



Arkansas Department of Health

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Governor Mike Beebe

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

March 21, 2014

Duncan White, Chief
Agreement State Program Branch
Office of Federal and State Materials and
Environmental Management Program
United States Nuclear Regulatory Program
Two White Flint North
11545 Rockville Pike
Rockville, Maryland 20852

Dear Mr. White:

The Department has received and reviewed the draft Integrated Materials Performance Evaluation Program (IMPEP) report dated February 20, 2014. The Department appreciates the Review Team's internal decision to reevaluate the initial findings identified on November 1, 2013.

Attached are comments and corrections regarding the draft report and actions taken regarding the three (3) recommendations. We ask that the Review Team consider the comments and corrections and make appropriate revisions in the draft report.

The Radioactive Materials Program will continue to seek improvement as a co-regulator with the NRC to protect public health and safety and to secure the safe use of radioactive material. Since the last IMPEP review in 2009, this Program has successfully been able to completely remove a licensing backlog. I am proud of the staff's dedication, professionalism and endurance in the accomplishment of this monumental achievement.

The State of Arkansas continues to fully support the IMPEP process and further acknowledges in this case NRC's ability to be flexible and make appropriate changes outside the normal operating procedures.

Duncan White, Chief
Agreement State Program Branch
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Thank you for the opportunity to review and comment on this draft document. I look forward to continuing a strong and positive working relationship between the Department and 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,

A handwritten signature in black ink, appearing to read 'N. Smith'.

Nathaniel Smith, MD, MPH
Director and State Health Officer

Enclosures

cc: Janine Katanic, Ph.D., Team Leader
USNRC Region IV Office

Jared Thompson, Program Manager
Radioactive Materials Program

APPENDIX A

ARKANSAS ACTIONS RELATED TO IMPEP RECOMMENDATIONS

MARCH 21, 2014

1. *"The review 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)"*

The Radioactive Materials Program began conducting inspector refresher training for inspection staff in November 2013. The refresher training was completed in March 2014. The training consisted of a review of the NRC inspection procedures from Manual Chapter 2800 related to the types of specific licenses issued by the Department. Inspection refresher training has been completed for 15 license types.

Staff has been trained on RAM-01.10 entitled *"Inspection of Radioactive Materials and Particle Accelerator Licenses,"* which states that NRC Manual Chapter 2800 Inspection Procedures are the guide and reference for conducting materials inspections in the State of Arkansas.

The Program will continue to discuss inspections and inspection protocols during the bi-weekly staff meetings. This will ensure that staff maintains the inspection knowledge and improve the overall consistency in the inspection program.

2. *"The review team recommends that the State revise its licensing procedures to include current guidance to determine and document the basis of confidence for all new applications and transfers of control that radioactive materials will be used as intended, prior to authorizing the material on the license; and provide staff with training on the process and changes to the Program's licensing procedures. (Section 3.4)"*

RAM Procedure RAM-06.0 has been revised to indicate the usage of NRC RCPD-08-20 document entitled *"Requesting Implementation of the Checklist to Provide a Basis for Confidence that Radioactive Material will be used as Specified on a License and the Checklist for Risk-Significant Radioactive Material (RSRM.)"* Checklists have also been updated and revised. Staff received training on use of these checklists on December 20, 2013.

Using the guidance and checklists, the Program has reviewed 40 new or change of ownership license applications to validate and provide a basis of confidence that radioactive materials will be used as intended. These licenses were issued from 2006 to present. No suspicious activities were identified.

3. *“The review 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)”*

The Program is in the process of developing an incident response guidance document entitled “*RAM LICENSEE MEDICAL INCIDENTS.*” This is a draft document still under review awaiting final approval. We expect the final document and training to be completed October 31, 2014.

APPENDIX B

ARKANSAS COMMENTS ON IMPEP DRAFT REPORT DATED FEBRUARY 20, 2014

The Department requests that the following comments be reviewed and appropriate revisions or changes be made in the draft IMPEP report dated February 20, 2014.

ITEM 1. Cover letter, page 1:

“The review team’s revised recommendations and preliminary findings were discussed with Arkansas management on December 12, 2013.”

Draft report, Introduction, page 1:

“The review team’s revised recommendations were discussed with Arkansas management on December 12, 2013.”

Draft report, Technical Quality of Inspections, page 7:

“These changes were discussed with the Program Manager on December 12, 2013.”

For consistency and accuracy, please change these statements in the draft report to read:

“The revised preliminary findings were discussed with the Radioactive Materials Program Manager on December 12, 2013 which was shared with the Department’s upper management.”

ITEM 2. Draft Report, Technical Quality of Licensing, page 8:

a. *“Licenses are issued for a 10 year period under a timely renewal system.”*

According to Program Procedures, radioactive material licenses are issued for a 7 year period. Please make this correction in the draft report.

b. *“In another case file reviewed, a licensee requested to have a location removed from a license, but did not include radiation surveys or leak test records to demonstrate that the facility could be released for unrestricted use; however, the location was removed from the license.”*

The storage location for this radiography licensee was a portable building owned by the licensee and used for permanent storage at the use location in Arkansas. The portable storage building was identified during the pre-license visit.

The licensee removed the portable building containing the radiography cameras to another location in another state. The actual use location in Arkansas would not require radiation surveys or leak test records to demonstrate compliance for release. It should be noted that the licensee did not request that the portable building be released for unrestricted use.

This is also identified in Appendix D, File Number 5.

The Department requests that this, information be removed from the draft report and Appendix D.

ITEM 3. Draft report, Technical Quality of Incident and Allegation Activities, pages 10-11:

“The review team inquired regarding commensurate procedures for responding to medical events. The Program Manager indicated that procedures for responding to medical events were not developed because the Program does not receive many medical event reports. Given the infrequency of reported or identified medical events and the Program’s inexperience, the team determined the Program would benefit from procedures addressing medical events.”

The Department would like to offer information that may further clarify the above referenced statements. The Radiation Control Section has the responsibility to respond to all emergencies involving radiation. The Section maintains and provides training on very detailed internal procedures for possible emergencies at Arkansas Nuclear One. The internal guidance document entitled “EMERGENCY RESPONSE PROCEDURES FOR NON-ANO INCIDENTS” finalized in 2013 was prepared for use by any RADIATION CONTROL SECTION STAFF who might receive a notification of an incident involving radioactive materials. The RAM Program has more detailed procedures for incidents involving materials.

Medical event notifications were not included in these internal procedures. Medical event notifications are rarely, if ever, received by other RADIATION CONTROL STAFF. Based on past history and experience, notifications of medical events have been directly reported to RAM PROGRAM STAFF. This was apparently miscommunicated by the RAM Program Manager.

RADIATION CONTROL SECTION STAFF may be inexperienced in handling the notification of medical events, but they are trained to promptly direct these events to the RAM PROGRAM STAFF. The Department recognizes the importance of cross training and encourages a teamwork concept in emergencies and incidents.

Due to this finding, the RAM PROGRAM STAFF, with the assistance of the RADIATION CONTROL SECTION STAFF, is in the process of developing an incident response guidance document entitled “*RAM LICENSEE MEDICAL INCIDENTS*.” This is a draft document and is still under review for final approval. Training will be provided once the document has received final approval.

The Department requests that the referenced statement be removed or revised to correctly reflect the role of the RADIATION CONTROL SECTION STAFF in response to medical events. We believe that the RAM PROGRAM STAFF does have the experience and knowledge to properly handle a medical event notification.

We agree that there is a need for a medical event procedure and additional training for RADIATION CONTROL SECTION STAFF.

ITEM 4. Appendix C Inspection Casework Reviews

We have reviewed the information in this Appendix and request the following corrections be made to the report.

a. *File No.: 4*

Licensee: University Nuclear & Diagnostic
Inspection Type: Initial,
Inspection Date: 5/21-25/13

License No.: ARK-1019-02201
Announced Priority: 5
Inspectors: RP, AS, JT

The initial on-site inspection was conducted on 05/21/2010 by RP, JT. There is no RAM Staff member with initials AS. Please make appropriate changes in the draft report.

ITEM 5. Appendix D License Casework Reviews

We have reviewed the information in this Appendix and request the following corrections or additions be included in the report.

a. *File No.: 10*

Licensee: St. Vincent Infirmary Medical Center
Type of Action: Amendment
Date Issued: 8/27/13

License No.: ARK-0394-02120
Amendment No.: 143
License Reviewer: AH

“Comments:

- 1) Sealed Sources for manual brachytherapy therapy authorized as “Seeds” on the license and did not specify manufacturer or model number.*
- 2) Sealed Sources for manual brachytherapy and calibration sources did not specify Manufacturer or model number.*

- 3) *Sealed sources listed in sections 8.H., 8.O., and 8.P did not list the maximum activity authorized per single source as directed in Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Licenses (RCPD-10-007).*
- 4) *Cover letter mailed with license amendment did not include the standard language for releasing a specific authorized use location for unrestricted use in accordance. "*

The Department issued Amendment 144 on 01/06/2014 to correct the items identified in the comment.

b. *File No.: 15*

Licensee: CARTI

Type of Action: Renewal

Date Issued: 7/11/13

License No.: ARK-0654-02200

Amendment No.: 61

License Reviewers: KA, JT

"Comment:

Licensee upgraded the high dose rate remote afterloader (HDR) unit to a new model with pulsed dose mode (PDR) capabilities, as well as interlock, and software updates. The Operating and Emergency procedure that was a tie-down condition to the license did not reflect the change in the model number of the HDR unit, the changes associated with its operation, and additional training on the upgraded HDR unit. "

According to Program License Files, the document identified as a Renewal action is Amendment Number 56 issued on 04/09/2012 reviewed by KA, KW. The Department requests that the draft report be changed to reflect the correct information for the renewal document.

The Department has requested information from the licensee to correct the Operating and Emergency Procedures to correctly identify the correct model number of the HDR unit.