



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

June 17, 2019

Nathaniel Smith, M.D., M.P.H.
Director of Health and State
Public Health Officer
Arkansas Department of Health
4815 W. Markham Street
Little Rock, Arkansas 72205

Dear Dr. Smith:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the IMPEP review held in Arkansas on May 21 – May 23, 2019. This review was a follow-up to the 2017 IMPEP review, and was focused on the indicator, Technical Quality of Licensing Actions. The team's preliminary findings were discussed with you and your staff on the last day of the review. The review team's proposed recommendations are that the Arkansas Agreement State Program be found adequate, and compatible with the NRC's program.

Additionally, a periodic meeting was conducted on May 21, 2019 with members of your staff. The summary report can be found in Enclosure 2 of this letter.

The NRC conducts periodic reviews of radioactive materials programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The IMPEP process uses a team comprised of NRC and Agreement State staff to perform the reviews. All reviews use common criteria in the assessment and place primary emphasis on performance. As stated above, this review is a follow-up IMPEP review. The team examined the progress made by Arkansas to address the performance issues that were identified during the 2017 IMPEP review regarding the indicator, Technical Quality of Licensing Actions. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

N. Smith

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The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting is scheduled for Thursday, August 8, 2019, at 1:00 p.m. ET. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland. The NRC has video Skype capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to participate in the meeting using Skype.

If you have any questions regarding the enclosed report, please contact me at 301-415-5804 or Michelle Beardsley at 301-415-0275.

Thank you for your cooperation.

Sincerely,

/RA/

Paul Michalak, Chief
State Agreement and Liaison Programs Branch
Division of Material Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Enclosures:

- 1) 2019 Draft IMPEP Report
- 2) Periodic Meeting Summary

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
FOLLOW-UP REVIEW OF THE ARKANSAS AGREEMENT STATE PROGRAM

May 21 – May 23, 2019

DRAFT REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) follow-up review of the Arkansas Agreement State Program. The review was conducted during the period of May 21 – May 23, 2019 and focused on the performance indicator, Technical Quality of Licensing Actions.

Based on the results of this review, Arkansas's performance was found satisfactory, but needs improvement for the indicator, Technical Quality of Licensing Actions.

The team kept open and modified one recommendation from the 2017 IMPEP review (see Section 4.0) and determined that the other three recommendations from the 2017 IMPEP review should be closed (see Section 2.0). The team did not make any new recommendations.

Accordingly, the team recommends that the Arkansas Agreement State Program be found adequate to protect public health and safety, and compatible with the NRC's program. Due to the progress that the Program has made in improving their licensing program, the team recommends that the period of monitoring be discontinued. The team recommends that the next full IMPEP review take place in approximately 2 years from this review. In addition, the team recommends that a Periodic Meeting should be scheduled in approximately 1 year to assess the Program's continued progress.

1.0 INTRODUCTION

This Arkansas Agreement State Program follow-up IMPEP review, conducted during the period of May 21-23, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Texas. Team members are identified in Appendix A. The team examined the progress made by Arkansas to address the performance issues that were identified during the 2017 IMPEP review regarding the indicator, Technical Quality of Licensing Actions. The follow-up 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 5.6 (MD 5.6), "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the follow-up review, which covered the period of December 2, 2017 to May 23, 2019, were discussed with Arkansas managers on the last day of the review.

In preparation for the follow-up review, a questionnaire addressing the common performance indicator, Technical Quality of Licensing Actions, was sent to Arkansas on November 13, 2018. Arkansas provided its response to the questionnaire on May 13, 2019. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML19135A442.

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 176 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 the performance indicator, Technical Quality of Licensing Actions, 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 December 1, 2017. The final report is available in ADAMS (Accession Number ML18054A662). 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: Unsatisfactory

Recommendation 1: Arkansas should provide additional training regarding 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)

Status: The Program provided refresher training on their procedure, Guidance for Completion of Security Risk Checklists for Arkansas Radioactive Materials Licenses. This procedure includes both the Pre-licensing Guidance checklist and the Risk Significant Radioactive Materials checklist. The team evaluated casefiles for new licenses and change of control amendments and determined that the Program staff was completing the current Pre-licensing Guidance Checklist issued August 2018.

The team determined this recommendation should be closed.

Recommendation 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)

Status: The Program provided training regarding their procedure for Medical Preceptor Verifications. The team evaluated casefiles for amendments that added authorized medical users and found that the Program staff verified the preceptors' qualifications for new authorized medical users, medical physicists or radiation safety officers that were added to the license for these actions.

The team determined this recommendation should be closed.

Recommendation 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)

Status: The Program reported that they reviewed all 85 medical licenses and found that 15 out of the 200 amendments with preceptor statements had issues related to the verification of the preceptor. The Program stated that they re-reviewed these 15 actions and the preceptors were able to be verified. The team reviewed a sampling

of these actions and determined that the Program verified the preceptors accordingly.

The team determined this recommendation should be closed.

Recommendation 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).

Status: In response to this recommendation, the Program implemented a multi-step Quality Improvement Procedure to address the previous issues identified during the 2017 IMPEP review. However, this review team identified similar issues with thoroughness and consistency of the license reviews; see Section 3.1 of this report for details.

The team determined this recommendation should be kept open but modified (Section 3.1 of this report).

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

Compatibility Requirements: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety, but needs improvement, and compatible with the NRC's Program. The Program was placed on monitoring.

3.0 COMMON PERFORMANCE INDICATOR

As mentioned in this report, this is a follow-up review which focused on the indicator, Technical Quality of Licensing Actions.

3.1 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. Discussion

During the follow-up review period, Arkansas performed 289 radioactive materials licensing actions. The team evaluated 25 radioactive materials licensing actions. The licensing actions selected for review included 2 new applications, 16 amendments, 2 renewals, 2 terminations, and 3 transfers of control notifications. The team evaluated casework which included the following license types and actions: medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, gauging devices, well logging, and financial assurance. The casework sample represented work from four license reviewers.

The team found that many of the licensing actions reviewed were thorough, complete, consistent, and of acceptable quality with health, safety, and security issues properly addressed. In response to the issues identified during the 2017 review, the Program implemented a quarterly "Quality Improvement" audit procedure. The team reviewed the audit results and found that while the Program was identifying errors in the licensing actions, there were still cases in which the team identified issues with license conditions. These issues included licenses in which standard license conditions, authorized materials and use conditions, and medical user materials authorizations were not in accordance with the Program's licensing procedures specified in RAM-01.1. Specifically, certain license conditions were old and obsolete, or used inconsistently; authorized medical users' material authorizations were written inconsistently among

licenses, and not in accordance with the Program's licensing procedure; and an authorized material and use condition did not reflect the actual use of the material. The team did not identify any issues that were of health and safety, or security significance.

The team examined the Program's licensing practices regarding requests for Risk Significant Radioactive Material (RSRM). 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 the Program is implementing the procedure. However, the team found instances where the Program was not completing the checklist in cases where the request was to remove or decrease RSRM. The Program reported it was not aware of this requirement (included in Step 1 of the RSRM checklist), but committed to complete the checklist for these cases as well.

The team determined that the appropriate Pre-Licensing checklist was being implemented in all applicable cases reviewed, including new license actions and change of control amendments. The team also determined that, as of February 2019, the Program is implementing a compatible procedure to the Pre-Licensing Guidance that was issued by the NRC in August 2018.

Based on the findings mentioned above, the team recommends that the Program continue to perform their quarterly Quality Improvement audits to ensure that licensing actions are thorough, consistent, and adhere to the Program's licensing procedures pertaining to the use of standard license conditions, standard authorized use conditions and standard authorized medical user materials authorizations.

c. Evaluation

The team determined that, except as noted below, during the review period, Arkansas met the performance indicator objectives listed in Section 3.1.1

- Licensing action reviews were not thorough, complete, consistent, and of acceptable technical quality

The team identified certain license conditions that were old and obsolete, or used inconsistently, for example several licenses contained conditions that were redundant to their regulations and no longer necessary. The Program's licensing procedure states that during each amendment, the license reviewer should review the license conditions to determine that they are still current and applicable. The team found that authorized medical users', material authorizations for the use of materials for cardiology procedures, and the use of materials requiring a written directive were written inconsistently among licenses, and not in accordance with the Program's licensing procedure. The team also identified one license in which an authorized material and use condition did not reflect the actual use of the material, i.e., the licensee possessed depleted uranium but the authorization for depleted uranium was missing, and the licensee was storing material at the licensed site although storage was not specifically authorized on the license. However, the team did not identify any issues that were of health and safety, or security significance.

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

d. MRB Decision

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

4.0 SUMMARY

Arkansas's performance was found to be satisfactory, but needs improvement for the performance indicator, Technical Quality of Licensing Actions. The team kept open and modified one recommendation (Recommendation 4) regarding Arkansas's performance, and determined that the other three recommendations from the 2017 IMPEP review should be closed.

Accordingly, the team recommends that the Arkansas Agreement State Program be found adequate to protect public health and safety, and compatible with the NRC's program. Due to the progress that the Program has made in improving their licensing program, the team recommends that the period of monitoring be discontinued. The team recommends that the next full IMPEP review take place in approximately 2 years from this review. In addition, the team recommends that a Periodic Meeting should be scheduled in approximately 1 year to assess the Program's continued progress.

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

The team recommends that the Program continue to perform their quarterly Quality Improvement audits to ensure that licensing actions are thorough, consistent, and adhere to the Program's licensing procedures pertaining to the use of standard license conditions, standard authorized use conditions, and standard authorized medical user materials authorizations.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
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APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Michelle Beardsley, NMSS	Team Leader Technical Quality of Licensing Actions
Randy Erickson, Region IV	Periodic Meeting
Vanessa Danese, Texas	Technical Quality of Licensing Actions



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

PERIODIC MEETING WITH THE STATE OF ARKANSAS

TYPE OF OVERSIGHT: MONITORING

May 21, 2019

PERIODIC MEETING PARTICIPANTS

NRC

- Randy Erickson: State Agreements Officer, NRC Region IV

State of Arkansas

- Bernie Bevill: Section Manager
- Jared Thompson: Program Manager
- Steve Mack: Health Physicist
- Angie Morgan Hill: Health Physicist
- David Stephens, Health Physicist
- Christopher Talley, Health Physicist

1.0 INTRODUCTION

This report presents the results of the periodic meeting held between the U.S. Nuclear Regulatory Commission (NRC) and the State of Arkansas. The meeting was held on May 21, 2019. The meeting was conducted in accordance with NMSS Procedure SA-116 "Periodic Meetings between IMPEP Reviews," dated June 3, 2009; and, was conducted concurrently with the 2019 follow-up IMPEP review.

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. At the time of the meeting, the Arkansas Agreement State Program regulated approximately 176 specific licenses authorizing possession and use of radioactive materials. The meeting 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 Arkansas Agreement State Program has been subject to increased oversight by the NRC since February 2018. During a Management Review Board (MRB) held on February 13, 2018, to discuss the results of the December 2017 Integrated Materials Performance Evaluation Program (IMPEP) review, the MRB determined that the Arkansas Agreement State Program should be placed on Monitoring and overall found adequate to protect public health and safety but needs improvement and compatible with the NRC's Program. The timeframe for the next IMPEP review was shortened to 18 months and was held the week of May 20, 2019.

2.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC Regional Office and Agreement State radioactive materials programs during an IMPEP review. 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.

Because the periodic meeting was held concurrently with the follow up IMPEP review, and licensing was the focus of that review, the periodic meeting was limited to a discussion of the indicators excluding the licensing indicator.

2.1 Technical Staffing and Training (2017 IMPEP: Satisfactory)

The Arkansas Agreement State Program is made up of six full time equivalents which includes the Program Manager, four health physicists, and one administrative staff member. The health physicists are responsible for all licensing and inspection activities

within the Program. At the time of the 2017 IMPEP review, the Program had one vacancy which was filled shortly after the review. Since the 2017 IMPEP review, no staff have left the Program. Three of the health physicists are fully qualified and one is currently in training.

The Program has a documented training and qualification plan consistent with NRC's Inspection Manual Chapter (IMC) 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs." Program management tracks continuing education requirements of 24 hours every two years and provides ample opportunities for staff to fulfill this requirement.

2.2 Status of the Materials Inspection Program
(2017 IMPEP: Satisfactory)

The Arkansas Agreement State Program's inspection frequencies are the same as the NRC's inspection frequencies that are listed in IMC 2800. At the time of the meeting, no inspections were currently overdue, and none had been performed overdue during the review period. The Program issued 4 new licenses during the review period and all initial inspections of those licenses were performed within the 12-month requirement.

The Program reported they have been meeting the 20 percent requirement for performing reciprocity inspections this review period. The Program continues to perform annual supervisor accompaniments of each inspector with none being missed since the previous review. Additionally, inspection reports are typically issued within 30 days of the inspection exit meeting with the licensee.

2.3 Technical Quality of Inspections
(2017 IMPEP: Satisfactory)

Inspection guidance used by the Arkansas Agreement State Program is equivalent to the NRC's IMCs and Inspection Procedures. The Arkansas Agreement State Program issues all inspection findings, regardless of whether there is a violation, by written correspondence from the office. Inspection findings are routinely sent to the licensee within 30 days of the completion of an inspection.

2.4 Technical Quality of Licensing Actions
(2017 IMPEP: Unsatisfactory)

The licensing indicator and the four associated recommendations were reviewed during the IMPEP portion of the review.

2.5 Technical Quality of Incident and Allegation Activities
(2017 IMPEP: Satisfactory)

The Arkansas Agreement State Program has procedures and processes in place to maintain effective responses to incidents and allegations. 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. When an event is determined to have high health and safety significance, inspectors are dispatched immediately.

Since the 2017 IMPEP review, a total of eight events had been reported to the Nuclear Materials Events Database (NMED) by the Program. At the time of the periodic meeting all but one had been reviewed and closed. No allegations had been received from NRC or directly by the Program during this time; however, when allegations are received they are reviewed by the Program, concerned individuals are notified of the actions taken, and alleged identities are protected whenever possible in accordance with state law.

3.0 NON-COMMON PERFORMANCE INDICATORS

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

3.1 Compatibility Requirements (2017 IMPEP: Satisfactory)

No legislative changes affecting the Program have occurred since the last IMPEP review. At the time of the periodic meeting there were no regulation amendments overdue for adoption, nor were any submitted late. The Program did report that there will be an administrative change to the title of the Arkansas rules. They title will change from "Rules and Regulations" to "Rules". This will require the Program to amend many parts of their requirements to remove references to the word, "Regulations". Regulations applicable to the Arkansas Agreement State Program are not subject to sunset requirements.

3.2 Low-Level Radioactive Waste (LLRW) Disposal Program (2017 IMPEP: Not reviewed)

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 Arkansas Agreement State Program has 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 a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a commercial LLRW disposal facility in Arkansas. Accordingly, this indicator was not reviewed.

4.0 SUMMARY

Within the scope of the periodic meeting, no programmatic concerns were noted at this time. The Arkansas Agreement State Program is an effective and vital part of the Arkansas Department of Health. The Program continues to effectively manage its inspection activities and is responding to incidents and allegations as appropriate.