



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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July 13, 2016

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and Human Capital Programs
Office of the Executive Director for Operations

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FROM: Paul Michalak, Acting Chief */RA/*
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SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REVIEW OF LOUISIANA

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of Louisiana. The review was conducted by an interoffice team during the period of April 25–29, 2016. The team issued a draft report to Louisiana on May 27, 2016, for factual comment. Louisiana responded to the findings and conclusions of the review by letter dated July 6, 2016, from Bryan P. Riche, Administrator, Assessment Division. A copy may be found in the U.S. Nuclear Regulatory Commission's (NRC) Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16189A000. In its response, Louisiana noted a few typographical errors, requested one correction, one clarification, and offered planned actions to address the review team's proposed recommendations. The team's resolution of Louisiana's comments are provided in the comment resolution document (ML16189A222).

Overall, the review team is recommending that Louisiana's performance be found satisfactory for five out of seven indicators reviewed, and satisfactory, but needs improvement, for the indicators Technical Staffing and Training, and Technical Quality of Incidents and Allegations. Accordingly, the review team is recommending that the Louisiana Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program.

The MRB meeting to consider the Louisiana report is scheduled for July 21, 2016, 1:00 – 4:00 p.m. EDT. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is enclosed (Enclosure 2).

Enclosures:

1. Louisiana Proposed Final Report
2. Meeting Agenda

cc: Bryan Riche, Administrator
Assessment Division Radiation Section
Office of Environmental Compliance

David Howe, OR
Organization of Agreement States
Liaison to the MRB

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

APRIL 25 – 29, 2016

PROPOSED FINAL REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Louisiana Agreement State Program. The review was conducted during the period of April 25-29, 2016, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Washington.

Based on the results of this review, Louisiana's performance was found satisfactory, for five out of seven indicators: Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Sealed Source and Device Evaluation Program, and Compatibility Requirements. Two of the performance indicators, Technical Staffing and Training and Technical Quality of Incident and Allegation Activities, were found to be satisfactory, but needs improvement.

The review team made three recommendations: (1) The review team recommends that the Division perform an evaluation to determine the causes for the low staff retention rate and implement corrective actions to mitigate the causes; (2) The review team recommends that the Division implement a procedure that addresses at a minimum, the means for identifying, marking, properly handling, controlling access to, transmitting, and storing documents that contain sensitive information; and (3) The review team recommends that the State develop and implement a comprehensive incident and allegation procedure, provide incident and allegations training to the staff, and ensure management oversight of the incident and allegation program.

The review team determined that the recommendations from the 2012 IMPEP review should be closed (see Section 2.0).

Accordingly, the review team recommends that the Louisiana Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The review team recommends that the next IMPEP review take place in approximately 4 years and that a periodic meeting be held in 1 year to assess the State's actions on the recommendations with a second meeting approximately 18 months after the first periodic meeting.

1.0 INTRODUCTION

This report presents the results of the review of the Louisiana Agreement State Program radioactive materials safety program. The review was conducted during the period of April 25-29, 2016, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Washington. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 28, 2012 to April 29, 2016, were discussed with State managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the State on February 9, 2016. The State provided its response to the questionnaire on April 1, 2016. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16095A113.

The Louisiana Agreement State Program is administered by the Assessment Division (the Division), which is one of four Divisions under the Office of Environmental Compliance (the Office) located within the Department of Environmental Quality (the Department). Organization charts for the State can be found in ADAMS using the Accession Number ML16095A111.

At the time of the review, the Louisiana Agreement State Program regulated 460 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Louisiana.

The review 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 Louisiana Agreement State Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on April 27, 2012. The final report is available in ADAMS (Accession Number ML12199A224). The results of the review and the status of the recommendations 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: The review team recommends that the Department evaluate its review processes and develop and implement appropriate actions to ensure that products issued are of high technical quality and meet the standard expectations of the Department. (Section 3.4 and 4.2.2 of the 2012 IMPEP Report)

Status: The Division has provided training to staff and has reemphasized the use of standard operating procedures to ensure products issued by the Division are of high technical quality. Prior to issuance of licensing documents and sealed source and device evaluations, the Division performs several reviews to ensure the product is of high quality. The review process includes peer reviews, subject matter expert technical reviews, as well as supervisory and management reviews prior to issuance. The end product meets the standard expectations of the Division and is of high technical quality.

The review team recommends to the Management Review Board (MRB) that this item be closed.

Technical Quality of Incident and Allegation Activities: Satisfactory

Recommendation: None

Sealed Source and Device Evaluation Program: Satisfactory

Recommendations:

1. The review team recommends that the Division adhere to the document format and content guidance in the current version of NUREG-1556, Volume 3. (Section 4.2.2 of the 2008 and 2012 IMPEP Report); and
2. The review team recommends that all of the active sealed source and device registration commitments be located and made readily accessible by the Division. (Section 4.2.2 of the 2012 IMPEP Report)

Status:

1. Prior to issuance of licensing documents and sealed source device evaluations, the Division performs several reviews to ensure the product is of high quality. The review process includes peer reviews, subject matter expert technical reviews, as well as, supervisory and management reviews prior to issuance. The Division currently uses a peer review process to ensure that the supporting documentation is contained in the individual Sealed Source and Device (SS&D) registry folder before issuing the registration in accordance with the guidance in NUREG-1556, Volume 3, "Application for Sealed Source Device Evaluation and Registration."
2. The Division reviewed and updated all 61 SS&D registries dating back to 1972, obtained missing documents to the extent possible, and identified what documents could not be located. The SS&D registries for devices and sealed sources no longer being manufactured and distributed have been reviewed, updated, and inactivated. The Division is currently using the format and content guidance in the current version of NUREG-1556, Volume 3, "Application for Sealed Source Device Evaluation and Registration."

The review team recommends to the MRB that these recommendations be closed.

Compatibility Requirements: Satisfactory but needs improvement
Recommendation: None

Overall finding from the 2012 IMPEP review: 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 thus could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires a consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

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

b. Discussion

The Louisiana Agreement State Program is composed of 19 technical staff members, 2 supervisors, 1 manager, and 1 administrative assistant which equals 12 full-time equivalent (FTE) staff for the radioactive materials program including current vacancies in the Division. In addition to implementing the radioactive materials program, the

Division staff also perform X-ray, mammography, and emergency preparedness activities which account for the rest of the FTE allocation. At the time of the IMPEP review, there was one vacancy. During the review period, 14 staff members left the program, 12 staff members were hired, and 1 technical staff position was moved to a different division. The positions were vacant from 1 to 3 months.

c. Evaluation

The review team interviewed Division staff and managers, reviewed the questionnaire response, and evaluated the Division's hiring and training data. During the current IMPEP review period 14 staff members left the Division. During the previous IMPEP review period from 2008-2012, 10 staff members left the Division. During this review period, 6 of the 12 current inspection staff members and 2 of the 5 current licensing staff members are new to the Division and undergoing training and qualification. Although the Division's management was able to fill each vacancy in about 1 to 3 months, the Division has been challenged with keeping the positions filled. The low staff retention rate has caused an increased workload for the fully qualified materials inspectors and license reviewers. Based on interviews with the Division's staff and management, the review team concluded that the most significant factor contributing to the low staff retention rate is the low salary offered by the Division; however, additional factors may also be contributing to the low retention rates. The review team recommends that the Division perform an evaluation of its staff turnover to determine the causes for the low staff retention rate and implement corrective actions to mitigate the causes.

The Division has implemented a training and qualification manual compatible to the NRC's IMC 1248. On average it takes about three years for a new staff member to become qualified in one area of the radioactive materials program, e.g., industrial or medical licensing and inspection. The qualification process begins with staff attending NRC training courses; however, the staff is initially qualified on the X-ray and mammography programs for the first year or two before progressing to complete the radioactive materials training and qualification. Due to the staff turnover mentioned above, only a few of the staff that completed the NRC training stayed in the Division and completed the radioactive materials qualification. The Division's management stated that the training and qualification program has the flexibility to expedite radioactive material qualifications and that additional strategies could be explored to reduce the average radioactive material program qualification time.

d. Results

The review team determined that the amount of staff turnover, lack of management attention to the high rates of attrition, and the length of time that it takes for individuals to complete all of the training and qualification requirements was indicative of less than satisfactory performance for this indicator.

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Louisiana's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory, but needs improvement.

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

The Division performed a total of 730 Priority 1, 2, and 3, and initial inspections over the review period. The Division conducted 1.4 percent of these inspections overdue. Nine of 699 Priority 1, 2, or 3 and one of 31 initial inspections were conducted overdue. No inspections were overdue at the time of the review. A sampling of 23 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond the Division's goal of 30 days following the inspection exit. Each year of the review period, the Division performed greater than 20 percent of candidate reciprocity inspections. Louisiana's inspection frequency is the same or more frequent for similar license types in IMC 2800.

c. Evaluation

The team determined that during the review period Louisiana met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Louisiana's performance with respect to the indicator, Status of the Materials Inspection Program, be found 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 a program's inspection capability.

a. Scope

The review team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Louisiana'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 conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, to verify that procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, to determine if inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 23 materials inspections conducted during the review period. The casework reviewed included inspections conducted by 13 of the Division's inspectors and covered therapeutic medicine, industrial radiography, well logging, manufacturing and distribution, nuclear pharmacy, academic research and development, and reciprocity licenses.

Review team members accompanied five Division inspectors on seven inspections from March 21 through 24, 2016. The inspector accompaniments are identified in Appendix B.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Louisiana's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

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, and security. An assessment of licensing procedures, actual implementation of these procedures, and documentation of communications and associated actions between the Louisiana licensing staff and regulated community will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Louisiana'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 meet current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled and secured.

b. Discussion

During the review period, the Division performed 2000 radioactive materials licensing actions. The review team evaluated 25 radioactive materials licensing actions. The licensing actions selected for review included 5 new applications, 15 amendments, 4 renewals, and 1 termination. The review team evaluated casework for the following license types and actions: broad scope, medical diagnostic and therapy, veterinary, research and development, industrial radiography, nuclear pharmacy, well logging, academic, gauges, service providers, and financial assurance.

c. Evaluation

The review team determined that during the review period Louisiana met the performance indicator objectives listed in Section 3.4.a., with one exception. The exception is noted for the security of licensing documents containing sensitive information. The Division's licensing system is entirely electronic. Radioactive material licenses marked "Security Related Information" are stored in the State's Electronic Document Management Database. Any Department employee has access to the

database and a member of the public can submit a request to the State and receive a copy of a radioactive materials license within 3 to 4 business days. A similar issue of marking licenses containing sensitive security related information was described in the 2012 review. At that time, the Department received approval from its legal counsel that the increased control licenses, which are maintained on the electronic system, may be marked (under the State's Public Records Act) to indicate they are security-related. Currently, licensing documents with security-related information are marked. However, the marking does not prevent disclosure of licensing information with a security marking to those without a need to know the information. The Division indicated it has an informal unwritten process to review public requests for information before authorizing the release of licensing documents containing security-related information. The review team recommends that the Division implement a procedure that addresses at a minimum, the means for identifying, marking, properly handling, controlling access to, transmitting, and storing documents that contain sensitive information.

d. Results

The review team considered if the finding for the indicator was satisfactory, but needs improvement. Because the team did not identify any inadvertent releases of security related information and because the Division has an informal process for reviewing document requests, the team supports a satisfactory finding.

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

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health 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 procedures and actions will be a significant indicator of the overall quality of the program.

a. Scope

The review team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Louisiana'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 the 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, 235 incidents were reported to Louisiana, 56 of these were related to radioactive materials versus issues dealing with X-ray or naturally occurring radioactive material. The review team evaluated 20 radioactive materials incidents which included 5 lost/stolen/abandoned radioactive sources, 4 potential overexposures, 3 medical events, and 8 related to damaged equipment. Louisiana dispatched inspectors for onsite follow-up for 12 of the cases reviewed.

During the review period, two allegations were received by Louisiana. The review team evaluated both allegations, including the allegation that the NRC referred to the State, during the review period.

The review team evaluated Louisiana's "Standard Operating Procedure for Radiation Incidents and Allegations," and interviewed Division staff as to their familiarity and involvement with incidents and allegations.

c. Evaluation

The team determined that Division's incident and allegation procedure lacked guidance for the handling of allegations and had limited guidance for the handling of incidents. The applicable portions of the Division's procedure regarding management review and coordination are not being followed. Most of the Division's procedure is taken from the SA-105 "Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities," procedure used by IMPEP teams to evaluate this indicator, and has not been edited to provide guidance to Division staff. For example, the Division's procedure makes reference to Appendices A and B to be used for incident and allegation intake; however, the forms appended to the procedure are those contained in SA-105 for casework reviews, rather than meaningful tools for managing the intake of information for incidents and allegations.

Despite the lack of written guidance, the review team found, after review of gathered documentation and discussion with Division personnel, that Louisiana's response to incidents was complete and comprehensive, albeit poorly documented. Initial responses were prompt and well-coordinated, and the level of effort commensurate with the health and safety significance. Response to incidents was timely and prompt inquiries were made to evaluate the need for an on-site investigation. The Division dispatched inspectors to 12 of the incidents reviewed and took suitable enforcement and follow up actions. If the incident met the reportability thresholds, established in SA-300 "Reporting Material Events," the Division notified the NRC Headquarters Operations Center (HOO) in a prompt manner. However, in most cases, the Division relied on the HOO to ensure that the information got into NMED, and 10 of the 56 events were still marked as "open" in NMED even though all follow-up actions had been completed. The strength of the incident response actions can be attributed to the Division's senior staff supporting NMED.

There is limited discussion of allegations in the Division's procedure and none of the staff have received allegations training. The allegation that was referred to Louisiana by

the NRC was appropriately investigated and closed. However, another potential allegation was referred to Louisiana via the 24 hour “hot line” in July 2015. A radiography company’s radiation safety officer (RSO) called to advise Louisiana that some of the company’s radiographers were performing work in North Dakota outside the scope of the license. Later, one of these radiographers called the Louisiana to report wrong doing on the part of the RSO. The State of North Dakota issued escalated enforcement against the Louisiana licensee as a result of these activities. At the time of the IMPEP review, the Division had not responded to these concerns or performed an inspection of the licensee.

The review team recommends that the Division develop and implement a comprehensive incident and allegation procedure, provide incident and allegations training to the staff, and ensure adequate management supervision in the incident and allegation program.

d. Results

The review team determined that the Division’s lack of a significant incidents and allegations procedure, lack of allegations training for the staff, and lack of management coordination in the incidents and allegations process was indicative of less than satisfactory performance for this indicator.

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Louisiana’s performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation (SS&D) Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery Program. The NRC’s Agreement with Louisiana does not relinquish 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 review team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Louisiana'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/rss_regamendments.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.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

Louisiana became an Agreement State on May 1, 1967. The Louisiana Agreement State Program's current effective statutory authority is contained in Title 33, "Environmental Quality," Part XV, "Radiation Protection," of the Louisiana Administrative Code. The Department is designated as Louisiana's radiation control agency. No legislation affecting the radiation control program was passed during the review period.

Louisiana's administrative rulemaking process takes approximately six months from drafting to finalizing a rule. The public, the 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 Legislative Oversight Committee. The review team noted that Louisiana's rules and regulations are not subject to "sunset" laws.

During the review period, Louisiana submitted 23 final regulation amendments to the NRC for a compatibility review. Thirteen of the 23 regulation amendments were adopted overdue during the review period. Twelve of the 13 overdue regulation amendments were identified as overdue during the 2012 IMPEP review and were finalized during the 2016 IMPEP review period. Eight of the 23 regulation amendments were due for adoption by Louisiana during the current review period and three are not due yet for adoption. Louisiana submitted 10 of the 11 amendments for a compatibility review in a timely manner and adopted the regulations before the due date. One regulation amendment that was due for adoption on September 28, 2012, was adopted by Louisiana on November 20, 2012.

No regulation amendments were overdue for adoption at the time of this IMPEP review.

c. Evaluation

The 2012 IMPEP review team found Louisiana to be Satisfactory but needs improvement for this performance indicator. For the 2012 review period, there were 14 regulation amendments that were overdue for adoption. Twelve of those regulation amendments were carried over into this current review period. During the current IMPEP review period, the Division's staff cleared the backlog of overdue regulation amendments and ensured that new regulations were adopted by the due date.

The review team determined that during the review period Louisiana met the performance indicator objectives listed in Section 4.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Louisiana's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Sealed Source and Device 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 review teams. Three sub elements: technical staffing and training, technical quality of the product evaluation program, and evaluation of defects and incidents regarding SS&D's, will be 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 review team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated Louisiana's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or that qualification criteria will be established if new staff members are hired.
- Any vacancies are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

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

Evaluation of Defects and Incidents

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

b. Discussion

Technical Staffing and Training

The Division had four qualified SS&D reviewers over the review period. Two reviewers left the Division. The Division currently has two qualified individuals. The review team determined that current staffing levels are sufficient for the Division's SS&D program. The Division's training program is compatible with the training requirements identified in Appendix D to IMC 1248.

Technical Quality of the Product Evaluation

Louisiana has 13 SS&D licensees. Over the review period, the Division issued 74 SS&D actions of which 7 were new applications and 6 were amendments to existing device sheets. In response to recommendations from the 2012 IMPEP review, the Division processed 61 SS&D actions. In the 2012 IMPEP review, the review team found amendments to registries originally written as far in the past as 1972 lacked supporting documentation. Several SS&D registries had not been updated for safety considerations or transferred to inactive status as required. Some required either reactivation or a change of vendor number due to a change in company ownership. Division staff reviewed and updated all historical SS&D registries in addition to their new applications, to research, acquire, and document old and no longer existing paperwork. In this effort, eight SS&D registries were transferred to inactive status, and six supersession amendments were issued with all safety updates and documentation for reactivation or change of vendor number due to change of ownership. In addition the System International units were also added to amended registries. All SS&D registries were updated to current NUREG 1556, Volume 3 standards to the extent possible.

The review team evaluated 15 SS&D actions processed during the review period including six of the new applications and nine amendments. The review team determined that the SS&D reviewers evaluated the cases against applicable guidance and standards. The work performed was found to be comprehensive and of high quality.

Evaluation of Defects and Incidents Regarding SS&Ds

The review team evaluated three incidents involving SS&D registered products during the review period. Two of the incidents involved equipment failures and one, a source leakage. Senior technical staff evaluated the incidents to determine if the incidents require any amendment to the SS&D registry.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Louisiana's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-level Radioactive Waste Disposal Program

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

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Louisiana's performance was found satisfactory for five out of seven performance indicators reviewed and satisfactory, but needs improvement, for the indicators, Technical Staffing and Training, and Technical Quality of Incidents and Allegation Activities. The review team made three recommendations regarding program performance by the State and determined that the recommendations from the 2012 IMPEP review should be closed.

Accordingly, the review team recommends that the Louisiana Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next IMPEP review take place in approximately 4 years and that a periodic meeting be held in 1 year to assess the State's actions on the recommendations with a second meeting approximately 18 months after the first periodic meeting.

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

1. The review team recommends that the Division perform an evaluation to determine the causes for the low staff retention rate and implement corrective actions to mitigate the causes. (Section 3.1)
2. The review team recommends that the Division implement a procedure that addresses at a minimum, the means for identifying, marking, properly handling, controlling access to, transmitting, and storing documents that contain sensitive information. (Section 3.4)
3. The review team recommends that the Division develop and implement a comprehensive incident and allegation procedure, provide incident and allegations training to the staff, and ensure adequate management supervision in the incident and allegation program. (Section 3.5)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Orysia Masnyk Bailey, Region 1	Review Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Binesh Tharakan, Region IV	Technical Staffing and Training Compatibility Requirements
Michelle Simmons, Region IV	Technical Quality of Licensing
Geoffrey Warren, Region III	Status of Materials Inspection Technical Quality of Inspections
Anine Grumbles, Washington	Sealed Source and Device Evaluation Program

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: LA-7072-L01
License Type: Industrial Radiography	Priority: 1
Inspection Date: 03/21/2016	Inspector: MC

Accompaniment No.: 2	License No.: LA-7985-L01
License Type: Industrial Radiography	Priority: 1
Inspection Date: 03/21/2016	Inspector: MC

Accompaniment No.: 3	License No.: LA-3773-L01A
License Type: Industrial Radiography	Priority: 1
Inspection Date: 03/21/2016	Inspector: MC

Accompaniment No.: 4	License No.: LA-11296-L01A
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 03/22/2016	Inspector: JE

Accompaniment No.: 5	License No.: LA-10950-L01
License Type: Well Logging	Priority: 1
Inspection Date: 03/23/2016	Inspector: JF

Accompaniment No.: 6	License No.: LA-2966-L01
License Type: Manufacturing and Distribution	Priority: 1
Inspection Date: 03/24/2016	Inspector: TB

Accompaniment No.: 7	License No.: LA-4266-L01
License Type: Industrial Radiography	Priority: 1
Inspection Date: 03/24/2016	Inspector: RC

**Agenda for Management Review Board Meeting
July 21, 2016, 1:00 p.m. – 4:00 p.m. (ET), OWFN-17B04**

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives and other participants.
3. Consideration of the Louisiana IMPEP Report.
 - A. Presentation of Findings Regarding Louisiana's Program and Discussion.
 - Technical Staffing and Training
 - Status of Materials Inspection Program
 - Technical Quality of Inspections
 - Technical Quality of Licensing Actions
 - Technical Quality of Incident and Allegation Activities
 - Compatibility Requirements
 - Sealed Source and Device Evaluation Program
 - B. IMPEP Team Recommendations.
 - Recommendation for Adequacy and Compatibility Ratings
 - Recommendation for Next IMPEP Review
 - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from Louisiana representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.

Invitees:

Glenn Tracy, OEDO	Dan Collins, NMSS
Mary Spencer, OGC	Pamela Henderson, NMSS
Scott Moore, NMSS	Paul Michalak, NMSS
Daniel Dorman, RI	Lisa Dimmick, NMSS
Dan Howe, OR, OAS	Lizette Roldan-Otero, NMSS
Orysia Masnyk-Bailey, RI	Karen Meyer, NMSS
Binesh Tharakan, RSAO/RIV	Duncan White, NMSS
Michelle Simmons, RIV	Michelle Sampson, OEDO
Geoffrey Warren, RIII	Bryan Riche, LA
Anine Grumbles, WA	Judith Schuerman, LA