



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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July 30, 2019

MEMORANDUM TO: 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

Mary B. Spencer, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

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

Mark R. Shaffer, Deputy Regional Administrator
Region IV

FROM: Paul Michalak, Chief */RA/*
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REVIEW OF THE STATE OF ALABAMA

This memorandum transmits to the Management Review Board (MRB) the proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of the State of Alabama Agreement State Program. The review was conducted by a team of U.S. Nuclear Regulatory Commission (NRC) and Agreement State technical staff during the period of May 20-24, 2019. The team's preliminary findings were discussed with representatives of the State of Alabama on the last day of the review. The team issued a draft report to Alabama on June 20, 2019, for factual comment. Alabama responded to the draft report by letter dated July 12, 2019, from David A. Turberville, Director, Office of Radiation Control (Enclosure 2). The team addressed the comments, as appropriate, in the report.

CONTACT: Robert K. Johnson, NMSS/MSST
(301) 415-7314

Overall, the team is recommending that the Alabama Agreement State Program's performance be found satisfactory for all performance indicators reviewed. Accordingly, the team recommends that the Alabama Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team also recommends that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

The MRB meeting to consider Alabama's report is scheduled for **Tuesday, August 6, 2019, from 1:00 p.m. to 4:00 p.m. ET, OWFN-17B04**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 2).

Enclosures:

1. Alabama Proposed Final Report
2. Alabama's Response to Draft IMPEP Report
3. Agenda for MRB Meeting

cc: David J. Allard, CHP, Director
Bureau of Radiation Protection
Department of Environmental Protection
Commonwealth of Pennsylvania
Organization of Agreement States
Liaison to the MRB

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE STATE OF ALABAMA DATED July 30, 2019

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OFFICE	MSST:TL	SALB:PM	SALB:LA	SALB:BC
NAME	LRakovan	RJohnson	KMeyer	PMichalak
DATE	07/16/19	07/22/19	07/23/19	07/30/19

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE ALABAMA PROGRAM

MAY 20–24, 2019

PROPOSED FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

The results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Alabama Agreement State Program (Alabama) are contained in this report. The review was conducted during the period of May 20–24, 2019.

Based on the results of this review, Alabama's performance was found satisfactory for all applicable indicators. The team determined that the recommendation from the 2015 IMPEP review should be closed (see Section 2.0) and made one new recommendation (see Section 3.3).

Accordingly, the team recommends that Alabama be found adequate to protect public health and safety and compatible with the NRC's program. The team recommends that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

1.0 INTRODUCTION

This report presents the results of the review of the Alabama Agreement State Program (Alabama). The review was conducted during the period of May 20–24, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New Jersey. 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 May 9, 2015, to May 24, 2019, were discussed with Alabama 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 indicator was sent to Alabama on January 30, 2019. Alabama provided its response to the questionnaire on April 1, 2019, by email from David Turberville, Director, Office of Radiation Control. A copy of the questionnaire response is available in the NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19114A039.

Alabama is administered by the Office of Radiation Control (the Office) which is in the Alabama Department of Public Health (the Department). Organization charts for Alabama are available in ADAMS using the Accession Number ML19114A043.

At the time of the review, Alabama regulated 371 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 Alabama.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on May 8, 2015. The final report is available in ADAMS using the Accession Number ML15196A321. The results of the review and the status of the associated recommendation are as follows:

Technical Staffing and Training: Satisfactory, but Needs Improvement

The team recommended that Alabama: (1) Create a formal training qualification program equivalent to Inspection Manual Chapter (IMC) 1248 and apply it to staff going through the qualification process, (2) Require 24 hours of refresher training every 2 years for currently qualified staff, and (3) Re-evaluate the qualifications of the two newest inspection staff to determine if additional training is needed.

Status: The Office revised Office Policy 417, "Training Program for Radioactive Materials Staff," to make it equivalent to the NRC's IMC 1248. The current version is dated July 9, 2017. Once the Radiation Physicist Supervisor decides the inspector is ready, a memo is sent to the Office Director for a request to have the individual accompanied for approval to perform a specified type of inspection independently. These accompaniments are performed by either the Director or Assistant Director. Additionally, Office Policy 417 specifies that all qualified staff are expected to maintain their qualification by completing 24 hours of refresher training every 24 months. Lastly, the Office restarted the qualification process for the two inspectors noted as part of the recommendation using the revised Office Policy 417.

The team considers this recommendation should be closed.

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

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 Alabama'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 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

Alabama is comprised of 10 staff members, which is equivalent to 5.5 full-time equivalents (FTE) for the radioactive materials program when fully staffed. The Office oversees the regulation of both radioactive materials and radiation producing machines, and all staff with duties associated with radioactive materials also have duties associated with these other matters. The team determined that the Office has sufficient staff to carry out the responsibilities of the Agreement State Program and a good balance between licensing and inspection staffing levels.

At the time of the review, there was one vacancy related to radioactive materials inspection. The vacancy was created due to a series of promotions that began when the former Office Director retired in September 2018. At the time of the review, the current Office Director was taking steps to fill the vacant position. During the review period, one staff member left and four staff members were hired. As the FTE dedicated to the Agreement State Program increased during the review period, any vacancies had minimal impact on performance. At the time of the review, management and staff were compensating for the vacancy by distributing the workload to other staff members with no apparent impact on performance.

As noted in Section 2.0, the Office now has a training and qualification manual compatible with the NRC's IMC 1248. The training program is managed by the Assistant Office Director who sets personal training goals for staff, as well as documents and discusses progress with staff. The Assistant Office Director also determines when staff are sufficiently trained to work independently while performing licensing and inspection-related activities, including partial qualification for certain activities.

Alabama's staff understand training expectations and are qualified in an appropriate amount of time. Staff spoke highly of the Office's commitment to training, especially support to attend NRC-sponsored training and peer assistance while learning new duties. Experienced staff also receive support for refresher training that is compatible with the expectations detailed in the NRC's IMC 1248.

c. Evaluation

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

d. MRB Decision

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

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 Alabama'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

Alabama performed 395 Priority 1, 2, 3, and initial inspections during the review period. The inspection staff conducted 1.5 percent of these Priority 1, 2, 3, and initial inspections overdue. One of 377 Priority 1, 2, and 3 inspections was performed overdue and two were overdue at the time of the review. One of 18 initial inspections was performed overdue, and two were overdue at the time of the review. All six licensees related to the overdue inspections were Alabama licensees located outside of Alabama who did not maintain an office in the State and were licensed only for temporary job sites. Alabama inspectors are not authorized to travel outside the state for inspection, so they must complete these inspections at temporary job sites. While such licensees are required to send a notification to the Office each time they enter Alabama to perform licensed activities, the work is often in remote portions of the state, and the notifications often allow insufficient time for an inspector to get to the site while licensed activities are ongoing.

Except for one licensed activity, Alabama’s inspection frequencies are the same or more frequent for similar license types in IMC 2800. However, as noted in the 2015 final IMPEP report, licensees who perform microspheres (SIR-Spheres or TheraSpheres) medical therapy procedures are inspected at a 3-year frequency rather than at a 2-year frequency. Alabama has a written policy describing the basis for this difference. The team did not identify any issues with regards to health and safety based on this difference. In its response to the draft report, the Office noted that this policy was re-evaluated and the six licensees that perform the microsphere therapy procedures were changed to a 2-year frequency.

A sampling of 25 inspection reports indicated that all inspection findings were communicated to the licensees within Alabama’s goal of 30 days after the inspection exit.

Alabama performed 14 percent of candidate reciprocity inspections in 2015, 44 percent in 2016, 15 percent in 2017, and 83 percent in 2018. The team noted that Alabama regulations allow for 30 days of radioactive materials use in the State under reciprocity, as compared to 180 days of use under NRC regulations. This shortened period limits the opportunity to inspect these reciprocity licensees. After 30 days, each reciprocity licensee is expected to apply for and receive a specific license for use of the licensed materials in Alabama. As with the out-of-state licensees, reciprocity licensees often do work in remote portions of Alabama with required notifications providing insufficient time for an inspector to get to the site while licensed activities are ongoing.

c. Evaluation

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

d. MRB Decision

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

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 Alabama'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 inspection reports and enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The casework reviewed included 25 inspections conducted by five of the Office's current and former inspectors and covered medical, industrial, commercial, academic, research, and service licenses.

The team found that inspection findings were clearly communicated to the licensee and violations were written with a direct link to a regulation or a license condition. In the inspection files reviewed, every inspection addressed previously identified open items and violations. Additionally, the team found that inspection documents were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security properly addressed.

The team noted that the Office uses the NRC's IMC 2800, and the associated NRC inspection procedures when performing inspections. However, the team determined that the inspection procedure for industrial radiography inspections was not being followed by inspectors to help identify poor licensee performance. Specifically, based on a review of six of the Office's twenty in-state industrial radiography files, the team determined that the Office was not following the guidance in the NRC's Inspection Procedure 87121, "Industrial Radiography Inspections." The team could not find an instance where the Office performed a temporary jobsite inspection for those licensees during the review period. The team discussed this issue with Office management and staff and determined that on the day of the inspection, if the licensee being inspected was not performing work at a temporary jobsite or if the inspector felt the temporary jobsite was too far away, no additional attempt was made to perform an inspection of the licensee at a temporary jobsite. Additionally, staff were not requesting that the licensee let them know when future work was planned so that an attempt to inspect licensee performance could be made. Therefore, to better assess the performance of industrial radiography licensees, the team recommends that Alabama follow the direction in the NRC's Inspection Procedure 87121, "Industrial Radiography Programs," to conduct inspections at temporary job sites for licensees whose primary operations are conducted at such sites and have not had a temporary job site inspection for the last three consecutive routine inspections. Additional steps may include, but are not limited to, requesting the temporary job site schedule prior to the inspection, or holding an inspection open until a temporary job site is available. However, in Alabama's response to the draft IMPEP report, it was noted that "the Office of Radiation Control does not believe that a recommendation is warranted on this matter," and requested the recommendation be removed.

A team member accompanied three program inspectors on the week of March 25, 2019. No performance issues were noted during the inspector accompaniments. The inspectors were well prepared and thorough and assessed the impact of licensed activities on health, safety, and security. Inspector accompaniments are identified in Appendix B.

Supervisory accompaniments for each materials inspector were performed in each year of the review period for all staff, except for the individual who, for most of the review period, held the position of Director, Radioactive Materials Compliance Branch (previously the Radioactive Materials Inspection Branch Director). The team noted that this individual, who was not accompanied during the 2015 IMPEP review period, performed inspections during this review period and was not accompanied by a supervisor in any year covered by the current review. At the time of the 2015 IMPEP review, the Office agreed to accompany the individual in this position; however, this individual was promoted in the fall of 2018 and there are no plans for him to perform

inspections going forward. The current Director of the Radioactive Materials Compliance Branch has been accompanied since obtaining this position and Office management committed to continue accompanying the staff member in this position at least once each year. Therefore, the team determined that no recommendation was needed for this finding.

The team verified that the Office maintains a wide variety of appropriately calibrated survey instruments to support the inspection program and to respond to radioactive materials incidents and emergency situations. Each inspector is assigned a Ludlum 14-C kit and has access to pressurized ion chambers and to spectrum collection devices. Equipment calibration is administered through the Office's Emergency Planning Branch.

c. Evaluation

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

- Procedures are in place; however, they are not being followed in a manner that helps to identify root causes and poor licensee performance for industrial radiography licensees.
- Supervisors, or senior staff as appropriate, did not conduct annual accompaniments of the former Director of the Radioactive Materials Compliance Branch to assess performance and assure consistent application of inspection policies.

As noted in Section 3.3.b., the Office was not following their inspection procedure for industrial radiography inspections and several in-state industrial radiography licensees went the entire review period without being inspected at a temporary jobsite even though work was being performed by those licensees at temporary jobsites within Alabama's jurisdiction. Based on the team's findings and discussions with the Office management and staff, the team is making one recommendation for improved performance: the team recommends that Alabama follow the direction in the NRC's Inspection Procedure, 87121 "Industrial Radiography Programs," to conduct inspections at temporary job sites for licensees whose primary operations are conducted at such sites and have not had a temporary job site inspection for the last three consecutive routine inspections.

Additionally, although committing, at the time of the 2015 IMPEP review, to accompany the Director of the Radioactive Materials Compliance Branch, the team determined that this individual was not accompanied during this review period even though the Director performed independent inspections.

During internal discussions, the team considered findings of both satisfactory and satisfactory but needs improvement for this indicator. The team determined that although the Office met one of the bulleted items under the criteria for satisfactory but needs improvement, the Office met five of the bulleted items for a finding of satisfactory. Therefore, based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Alabama's performance with respect to the indicator, Technical Quality of Inspections,

be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion 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, actual implementation of those procedures, and documentation of communications and associated actions between the Alabama 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 Alabama'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

The Office regulates 371 Radioactive Materials Licenses. During the review period, the Office performed 1,058 radioactive materials licensing actions. The team evaluated 29 of those actions. The licensing actions selected for review included four new applications, nine amendments, nine renewals, and seven terminations. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, accelerators, industrial radiography, research

and development, academic, nuclear pharmacy, gauges, panoramic and self-shielded irradiators, well-logging, service providers, decommissioning, and financial assurance. No licenses were denied during the review period and no bankruptcies were processed. At the time of the review, there was no backlog of licensing actions. The casework sample represented work from four current license reviewers.

The team found that licensing actions were thorough, complete, consistent, clear, of acceptable technical quality, adherence to procedures with health, safety, and security issues properly addressed. The license review staff has robust administrative support, and all actions are processed without delay. All license reviewers submit completed licensing actions to the Director, Licensing & Registration Branch. If the Licensing Director reviews a licensing action, the Assistant Director, Office of Radiation Control, also reviews the action. All completed license documents are signed by the Office Director and the State Health Officer.

The team determined that the Office is implementing a compatible procedure to the NRC's Pre-Licensing Guidance. The team determined that Pre-Licensing site visits were being conducted adequately in all applicable cases reviewed, including new license actions and change of control amendments.

Licenses that are authorized for Risk Significant Radioactive Materials (RSRM) are kept in separate locked filing cabinets. RSRM license documents are not marked as sensitive information; however, cover letters sent to licensees with the document are marked as sensitive. The team and Office management discussed marking the license document as well as the cover letter. The Office reviewed this aspect of their marking/handling procedures and made changes based on the team's observations.

During the review period, the Office processed licensing actions in a timely fashion, generally within 90 days. Requests for additional information sent to licensees were clear and focused on relevant health and safety performance. The Office allows 90 days for a licensee to respond to requests for additional information. If the Office does not receive a reply to their requests, it terminates the action without prejudice based on the licensee's inaction.

c. Evaluation

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

- Documents containing sensitive security information were not properly marked.

The team and Office management discussed marking license documents as well as cover letters. The Office reviewed this aspect of their marking/handling procedures and made changes based on the team's observations.

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

d. MRB Decision

The final report will present the MRB's conclusion 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 and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, 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 State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Alabama'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 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.
- 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, 177 incidents were reported to the Office. The team evaluated 20 radioactive materials incidents which included 6 lost/stolen/found radioactive materials, 2 potential overexposures, 10 damaged equipment, and 2 leaking sources. The team determined the Office receives and categorizes incidents and allegations on the basis of potential health, safety, and/or security significance. Incidents are provided a high quality and thorough review to determine the appropriate response by the Office. As such, inspectors were dispatched for onsite response for six of the cases reviewed. The team noted that onsite response was thorough and high quality, as was follow-up during the subsequent inspection.

The team determined that incidents associated with fixed gauging devices were initially categorized as having a lower health and safety significance, and as such were improperly reported to the NRC. Specifically, the fixed gauging incidents should have been reported within 24 hours as required by 10 CFR 30.50, and not the 30-day report as required by 10 CFR 31.5 that the Office submitted. The Office Director agreed during the onsite review, that all staff would review the SA-300 procedure, "Reporting Materials Events" and make the necessary changes to their procedures.

During the review period, seven allegations were received by the Office. The team evaluated the one allegation which the NRC referred to the Office during the review period; the only allegation pertaining to radioactive materials related to Alabama's Agreement with the NRC. The Office uses an allegation intake and review form, which is similar to the one utilized by the NRC. The protection of alleege's identities is in accordance with NRC's allegation handling process. The team determined the Office followed its process and the follow-up to the allegation was appropriate.

c. Evaluation

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

d. MRB Decision

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

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 Alabama retains regulatory authority for a low-level radioactive waste disposal and a uranium recovery program; therefore, only the first two 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. 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 Alabama’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

Alabama became an Agreement State on October 1, 1966. Alabama’s current effective statutory authority is contained in the Acts of 1963, No. 582 of the Alabama Statutes. The Department is designated as the State’s radiation control agency. No legislative amendments affecting the radiation control program were passed during the review period.

Alabama’s administrative rulemaking process takes approximately 6 months to 1 year from drafting to finalizing a rule. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the State Committee of Public Health. The team noted that the State’s rules and regulations are not subject to “sunset” laws.

During the review period, Alabama submitted 7 proposed final regulation amendments, 7 final regulation amendments, and 17 revised final regulation amendments to the NRC for compatibility review. Only one amendment, RATS ID 2015-2, "Safeguards Information – Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73 and 150," was submitted and went into effect after the 3-year window provided to the Agreement States for regulation adopted. The regulation went into effect approximately six months late. At the time of the review, no amendments were overdue for adoption, although there are three regulations the Office needs to make minor corrections to:

- RATS ID 2007-3, Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 33, 33, 35, 61 and 150 72 FR 55864;
- RATS ID 2012-3, Technical Corrections Parts 30, 34, 40 and 71 && FR 39899; and
- RATS ID 2015-5, Miscellaneous Corrections, Parts 19, 20, 30, 32, 37, 40, 61, 70, 71 and 150 80 FR 74974.

The Office intends to correct these regulations along with a regulation package currently being processed that addresses regulations required for compatibility due in 2020 and 2021.

c. Evaluation

The team determined that, during the review period, Alabama met the performance indicator objectives listed in Section 4.1.a. Based on the criteria in MD 5.6, recommends that Alabama's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

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

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

Although Alabama has authority to conduct SS&D evaluations for byproduct, source, and certain special nuclear materials, the Office did not conduct any SS&D evaluations during the review period nor did the Office have any pending applications for an SS&D evaluation. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Alabama's performance was found to be satisfactory for all applicable performance indicators. The team determined that the recommendation from the 2015 IMPEP review should be closed and made one new recommendation (see below).

Accordingly, the team recommends that the Alabama be found adequate to protect public health and safety and is compatible with the NRC's program. The team recommends that the next IMPEP review take place in approximately 4 years with a periodic meeting in approximately 2 years.

Below is the team's recommendation, as mentioned in the report, for evaluation and implementation by Alabama:

The team recommends that Alabama follow the direction in the NRC's Inspection Procedure 87121, "Industrial Radiography Programs," to conduct inspections at temporary job sites for licensees whose primary operations are conducted at such sites and have not had a temporary job site inspection for the last three consecutive routine inspections.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspector Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Lance Rakovan, NMSS	Team Leader Technical Staffing and Training Compatibility Requirements
Monica Ford, NRC Region I	Technical Quality of Inspections Inspector Accompaniments
Geoff Warren, NRC Region III	Team Leader-in-Training Status of Materials Inspection Program
Shawn Seeley, NRC Region I	Technical Quality of Incident and Allegation Activities
Jack Tway, State of New Jersey	Technical Quality of Licensing Actions

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 1118
License Type: Industrial Radiography	Priority: 1
Inspection Date: 03/25/19	Inspector: RC

Accompaniment No.: 2	License No.: 379
License Type: Medical Institution Written Directive Required	Priority: 3
Inspection Date: 03/26/19	Inspector: CC

Accompaniment No.: 3	License No.: 459
License Type: HDR	Priority: 2
Inspection Date: 03/27/19	Inspector: LS



ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Scott Harris, M.D., M.P.H.
State Health Officer



July 12, 2019

Paul Michalak, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Materials Safety and Safeguard
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Michalak:

Re: Alabama Draft IMPEP Report

In response to your letter dated June 20, 2019, please consider the following comments regarding the draft IMPEP report for the Alabama review held on May 20-24, 2019.

3.2 Status of Materials Inspection

1. Page 5 – In b. Discussion, the report references the program's past decision to inspect licensees who perform microspheres therapy procedures at a 3-year frequency rather than at a 2-year frequency. This was re-evaluated by the program director and by memorandum dated May 28, 2019, the six current radioactive material licensees that perform the microsphere therapy procedures were changed to a 2-year inspection frequency.

3.3 Technical Quality of Inspections

1. Page 7 – In b. Discussion, the report states that eight of the twenty in-state industrial radiography files were part of the review. Since then, the IMPEP team has clarified that only six of the in-state industrial radiography files were part of this review. Please reflect this in the final report.

Physical Address:
The RSA Tower, 201 Monroe Street
Montgomery, AL 36104

alabamapublichealth.gov

Mailing Address:
P.O. Box 303017
Montgomery, AL 36130-3017

Enclosure 2

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2. Page 7 – In the same paragraph and on the same subject, the report states that the team could not find an instance when the Office performed a temporary jobsite inspection for those licenses reviewed. Our office conducted our own review of the six industrial radiography files reviewed by the IMPEP team. Of the six files reviewed by the IMPEP team, two jobsite inspections were performed by our inspectors during the review period. This contradicts the team’s assessment. Also, our office reviewed the remaining industrial radiography files that were not part of the IMPEP review. From our review, we noted that at the beginning of each routine inspection, the inspector asks and documents if radiography was being performed at that time. Our review of the in-state license files determined that of the 71 routine annual inspections conducted during the review period, there were 23 times when radiography was being conducted on the day of the inspection. Of those 23 occasions, 11 field radiography inspections were conducted by the inspectors, which is 48% of the time. This is a conservative estimate, based on the fact the distances from the office location to the jobsite for those 23 jobs were not considered in the final numbers. Also, we noted that two additional field inspections were attempted during the review period that were not included in the final assessment.

We recognize the importance of conducting field inspections and have since provided guidance to our inspection staff to not only ask if radiography is being conducted at the time of the office inspection but also ask if radiography work is being conducted during that week. We have stressed that field inspections should be a priority even if it means canceling another routine inspection. Further, future inspection trips will be coordinated to allow inspectors to work as a team on a periodic basis to make radiography field inspections a priority. We believe that this additional guidance will adequately address the concerns of the IMPEP reviewer and will enhance our overall inspection program.

Based on our assessment of all in-state industrial radiography licenses, the Office of Radiation Control does not believe that a recommendation is warranted on this matter. Therefore, we respectfully request that the recommendation be removed.

3. Page 7 – Under b. Discussion, the report states the team noted that the previous Director, Radioactive Materials Compliance Branch, was not accompanied by a supervisor in any year covered by the review period. The report further states that the team determined that no recommendation was needed for this finding. Please note that the person not audited has been with the Office of Radiation Control for

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over 28 years and was audited by the previous IMPEP team in 2015 with no issues noted. Furthermore, Management Directive 5.6 states that for a program to be satisfactory for this indicator, supervisors accompany nearly all inspectors on an annual basis. Based on Management Directive 5.6, no such recommendation should be considered.

3. Page 8 – Under c. Evaluation, the report states that the team considered findings of both satisfactory and satisfactory but needs improvement. The Office of Radiation Control takes exception to this statement. The consideration of satisfactory but needs improvement was never mentioned any time during the week of the review. Furthermore, it is the opinion of this office that such consideration is unwarranted. As stated in the report, the Office met only one of the bulleted items under the criteria for a finding of satisfactory but needs improvement while meeting five of the six bulleted items for a finding of satisfactory. As stated earlier, we believe that efforts were made by inspection staff to address field inspections of industrial radiography licensees, and that the recommendation noted is not warranted. We believe we meet all six bulleted items under the satisfactory criteria, and therefore, respectfully request that the team reconsider their statement that satisfactory but needs improvement was considered for this indicator.

3.5 Technical Quality of Incident and Allegation Activities

1. Page 11 – Under b. Discussion, the report states that incidents associated with fixed gauging devices were improperly reported to the NRC. To address this, an in-house training session on SA-300 and notification requirements was held on July 10, 2019.

We want to thank the team for their thorough review while on-site. We appreciate their suggestions for improvement and their professionalism. We also appreciate the opportunity to comment on the draft IMPEP report and we ask that you thoughtfully consider the comments as presented. If you have any questions or need additional information, please feel free to call me at 334-206-5401.

Sincerely,



David A. Turberville, Director
Office of Radiation Control

DAT

Agenda for Management Review Board Meeting
August 6, 2019, 1:00 p.m. – 4:00 p.m. (ET), OWFN-17B04

1. Meeting Convened.
 - a. Announcement of public meeting.
 - b. Request for members of the public to indicate they are participating and their affiliation.
 - c. Introduction of MRB members, team members, State representatives, and other participants.

2. MRB Chair Convenes the Business Portion of the Meeting
 - a. Consideration of the Alabama Agreement State's IMPEP Report.
 - b. Presentation of Findings Regarding Alabama's Program and Discussion.
 - i. Technical Staffing and Training
 - ii. Status of Materials Inspection Program
 - iii. Technical Quality of Inspections
 - iv. Technical Quality of Licensing Actions
 - v. Technical Quality of Incident and Allegation Activities
 - vi. Compatibility Requirements
 - c. IMPEP Team Recommendations.
 - d. MRB Consultation/Comments on Issuance of Report.
 - e. Request for comments from Alabama representatives, OAS Liaison, and State IMPEP team members.
 - f. Overall MRB Determination

3. MRB Chair Closes the Business Portion of the Meeting

4. Questions or comments from members of the public.

5. Meeting adjournment.