

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 23, 2014

Nathaniel Smith, M.D., MPH Director and State Health Officer Arkansas Department of Health 4815 West Market Street Little Rock, AR 72205-3867

Dear Dr. Smith:

On April 1, 2014, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Arkansas Agreement State Program. The MRB found the Arkansas program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 15 of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. The review team made three recommendations regarding the performance of the State. The review team determined that the recommendation from the 2011 follow-up IMPEP regarding tracking the status of license actions reviews was addressed by the Program and should be closed. Based on the results of the current IMPEP review, the next full review of the Arkansas Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for October 2015. The corrective actions taken to address the open recommendations will be reviewed during the periodic meeting and subsequently verified for closure at the next IMPEP. No additional written response is required at this time to address the open recommendations.

Dr. Smith -2-

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

Sincerely,

/RA/

Michael F. Weber Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs Office of the Executive Director for Operations

Enclosure: Arkansas Final IMPEP Report

cc: Earl Fordham, Washington Organization of Agreement States Liaison to the MRB

Jared Thompson, Program Manager Radiation Control Section



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

OCTOBER 28-NOVEMBER 1, 2013

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 October 28–November 1, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New Mexico.

Based on the results of this review, the review team recommended, and the Management Review Board (MRB) agreed, that Arkansas' performance be found satisfactory, but needs improvement for the indicator Technical Quality of Licensing Actions, and satisfactory for the remaining indicators reviewed.

The review team found that the recommendation from the 2011 follow-up IMPEP review regarding tracking the status of license actions reviews to ensure timely completion was addressed by the Program and can be closed.

Based on this review, the review team made three recommendations regarding the performance of the Arkansas Agreement State Program. These recommendations, which are briefly described below, included areas for improvement to correct identified performance deficiencies and weaknesses in Arkansas' Agreement State Program. The review team recommends that the State: (1) 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; (2) 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; and (3) strengthen its incident response program by developing guidance and providing training to the staff on evaluating and responding to reported medical events.

The review team recommended, and the MRB agreed, that the Arkansas Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The review team recommended, and the MRB agreed, that a Periodic Meeting be held in 2 years and that the next IMPEP review take place in approximately 4 years.

1.0 INTRODUCTION

This report presents the results of the review of the Arkansas Agreement State Program. The onsite portion of the review was conducted during the period of October 28–November 1, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New Mexico. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of October 31, 2009, to October 27, 2013, were discussed with Arkansas managers on the last day of the review. Subsequent to the exit meeting, the review team reconvened to discuss and reconsider the preliminary results of the review. The review team's revised recommendations were discussed with the Radioactive Materials Program Manager on December 12, 2013.

A draft of this report was provided to Arkansas for factual comment on February 21, 2014. The State responded to the findings and conclusions by email dated March 21, 2014. A copy of the State's response is included as an Attachment to this report along with a comment resolution document. A Management Review Board (MRB) met on April 1, 2014, to consider the proposed final report. The MRB found the Arkansas Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

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. Organizational charts from the Governor's office down to the Program office are included as Appendix B.

At the time of the review, the Arkansas Agreement State Program regulated 198 specific licenses authorizing byproduct, source, and certain special nuclear 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.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Program on June 26, 2013. The Program provided its response to the questionnaire, which was received by the NRC via mail on October 3, 2013, with supplemental information provided by the Program to the NRC in an October 24, 2013 email. Publicly available versions of the questionnaire response and supplemental response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Numbers ML13276A186 and ML13301A002, respectively.

The review team's general approach for conduct of this review consisted of (1) examination of the Program's response to the questionnaire, (2) review of applicable Arkansas statutes and

regulations, (3) analysis of quantitative information from the Program's databases, (4) technical review of selected regulatory actions, (5) field accompaniments of five inspectors; and (6) interviews with Program staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Arkansas Agreement State Program's performance.

Section 2.0 of this report describes the State's actions in response to recommendations made during previous reviews. Results of the review for the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on October 30, 2009, the review team made four recommendations regarding Program performance. All four of the recommendations were reviewed and closed during the follow-up IMPEP, which concluded on April 8, 2011. The review team for the follow-up IMPEP made one recommendation regarding Program performance. The status of the recommendation is as follows.

Recommendation: "The review team recommends the State develop and implement a method for tracking the status of license actions reviews to ensure timely completion. (Section 2.3 of the 2011 follow-up IMPEP Report)"

Status: The Program developed databases and procedures to track the status of licensing actions and have successfully eliminated the licensing action backlog. Incoming licensing actions for license amendment requests are entered in a database by the Program's Administrative Specialist. Amendment requests are tracked by licensee, receipt date, assigned Program staff, and other pertinent information. Applications for new licenses and license renewals are also tracked by the Program Manager in a database that includes licensee, receipt date, assigned Program staff, and other pertinent information. The review team evaluated the Program's actions to implement a tracking method and found it to be effective in preventing a recurrence of a backlog in licensing actions, including amendment requests and renewals. At the time of the review, there were seven pending renewals, five of which were received during 2013. The remaining two pending licensing renewals were received in 2008 and the Program was actively taking measures to process these renewals. The review team verified the Program's database capabilities, staff responsibilities, and procedures to track the status of licensing actions to prevent a reoccurrence of a backlog in licensing. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review 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

Issues central to the evaluation of this indicator include the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Program's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered any workload backlogs.

Full staffing of the Program consists of the Program Manager, six Health Physicists, and one administrative staff member. Five of the Health Physicists perform licensing, inspection, and incident response duties, as well as emergency response activities related to the nuclear power plant in the State. The sixth Health Physicist works primarily on regulations but also drafts information notices, issues Department of Transportation permits, responds to certain events, and works on radon issues. At the time of the review, the Program had caught up on its long-existing backlog of licensing renewals, so the two part-time consultants previously used to assist with licensing actions and special projects are rarely called upon to assist the Program. The review team determined that the number of staff in the Program is sufficient based on the Program's current and projected workloads.

The Program has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." All Program Health Physicists have Bachelor's degrees or equivalent work experience. Qualification is achieved through a combination of education and experience, formal classroom training, and on-the-job training. Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Program's training program is adequate to carry out its regulatory duties and noted that Program management strongly supports training opportunities. The review team also discussed with the Program manager the April 19, 2013, publication of NRC's IMC 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs." The Program's implementation of the training and qualification requirements described in IMC 1248 will be reviewed during the next IMPEP review.

While all but one of the Health Physicists are considered fully qualified, as described in subsequent sections of this report, the review team identified an area for improvement regarding the familiarity of the Program staff with the inspection procedures when performing inspections. 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.

In addition to core training courses, the Department implemented an increased salary grid consisting of three tiers. To progress through the salary grid, staff members are required to be in service to the Department for a specific number of years, must take additional advanced NRC and FEMA training, and have satisfactory performance evaluations. The effectiveness of the salary grid was reviewed in June 2012 by the Committee on Uniform Personnel Classification and Compensation of the Department's Office of Personnel Management and has been approved to continue.

During the previous review period, the Program experienced a high attrition rate with six staff leaving and six others being hired to fill those positions. The Program also had one vacancy at the time of the previous review. During the current review period, staffing had stabilized. The vacancy during the previous review was filled and the Program has not experienced any additional staff losses. Since the last review, the program implemented a general increase in salary, provided staff with new opportunities through an advanced training plan, and senior management is directly involved with the staff in the general day-to-day operations of the Program.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arkansas' performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Program's questionnaire response relative to this indicator, data gathered from the Program's database, examination of completed inspection casework, and interviews with the Program Manager and staff.

The review team verified that Arkansas' inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program."

During the review period, the Program conducted a total of 137 routine inspections of Priority 1, 2, and 3 licensees. Of these 137 inspections, the review team identified two inspections that were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The two overdue inspections were conducted 13 days and 133 days beyond the required timeframe. The review team did not identify any Priority 1, 2, or 3 inspections that were overdue for inspection at the time of the review. The review team also evaluated the Program's timeliness for conducting initial inspections. As required by IMC 2800, initial inspections shall be completed within 12 months of license issuance. The Program conducted 20 initial inspections during the review period. The review team verified that the Program performed all 20 initial inspections within 12 months, and there were no overdue initial inspections at the time of the review. Overall, the review team calculated that the Program performed 1.3 percent of all Priority 1, 2, and 3, and initial inspections overdue during the review period.

The review team evaluated the Program's timeliness of issuance of inspection findings. The Program's policy is that licensees are made aware of the inspectors' preliminary findings at the conclusion of the inspection. The Program has a goal of issuing inspection findings letters to licensees within 30 days of the final date of the inspection. Of the 25 inspection reports reviewed, four reports were issued greater than 30 days after the inspection. These letters were issued within 18 days beyond the 30-day goal.

During the review period, the Program granted 65 reciprocity licenses that were candidates for inspection based upon the criteria 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." In accordance with IMC 1220, onsite inspection is required of 20 percent of candidate licensees operating under reciprocity. The review team determined that the Program exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arkansas' performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

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

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 26 radioactive materials inspections conducted during the review period. The casework examined included a representative sample of inspections conducted by five current inspectors and covered a wide variety of inspection types involving initial and routine inspections. The casework reviewed included the following license types: industrial radiography, self-shielded irradiator, service provider, positron emission tomography, high dose-rate remote after loader, nuclear pharmacy, diagnostic nuclear medicine, portable gauge, panoramic irradiator, and reciprocity licensees. The review also included initial and follow-up Increased Controls inspections. Appendix C lists the inspection casework files reviewed.

Based on the evaluation of the casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that inspection records were thorough, complete, consistent, and of sound quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. The review team noted that inspectors were conducting confirmatory reviews of source inventories in the National Source Tracking System for affected licensees. Inspection record documentation supported identified violations and recommendations made to licensees, and also described unresolved safety issues.

The review team evaluated the Program's handling and storing of sensitive documents. The review team determined that documents containing sensitive information were maintained and secured in a locked file cabinet, segregated from non-sensitive document files, with access limited to staff with a need to know. The review team determined that these files were not subject to Freedom of Information Act-equivalent State law and verified that staff handling the files was aware of the sensitive information and its special handling requirements associated with these licensees.

The Program has a policy and associated procedure for performing supervisory accompaniments of inspectors. The review team verified that the Program Manager conducted supervisory accompaniments of all of the staff at least annually for two of the years covered by the review period. The review team noted that for the other two years covered by the review period, one inspector was not accompanied during 2011 and one inspector was not accompanied during 2012.

The Program possesses a variety of calibrated survey instruments used to support the inspection program and to respond to radioactive materials incidents and allegations. The Program sends all survey instruments to the manufacturer for calibration on an annual basis. At the time of the review, instruments that were out of calibration were segregated from calibrated survey equipment. The Program's policy states that the Arkansas Radioactive Materials Program utilizes the Arkansas Department of Health Radiochemistry Laboratory to perform sample counting and assay services, as needed.

Accompaniments of five Program inspectors were conducted during the weeks of August 19, 2013, and September 9, 2013. The inspectors were accompanied during health and safety inspections of the following types of licensees: nuclear pharmacy; well logging; panoramic irradiator; industrial radiography; medical-written directives required; and broad scope, which included high dose rate remote afterloader, stereotactic radiosurgery, and unsealed radioactive material therapy. Three of the inspections included a review of the licensee's implementation of the Increased Controls and Fingerprinting requirements. The inspections selected were for licensed activities that each respective inspector was fully qualified to inspect. The accompaniments and associated comments are identified in Appendix C.

With one exception, the inspectors were well-prepared for the inspections, demonstrated knowledge of the licensed activities, and were familiar with the applicable regulations. During one accompaniment inspection, the inspector was not adequately prepared for the inspection, was not sufficiently familiar with the licensed activity, and was not sufficiently familiar with the regulatory requirements for the licensed activity. The inspector demonstrated poor health physics practices by entering the cell of a panoramic irradiator without performing a radiation survey but instead relying on an alarming dose rate meter. It was observed during the inspection that the inspector did not have an appropriate focus on risk-significant health and safety matters. It was further observed that the inspector was not following an inspection procedure for this type of inspection and was relying on the inspection notes from the previous inspection of the facility as a guide to conduct the current inspection, resulting in items important to health and safety not being addressed. The Program took swift action and removed the individual from performing inspections independently until performance is further evaluated.

The Program has inspection report forms for several inspection activities (i.e. medical, portable and fixed gauge, radiography, etc.), but not for all of the activities that the Program regulates (i.e. panoramic irradiators, specific therapeutic modalities). The forms do not contain specific inspection guidance for the conduct of inspections. This was discussed with the Program Manager, who stated that the expectation was that Program staff use NRC's inspection procedures, but staff did not demonstrate knowledge of this expectation. The Program's procedure RAM-01.10, "Inspection of Radioactive Materials," provides a general overview of the Arkansas inspection program and the general conduct of inspections. However, the procedure did not document the Program Manager's expectations that the NRC inspection procedures be used for the conduct of inspections. During the IMPEP, the Program Manager addressed this concern and revised procedure RAM-01.10 to clearly articulate that the NRC inspection procedures should be used as guidance to perform inspections and also included a link to the NRC's web page for inspection procedures. Language was also added to RAM-01.10 regarding the NRC's inspection procedure for the performance of Increased Controls inspections.

During the exit meeting at the conclusion of the onsite IMPEP review, the team recommended that Arkansas' performance with respect to this indicator, be found satisfactory, but needs improvement. The team also recommended that the State provide additional training to the inspection staff on the inspection procedures and incorporate them into their training and qualification program to ensure consistent implementation during inspections. The team discussed and agreed that this finding was appropriate based on several considerations, including: staff lack of awareness of the Program's expectations with respect to the use of inspection procedures; observations made during an IMPEP accompaniment inspection at a high risk significance licensed activity, when items important to health and safety were not adequately addressed; an observed misunderstanding of the role of the regulatory authority in inspecting broad scope licensees; and during two years of the review, not all inspectors were accompanied by the Program Manager. At the exit meeting, the State disagreed with the team's finding.

Subsequent to the exit meeting, the team reconsidered the initial finding and it was determined that a finding of satisfactory was more appropriate for this indicator. In revising its finding, the team considered that the observations made during one inspector accompaniment that demonstrated poor performance was indicative of one inspector's performance, and the Program subsequently took actions to address these performance issues. Although some performance issues were observed during other accompaniment inspections, the inspector performance was of generally acceptable quality. Furthermore, the Program revised its policies to document its expectations regarding the use of inspection procedures. After additional discussion amongst the team, it was concluded that the finding should be changed to satisfactory. The team agreed that the recommendation regarding additional training on the inspection procedures should remain, but that the recommendation would be more appropriate if included under the indicator, Technical Staffing and Training. These changes were discussed with the Radioactive Materials Program Manager on December 12, 2013.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arkansas' performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined the completed licensing casework and interviewed license reviewers for 18 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, security basis for confidence that radioactive material will be used as appropriate, qualifications of authorized users, adequacy of facilities and equipment, marking of security related documents, financial assurance, operating and emergency procedures, appropriateness and consistency of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate correspondence, references to appropriate regulations, application of the most recent licensing guidance, supporting documentation, pre-licensing visits, peer or supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing activities completed during the review period. Licensing actions selected for evaluation included: four new licenses; three renewals; nine amendments; and two terminations. Files reviewed included

a cross-section of license types: industrial radiography, medical diagnostic, medical therapy including permanent implant brachytherapy and stereotactic radiosurgery, nuclear pharmacy, broad scope, and industrial gauging licensees. The casework sample included technical reviews performed by each of the license reviewers, including licensing work performed by the two contract employees. A listing of the licensing casework reviewed, with case-specific comments, is provided in Appendix D.

Licensing actions are all tracked via two databases. The information is entered into a primary database by the administrative staff upon receipt, and then the Program Manager enters the same information in a separate database and assigns the licensing action. This provides the Program Manager with a way to separately track and confirm that licensing actions are being completed in a timely manner by the reviewer. There was no backlog of amendment requests or new applications at the time of the review. The staff responds to new applications, amendment requests, and renewals within 10 business days, and issues completed licensing actions within 30 to 45 days. Three license evaluators have signature authority for licensing actions. The Program Manager performs a technical and supervisory review on all licensing actions before issuance to the licensee. Licenses are issued for a 7 year period under a timely renewal system.

The review team evaluated the Program's application of the State's financial assurance requirements. At the time of the review, the Program had one licensee that was authorized for possession of radioactive material in excess of the quantities requiring financial assurance, and one licensee with a pending renewal that still needed to submit financial assurance. The review team verified that the proper financial assurance documentation was on file and that the information was appropriately protected.

With some exceptions, the review team found that licensing actions were complete with health and safety issues properly addressed. During the review period, the license reviewers were thorough in identifying deficiencies in licensing action requests and preparing requests for additional information from licensees; however, the review team found instances where the responses received from the licensees were not adequately reviewed for accuracy and completeness and licensing actions were subsequently issued. In one case, a licensee submitted operating and emergency procedures that included operating and emergency procedures for off-shore operations, and these procedures were approved by the Program as tie-down conditions without being reviewed. In another case, a licensee submitted sealed source information to be added to the license, but the model and manufacturer number were not included in the possession authorization, and the license was issued without a model designation. In another case file reviewed, a license was amended to remove a permanent storage location; however, the licensing case file did not include justification for removing the location from the license, such as radiation surveys or leak test records. In another case, the Operating and Emergency procedures tied-down as a license condition did not reflect the correct model number of the device authorized by the license. In discussing the issues with the Program, the Program and team attributed the quality issues to the Program's extensive effort to eliminate the licensing backlog initiative.

The review team assessed the program's implementation of pre-licensing guidance. The Program's practice is to prepare the license and subsequently hand-deliver the license during an onsite visit. The review found that several case files including four new licenses and one

change of ownership did not have the documentation to support a basis of confidence that the radioactive material would be used as requested. In addition, the Program's procedure for conducting such reviews predates RCPD-08-20, "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)," issued on September 22, 2008, and the onsite visits alone do not meet the objective of establishing if an entity is "unknown" and do not support a basis of confidence that the radioactive material will be used as requested. The license reviewers were not following the Program's procedures on pre-licensing guidance and were unaware of the most current guidance (RCPD-08-020). Therefore, the review team recommends 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 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.

The review team examined the Program's licensing practices in regard to requests for RSRM (i.e. Increased Controls and Fingerprinting Orders). The review team determined that the Program has a licensing procedure to identify new and amended licenses that should be subject to additional security measures. While the Program did not always document this process, the team did not identify any new or amended licenses that were missing the required license conditions and concluded that the Program added legally binding license conditions to the licenses that met the criteria for Increased Controls, including fingerprinting, as appropriate.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arkansas' performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement.

3.5 <u>Technical Quality of Incident and Allegation Activities</u>

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Arkansas in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for 10 radioactive materials incidents. A list of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Program's response to six allegations involving radioactive materials, including two allegations referred to the State by the NRC during the review period.

The incidents/events selected for review included the several categories: equipment failure, lost radioactive material, damage to equipment/equipment failure, damage to radioactive sources, contamination, medical event, overexposure, and abandoned radioactive material. The review team compared the Program's reporting of events to NRC with those established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events." The Program has procedures in place for reporting events to the NRC Headquarters Operations Officer, and into the NMED system. Of the 10 events reviewed, 5 were reportable to NRC. Three of the five reportable events were reported to NRC in a time frame consistent with the reporting category. Of the five events that were not

reportable to the NRC, the review team confirmed that these events did not meet the reportability thresholds.

The Program Manager explained that the Program's goal is to respond onsite to all reported events. Of the 10 events reviewed, 1 was identified during a routine inspection, 7 resulted in an onsite visit by the Program, and 2 did not result in onsite visits by the Program. Of the seven that resulted in a site visit by the Program, the Program's response was prompt. In some cases, the Program responded the same day as the reported event. The Program's onsite event response was documented in a memo to file that was placed in the Program's event files along with other supporting documentation. In general, the Program's onsite event response memos to file contained information about the event, such as the circumstances leading up to the event; synopses of interviews with licensee employees; results of radiation surveys when applicable; and the timeline of the event. The Program Manager did not routinely review these memos to file although response activities were discussed during routine staff meetings. The Program's event files did not routinely document an independent evaluation of the event that included a determination of the contributing factors and root causes of the event rather than relying on the licensee's conclusions.

For the two reported events that did not result in an onsite inspection, the Program reviewed the licensee's written reports and followed up during the next routine inspection. Both of these events occurred at the same broad scope licensee facility. One event involved the loss of an iodine-125 sealed brachytherapy source during a source disposal procedure, and in this event, the Program did not identify that the licensee's written report did not contain all of the information required by regulation, including corrective actions to prevent recurrence. Three weeks later, a related event, involving the same type of source disposal procedure, equipment, and iodine-125 sealed brachytherapy sources occurred at the same broad scope licensee facility. The Program performed an onsite response for the second event and the licensee subsequently provided a written report that contained corrective actions to address both events.

The other event reviewed for which the Program did not respond onsite was a reported medical event involving brachytherapy with yttrium-90 microspheres in which a problem was encountered with the administration of the radioactive material, resulting in a dose to the patient that was less than the prescribed dose. Although it is the Program Manager's expectation that all reported events result in an onsite response, the Program did not respond onsite to this medical event at the broad scope licensee facility. Another contributing factor was that the Program does not have criteria for evaluating reported medical events in order to identify which ones may warrant an onsite response. The Program indicated that staff was not as familiar with yttrium-90 microspheres and the associated treatment administration equipment as the licensee. A search of the Program's event records in NMED indicated that this event was the only medical event reported by the Program during the review period. Interviews with Program staff and a review of Program files did not reveal any additional medical events.

The Program's procedure RAM-04.4, dated September 3, 2013, "Responding to Events Involving Radioactive Material," references "Emergency Response Procedures for non-Arkansas Nuclear One Incidents," issued on September 4, 2013. These referenced procedures contain Radiation Control Section Staff guidance for the receipt of notifications involving the following types of events: transportation, licensee work-site incident, missing radioactive material, recovered radioactive material, irretrievable down-hole radioactive source,

and stuck radiography source. These procedures do not address how to respond to events but rather how to collect information when an event notification is received by Radiation Control Program staff.

The review team inquired regarding commensurate procedures for receiving notifications of medical events or for responding to medical events. The Program Manager indicated that procedures for receiving medical event notifications were not developed because the Radiation Control Section Staff does not receive many medical event reports. The review team found that the Radioactive Materials Program procedure RAM-04.4 "Responding to Events Involving Radioactive Material" describes general event response procedures and does not contain specific guidance associated with responding to or evaluating medical events. Given the infrequency of reported or identified medical events and the Program's inexperience in responding to medical events, the team determined the Program would benefit from procedures addressing medical events. 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.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the completed casework for six allegations, including two that were referred to the Program by NRC during the review period, and one that was referred to the Program from another Agreement State during the review period. The Program's incident and allegation log indicated that the Program received 16 allegations during the review period. Of the casework files evaluated, the review team concluded that the Program's actions in response to allegations were prompt, well-coordinated, and commensurate with the potential health and safety or security consequences of the identified concerns. In some cases, the Program responded onsite the same day as the allegation.

It was noted by the Program Manager and documented in Program procedure AD-06.9, "Investigation of Allegations," dated August 16, 2009, that during all phases of an investigation into an allegation, any and all memoranda, letters, reports, emails, photographs, electronic images, telephone messages and notes, regardless of form, are subject to release under the Arkansas Freedom of Information Act. This includes the concerned individual's identity as well as any information that is related to concerns that is forwarded to the Program by NRC.

During the exit meeting at the conclusion of the onsite IMPEP review, the team recommended that Arkansas' performance with respect to this indicator, be found satisfactory, but needs improvement. The team also recommended that the State develop, implement, and provide training to the staff for responding to medical events. In making this recommendation, the team considered the Program's lack of a procedure for responding to medical events; the Program's lack of an onsite response to the one medical event that was reported during the review period, for which a reason offered was that the Program staff was not as familiar with the particular equipment as the licensee; for another event, corrective actions were not identified in the licensee's report and this was not recognized by the Program; and there were a few instances where event reports to NRC were not made within the required time frame. At the exit meeting, the State disagreed with the team's finding.

Subsequent to the exit meeting, the team reconsidered the initial finding and it was determined that a finding of satisfactory was more appropriate for this indicator. Consideration was given

that with the exception of the medical event and one other event, the State performed onsite reviews for other reported events, demonstrating a strong commitment by the Program to review events. The team agreed that the recommendation regarding developing a procedure to respond to medical events should remain. These changes were discussed with the Radioactive Materials Program Manager on December 12, 2013.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arkansas' performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State Programs:

- (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program,
- (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with the State of Arkansas does not relinquish authority to regulate a sealed source and device evaluation program, or a uranium recovery program, so only the first and third non-common performance indicators were applicable to this review.

4.1 <u>Compatibility Requirements</u>

4.1.1 Legislation

Arkansas became an Agreement State on July 1, 1963. Legislative authority to create a radiation control agency and enter into an Agreement with NRC was granted in the "Arkansas Code of 1987 Annotated, Volume 20A, Title 20, Subtitle 2, Chapter 21." The Department is designated as the State's radiation control agency.

The review team noted one new piece of legislation adopted during the review period. Act 596, approved on March 23, 2011, transferred the authority for radioactive material licensing fee increases from the Arkansas Legislature to the Arkansas State Board of Health (the Board). Under this Act, the Board was given the authority to establish radioactive material license fees not to exceed 25 percent of NRC's comparable annual fees. At the time of the review, the Program's fees for radioactive materials licenses were 15 percent of NRC's comparable annual fees.

4.1.2 Program Elements Required for Compatibility

Arkansas's regulations for the control of radiation are found in the Rules and Regulations for Control of Sources of Ionizing Radiation of the Arkansas State Board of Health and apply to all sources of ionizing radiation used within the State. Arkansas requires a license for possession and use of all radioactive materials and requires registration of all machines specifically designed to produce x-rays including accelerators, cyclotrons and other ionizing radiation.

The review team examined the State's rulemaking process and found that draft regulations are sent to NRC for review and comment and those comments are incorporated prior to final adoption. Rule packages prepared by the Program require an appearance before the Executive Committee of the Arkansas Department of Health Administration to seek approval to proceed to

the Arkansas Board of Health. After an appearance in front of, and approval by, the Arkansas State Board of Health, rule packages move to public hearings and then on to the State House and Senate Interim Committees on Public Health, Welfare, and Labor of the Arkansas General Assembly. The rules then undergo a review by the Arkansas Administrative Rules and Regulations Subcommittee of the Arkansas Legislative Council. Afterward they proceed to the Arkansas State Board of Health to receive final approval and, once approved, they are sent for signature by the Director of the Arkansas Department of Health. During this final step, they are also sent to the NRC for a final review. This entire process takes approximately nine months to complete.

The review team noted that the State has emergency rule capability for situations where public health and safety are at risk. The Arkansas State Board of Health *Rules and Regulations for Control of Sources of Ionizing Radiation* are not subject to "sunset" laws, and the Program has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team noted that the Program does not have an advisory board; however, if needed a Medical Advisory Committee can be convened to approve alternative uses of radioactive materials.

The review team evaluated the Program's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the Program under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains.

During the review period, Arkansas submitted 5 regulation packages to NRC for a compatibility review, which addressed 17 final regulation amendments, including 10 proposed regulation amendments and 10 revisions to final regulations addressing all previous NRC comments. The following eight amendments were submitted overdue during this review period. For the first three listed, Arkansas had submitted proposed regulations for NRC review and NRC provided comments in 2008; however, Arkansas had not submitted the final regulations for review prior to the 2009 IMPEP, but provided the revised final regulation addressing NRC's comments in 2012.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that was due for Agreement State adoption on October 1, 2007.
- "Medical Use of Byproduct Material Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926) that was due for Agreement State adoption on April 29, 2008.
- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005) that was due for Agreement State adoption on March 27, 2009.
- "Medical Use of Byproduct Material Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendments (72 FR 45147; 72 FR 54207) that was due for Agreement State adoption on October 29, 2010.

- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendments (72 FR 58473) that was due for Agreement State adoption on December 17, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864) that was due for Agreement State adoption on November 30, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,"
 10 CFR Parts 19 and 20 amendments (72 FR 68043) that was due for Agreement State adoption on February 15, 2011.
- "Medical Use of Byproduct Material Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that was due for Agreement State adoption on September 28, 2012.

In addition, in the 2009 IMPEP review, the following two amendments were erroneously listed as overdue. The correct status is as follows:

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that was due for Agreement State adoption February 16, 2004.
 - Arkansas provided final regulations in 2008, addressing comments previously provided by NRC in 2006. Additional comments on the final regulations and proposed revisions were provided by NRC in 2008. This amendment was not considered overdue; however the outstanding comments needed to be addressed. All comments were resolved with the review and promulgation of Arkansas' October 1, 2012, final regulations.
- "National Source Tracking System," 10 CFR Part 20 amendments (71 FR 65685) that was due for Agreement State adoption January 31, 2009.
 - Arkansas' license condition to implement this requirement was reviewed by NRC and had no comments as noted in the letter dated January 22, 2009. Arkansas has since adopted these legally binding requirements in their regulations as of October 1, 2012. This amendment was not considered overdue, since Arkansas was implementing the requirement by license conditions prior to the adoption of final regulations.

Arkansas' regulations were published as final and became effective on October 1, 2012. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of the NRC's regulations. Since the 2009 IMPEP review, the State has adopted all regulation amendments that were overdue and addressed all outstanding comments on final regulations that were previously reviewed by the NRC. At the time of the review, there were no amendments overdue for State adoption.

Prior to this review period, the Program had frequently experienced issues with overdue regulatory amendments. This was primarily because regulation development had been assigned to the Section Chief as a secondary responsibility. To remain timely in rule development, the Program reassigned one Health Physicist to work on rulemaking. As a result of the reassignment, the Program has caught up the backlog of overdue amendments. With the upcoming amendments scheduled for adoption over the next review period, the Program plans to continue the assignment of a Health Physicist in order to maintain regulations that are current with the NRC's regulations.

A complete list of upcoming regulation amendments that will need to be addressed in the future may be found on the NRC website at the following address: http://nrc-stp.ornl.gov/rss_regamendents.html.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arkansas' performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, 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, 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 compatibility LLRW program. There are no plans for a commercial LLRW disposal facility in Arkansas. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the team initially recommended that Arkansas' performance, with respect to the indicators Technical Quality of Inspection, Technical Quality of Licensing, and Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement, and that the other indicators reviewed be found satisfactory. Based on its initial recommendation of three satisfactory, but needs improvement, indicators, and in accordance with NRC Management Directive 5.6, the team recommended that the Arkansas program be found adequate, but needs improvement, to protect public health and safety and compatible with NRC's program. Furthermore, the team recommended that Monitoring should be considered for the Program.

After the exit meeting, the team reconsidered its findings and revised its recommendations, resulting in the team recommending that Arkansas' performance be found satisfactory, but needs improvement, for the indicator Technical Quality of Licensing Actions, and satisfactory for the other indicators reviewed. Accordingly, the team revised its adequacy finding, resulting in

the team recommending, and the MRB agreed, that the Arkansas Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program. The review team recommended, and the MRB agreed that a Periodic Meeting be held in 2 years, and that the next IMPEP review take place in approximately 4 years. The revised recommendations were provided to the Radioactive Materials Program Manager on December 12, 2013.

The review team made three recommendations regarding the performance of the State. As noted in Section 2.0, the review team determined that the recommendation from the 2011 Follow-up IMPEP regarding tracking the status of license actions reviews to ensure timely completion was addressed by the Program and should be closed.

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

- 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)
- 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)
- 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)

LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Arkansas Organization Charts

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E Incident Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

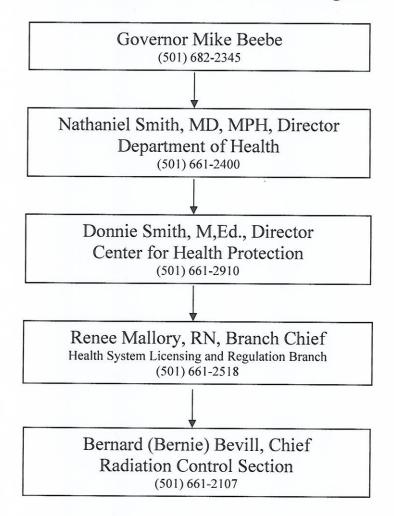
Name	Area of Responsibility
Janine Katanic, FSME	Team Leader Inspector Accompaniments Technical Quality of Incident and Allegation Activities
Randy Erickson, Region IV	Technical Staffing and Training Compatibility Requirements
Binesh Tharakan, Region IV	Status of Materials Inspection Program
Michelle Hammond, Region IV	Technical Quality of Licensing Actions
Santiago Rodriguez, New Mexico	Technical Quality of Inspections

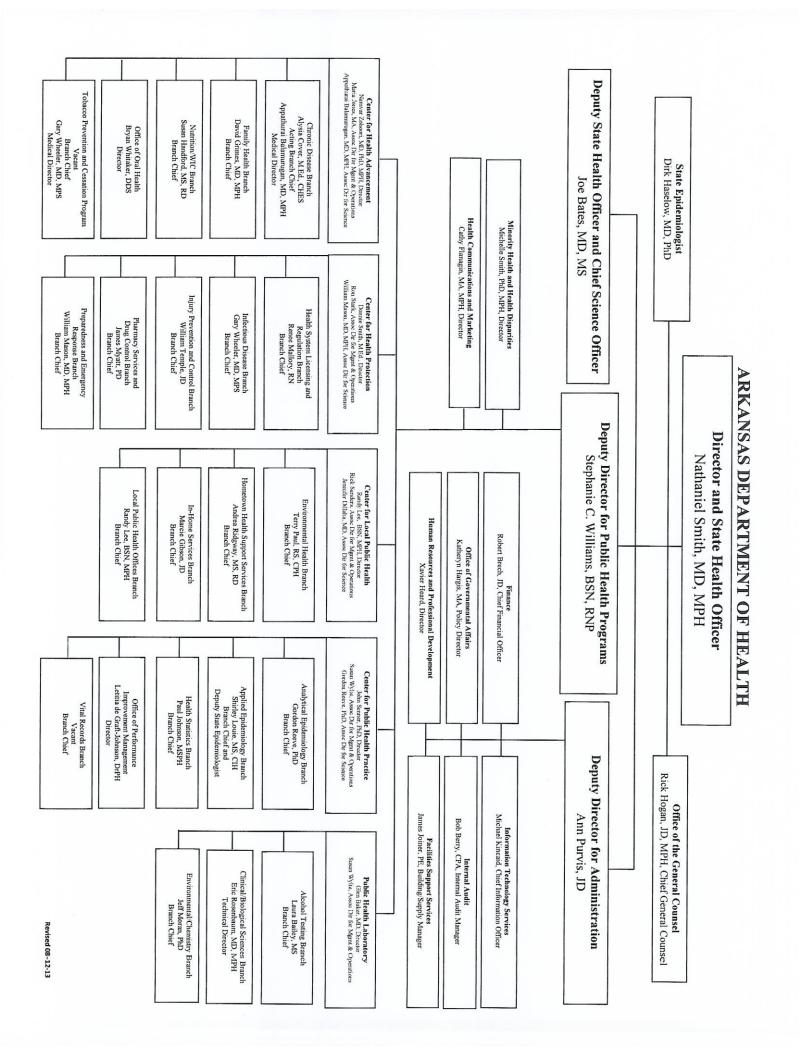
APPENDIX B

ARKANSAS ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML13276A239

Organization Chart from Governor to Program Director





Department of Health Radiation Control Section

Jared Thompson, Health Physicist Supervisor (Radioactive Material Program) 22105717 B044C/C121

Angela Hill, Health Physicist 22105032 B063C/C119

Tammy Kriesel, Health Physicist 22106796 B063C/C119

Kayla Avery, Health Physicist 22105862 B063C/C119

Robert Pemberton, Health Physicist 22105772 B063C/C119

Steve Mack, Health Physicist 22106313 B063C/C119

Sandra Page, Administrative Specialist III 22104773 C056C/C112

Kim Wiebeck, Extra Help 22076921 9999,9999

David Snellings, Extra Help 22112197 9999,9999

> Bernie Bevill, ADH Public Health Section Chief III 22109693 L025C/C123

Angela Minden, Health Physicist 22105697 B063C/C119
Wendy Krause, Budget Specialist 22106759 R027C/C117

Vernessa Minor, Admin. Specialist II 22105550 C056C/C112

Valerie Brown, Health Program Specialist II (Radiologic Technologist Program) 22131671 L048C/C118

Glynis Elmore, Administrative Specialist III 22105910 C056C/C112

VACANT, Administrative Specialist II 22104727 C073C/C109

Sherry Davidson, Health
Physicist Supervisor (X-ray and
Mammography Programs)
22105061 B044C/C121

Susan Dooley, Health Physicist 22106310 B063C/C119

VACANT, Health Physicist 22105428 B063C/C119

David Stephens, Health Physicist 22106551 B063C/C119

Kendra Christian, Health Physicist 22107001 B063C/C119

Melinda Davis, Health Physicist 22105104 B063C/C119

Donna Thompson, Health Physicist 22104916 B063C/C119

Ruby Forrest, Administrative Specialist III 22107005 C056C/C112

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Team Industrial Services, Inc. License No.: ARK-0344-03310

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 3/13/13 Inspectors: AH, RP

File No.: 2

Licensee: Huber Specialty Hydrates, LLC License No.: ARK-1029-03120

Inspection Type: Initial, Announced Priority: 5

Inspection Date: 12/14/12 Inspectors: AH, KA

File No.: 3

Licensee: Schultz Surveying & Engineering License No.: ARK-1032-03121

Inspection Type: Initial Priority: 5
Inspection Date: 8/13/13 Inspector: RP

File No.: 4

Licensee: University Nuclear & Diagnostic License No.: ARK-1019-02201

Inspection Type: Initial, Announced Priority: 5

Inspection Date: 5/21/10 Inspectors: RP, JT

File No.: 5

Licensee: U.S. Cardiovascular Radiopharmacy License No.: ARK-1024-02500

Inspection Type: Routine, Unannounced Priority: 2

Inspection Date: 3/13/13 Inspectors: AH, RP

File No.: 6

Licensee: MISTRAS Group License No.: ARK-1034-03310

Inspection Type: Initial, Announced Priority: 1

Inspection Date: 6/10/13 Inspector: SM

File No.: 7

Licensee: MISTRAS Group License No.: REC-372-03310

Inspection Type: Reciprocity, Unannounced Priority: 1

Inspection Date: 6/21/12 Inspectors: KA, RP

File No.: 8

Licensee: Red River Pharmacy Services License No.: ARK-1033-02500

Inspection Type: Initial, Unannounced Priority: 2

Inspection Date: 10/24/12 Inspectors: AH, RP

File No.: 9

Licensee: Subsurface Xplorations, LLC License No.: ARK-1018-03121

Inspection Type: Initial, Unannounced Priority: 5 Inspection Date: 5/6/10

Inspector: KA

File No.: 10

Licensee: National Inspection Services, LLC License No.: ARK-1026-03310

Inspection Type: Initial, Announced Priority: 1 Inspection Date: 10/3/11

Inspector: RP

File No.: 11

License No.: REC-376-03310 Licensee: National Inspection Services, LLC

Inspection Type: Reciprocity, Unannounced Priority: 1 Inspection Date: 4/14/10

Inspector: TK

File No.: 12

License No.: ARK-0837-03310 Licensee: URS Energy & Construction

Inspection Type: Routine, Unannounced Priority: 1 Inspection Date: 10/2/13 Inspector: TK

File No.: 13

License No.: ARK-0421-03620 Licensee: University of Arkansas at Little Rock

Inspection Type: Routine, Announced Priority: 5 Inspection Date: 2/4/10 Inspector: TK

File No.: 14

Licensee: Arkansas Children's Hospital License No.: ARK-0572-02110

Inspection Type: Routine, Announced Priority: 2

Inspectors: SM, AH Inspection Date: 3/12-13/12

File No.: 15

Licensee: Sterigenics US, LLC License No.: ARK-0903-03521

Inspection Type: Routine, Unannounced Priority: 2 Inspection Date: 9/17/10 Inspector: RP

File No.: 16

License No.: ARK-0576-03310 Licensee: Applied Inspection Systems, Inc.

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 5/29/13 Inspectors: AH, SM

File No.: 17

Licensee: H & H X-Ray Services, Inc. License No.: ARK-0650-03310

Inspection Type: Routine, Unannounced Priority: 1

Inspection Date: 10/3/13 Inspector: AH

Priority: 1

Priority: 5

Priority: 3

Priority: 2

Priority: 3

Priority: 3

Priority: 2

Priority: 2

Inspector: AH

Inspector: SM

Inspector: RP

Inspectors: TK, AH

Inspector: TK

Inspectors: SM, TK

File No.: 18

Licensee: International Testing & Inspection Services License No.: ARK-0773-03310

Inspection Type: Routine, Unannounced

Inspection Date: 7/12-13,15/10

File No.: 19

Licensee: University of Arkansas License No.: ARK-0711-03222

Inspection Type: Routine, Announced

Inspection Date: 3/12-14/13

File No.: 20

Licensee: Costal Wireline Services License No.: REC-238-03110

Inspection Type: Reciprocity, Unannounced

Inspection Date: 4/27/10 Inspectors: AM, RP

File No.: 21

Licensee: CARTI-UAMS License No.: ARK-0930-2230

Inspection Type: Routine, Unannounced

Inspection Date: 6/10/10 Inspector: KA

File No.: 22

Licensee: Drew Memorial Hospital License No.: ARK-0482-02120

Inspection Type: Routine, Unannounced

Inspection Date: 8/13/13

File No.: 23

Licensee: Arkansas Methodist Hospital License No.: ARK-0355-02120

Inspection Type: Routine, Unannounced

Inspection Date: 4/25/12

File No.: 24

Licensee: PETNET Solutions, Inc. License No.: ARK-0953-02500

Inspection Type: Routine, Unannounced

Inspection Date: 4/22/13

File No.: 25

Licensee: Schlumberger Technology Corp. License No.: ARK-0657-03110

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 6/6/12 Inspectors: SM, AH

File No.: 26

Licensee: Ouachita County Medical Center License No.: ARK-208-02121

Inspection Type: Routine, Unannounced

Inspection Date: 9/7/11

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the onsite IMPEP review:

Accompaniment No.: 1

Licensee: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Date: 8/19/13
License No.: ARK-0642-02500
Priority: 2
Inspector: AH

Accompaniment No.: 2

Licensee: Halliburton Energy Services, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 8/20/13

License No.: ARK-0319-03110
Priority: 3
Inspector: SM

Accompaniment No.: 3

Licensee: Sterigenics US, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 8/21/13
License No.: ARK-903-03521
Priority: 2
Inspector: RP

Comment:

The inspector was not adequately prepared for the inspection, was not familiar with the regulatory requirements for this type of licensed activity, and was not familiar with the facility and health and safety information contained in the license. The inspector demonstrated poor health physics practices and did not have due attention to radiation safety and the risk significance of this type of licensed activity.

Accompaniment No.: 4

Licensee: H&H X-Ray Services, Inc.

Inspection Type: Temporary Job Site, Unannounced
Inspection Date: 8/22/13

License No.: ARK-0650-03310
Priority: 1
Inspector: AH

Accompaniment No.: 5

Licensee: Saint Vincent Infirmary Medical Center License No.: ARK-0394-02120 Inspection Type: Routine, Announced Priority: 3 Inspection Date: 9/9-10/13 Inspector: KA

Accompaniment No.: 6

Licensee: University of Arkansas for Medical Sciences
Inspection Type: Routine, Announced
Inspection Date: 9/11-13/13
License No.: ARK-0001-02110
Priority: 2
Inspector: TK, KA

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Red River Pharmacy License No.: ARK-1033-02500

Type of Action: New Amendment No.: 0

Date Issued: 10/24/12 License Reviewers: AH, SM

Comment:

Pre-licensing guidance was not used.

File No.: 2

Licensee: National Inspection Services, LLC License No.: ARK-1026-03310

Type of Action: New Amendment No.: 0

Date Issued: 5/3/11 License Reviewers: RP, SM

Comment:

Pre-licensing guidance was not used.

File No.: 3

Licensee: Subsurface Xplorations

License No.: ARK-1018-03121

Type of Action: Termination

Amendment No.: 3

Date Issued: 4/29/13 License Reviewers: KA, JT

File No.: 4

Licensee: Mistras Group

Type of Action: New

License No.: ARK-1034-03310

Amendment No.: 0

Date Issued: 12/20/12 License Reviewers: KA, JT

Comments:

1) Pre-licensing guidance was not used.

2) Off-shore operating and emergency procedures for conducting radiographic operations in exclusive federal jurisdiction were tied down to the license.

File No.: 5

Licensee: Mistras Group

License No.: ARK-1034-03310

Type of Action: Amendment

Amendment No.: 1

Type of Action: Amendment No.: 1
Date Issued: 3/20/13

Amendment No.: 1
License Reviewers: RP, JT

Comment:

The license was amended to remove a permanent storage location; however, the licensing case file did not include justification for removing the location from the license, such as radiation surveys or leak test records.

File No.: 6

Licensee: University Nuclear and Diagnostics License No.: ARK-1019-02201

Type of Action: Termination Amendment No.: 4

Date Issued: 3/11/13 License Reviewers: KA, JT

File No.: 7

Licensee: University of Arkansas for Medical Sciences License No.: ARK-0001-02110

Type of Action: Renewal Amendment No.: 31
Date Issued: 12/18/12 License Reviewers: KA, JT

File No.: 8

Licensee: Construction Materials Testing Services License No.: ARK-0750-03121

Type of Action: Renewal Amendment No.: 49

Date Issued: 7/28/10 License Reviewers: DS, JT

File No.: 9

Licensee: Insight Health Corporation License No.: ARK-0994-02231

Type of Action: Amendment No.: 4
Date Issued: 10/13/10

Amendment No.: 4
License Reviewers: AM, JT

File No.: 10

Licensee: St. Vincent Infirmary Medical Center License No.: ARK-0394-02120

Type of Action: Amendment Amendment No.: 143
Date Issued: 8/27/13 License Reviewers: AH, JT

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 with Program procedures.

File No.: 11

Licensee: NEA Baptist Clinic License No.: ARK-0925-02201

Type of Action: Amendment Amendment No.: 11
Date Issued: 3/1/10 License Reviewers: RP, JT

Comment:

Pre-licensing guidance was not used.

File No.: 12

Licensee: Southwestern Electric Power Company License No.: ARK-1025-03120

Type of Action: Amendment No.: 2

Date Issued: 5/11/12 License Reviewers: RP, SM

File No.: 13

Licensee: Huber Specialty Hydrates, LLC License No.: ARK-1029-03120

Type of Action: New Amendment No.: 0

Date Issued: 6/27/12 License Reviewers: KA, SM

Comment:

Pre-licensing guidance was not used.

File No.: 14

Licensee: Apex Geoscience, Inc. License No.: ARK-1027-03121

Type of Action: Amendment No.: 5

Date Issued: 12/20/12 License Reviewers: RP, JT

File No.: 15

Licensee: CARTI License No.: ARK-0654-02200

Type of Action: Renewal Amendment No.: 56
Date Issued: 4/9/12 License Reviewers: KA, KW

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.

File No.: 16

Licensee: CARTI License No.: ARK-0654-02200

Type of Action: Amendment No.: 58

Date Issued: 7/9/12 License Reviewers: RP, JT

File No.: 17

Licensee: Mercy Health Center License No.: ARK-0880-02120

Type of Action: Amendment No.: 13

Date Issued: 9/27/12 License Reviewers: AH, JT

File No.: 18

Licensee: Mercy Health Center License No.: ARK-0880-02120

Type of Action: Amendment No.: 14

Date Issued: 10/5/12 License Reviewers: TK, JT

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Flakeboard America License No.: ARK-0664-03120

Date of Incident: 2/2/11 NMED No.: 130354 Investigation Date: 8/8/13 Type of Incident: Equipment Failure

Type of Investigation: Inspection

Comment:

This event was not reported by the licensee but was instead identified during a

routine inspection on 8/8/13 and subsequently reported to NRC.

File No.: 2

Licensee: Applied Inspection Systems License No.: ARK-0576-03320

Date of Incident: 7/26/10 NMED No.: 10038

Investigation Date: 7/27/10 Type of Incident: Equipment Failure

Type of Investigation: Site

File No.: 3

Licensee: University of Arkansas for Medical Sciences License No.: ARK-001-02110

Date of Incident: 8/27/10 NMED No.: 100496

Investigation Date: 9/13/10 Type of Incident: Lost RAM

Type of Investigation: Review licensee report

Comment:

The licensee's written report did not contain all of the information required by regulation, including information regarding corrective actions to prevent recurrence.

File No.: 4

Licensee: University of Arkansas for Medical Sciences License No.: ARK-001-02110

Date of Incident: 9/17/10 NMED No.: 100551

Investigation Date: 9/20/10 Type of Incident: Damage to Equipment/Source

Type of Investigation: Site

File No.: 5

Licensee: Johnson Regional Medical Center License No.: ARK-0523-02120

Date of Incident: 11/9/10 NMED No.: N/A

Investigation Date: 11/17/10 Type of Incident: Contamination

Type of Investigation: Site

File No.: 6

Licensee: University of Arkansas for Medical Sciences

Date of Incident: 3/16/11

Investigation Date: 8/2/11

License No.: ARK-001-02110

NMED No.: 110154

Type of Incident: Medical Event

Type of Investigation: Review licensee report

Comment:

The State did not report the event to NRC within the required timeframe. The reporting category is 24 hours. The licensee informed the Program on 3/17/11 and the Program reported the event to NRC on 4/1/11.

File No.: 7

Licensee: Protechnics

Date of Incident: 10/25/12

Investigation Date: 10/26/12

License No.: REC-084

NMED No.: N/A

Type of Incident: Contamination

Type of Investigation: Site

File No.: 8

Licensee: Pathfinder Energy Services

Date of Incident: 3/15/11

Investigation Date: 3/18/11

License No.: Reciprocity 336

NMED No.: 120038

Type of Incident: Abandoned RAM

Type of Investigation: Review licensee report/Site

File No.: 9

Licensee: International Testing & Inspection License No.: ARK-773-03320

Date of Incident: 4/29/12 NMED No.: N/A Investigation Date: 5/22/12 Type of Incident: Overexposure Type of Investigation: Site

File No.: 10

Licensee: Team Industrial Services, Inc. License No.: ARK-0344-03320

Date of Incident: 10/3/10 NMED No.: 100503

Investigation Date: 10/18/10 Type of Incident: Equipment failure

Type of Investigation: Site

Comment:

The State did not report the event to NRC within the required timeframe. The reporting category is 24 hours. The licensee informed the Program on 10/4/10 and the Program reported the event to NRC on 10/7/10.

ATTACHMENTS

March 21, 2014 Letter from Nathaniel Smith Arkansas' Response to the Draft Report ADAMS Accession No.: ML14083A332

NRC Comment Resolution to March 21, 2014 Letter ADAMS Accession No.: ML14084A017



Arkansas Department of Health

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

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 March 21, 2014 Page 2

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,

N.J.S M

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.

<u>Draft report, Technical Quality of Inspections, page 7:</u>

"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 License No.: ARK-1019-02201 Inspection Type: Initial, Announced Priority: 5

Inspection Type: Initial,Announced Priority: 5Inspection Date: 5/21-25/13Inspectors: 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 License No.: ARK-0394-02120

Type of Action: Amendment Amendment No.: 143
Date Issued: 8/27/13 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 License No.: ARK-0654-02200

Type of Action: Renewal Amendment No.: 61

Date Issued: 7/11/13 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.

2013 ARKANSAS IMPEP

Comment Resolution for the March 21, 2014 letter, Appendix B, from ADH (ML14083A332) regarding the February 20, 2014, draft IMPEP report

ARKANSAS' COMMENTS REGARDING THE DRAFT REPORT:

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."

Response:

The referenced statements have been corrected to read: "The revised preliminary Findings were discussed with the Radioactive Materials Program Manager on December 12, 2013." The IMPEP team is unable to report on further actions taken by the Program Manager to disseminate the information, and therefore, did not include the suggested revision "...which was shared with the Department's upper management."

ITEM 2.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.

Response:

The statement has been corrected to reflect a 7 year renewal period.

ITEM 2.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.

Response:

The permanent storage location in Arkansas was removed from the license via an amendment request. The licensing case file did not include justification for removing the storage location from the license, such as surveys or leak tests. The text was revised to reflect this clarification. The comment listed in Appendix D, File No. 5, was also revised accordingly.

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 Section 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.

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."

Response:

The referenced text has been clarified to indicate that the "Emergency Response Procedures for non-ANO Incidents" address how the Radiation Control Section receives notifications of events. It was further clarified that the Radiation Materials Program procedure RAM-04.4 "Responding to Events Involving Radioactive Material" describes general event response procedures and does not contain specific guidance associated with responding to or evaluating medical events.

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.

Response:

The date of the inspection has been corrected to 5/21/10 and the Inspector initials "AS" have been deleted.

ITEM 5.a.:

Appendix D License Casework Reviews

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

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/or manual brachytherapy therapy authorized as "seed" 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.

Response:

Although the team appreciates the stated actions taken by the State to address the comments and correct the license, the action was taken by the State after the review period. The IMPEP team cannot include a comment regarding an action taken by the State that was performed outside of the review period and not reviewed by the team; however the State can address this at the MRB meeting.

ITEM 5.b.:

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/raining 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.

Response:

The Amendment Number has been corrected to 56; the License reviewer initials were corrected to "KA, KW;" and the Date Issued was corrected to 4/9/12. Similar to the above, the team appreciates the stated action taken by the State to address the comment. The IMPEP team cannot include a comment regarding an action taken by the State that was performed outside of the review period and not reviewed by the team; however the State can address this at the MRB meeting.