



Arkansas Department of Health

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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.

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.