



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

February 6, 2018

MEMORANDUM TO: 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

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

Marc L. Dapas, Director  
Office of Nuclear Material Safety  
and Safeguards

Darrell J. Roberts, Deputy Regional Administrator  
Region III

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

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION  
PROGRAM REVIEW OF ARKANSAS

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 Arkansas. The review was conducted by a team of U.S. Nuclear Regulatory Commission (NRC) and Agreement State technical staff during the period of November 27 – December 1, 2017. The team's preliminary findings were discussed with Arkansas on the last day of the review. The team issued a draft report to Arkansas on January 2, 2018, for factual comment. Arkansas responded to the findings and conclusions of the review by letter from Stephanie C. Williams RNP, MPH, Deputy Director for Public Health Programs, Arkansas Department of Health on February 2, 2018 (Enclosure 2).

Overall, the team is recommending that Arkansas's performance be found 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.

CONTACT: Lance Rakovan, MSST  
(301) 415-2589

Accordingly, the team recommends that the Arkansas Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Additionally, the team recommends that a followup IMPEP review take place in approximately 2 years to review the Technical Quality of Licensing Actions indicator and that a Periodic Meeting be scheduled in approximately 1 year to discuss Arkansas' status and performance including, the expected influx of license renewals and the Technical Quality of Licensing Activities.

Based on Arkansas' positive feedback, its recognition and ownership of the licensing issues identified during the review, and its excellent implementation and quality in other performance areas, the team is recommending that a period of Monitoring be initiated for Arkansas. Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program. The team believes this will facilitate Arkansas taking the necessary steps to rectify the licensing issues identified during the review.

The MRB meeting to consider the Arkansas report is scheduled for **Tuesday, February 13, 2018, from 1:00 p.m. to 4:00 p.m. ET**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 3).

Enclosures:

1. Arkansas Proposed Final Report
2. Arkansas Response to Draft IMPEP Report
3. Meeting Agenda

cc: Stephanie C. Williams RNP, MPH,  
Deputy Director for Public Health Programs  
Arkansas Department of Health

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



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

November 27, 2017 – December 1, 2017

**PROPOSED 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 – 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, Arkansas's performance was found 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 team made four recommendations (see Section 5.0) and determined that the recommendations from the 2013 IMPEP review should be closed (see Section 2.0).

Accordingly, the team recommends that the Arkansas Agreement State Program be found 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 the State 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 necessary. These factors have led the team to conclude that the Arkansas Agreement State Program should be placed on Monitoring, which will facilitate Arkansas taking the necessary steps to rectify the licensing issues identified during the review. To verify that Arkansas has corrected the licensing issues identified in the review, the team recommends that a followup IMPEP review take place in approximately 2 years to review the Technical Quality of Licensing Actions indicator. In addition, the team recommends that a Periodic Meeting be scheduled in approximately 1 year to discuss Arkansas's status and performance, including the expected influx of license renewals and the Technical Quality of Licensing Activities.

## 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 – 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 managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicator was sent to 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.

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 Inspection Manual Chapter 2800. 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 and the use of procedures during inspections is observed during inspector accompaniments.

The team believes this recommendation should be closed.

Status of Materials Inspection Program: Satisfactory

Recommendation: None

Technical Quality of Inspections: Satisfactory

Recommendation: None

Technical Quality of Licensing Actions: Satisfactory 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: In response to this recommendation, the Program revised their licensing procedures to include current guidance and provided training to the staff in December 2013.

The team believes this recommendation should be closed. However, a recommendation focusing on unknown applicants and transfer of control requests is provided later in this 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.

The team believes this recommendation should be 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 Technical Staffing and Training

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

##### a. Scope

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

##### b. Discussion

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 (HP), 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 is currently frozen and, at the time of the review, management did not have information on when that position

would be filled. 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 for a better opportunity in the private sector. The 2014 vacancies were quickly refilled; however, as previously noted, the 2017 vacancy is currently subject to a hiring freeze and the Program is uncertain when that position will be 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 Inspection Manual Chapter (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 7 years of experience with the radioactive materials program and the other has approximately 3 years of experience.

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 an impending influx of licensing renewals that are expected to begin in 2019, 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.

c. Evaluation

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

d. MRB Decision

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

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of



operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

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

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 inspections were performed at the same frequency or more frequent for similar license types than 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 overdue. Four of the 213 Priority 1, 2, or 3, and one of nine initial inspections were conducted overdue. 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 recommends that Arkansas's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

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

3.3 Technical Quality of Inspections

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

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated 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 found thorough, consistent, and complete documentation of inspection findings. Documentation reviewed included followup actions from previous inspection findings and verification of the National Source Tracking System inventory. The team found timely approval from management and effective communication of inspection findings, including citations and acceptance of corrective actions. The team found 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 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 supervisory accompaniment for this individual had been overlooked in error due to the staff member's seniority and other occurrences during that year. 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 found 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 the normal handling of all sensitive records, and immediately marked and removed the sensitive records from 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 are provided the code and awareness of the location of the key to the file cabinet was further restricted.

The Program possess 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 six 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 recommends that Arkansas's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

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

### 3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the 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 review period, Arkansas performed 536 radioactive materials licensing actions. The team evaluated 25 radioactive materials 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, accelerator, 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 they are 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. In general, the team found that licensing actions were thorough, complete, consistent, and of acceptable quality with health, safety, and security issues properly addressed, when new applications or amendment requests were submitted for infrequently reviewed modalities. However, for routine or frequently reviewed modalities, which were the majority of the licensing actions reviewed, the team found 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 found 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 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 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 reviewer indicated that the company 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 material license.

The team also identified a recurring issue involving the Program's application of the Pre-Licensing guidance for transfers of control (e.g., 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, although 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 found 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 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, the team recommends that the Program provide training with regards to the implementation of the Pre-Licensing guidance to ensure that staff are properly identifying unknown applicants and transfer of control requests, and 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. The team identified this issue in licensing actions where the preceptor was from another Agreement State or listed on an NRC license. This issue has potential transboundary implications because users would 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, the team recommends that the Program 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, the team recommends that the Program 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.

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 found several instances of the 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 amendments 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 found 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. Signed application and amendment requests by management, or an individual authorized by management, verify that the applicant understands that all statements contained in the application, including abiding by commitments made to the program by the applicant on how they will manage their radioactive material program, are true and correct.

Based on the findings mentioned above, the team recommends that the Program establish a quality control/quality assurance process or similar tool to help improve the thoroughness, completeness, consistency of the license reviews and 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 guidance. Previous reviews have identified instances where material dispositions and license terminations were approved without receiving supporting documentation, licensee requests in which the licensee's documentation was inconsistently included in the tie-down condition of the license, inconsistencies in licensing practices among the staff due to a lack of adherence to or awareness of the Program's licensing guidance, and instances where the responses received from licensees were not adequately reviewed for accuracy and completeness and 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 recommends that Arkansas's performance with respect to the indicator, Technical Quality of Licensing Actions, be found unsatisfactory.

d. MRB Decision

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

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and 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. Discussion

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 should have been reported to the HOO that were not.

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 allegeders' 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 recommends that Arkansas's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

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



#### 4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery (UR) Program. The NRC's Agreement with Arkansas does not relinquish regulatory authority for sealed source and device evaluations, or a uranium recovery program; therefore, only the first and third non-common performance indicators applied to this review.

##### 4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

##### a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated 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 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

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 review, no amendments were overdue. With one exception, all regulation amendment packages were adopted well in advanced 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. The latter regulations, not associated to RATS ID 2011-2, received public comments 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 recommends that Arkansas's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

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

4.2 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC 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 of 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 recommends that Arkansas's performance be found satisfactory for five out of six performance indicators reviewed, and unsatisfactory for the performance indicator Technical Quality of Licensing Actions. The team made four recommendations regarding Arkansas's performance and determined that the three recommendations from the 2013 IMPEP review should be closed.

Accordingly, the team recommends that the Arkansas Agreement State Program be found 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 the State 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 necessary. These factors have led the team to conclude that the Arkansas Agreement State Program should be placed on Monitoring, which will facilitate Arkansas taking the necessary steps to rectify the licensing issues identified during the review. To verify that Arkansas has corrected the licensing issues identified in the review, the team recommends that a followup IMPEP review take place in approximately 2 years to review the Technical Quality of Licensing Actions indicator. In addition, the team recommends that a Periodic Meeting be scheduled in approximately 1 year to discuss Arkansas's status and performance, including the expected influx of license renewals and the Technical Quality of Licensing Activities.

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

1. The team recommends that the Program provide training with regards to the implementation of the Pre-Licensing guidance to ensure that staff are properly identifying unknown applicants and change of ownership requests, and completing the evaluation of the basis for confidence. (Section 3.4)
2. The team recommends that the Program 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. The team recommends that the Program 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. The team recommends that the Program establish a quality control/quality assurance process or similar tool to help improve the thoroughness, completeness, consistency of the license reviews and 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

<b>Name</b>	<b>Area of Responsibility</b>
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: <i>High Dose Remote Afterloader</i>	Priority: 2
Inspection Date: 08/15/17	Inspector: AH

Accompaniment No.: 2	License No.: ARK-576
License Type: <i>e.g., Radiography</i>	Priority: 1
Inspection Date: 08/16/17	Inspector: DS

Accompaniment No.: 3	License No.: ARK-1033
License Type: <i>e.g., Nuclear Pharmacy</i>	Priority: 2
Inspection Date: 08/17/17	Inspector: SM



## Arkansas Department of Health

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4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Asa Hutchinson

Nathaniel Smith, MD, MPH, Director and State Health Officer

January 31, 2018

Paul Michalak, Chief  
Agreement State Program Branch  
Office of Nuclear Material Safety and Safeguards  
United States Nuclear Regulatory Program  
Two White Flint North  
11545 Rockville Pike  
Rockville, Maryland 20852

Dear Mr. Michalak:

The Department has received and reviewed the draft Integrated Materials Performance Evaluation Program (IMPEP) report dated January 2, 2018. The Department appreciates the opportunity to provide comments on the document and the findings of the IMPEP team.

One item has been identified for correction. Under the Introduction on page 1, it states that the Arkansas Program regulates 201 specific licenses authorizing possession and use of radioactive materials. As indicated in the IMPEP questionnaire, Arkansas regulates 209 licenses.

Attached are comments regarding the actions taken regarding the four (4) recommendations. We ask that the Management Review Board (MRB) consider the actions taken for these recommendations. The Radioactive Materials Program will continue to seek improvements as a co-regulator with the NRC in the spirit of the National Materials Program to protect public health and safety, and to secure the safe use of radioactive material.

The Department respectfully requests consideration that the finding under Technical Quality of Licensing Actions be changed to *Satisfactory –But Needs Improvement*. Attached are comments that provide justification for the change for this performance indicator.

The Department recognizes, respects, and appreciates the NRC oversight for consistency during the IMPEP review and MRB process. We continue to support the IMPEP process as a useful tool in the evaluation of Agreement State Programs. We also deeply appreciate the IMPEP Team's professionalism and guidance provided during the IMPEP review.

Enclosure 2  
ML18036A065



The Department's Senior Management fully supports and is consistently involved in the protection of health, safety, and security of radioactive materials by the Radioactive Materials Program. We thank you for the opportunity to review and comment on this draft document and look forward to continuing a strong and positive working relationship between the Department and the NRC.

If you have any questions or need additional information related to the Radioactive Materials Program, please contact Jared Thompson, Program Manager at 501-661-2173.

Sincerely,



Stephanie C. Williams RNP, MPH  
Deputy Director for Public Health Programs  
Arkansas Department of Health

Enclosures

cc: Lizette Roldan-Oterero, Ph.D., Team Leader  
USNRC Region IV Office

Jared Thompson, Program Manager  
Radioactive Materials Program

## APPENDIX A

### ARKANSAS ACTIONS RELATED TO IMPEP RECOMMENDATIONS

**JANUARY 31, 2018**

1. *"The team recommends that the Program provide training with regards to the implementation of the Pre-Licensing guidance to ensure that staff are properly identifying unknown applicants and change of ownership requests, and completing the evaluation of the basis for confidence. (Section 3.4)".*

As a result of the IMPEP review, the Radioactive Materials Program began conducting license reviewer training for staff in December 2017. Training for all license reviewers was completed in January 2018. The training covered the procedure (**RAM-06.0—Guidance for Completion of Security Risk Checklists for Arkansas Radioactive Material Licenses**) and other associated NRC guidance documents. Refresher training on the use of the current Checklist one and training in the use of the newly revised Checklist two was also provided.

2. *"The team recommends that the Program 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)."*

As a result of the IMPEP review, the Radioactive Materials Program has written a new procedure 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. The procedure will include a checklist as a quality control review.

Final approval, implementation, and training will be completed by February 2, 2018.

3. *"The team recommends that the Program 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. (Section 3.4)".*

As a result of the IMPEP review, the Radioactive Materials Program reviewed 100% of the medical licenses, which totals 85 licenses. These 85 licenses contained approximately 200 amendments in which preceptors were identified. Thirteen licenses (13) containing fifteen (15) amendments were identified with issues related to the verification of preceptors. This review reveals that only 7.5% of the amendments required Program action.

All 15 licensing actions have been reviewed and preceptor qualifications are being verified. This will be completed by February 2, 2018.

4. *"The team recommends that the Program establish a quality control/quality assurance process or similar tool to help improve the thoroughness, completeness, consistency of the license reviews and 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)"*

As a result of the IMPEP review, the Radioactive Materials Program has developed a multi-step quality improvement procedure. This multi-step quality improvement procedure includes:

- A preceptor checklist to ensure that preceptors are properly verified.
- A revised procedure that all licensing action requests or applications must be properly signed by licensee management or designee. This procedure also states there will be no review performed and the request or application may be returned to the licensee for signature.
- Enhancement of the current License Reviewer's Guidance used during the primary and secondary license review. The enhancements include the specific elements identified for improvement by the IMPEP. This review is intended to confirm that all areas have been reviewed and the information is technically complete and acceptable, prior to issuance of license.
- A quarterly audit process will occur. The audit checklist, modeled on documents provided by NRC Region IV staff, will be used to assess if the licenses and amendments issued were technically complete and acceptable.
- The quality improvement tools will also serve to provide ongoing assessment of each license reviewer's competence and performance.

The program manager will review the quality improvement information and data to identify performance trends which may require additional training. Final approval, implementation and training will be completed by February 2, 2018.



## APPENDIX B

### ARKANSAS COMMENTS ON IMPEP DRAFT REPORT DATED JANUARY 2, 2018

The Department acknowledges that the Recommendations made by the IMPEP Team are needed improvements for the radioactive material licensing program. The Radioactive Materials Program will continue to seek improvement as a co-regulator with the NRC to protect public health, safety, and to secure the safe use of radioactive material.

The Department respectfully requests consideration that the finding under Technical Quality of Licensing Actions be changed to *Satisfactory –But Needs Improvement*. The draft report for this performance indicator includes complimentary remarks about the overall quality of the Arkansas licensing program. On page 9 of the draft report, it states: “*In general, the team found that licensing actions were thorough, complete, consistent, and of acceptable quality with health, safety, and security issues properly addressed, when new applications or amendment requests were submitted for infrequently reviewed modalities.*” Yet, the determination of unsatisfactory for technical quality of licensing actions was made based on a perception of chronic issues.

Management Directive 5.6 uses the wording “indicates chronic problems....” for a finding of *Unsatisfactory*. There is no clearly identified measurement metric for use of the word chronic. The Department believes that the licensing program has been and is technically adequate in completion of licensing actions. The Program reviewed minutes and correspondence of the Periodic meetings, IMPEP reviews, and findings from 2002 – 2012. The licensing program had multiple findings of *Satisfactory –But Needs Improvement* which related directly to a licensing backlog issue, rather than technical quality of licensing. Perhaps of most significance, the quality of licensing actions was found to be technically satisfactory throughout this period. During the 2013 and 2017 IMPEP reviews, one problem related to the use of the Pre-License Guidance for issuance of a license to an unknown entity was identified. If this is considered to be a repeated licensing problem rather than chronic, the finding should be *Satisfactory –But Needs Improvement*.

The Department respectfully requests that the finding of *Unsatisfactory* be changed to *Satisfactory –But Needs Improvement* for the performance indicator Technical Quality of Licensing Actions.

**Agenda for Management Review Board Meeting**  
**February 12, 2018, 1:00 p.m. – 4:00 p.m. (ET), OWFN-17-B04**

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 Arkansas IMPEP Report.
  - A. Presentation of Findings Regarding Arkansas'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
  - 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 Arkansas representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.