occur in September 2019.

c. Evaluation

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

- Inspections of certain licensed activities (e.g., security related, HDR, and GSR) did not fully focus on health, safety, and security.

- Inspections address previously identified open items and violations but are not documented.
- Procedures to formally provide feedback information to license reviewers are not always followed.

During the inspection accompaniments, the team identified knowledge gaps involving enhanced security (e.g., Part 37) and the use of sealed sources in medical therapy (e.g., HDR and GSR) inspections. Specifically, for enhanced security requirements, knowledge gaps were present in areas such as adequately assessing the security zone, licensee's means to detect unauthorized removal of radioactive material from the security zone (e.g., immediate vs weekly checks), the verification of security systems, and the access authorization program.

As it pertains to use of sealed sources in medical therapy inspections, the inspectors did not verify the adequacy of calibrations, spot-checks, security system operation, and shielding through discussions with cognizant licensee representatives, and observation of tests. These weaknesses, identified during the inspection accompaniments, could result in the Florida inspectors overlooking the following health and safety issues: (1) inoperable safety and security systems such as interlocks, warning lights, and alarm systems; (2) medical events; and/or (3) inadequate shielding when medical therapy source(s) are in use.

After the inspection accompaniment debriefs and prior to the on-site review, Florida immediately began addressing some of the concerns identified by the team. For instance, Florida management has taken or has planned the following corrective actions: (1) registered two inspectors in the upcoming NRC security class and is evaluating how to conduct additional training; (2) updated the inspection checklist to include assessment of the licensee's means to detect unauthorized removal of radioactive material from the security zone; (3) arranged training for inspectors with a licensee to demonstrate medical therapy (HDR/GSR) tests and checks (e.g., calibration and spot checks), including describing acceptance criteria and surveys conducted when new source(s) arrive; and (4) submitted names to the NRC for inspectors to be included in the NRC medical therapy course. Subsequent to the on-site review, Florida has continued to pursue additional training opportunities for staff to address security and HDR/GSR oversight with several training sessions planned for September 2019. The team determined that these corrective actions were adequate and addressed the concerns identified by the team.

Although, verbally communicated to the licensee during inspection exit meetings, the status of an open item or violation portion of the inspection was not documented and formally submitted to the licensee. Based on the team's findings, the team made a recommendation: the team recommended that the outcome of previously identified open items and violations be documented and communicated formally to the licensee.

The team identified that there are deficiencies in following the procedure currently in place for communication between the inspectors and license reviewers for instances where inspectors identify violations that would require a license amendment. For instance, if inspectors fail to document a licensing issue or do not document the

licensing issue in Section C of the Checklist, the issue may be overlooked. The lack of communication between inspector and license reviewers where a licensing action is necessary as a result of an inspection finding can lead to: (1) unlicensed material continuing to be used; (2) unlicensed personnel continuing to perform licensed activities; and (3) unlicensed facilities continuing to be used. In its response to the draft report, Florida management committed to send a reminder to inspection staff to correctly document identified licensing actions in Section C of the Checklist.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Florida's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory, but needs improvement.

d. MRB Decision

Overall, the MRB found Florida's performance with respect to this indicator, satisfactory, but needs improvement. The MRB also agreed with the team's recommendation that the outcome of previously identified inspection open items and violations be documented and communicated formally to the licensee.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the 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., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).

- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Florida performed 6,264 radioactive materials licensing actions. The team evaluated 34 of those licensing actions. The licensing actions selected for review included 5 new applications, 19 amendments, 7 renewals, and 3 terminations. The team evaluated casework which included the following license types and actions: academic and medical broad scope, medical diagnostic and therapy, mobile medical services, industrial radiography, nuclear pharmacy, gauges, panoramic and self-shielded irradiators, service providers, waste processors, and veterinary science. The casework sample represented work from seven license reviewers. The team found that most licensing actions were thorough, complete, consistent, and of acceptable technical quality, with health, safety, and security issues properly addressed. Licensing actions are reviewed by two license reviewers. The team identified a small number of actions that were not thoroughly reviewed. In one instance, a standardized procedure applicable to all nuclides was accepted for use in a research and development facility for a lab using alpha material. In this case, the license reviewer should have requested procedures specifically for the use of the alpha material.

However, after the team inspection accompaniments, Florida recommended, and the licensee implemented a number of actions to address this issue, including a bioassay program, and contamination survey protocol. In another example, a new license application for a diagnostic medical clinic did not contain several of the commitments needed to complete the action, yet the license was issued. These commitments impacted leak testing, inventory control, exposure evaluations, and other aspects of the licensee's radiation safety program; however, this is of low safety and security concern because these commitments are in the regulation. In another instance, a new license application for a portable gauge licensee contained a training certificate for the radiation safety officer (RSO) that had not been signed. The team determined that these were isolated instances, and Florida addressed the issues identified by the team during the review.

The team identified that Florida was using an outdated Pre-Licensing Guidance (PLG) and Risk Significant Radioactive Material (RSRM) Checklist, and regulatory guidance and checklists developed for the applicable Consolidated Guidance About Materials Licenses (NUREG-1556). In addition, the team determined that the PLG and RSRM Checklist were not being implemented correctly. The team did not identify any immediate health, safety, or security concern because Florida performs a pre-licensing site visit for all new applicants, regardless of whether they are a known or unknown entity, as well as require the applicant's or licensee's facility be fully in compliance with all security requirements prior to issuing the license.

Florida updated the PLG and the RSRM Checklist while the team was onsite. The team considered the outdated guidance as a compatibility issue, and as such, will be discussed further in Section 4.1 of the report.

In reviewing the financial assurance records and discussion with staff, the team noted that decommissioning funding plans were maintained for the majority of licensees, as applicable. However, universities that possess significant quantities of unsealed radioactive materials on their license did not have decommissioning funding plans. All licensees who would be required to have a decommissioning funding plan based on possession limit are required to submit a cost estimate every 3 years, even if they are not required to provide a financial assurance instrument as was the case for the universities. The team recognized that the funding for decommissioning would be provided by the State government. Therefore, the team determined that this was not a health and safety issue, involved a narrow set of licensees, and noted it as a documentation issue.

Although Florida has a formal training qualification journal, at the time of the on-site review the State was not able to provide documentation of training to determine the level of signature authority for the license reviewers. The team interviewed staff and determined that license reviewers with signature authority were knowledgeable and received training for the licensing actions they were authorized to sign and issue.

All licenses that are subject to Title 10 *Code of Federal Regulations* (CFR) Part 37 requirements are properly marked, and compliance with the 10 CFR Part 37 requirements was addressed by adding a license condition. This was administratively completed during this review period and all reviews of applicable licenses confirmed this action. In addition, all files containing sensitive records remain locked in a file cabinet in the records room. Financial assurance records were also properly secured.

c. Evaluation

The team determined that, except as noted below, during the review period Florida met the performance indicator objectives listed in Section 3.4.a.

- Essential elements of license applications were not submitted and elements are not consistent with current regulatory guidance (e.g., financial assurance).
- There was incomplete documentation to show that the license reviewers had the proper signature authority for the cases they review independently.

The team identified licensing actions where the license was issued with incomplete information, and instances where additional information should have been requested by the reviewer in order to complete the action. Licensing actions requiring further action from the license reviewer in order for the review to be adequate were corrected during the on-site review.

The team noted that Florida was not requiring decommissioning funding plans for a narrow set of licensees that met the regulatory requirement for the submittal of a decommissioning funding plan. Specifically, the team identified that Florida was not

requiring State universities in possession of significant quantities of unsealed radioactive materials to develop a decommissioning funding plan. During the on-site review, the team recommended that Florida review all State institution licenses that possess significant quantities of unsealed radioactive material to determine if any would be required to have a decommissioning funding plan (DFP) and ensure those documents are submitted as required. In response to the draft report, Florida completed an internal audit of all exempt government agencies and identified two licensees that require a DFP. The State has requested those licensees provide DFP and are awaiting response. Therefore, the team is no longer making the formal recommendation.

Florida currently has written training qualifications for license reviewer with a separate section in the journal that allows tracking of the license reviewer's training. Based on the team's findings, the team made a recommendation: the team recommended that the Program consistently document the training completed by license reviewers, including the license types for which each reviewer has obtained signature authority. Following the on-site review, Florida provided training qualification journal signature pages for several license reviewers. However, the team identified gaps in the documentation regarding staff training. For example, senior reviewers had incomplete journals even though Florida stated that these individuals have signature authority for all licensing modalities. The team noted that the most recently hired staff member had the training qualification documentation up to date. In addition, it was not clear if the training journal served as the documentation for granting the individual's signature authority.

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

d. MRB Decision

Overall, the MRB found Florida's performance with respect to this indicator, satisfactory. The MRB also agreed with the team's recommendation that Florida consistently document the training completed by license reviewers, including the license types for which each reviewer has obtained signature authority.

3.5 Technical Quality of Incident and Allegation Activities

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

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities",

and evaluated Florida'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.
- 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).
- 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, 816 incidents were reported to Florida, with 51 of the incidents being reported to the NRC. The team evaluated 17 radioactive materials incidents which included four lost/stolen radioactive materials, one abandonment, three potential overexposures, three medical events, three damaged equipment, one leaking source, one transportation, and one safety malfunction. Florida dispatched inspectors for on-site follow-up for 12 of the cases reviewed.

The team identified six instances where Florida did not report incidents to NMED in a timely fashion. While the team was onsite, Florida was evaluating its event database to identify any events that were inadvertently not reported to the NMED and NRC Headquarters Operation Officer, as appropriate.

During the review period, 22 allegations were received by Florida. Seven of the 22 were referred to Florida by the NRC. The team evaluated 15 allegations, including all 7 allegations that the NRC referred to the State, during the review period. The team determined that concerned individuals' (CI) identities were protected. In addition, the findings of the investigation were communicated by letter or phone call to the CI unless the CI decided to remain anonymous.

The team found that responses to incidents and allegations were appropriate, thorough, and timely, commensurate with the potential health and safety significance of the incident or allegation. Florida promptly conducted on-site inspections for most cases, and the cases without an on-site inspection were handled appropriately. Incidents and allegations were adequately investigated to determine cause, validity of complaints, and appropriate corrective actions.

c. Evaluation

The team determined that, except as noted below, during the review period Florida met the performance indicator objectives listed in Section 3.5.a.

- Incidents were not reported to the NMED.

The team attributed the lack of reporting of incidents to NMED to staff turnover. During the review period, management staff that performed the reporting to NMED left the program. The team also noted that the non-reporting of events occurred primarily at the beginning of the review period. Currently, Florida has centralized the NMED reporting process to the Orlando office. The team noted incidents were more consistently reported to NMED since the centralization of the process in 2016.

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

d. MRB Decision

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery Program. The NRC's Agreement with Florida retains regulatory authority for uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. 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. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," 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. The Florida Agreement State Program's current effective statutory authority is contained in the Florida Radiation Protection Act in Title XXIX, Chapter 404 of the State of Florida Statutes. Florida's rulemaking process is governed by the Administrative Act in Title X, Chapter 120, of the State of Florida Statutes. The Department, is designated as the State's radiation control agency. 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 Florida. The team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, between 2015 and 2018, 10 amendments became due for Agreement State adoption. Florida adopted the requirements equivalent to 10 CFR Part

37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," timely by license condition. On June 27, 2019, (during the last week of this review period), Florida submitted four proposed amendments to the NRC for a compatibility review (the last 4 in the list below). The following nine amendments are overdue for adoption by Florida at the time of this review:

- "Decommissioning Planning," 10 CFR parts 20, 30, 40, and 70 amendment (76 FR 35512), that was due for Agreement State adoption by December 17, 2015.
- "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), that was due for Agreement State adoption by August 10, 2015.
- "Technical Corrections," 10 CFR Parts 30, 34, 40, and 71 amendment (77 FR 39899), that was due for Agreement State adoption by August 6, 2015.
- "Requirements for Distribution of Byproduct Material," 10 CFR Parts 30, 31, 32, 40, and 70 amendment (77 FR 43666), that was due for Agreement State adoption by October 23, 2015.
- "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions," 10 CFR Parts 30, 40, and 70 (78 FR 32310), that was due for Agreement State adoption by August 27, 2016.
- "Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments," 10 CFR Part 70 amendment (79 FR 57721, 80 FR 143), that was due for Agreement State adoption by January 26, 2018.
- "Safeguards Information – Modified Handling Categorization, Change for Materials Facilities," 10 CFR Parts 30, 37, 73, and 150 amendment (79 FR 58664, 80 FR 3865), that was due for Agreement State adoption by January 28, 2018.
- "Miscellaneous Corrections," 10 CFR Parts 37 and 40 amendment (80 FR 45841), that was due for Agreement State adoption by September 2, 2018.
- "Miscellaneous Corrections," 10 CFR Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150 amendment (80 FR 74974), that was due for Agreement State adoption by December 31, 2018.

The following nine amendments have been adopted by Florida; however, these amendments have 30 outstanding comments identified during the NRC review that need to be addressed. Those comments, which included safety significant issues (e.g., cross jurisdictional implications), remain unresolved since 2015:

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendment (62 FR 28947) that was due for Agreement State adoption by June 27, 2000.

- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, 32 amendment (65 FR 79162), that was due for Agreement State adoption by February 16, 2004 (10 CFR Part 32 only).
- “Medical Use of Byproduct Material,” 10 CFR 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State adoption October 24, 2005.
- “Medical Use of Byproduct Material – Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926), that was due for adoption April 29, 2008.
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005), that was due for Agreement State adoption March 27, 2009. (10 CFR Part 32 and 35 only).
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that was due for Agreement State adoption by December 17, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 33, 35, 61, and 150 amendment (72 FR 55864), that was due for Agreement State adoption by November 30, 2010.
- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Parts 35 amendment (74 FR 33901), that was due for Agreement State adoption by September 28, 2012.
- “Physical Protection of Byproduct Material,” 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, and 71 (78 FR 16922) that was due for Agreement State adoption by March 19, 2016. **Note: Florida submitted a License Condition for the Part 37 requirements only.

In addition, during the review period, Florida adopted 10 CFR Part 71 regulations by reference. However, these regulations were not submitted to the NRC for a compatibility review. During the on-site review, the team identified several Compatibility Category NRC regulations in Florida’s compatible 10 CFR part 71 regulations that should not have been adopted by Florida (i.e., regulations that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act or provisions of 10 CFR regulations). The team determined that at the beginning of the review period, there were two individuals that collaborated on preparing the regulation packages. During the review period, the more experienced of the two individuals, who provided guidance on preparing the regulation packages for state adoption and submittal to the NRC, left the program. As a result, the other individual did not prioritize the preparation of regulation packages due to emerging work and lack of oversight.

Other program elements (e.g., licensing guidance documents) were not adopted at the 6-month interval. Specifically, the PLG and RSRM Checklist were not adopted timely. The team identified that Florida was using an outdated PLG and RSRM Checklist. While the team was onsite, Florida updated the PLG and RSRM Checklist with the most recent version. In addition, license reviewers use checklist and regulatory guidance developed from NRC's NUREG 1556 series when reviewing licensing actions. Discussions with staff indicated that the information available in these documents were condensed and formatted into more user-friendly checklists. However, most of the utilized procedures have not been updated to the most recent version of the NUREG series.

c. Evaluation

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

- The Agreement State program does 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 were not adopted by the Agreement State for purposes of compatibility or health and safety within 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 not been adopted and implemented within 6 months of NRC designation.

Florida did not adopt final regulations for nine NRC amendments within the required 3-year frequency and all nine remain overdue for adoption at the time of this review. In addition, 30 regulation review comments that were provided to Florida by the NRC staff in 2015, remain unresolved. These comments address regulations with cross jurisdictional implications (e.g., 10 CFR Part 35 regulations) and are considered significant issues. In addition, Florida has incorporated 10 CFR Part 71 into its regulations by reference. This regulation package was not submitted by Florida to the NRC for review, and the incorporation by reference, included regulations that are designated Compatibility Category NRC. During the on-site review, Florida initiated conversations with NRC's regulation specialist to determine the path forward. Based on the team's findings, the team made a recommendation: 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. In its response to the draft report, Florida stated that a knowledge management program has been instituted as part of the monthly management meetings. Florida further stated, that this will allow for a continual review of regulations and comments as well as status updates and tracking for appropriate staff.

The team identified licensing guidance documents that were not adopted and implemented within 6 months of NRC designation. Florida updated two program elements (e.g., PLG and RSRM Checklist) while the team was onsite.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Florida's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

d. MRB Decision

Overall, the MRB found Florida's performance with respect to this indicator, unsatisfactory. The MRB also agreed with the team's recommendation 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.

4.2 Sealed Source and Device (SS&D) Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for teams. Under this guidance, three sub-elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated 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 three staff qualified to perform SS&D reviews. Only two of those staff were involved in SS&D reviews during the review period. One staff member associated with the SS&D program left and no staff members were hired during the review period. Currently, there are no vacancies.

Florida's SS&D qualification journal is listed as an additional materials qualification within the inspector's qualification journal. SS&D staff stated that their qualifications included taking NRC courses, including the NRC SS&D Workshop, in-house casework, and on the job training. Staff also stated that they utilize the SS&D workshop binder and other references, including NRC guidance and industry standards, to complete their reviews.

During the on-site review, the team identified that the program did not keep physical or electronic evidence that SS&D reviewers had attained signature authority. Although the State did not have a formal and detailed SS&D qualification journal, staff interviews indicated that Florida was implementing a qualification program which met the intent of, and was equivalent to, NRC training requirements listed in the NRC's IMC 1248, Appendix D. In response to the team's report, Florida has formalized and revised its SS&D qualification journal to include a review of applicable State and NRC regulations, NRC guidance and applicable generic communications, and review of casework. Florida also added sections to record attendance to the NRC SS&D Workshop and to record fulfillment of all requirements to obtain signature authority.

Technical Quality of the Product Evaluation

Florida has five SS&D licensees. The team evaluated all nine of the SS&D actions processed during the review period. Florida currently has no open SS&D actions. The actions reviewed included eight amendments and one SS&D transfer for SS&D licensees in the commercial/industrial and medical areas. Three of the amendments were SS&D license renewals, which are administrative in nature, and did not require

changes to the SS&D registrations. Amendments included changes to source quantities and source activities for different devices, changes to licensee name and address, and registration of a source as part of a device. SS&D evaluations were thorough and of acceptable technical quality and addressed product integrity under normal and likely accident conditions. Health and safety issues were properly addressed, and registrations clearly summarized the product evaluation.

Florida SS&D evaluators use the NUREG-1556, Volume 3 checklist for all SS&D actions to ensure that all health and safety aspects have been adequately addressed. The checklists are signed and dated by the lead reviewer and a concurrence reviewer. The concurrence review provides an additional “quality check” to the safety evaluation process. Florida registered a source as part of the device when the source was not previously registered. Florida ensured that the registration certificate stated that the source was only approved for use as part of that device.

Florida generates a SS&D license for every SS&D registration certificate to allow the State to recover fees associated to safety evaluations of sources and devices and to enforce commitments. Possession and/or distribution license(s) are listed in the SS&D license. The SS&D license contains the references listed in the SS&D registration certificate. Additionally, the possession and/or distribution license(s) associated with the SS&D is/are listed above the signature block of every SS&D. The SS&D license is amended every time changes are made to the SS&D registration certificate.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated 23 incidents involving Florida SS&D registered products during the review period. None of the incidents were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered by Florida.

c. Evaluation

The team determined that, during the review period, Florida met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommended that Florida’s performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team’s recommendation and found Florida’s performance with respect to this indicator, 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

Low-Level Radioactive Waste 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

As noted in Sections 3.0 and 4.0 above, Florida's performance was found to be satisfactory for five out of seven performance indicators reviewed; satisfactory, but needs improvement, for the indicator, Technical Quality of Inspection; and unsatisfactory for the performance indicator Compatibility Requirements. There were no recommendations for the team to consider and the team made three recommendations.

Accordingly, the team recommended, and the MRB agreed that Florida be found adequate to protect public health and safety, but needs improvement and not compatible with the NRC's program. The team recommended that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years. The MRB agreed with the team that the next IMPEP review take place in 4 years but determined that two periodic meetings should be conducted in approximately 1 and 3 years, respectively. Based on the findings at the time of the review, the team also recommended that Florida initiate a period of Monitoring. However, the MRB took into consideration actions taken by the Program subsequent to the review, which the team was able to confirm, and determined not to implement a period of Monitoring.

Below are the team's recommendations, as mentioned in the report, for evaluation and implementation by Florida:

1. The team recommends that the outcome of previously identified inspection open items and violations be documented and communicated formally to the licensee. (Section 3.3)
2. The team recommends that the Program consistently document the training completed by license reviewers, including the license types for which each reviewer has obtained signature authority. (Section 3.4)
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. (Section 4.1)

LIST OF APPENDICES

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| Appendix A | IMPEP Review Team Members |
| Appendix B | Inspector Accompaniments |

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

| Name | Areas of Responsibility |
|---|---|
| Lizette Roldan-Otero, NMSS | Team Leader Compatibility Requirements Inspector Accompaniments |
| John Miller, Region I | Technical Staffing and Training Status of Materials Inspection Program Inspector Accompaniments |
| Penny Lanzisera, Region I | Technical Quality of Inspections Inspector Accompaniments |
| Jennifer Dalzell, Region III | Technical Quality of Licensing |
| Celimar Valentin-Rodriguez, NMSS | Sealed Source and Device Evaluation Program |
| Beth Schilke, Commonwealth of Virginia | Technical Quality of Licensing |
| Brian Goretzki, State of Arizona | Technical Quality of Incident and Allegation Activities |

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

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|---|----------------------|
| Accompaniment No.: 1 | License No.: 2825-2 |
| License Type: Gamma Stereotactic Radiosurgery | Priority: 2 |
| Inspection Date: 04/15/19 | Inspector: NP |
| <p>Comment: The inspector demonstrated deficiencies and lack of knowledge during the security portion of the inspection. The inspector did not adequately identify issues with the licensee's implementation of both the access authorization program, and the security program requirements.</p> | |
| Accompaniment No.: 2 | License No.: 2213-4 |
| License Type: Mobile Medical | Priority: 3 |
| Inspection Date: 04/15/19 | Inspector: WG |
| Accompaniment No.: 3 | License No.: 4195-1 |
| License Type: Portable Gauge | Priority: 5 |
| Inspection Date: 04/15/19 | Inspector: AC |
| Accompaniment No.: 4 | License No.: 0984-1 |
| License Type: <i>Medical Institution WD required</i> | Priority: 3 |
| Inspection Date: 04/16/19 | Inspector: KC |
| Accompaniment No.: 5 | License No.: 0356-1 |
| License Type: Academic Broadscope (Part 37 only) | Priority: 3 |
| Inspection Date: 04/16/19 | Inspector: KM |
| Accompaniment No.: 6 | License No.: 1099-1 |
| License Type: <i>Medical Institution WD required</i> | Priority: 3 |
| Inspection Date: 04/17/19 | Inspector: DG |
| Accompaniment No.: 7 | License No.: 0032-10 |
| License Type: Academic Broad Scope | Priority: 2 |
| Inspection Date: 04/17-18/19 | Inspector: BC |
| Accompaniment No.: 8 | License No.: 0555-2 |
| License Type: <i>HDR</i> | Priority: 2 |
| Inspection Date: 04/18/19 | Inspector: ML |
| Accompaniment No.: 9 | License No.: 3955-2 |
| License Type: <i>Industrial Radiography</i> | Priority: 1 |
| Inspection Date: 04/19/19 | Inspector: RC |
| <p>Comment: The inspector demonstrated deficiencies and lack of knowledge of certain aspects of the security portion of the inspection. Specifically, the inspector was unaware of the weekly verification checks required by regulation, and improperly defined the security zone.</p> | |

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| Accompaniment No.: 10 | License No.: 3111-4 |
| License Type: Gamma stereotactic Radiosurgery | Priority: 2 |
| Inspection Date: 04/19/19 | Inspector: MC |
| <p>Comment: The inspection accompaniment was only for the health and safety portion. The inspector did not address several attributes critical to health and safety, including Spot Checks (e.g., door interlock, etc.), surveys to verify proper shielding when used, annual drills, presence of emergency response equipment, or full calibrations.</p> | |

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|-----------------------------|---------------------|
| Accompaniment No.: 11 | License No.: 3453-3 |
| License Type: Radiopharmacy | Priority: 3 |
| Inspection Date: 04/29/19 | Inspector: GH |

| | |
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| Accompaniment No.: 12 | License No.: 1797-2 |
| License Type: HDR | Priority: 2 |
| Inspection Date: 04/30/19 | Inspector: JL |
| <p>Comment: Inspector did not review performance of Spot Checks, Full Calibrations, or Treatment Planning (e.g., to verify administration of WD).</p> | |

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|---|---------------------|
| Accompaniment No.: 13 | License No.: 2553-1 |
| License Type: Medical, Private Practice | Priority: 5 |
| Inspection Date: 05/01/19 | Inspector: JA |

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|--|---------------------|
| Accompaniment No.: 14 | License No.: 1739-3 |
| License Type: HDR | Priority: 2 |
| Inspection Date: 05/02/19 | Inspector: AO |
| <p>Comment: Inspector did not review performance of Spot Checks, Full Calibrations, or Treatment Planning (e.g., to verify administration of WD).</p> | |