

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

March 22, 2018

Mr. Nathaniel Smith, MD, MPH Director of Health and State Public Health Officer Department of Health 4815 W. Markham Street Little Rock, AR 72205

Dear Dr. Smith:

On February 13, 2018, the Management Review Board (MRB) met, which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Arkansas Agreement State Program. The MRB found the Arkansas program adequate to protect public health and safety but needs improvement, and compatible with the NRC program.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0) and recommendations. The review team made four recommendations regarding the performance of the Arkansas Agreement State Program during this review. Based on the results of the current IMPEP review, a followup IMPEP review of the Arkansas Agreement State Program will take place in approximately 18 months.

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

Sincerely,

/RA/

Daniel H. Dorman
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Enclosure: Arkansas Final IMPEP Report

cc: David Walter, AL
Organization of Agreement States
Liaison to the MRB

N. Smith 2

SUBJECT: ARKANSAS FY2018 FINAL IMPEP REPORT, DATED March 22, 2018

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

November 27 – December 1, 2017

FINAL REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Arkansas Agreement State Program. The review was conducted during the period of November 27 to December 1, 2017, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Virginia.

Based on the results of this review, the team recommended, and the Management Review Board (MRB) agreed, that Arkansas's performance was satisfactory for five indicators, Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Incident and Allegation Activities, and Compatibility Requirements, and unsatisfactory for the indicator Technical Quality of Licensing Actions.

The MRB supported the team's four recommendations (see Section 5.0) and agreed that the recommendations from the 2013 IMPEP review should be closed (see Section 2.0).

Accordingly, the team recommended, and the MRB agreed, that the Arkansas Agreement State Program is adequate to protect public health and safety, but needs improvement; and, compatible with the NRC's program. The team also recommended, and the MRB agreed, that the Arkansas Agreement State Program be placed on monitoring, which will facilitate Arkansas taking the necessary steps to rectify the licensing issues identified during the review. The team recommended that a followup IMPEP review take place in approximately 2 years to review the Technical Quality of Licensing Actions indicator. However, the MRB directed that a followup IMPEP review take place in 18 months instead of 2 years.

1.0 INTRODUCTION

This report presents the results of the review of the Arkansas Agreement State Program radioactive materials safety program. The review was conducted during the period of November 27 to December 1, 2017, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Virginia. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017, 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 November 2, 2013, to December 1, 2017, were discussed with Arkansas management 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 Arkansas on August 8, 2017. Arkansas provided its response to the questionnaire on November 8, 2017. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML17353A151.

A draft of this report was issued to Arkansas on January 2, 2018, for factual comment (ADAMS Accession Number ML17362A184). Arkansas responded to the findings and conclusions of the review by letter dated January 31, 2018. A copy of the response is available in ADAMS (Accession Number ML18036A065). The Management Review Board (MRB) convened on February 13, 2018, to discuss the team's findings.

The Arkansas Agreement State Program is administered by the Radioactive Materials Program (the Program). The Program is one of three organizations within the Radiation Control Section, which is part of the Health Systems Licensing and Regulation Branch. The Health Systems Licensing and Regulation Branch is part of the Center for Health Protection, which is within the Arkansas Department of Health (the Department). The director of the Department is the State Health Officer, who reports to the governor. Organization charts for Arkansas are available in ADAMS (Accession Number ML17355A167).

At the time of the review, the Arkansas Agreement State Program regulated 209 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 Arkansas.

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

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on November 1, 2013. The final report is available in ADAMS (Accession Number ML14098A338). The results of the review and the status of the recommendations are as follows:

Technical Staffing and Training: Satisfactory

Recommendation: The team recommends that the State provide refresher training to the inspection staff on the inspection procedures and incorporate the inspection procedures into the

training and qualification program for inspectors to ensure consistent implementation during inspections. (Section 3.1 of the 2013 IMPEP report).

Status: In responding to this recommendation, the Program provided refresher training for the inspection staff which began immediately following the 2013 IMPEP review, in November 2013, and concluded in March 2014. The Program provided training on inspection procedures for each inspection type found in NRC Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." Refresher training was also provided on the Program's RAM-01-10, which directs staff to use NRC inspection procedures. The Program continues to hold biweekly meetings where the use of these procedures are reinforced. Additionally, managers observe the use of procedures during inspector accompaniments.

This recommendation is closed.

Status of Materials Inspection Program: Satisfactory

Recommendation: None

Technical Quality of Inspections: Satisfactory

Recommendation: None

Technical Quality of Licensing Actions: Satisfactory but Needs Improvement

Recommendation: The team recommends that the Program revise its licensing procedures to include the current guidance to determine and document the basis of confidence for all new applications and transfers of control (i.e., change in ownership) that radioactive materials will be used as intended, prior to authorizing the material on the license; and provide the staff with training on the process and changes to the Program's licensing procedures. (Section 3.4 of the 2013 IMPEP report)

Status: During the 2013 IMPEP review, the team noted that Program staff were using an outdated procedure to determine and document the basis of confidence for new applications and transfer of controls. In response to this recommendation, the Program revised its licensing procedures, adopted RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence that Radioactive Material will be Used as Intended" as written, and provided training to the staff in December 2013. Although Arkansas took the actions suggested in this recommendation, the current IMPEP team identified continuing deficiencies in this area.

While this recommendation is closed, a separate recommendation that more closely focuses on current circumstances related to this area is provided in Section 3.4 of the report.

Technical Quality of Incident and Allegation Activities: Satisfactory

Recommendation: The team recommends that the State strengthen its incident response program by developing guidance and providing training to the staff on evaluating and responding to reported medical events. (Section 3.5 of the 2013 IMPEP report)

Status: In responding to this recommendation, the Program revised its guidance and provided refresher training for inspectors in conjunction with the inspection procedure training to staff which began immediately following the 2013 IMPEP review, in November 2013, and concluded in March 2014.

This recommendation is closed.

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 <u>Technical Staffing and Training</u>

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires 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 Arkansas'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. <u>Discussion</u>

While evaluating this indicator, the team considered the number of staff who have left the Program over the review period and how those losses could potentially impact the Program's performance. The Program, when fully staffed, is comprised of six full time equivalents which includes the Program Manager, four health physicists (HPs), and one administrative staff member. The HPs are responsible for all licensing and inspection activities within the Program. At the time of the review, there was one vacant HP position which has been vacant since July 2017. That position was frozen and, at the

time of the review, management did not have information on when that position would be filled. At the time of the MRB meeting, Arkansas stated that the position had been released and the position had been posted. The team verified that the position had been posted on the Arkansas Web site. A fifth HP position existed during the 2013 IMPEP review; however, that position is no longer funded.

Over the review period, four HPs left the program for various reasons. In 2014, one was terminated and two others moved to other positions with the State. In 2017, one left the State. The 2014 vacancies were quickly refilled and the 2017 vacancy is currently posted and in the process of being filled.

The team found that through the review period, the Program successfully managed losses, quickly filled most vacant positions, and provided training to new staff. While the team did identify issues with licensing as noted in Section 3.4, the team did not find any performance issues that were directly related to staffing levels.

Arkansas has a training and qualification program that is consistent with NRC's IMC 1248. The training program is managed by the Program Manager who meets regularly with staff under qualification and guides them through the training process. The Program Manager also determines when staff are sufficiently trained to work independently both for licensing and inspection-related activities.

The three HPs currently in the Program are all fully qualified as inspectors. However, only the most senior HP, with approximately 25 years of experience, is fully qualified as a licensing reviewer. The other two HPs are in various stages of the licensing qualification process; one has seven years of experience with the radioactive materials program and the other has approximately 3 years of experience. Although they do not have signature authority, the two HPs in various stages of the licensing qualification process are qualified to review the most commonly received licensing actions. The completion of the process for these individuals to become fully qualified with signature authority is highly dependent upon the type of licensing actions received by the Program. The Program has not received sufficient new or renewal licensing actions for infrequent modalities to be able to fully qualify these individuals for all modalities. The Program stated in the questionnaire that it will use the impending influx of license renewals expected to begin in 2019 to fully qualify these individuals.

Both Program staff and management stated that while they have been able to keep up with the wide range of Program activities through this review period, they are concerned about the impending influx of licensing renewals, and how that influx has the potential to overwhelm the staff given their current staffing levels and the time it takes to adequately train new individuals. License renewal backlogs have been a reoccurring issue for the Program and were identified in six IMPEP reviews between 1995 and 2011. The Program stated during the MRB meeting that it will be mirroring the NRC's approach with regards to renewal actions and extending the expiration dates for some of the renewal actions to 15 years.

c. Evaluation

The team determined that, during the review period, Arkansas met the performance indicator objectives listed in Section 3.1.a., and recommended that that Arkansas's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

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

3.2 <u>Status of Materials Inspection Program</u>

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 Arkansas'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. <u>Discussion</u>

When evaluating this indicator, the team considered five factors, including inspection frequency, performance of reciprocity inspections, overdue inspections, initial inspection of new licenses, and timely dispatch of inspection findings to licensees. Arkansas's inspections were performed at the same frequency or more frequent for similar license types as those established in IMC 2800. Arkansas performed 213 Priority 1, 2, 3, and initial inspections during the review period. Only two percent of these inspections were conducted past their due date. Four of the 213 Priority 1, 2, or 3, and one of nine initial inspections were conducted past their due date. Each year of the review period, Arkansas performed greater than 20 percent of candidate reciprocity inspections.

A sampling of 35 inspection reports indicated that three of the inspection findings were communicated to the licensees beyond Arkansas's goal of 30 days after the inspection exit. The team found that of the three reports that were issued late, two of them were two weeks late, and one was a month overdue. All three reports that were issued past

the 30 calendar day deadline contained documentation explaining the reason for the late report. The team confirmed that Arkansas has a plan in place to perform all overdue inspections and reschedule any missed inspections.

c. Evaluation

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

d. MRB Decision

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

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

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 Arkansas's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 30 materials inspections conducted during the review period. The casework reviewed included inspections conducted by seven of Arkansas's inspectors and covered medical, industrial, commercial, academic, research, and service licenses for routine, initial, special and reciprocal inspections.

The team concluded that the documentation of inspection findings was thorough, consistent, and complete. Documentation reviewed included followup actions from previous inspection findings and verification of the National Source Tracking System inventory. The team noted timely approval from management and effective communication of inspection findings, including citations and acceptance of corrective actions. The team identified three instances where inspection reports were issued beyond 30 days. Each instance was documented for awareness and to note the cause for a delay with appropriate notification to management.

A team member accompanied three program inspectors on August 15 - 17, 2017. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared and thorough, and conducted performance-based inspections. The inspections were adequate to assess the impact of licensed activities on health, safety, and security. Inspector accompaniments are identified in Appendix B.

The team assessed the performance of supervisory accompaniments of applicable staff. The Program performs supervisory accompaniments of all staff at least annually. Supervisory accompaniments were conducted each year of the review period. However, in 2014, two inspectors did not receive supervisory accompaniments. One staff member had been recently qualified and subsequently terminated employment in April of 2014. Due to the short length of qualification and the employment not exceeding a year, the Program was unable to conduct a supervisory accompaniment. The second exception resulted in a senior staff member not being accompanied in 2014. Management stated that the missed supervisory accompaniment for this individual was due to a management oversight. This staff member has been accompanied every year since 2014.

The team evaluated the handling and storage of sensitive documents by Program staff. The team identified one occurrence of sensitive records maintained outside the secured file cabinet in the form of a licensee's corrective action letter and the Program's letter of citation. A staff member clarified expectations regarding the normal handling of all sensitive records, and immediately marked and removed the sensitive records from the non-secured file. In addition, training has been given to the staff member responsible for the filing and handling of the majority of records to promote awareness. With the exception of this one occurrence, all sensitive records were secured in a locked file cabinet within the Department's coded entry work area. Only individuals with a need to know are provided the code, and awareness of the location of the key to the file cabinet was further restricted.

The Program possesses a variety of calibrated survey instruments used to support the inspection program, emergency response, and incident and allegation investigation. Instruments are sent to the manufacturer at least annually with several Program designated instruments being sent every 6 months. Staff members discussed instrument checks and actions taken if an instrument fails any check. The Program designates a staff member to manage these instruments and performs quarterly checks of all instruments in its possession with the exception of any instrument already tagged out of service. A record of these instruments is maintained in addition to the tag being placed on the instrument to ensure it is not used. If an instrument fails a check, either day of use or quarterly, it is tagged and removed from the active instruments to prevent accidental use. Careful and precise records are maintained of the instrumentation.

c. Evaluation

The team determined that, during the review period, Arkansas met the performance indicator objectives listed in Section 3.3.a., and recommended that Arkansas's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Arkansas's performance with respect to this indicator to be 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, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the Arkansas 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 Arkansas'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. <u>Discussion</u>

During the review period, Arkansas performed 536 radioactive materials licensing actions. The team evaluated 25 of those licensing actions. The licensing actions selected for review included seven new applications, nine amendments, four renewals, three terminations, and two transfers of control notifications. The team evaluated casework which included the following license types and actions: medical diagnostic and therapy, cyclotron, commercial manufacturing and distribution, industrial

radiography, veterinary, gauging devices, panoramic irradiators, financial assurance, and notifications. The casework sample represented work from seven license reviewers.

The team examined the Program's licensing practices with regard to requests for Risk Significant Radioactive Material. The team determined that the Program has a licensing procedure to identify new and amended licenses that should be subject to additional security measures and that it is implementing the procedure correctly.

For 14 out of the 25 licensing actions reviewed, the team found issues either in the license or with the license review ranging from thoroughness, completeness, consistency, adherence to current regulatory guidance; to health, safety, and security issues not being properly addressed. For infrequently reviewed modalities, the team found that licensing actions were thorough, complete, consistent, and of acceptable quality with health, safety, and security issues properly addressed. However, for routine or frequently reviewed modalities, which were the majority of the licensing actions reviewed, the team identified a number of instances where licensing actions were not thorough, complete, consistent, and of acceptable quality, and where health and safety issues were not properly addressed. The issues identified included the improper implementation of guidance documents (e.g., financial assurance, pre-licensing guidance), inconsistencies in the Program's license reviews, typographical errors, and applications and amendment requests lacking the appropriate management signatures.

The team identified deficiencies in the Program's implementation of the Checklist to Provide a Basis for Confidence that Radioactive Material will be Used as Specified on the License (Pre-Licensing guidance). During the 2013 IMPEP review, the team found that several case files, including four new licenses and one change of ownership, did not have the documentation per the Pre-Licensing guidance to support a basis for confidence that radioactive material would be used as requested. The current team identified similar examples. The Program had suspended the practice of hand delivering the license at the time of the pre-licensing site visit after the 2015 Government Accountability Office audit. This action was taken because the pre-licensing site visit is part of the evaluation process to determine the basis for confidence that radioactive material will be used as intended and should be conducted separate from any practice of the hand delivery of a license. Nevertheless, the team found that the license was hand delivered at the same time as the pre-licensing site visit for a new license application processed after 2016. In another instance, the Program licensing reviewer indicated that the company requesting a license was a known entity based on the company maintaining a Facebook page. The improper implementation of the Pre-Licensing guidance has health, safety, and security implications because without proper documentation review there is a potential for an individual with nefarious intentions to obtain a radioactive materials license.

The team also identified a recurring issue involving the Program's application of the Pre-Licensing guidance for transfers of control (i.e., change of ownership). The Program did not use the Pre-Licensing guidance for transfers of control in any of the licensing actions reviewed by the team, even though this issue was identified in the 2013 IMPEP review. In two transfer of control cases that were reviewed, the documentation to support a basis of confidence that the radioactive material would be used as requested, was not included in the file. In addition, the team identified two additional transfer of control notifications where the Program had noted a change in ownership had occurred for the licensees; however, a review of the change and a basis for confidence determination were not completed. In one of those cases, the Program amended the

license to change the company name and radiation safety officer without first receiving the transfer of control documentation the reviewer had requested.

As a result of these identified deficiencies, Arkansas should provide additional training with regard to the implementation of the Pre-Licensing guidance to ensure that staff understand how to properly identify unknown applicants and transfer of control requests, when completing the evaluation of the basis for confidence.

While reviewing license amendment requests to add new authorized users, authorized medical physicists, and radiation safety officers, the team noted an inconsistency amongst the licensing staff with regards to verifying the qualifications of the preceptor. The team found that not all reviewers would verify that the preceptor was properly qualified for the modalities the proposed user was seeking authorization. The team identified this issue during its review of licensing actions where the preceptor was from another Agreement State or listed on an NRC license. This issue has potential transboundary implications because users could be authorized by the NRC and other Agreement States if they are currently authorized on an Arkansas license. Other regulatory programs do not require a user to repeat the authorization process if that individual is currently authorized on an NRC or Agreement State license.

Consequently, Arkansas should revise its procedures to ensure that the qualifications of preceptors are properly verified to attest to the training for new authorized users, authorized medical physicists, or radiation safety officers that are to be added to the licenses. In addition, Arkansas should verify that all previously approved authorized users, authorized medical physicists, and radiation safety officers, where the preceptor is not listed on an Arkansas license, and were properly qualified to act as a preceptor.

The team identified issues with Arkansas's application of financial assurance program requirements. At the time of the review, the Program had three licensees that were authorized for possession of radioactive materials in excess of the quantities that would require financial assurance. The team verified that the proper financial assurance documentation was on file and that the information was appropriately protected. However, the team found that for one license, the license review was inconsistent with current regulatory requirements. The inconsistencies related to the annual verification of the financial assurance instrument and the proper financial assurance amount required based on the maximum possession limits listed on the license. The Program had not received the annual trust valuation, which is required to be provided by the Trustee for the licensee. In addition, the aforementioned license had been amended to increase the possession limit without any documentation on file (e.g. request from the licensee) to show why the change was made. In turn, the associated decommissioning funding plan had not been revised to account for the increase in the possession limit. At the time of the review, the Program initiated the process to obtain a revised decommissioning cost estimate.

During the review, the team identified several instances involving lack of attention to detail in the Program's licensing actions. Typographical errors identified during the review included two new licenses that contained amendment numbers, one instance where an incorrect date was added to a tie down condition, and another license that was incorrectly dated. These issues were self-corrected by the Program in the next amendment or were brought to the attention of the licensing staff by the team. The team also found that in several licensing requests, including new license applications and requests to change radiation safety officers, the application or amendment request was not signed. In addition, the team identified licensing action requests that were not

properly signed by an approved licensee official. Even though these requests were not properly signed by the licensee or new license applicant, the requests were processed by the Program and were often tied down on the license. The processing of these licensing actions is inconsistent with the Program's current regulatory guidance documents. Application and amendment requests signed by management, or an individual authorized by management, are necessary to verify that the applicant understands that all statements contained in the application, including commitments by the applicant on how they will manage their radioactive material program, are true and correct.

Based on the findings mentioned above, Arkansas should establish a quality control/quality assurance process or similar tool to help improve the thoroughness, completeness, and consistency of the license reviews, as well as to ensure license reviews are of acceptable technical quality with health, safety, and security properly addressed, and that licensing requests are properly signed before taking any action on a proposed request.

c. Evaluation

The team determined that the Program's licensing actions during the review period presented chronic problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing review guidance. Previous IMPEP teams have identified: (1) instances where material dispositions and license terminations were approved by the Program without receiving supporting documentation: (2) licensee requests in which the licensee's documentation was inconsistently included in the tie-down condition of the license; (3) inconsistencies in licensing practices among the staff due to a lack of adherence to, or awareness of, the Program's licensing quidance; and (4) instances where the responses received from licensees were not adequately reviewed for accuracy and completeness, but nonetheless licensing actions were subsequently issued. The team noted that for the last four IMPEP reviews, dating back to 2006, the Program's performance rating for this indicator has been satisfactory, but needs improvement. Accordingly, based on the IMPEP evaluation criteria in MD 5.6 and considering the Program's past and current performance, the team recommended that Arkansas's performance with respect to the indicator. Technical Quality of Licensing Actions, be found unsatisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Arkansas's performance with respect to this indicator to be unsatisfactory.

3.5 Technical Quality of Incident and Allegation Activities

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

a. Scope

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

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (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. <u>Discussion</u>

During the review period, 17 incidents were reported to the NMED database by Arkansas. The team examined each of the 17 event case files to evaluate the Program's response. The casework reviewed included four events involving lost or stolen radioactive material, one event involving a source found at a residence, one transportation event, two medical events, three events involving equipment failures, and six events involving stuck shutters on fixed gauges.

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

The team also evaluated the Program's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case reviewed where HOO notification was required, the Program reported the events within the required timeframe. Additionally, an evaluation was made to determine if the Program had failed to report any required events to the HOO. The team did not find any other events that met the reporting requirement but were not reported by the Program.

During the review period, four allegations were received by Arkansas. No allegations were referred by the NRC to Arkansas during the review period. The team evaluated all four allegations and found that the Program took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed, concerned individuals were notified of the actions taken, and allegers' identities were protected.

c. Evaluation

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

d. MRB Decision

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

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 <u>Compatibility Requirements</u>

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

Arkansas became an Agreement State on July 1, 1963. The Arkansas Agreement State Program's current effective statutory authority is contained in the Rules and Regulations for Control of Sources of Ionizing Radiation of the Arkansas Statutes. The Arkansas State Board of Health is designated as the State's radiation control agency, with the day-to-day administrative duties carried out by the Director of the Department. Since the 2013 IMPEP, Act 1258 of 2015, as codified in A.C.A. § 25-25-204, provided that each rule adopted by the Department is effective ten days after filing of the final rule with the Secretary of the State, unless a later date is specified. Previously, rules were adopted 30 days after filing of the final rule.

The State's administrative rulemaking process takes approximately 18 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 Arkansas State Board of Health. The team noted that the State's rules and regulations are not subject to "sunset" laws. During the review period, Arkansas submitted 16 proposed regulation amendments and 18 final regulation amendments to the NRC for a compatibility review. At the time of this IMPEP review, no amendments were overdue. With one exception, all regulation amendment packages were adopted well in advance of the adoption period.

The sole exception was the regulation package for "Licenses, Certifications, and Approvals for Materials Licensees," Parts 30, 36, 39, 40, 70, and 150, (RATS ID 2011-2), which was adopted 16 days late. The rule package containing the amendment became effective November 30, 2014, and the amendment was due November 14, 2014. Revisions addressing RATS ID 2011-2 were in a rule package that also contained regulations related to accelerator and therapeutic radiation machine regulations. Public comments on the latter regulations, not associated with RATS ID 2011-2, were received necessitating the rulemaking process to restart for the entire rule package submitted for adoption, thereby lengthening the time required for adoption.

c. Evaluation

The team determined that, during the review period, Arkansas met the performance indicator objectives listed in Section 4.1.a., and recommended that Arkansas's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

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

4.2 LLRW Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC 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. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need for an amendment. Although Arkansas has such authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for LLRW disposal. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Arkansas. Accordingly, the team did not review this indicator.

5.0 SUMMARY

The team recommended, and the MRB agreed, that Arkansas's performance was satisfactory for five out of six performance indicators reviewed, and unsatisfactory for the performance indicator Technical Quality of Licensing Actions. The MRB supported the four recommendations made by the team regarding Arkansas's performance, as well as the team's determination that the three recommendations from the 2013 IMPEP review should be closed.

Accordingly, the team recommended, and the MRB agreed, that the Arkansas Agreement State Program be considered adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Per the guidance criteria in SA-122, "Heightened Oversight and Monitoring," the team considered recommending that Arkansas be placed on either Heightened Oversight or Monitoring. Based on Arkansas's positive feedback, its recognition and ownership of the licensing issues identified during the review, and its excellent implementation and quality in the other performance areas, the team did not believe Heightened Oversight was warranted. The team recommended, and the MRB agreed, that the Arkansas Agreement State Program be placed on Monitoring, which will facilitate Arkansas taking the necessary steps to rectify the licensing issues identified during the review. The team recommended that a followup IMPEP review take place in approximately 2 years to review the Technical Quality of Licensing Actions indicator. However, the MRB directed that a followup IMPEP review should take place in 18 months instead of 2 years.

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

1. Arkansas should provide additional training with regard to the implementation of the Pre-Licensing guidance to ensure that staff understand how to properly identify unknown applicants and transfer of control requests, when completing the evaluation of the basis for confidence. (Section 3.4)

- 2. Arkansas should revise its procedures to ensure that the qualifications of preceptors are properly verified to attest to the training for new authorized users, authorized medical physicists, or radiation safety officers that are to be added to the licenses. (Section 3.4)
- 3. Arkansas should verify that all previously approved authorized users, authorized medical physicists, and radiation safety officers, where the preceptor is not listed on an Arkansas license, were properly qualified to act as a preceptor. (Section 3.4)
- 4. Arkansas should establish a quality control/quality assurance process or similar tool to help improve the thoroughness, completeness, and consistency of the license reviews, as well as to ensure license reviews are of acceptable technical quality with health, safety, and security properly addressed, and that licensing requests are properly signed before taking any action on a proposed request. (Section 3.4).

LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name Areas of Responsibility

Lizette Roldán-Otero, Ph.D., NMSS Team Leader

Status of Materials Inspection Program

Compatibility Requirements Inspection Accompaniments

Randy Erickson, Region IV Technical Staffing and Training

Technical Quality of Incidents and Allegations

Jennifer Dalzell-Bishop, Region III Technical Quality of Licensing Actions

Beth Schilke, VA Technical Quality of Inspections

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: ARK-920	
License Type: High Dose Remote Afterloader	Priority: 2	
Inspection Date: 08/15/17	Inspector: AH	
Accompaniment No.: 2	License No.: ARK-576	
License Type: e.g., Radiography	Priority: 1	
Inspection Date: 08/16/17	Inspector: DS	
Accompaniment No.: 3	License No.: ARK-1033	
License Type: e.g., Nuclear Pharmacy	Priority: 2	
Inspection Date: 08/17/17	Inspector: SM	