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

October 18, 2018

Ms. Kimberly Steves, Director
Kansas Radiation Control Program
Kansas Department of Health
and Environment
1000 SW Jackson Suite 330
Topeka, KS 66612

Dear Ms. Steves:

On September 18, 2018, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States Liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Kansas Agreement State Program. The MRB found the Kansas Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Because of the significance of the findings, the MRB determined that the Kansas Program should enter a period of Heightened Oversight. Heightened Oversight is an increased monitoring process the NRC uses to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bi-monthly conference calls, and submission of status reports prior to each call with the appropriate Kansas program and NRC managers and staff members.

We request that you prepare and submit a program improvement plan as part of your response to the review team's recommendations. I ask that you have your staff discuss the required elements of this plan with Mr. Daniel Collins, Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, to ensure that a path forward and measures of success are clearly identified. The plan should be submitted within 30 days of receipt of this letter. Upon review of your program improvement plan, NRC staff will schedule the first conference call. The initial conference call should be scheduled and conducted no later than 60 days from receipt of this letter.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0). The team did not make any new recommendations regarding the performance of the Kansas Agreement State Program during this review. The MRB agreed that the recommendation from the 2014 IMPEP review should be closed (see Section 2.0). Based on the results of the current IMPEP review, the next full IMPEP review will take place in approximately 2 years, with a periodic meeting in approximately 1 year.

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 respective organizations continuing to work cooperatively in the future.

Sincerely,

/RA Marc Dapas for/

Daniel H. Dorman
Acting Deputy Executive Director for Materials,
Waste, Research, State, Tribal, Compliance,
Administration, and Human Capital Programs
Office of the Executive Director for Operations

Enclosure:
Kansas Final IMPEP Report

cc: Debra Shults, TN
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE KANSAS PROGRAM

JUNE 25–29, 2018

FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Kansas Agreement State Program covering the period June 14, 2014, to June 29, 2018. The review was conducted during the period of June 25 – 29, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arizona.

Based on the results of this review, the Kansas Agreement State Program's performance was found satisfactory for two common performance indicators: Technical Staffing and Training, and Status of Materials Inspection Program; satisfactory, but needs improvement, for three indicators: Technical Quality of Inspections, Technical Quality of Licensing Actions, and Compatibility Requirements; and unsatisfactory for the indicator: Technical Quality of Incident and Allegation Activities. The indicator, Technical Quality of Inspections was found unsatisfactory by the IMPEP team. However, the Management Review Board (MRB) determined this indicator should be found satisfactory, but needs improvement after taking into consideration that the Radiation Control Program inspectors performed well on the inspection accompaniments, and that the frequency of the issues identified in the casework review did not meet the criteria for an unsatisfactory finding.

The team did not make any recommendations and the MRB agreed that the recommendation from the 2014 IMPEP review should be closed.

The team determined that the declining performance from the previous 2014 IMPEP review was mainly due to: (1) inadequate management oversight of inspection and event reports as described in Sections 3.3 and 3.5 of this report; (2) poorly documented inspection findings to licensees as described in Section 3.3; and (3) the pattern of untimely and insufficient responses to events (e.g., overexposure to an embryo fetus, extremity overexposure to a radiographer, medical events) as described in Section 3.5.

Based on the findings and the criteria in Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," the team recommended, and the MRB agreed, that the Kansas Agreement State Program be placed on Heightened Oversight. Heightened Oversight is an increased monitoring process used by the NRC to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate Kansas Agreement State Program and NRC staffs.

Accordingly, the team recommended, and the MRB agreed, that the Kansas Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Based on the results of this IMPEP review, the team recommended, and the MRB agreed, that the next IMPEP review take place in approximately 2 years with a periodic meeting in approximately 1 year.

1.0 INTRODUCTION

This report presents the results of the review of the Kansas Agreement State Program. The review was conducted during the period of June 25 – 29, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arizona. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of June 14, 2014, to June 29, 2018, were discussed with Kansas managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicators was sent to Kansas on February 2, 2018. Kansas provided its response to the questionnaire on May 10, 2018. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML18151A731. Kansas updated its response to the questionnaire on June 26, 2018 (ADAMS Accession Number ML18186A683).

A draft of this report was issued to Kansas on August 1, 2018, for factual comment (ADAMS Accession Number ML18207A242). Kansas responded to the draft report by letter dated August 29, 2018, from Kimberly Steves, Director, Radiation Control Program, Kansas Department of Health and Environment (Accession Number ML18248A084). The Management Review Board (MRB) convened on September 18, 2018, to discuss the team's findings.

The Kansas Agreement State Program is administered by the Radiation Control Program (the Program) which is located within the Bureau of Community Health Services (the Bureau). The Bureau is part of the Department of Health and Environment (the Department). Organization charts for the Kansas Agreement State Program are available in ADAMS (Accession Number ML18151A735).

At the time of the review, the Kansas Agreement State Program regulated 270 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Kansas.

The team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators and made a preliminary assessment of the Kansas Agreement State Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on June 13, 2014. The final report is available in ADAMS (Accession Number ML14261A157). The results of the review and the status of the associated recommendations are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory, but Needs Improvement
Recommendation: "The review team recommends that the State review all active medical licenses and verify that previously approved authorized physician users have the proper board certification or training requirements, and preceptor attestation, and develop and implement a process that will ensure proper verification and documentation of user qualifications for 10 CFR 35.300 (KAR 28-35-264) uses of byproduct material." (Section 3.4 of the 2014 IMPEP report)

Status: In its response to the questionnaire, the Program indicated that it completed a review of all active medical licenses authorizing 10 CFR 35.300 uses, corrected an additional two licenses with the identified error, and contacted all of the 10 CFR 35.300 medical licensees to confirm that users were only performing procedures that they were qualified to perform. The previous IMPEP team identified multiple licenses where authorized users were added for all 10 CFR 35.300 uses who were neither qualified for, nor who applied for, all of the uses in 10 CFR 35.300. The team reviewed the Program's processes for approving 10 CFR 35.300 users, and determined that the Program's corrective actions were effective and the issues found during the previous IMPEP review did not recur. Additional information can be found in Section 3.4.

This recommendation is closed.

Technical Quality of Incident and Allegation Activities: Satisfactory, but Needs Improvement
Recommendation: None

Compatibility Requirements: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety and compatible with the NRC's program.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

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

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated Kansas' performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed, or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Kansas Agreement State Program is comprised of eight staff members which equals 6.8 full-time equivalents (FTE) for the radioactive materials program when fully staffed. The 6.8 FTE is comprised of 2 supervisory/management FTE; 4.2 technical FTE; and 0.6 administrative FTE. At the time of the on-site review, there were no vacancies.

During the review period, the Program experienced turnover at both the management and staff levels. Four individuals left the Program, four were hired, and one was reassigned. The vacancies included one management, one technical, and three supervisory (i.e., the same position was vacated and filled three times) positions. The Program Director became the acting Director in July 2015 and was officially hired on September 28, 2015. The current Supervisor for Radioactive Materials/Licensing began their job on February 12, 2018, but during this review period, this position was held by four individuals. The three technical positions were vacant from 2 to 4 months. The team identified that management turnover contributed to a lack of oversight of the evaluation of licensees' root cause analyses and corrective actions for items of non-compliance; the documentation of reactive and follow-up inspections; and event response (see Sections 3.3 and 3.5).

The team determined that the Program has a training and qualification program compatible with the NRC's IMC 1248. Inspectors attend NRC required training, are provided on-the-job training, and a supervisor performs inspector accompaniments to determine qualification.

c. Evaluation

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

d. MRB Decision

The MRB agreed with the team's recommendation and found Kansas' performance with respect to this indicator to be satisfactory.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Kansas' performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.

- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections, or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

The Program performed 289 Priority 1, 2, 3, and initial inspections during the review period. Approximately one percent of the 289 inspections were completed overdue (three of the 36 initial inspections) and no Priority 1, 2, or 3 inspections were conducted overdue during the review period. Kansas' inspection frequencies are equal to, or more frequent than, similar license types in the NRC's IMC 2800.

A sampling of 25 inspection reports indicated that all inspection reports reviewed were communicated to the licensee within Kansas' goal of 30 days after the inspection exit.

Kansas performed 21.4 percent (3 of 14) of reciprocity inspections in 2014; 4.5 percent (1 of 22) in 2015; 23.8 percent (5 of 21) in 2016; and 17.6 percent (3 of 17) in 2017. For 2018, Kansas has performed 36.4 percent (4 of 11) of reciprocity inspections as of June 29, 2018. Reciprocity inspections have continued to challenge the Program. In the 2014 IMPEP report, it was stated that the reciprocity inspection rates were between 10–13 percent for 2011-2013, below the 20 percent target rates. Corrective actions since 2014 have not been effective as shown by the 2015 and 2017 statistics. The Program attributed the reciprocity inspection shortfall during this review period to: (1) a lack of management oversight that resulted in an insufficient number of reciprocity inspections being conducted; and (2) the geographical difficulty in traveling to reciprocity inspection sites due to the size of Kansas in relation to the physical location of the Program office in northeast Kansas. The Program's current strategy for addressing shortfalls is to: (1) have a designated staff member serve as a point-of-contact for overseeing the reciprocity requests; (2) inspect more candidates at the beginning of each year, thereby facilitating an increase in the overall number of reciprocity inspections conducted annually; and (3) discuss the status of reciprocity inspections at the monthly meeting with the Supervisor for Radioactive Materials/Licensing. The team determined that appropriate measures and supervisory oversight are now in place to meet the reciprocity inspection standards described in the NRC's IMC 1220.

c. Evaluation

The team determined that, except as noted below, during the review, period Kansas met the performance indicator objectives listed in Section 3.2.a.

- Candidate licensees working under reciprocity were not consistently inspected in accordance with the criteria prescribed in the NRC's IMC 1220.

Although reciprocity inspections have continued to challenge the Program, the team determined that appropriate measures and supervisory oversight are now in place to meet the reciprocity inspection standards described in the NRC's IMC 1220.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Kansas' performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Kansas' performance with respect to this indicator to be satisfactory.

3.3 Technical Quality of Inspections

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

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Kansas' performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.

- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports and enforcement documentation, and interviewed inspectors involved in 25 materials inspections conducted during the review period. The casework reviewed included inspections conducted by six inspectors and covered medical, industrial, commercial, academic, and research licenses for initial, routine, and special inspections. The team noted that the internal inspection reports were effective at documenting the scope of each inspection. The reports also included placeholders for inspectors to describe any areas of concern identified during the inspection and provided for the ability of the inspector to enter observation information specific to sections of the report. Once the team began to identify performance issues with reactive inspections, the team focused the review for this indicator on inspections that followed a reported incident.

From the casework reviewed and interviews with inspectors, the team determined that inspection findings were not well-founded or properly documented, inspections did not adequately address previously identified open items and violations, and inspection findings did not lead to appropriate or prompt regulatory action. When issues of non-compliance were identified, inspectors did not clearly document the specific regulation(s) that caused the licensee to be in non-compliance. The team determined that although supervisory and management reviews of inspection documentation were timely, they did not include an adequate assessment of, or address, the inspector's evaluations of the licensee's root cause, extent of condition review, evaluation of the effectiveness of corrective actions, or ensure the clear communication of inspection findings in inspection reports.

The team identified examples where inspection findings were not well-founded or properly documented. These examples included: (1) citing a medical licensee for a failure to properly train facility personnel, but documenting in the inspection report that there were no gaps in training; (2) not providing adequate documentation for closing previous violations; (3) not providing validation or verification of a licensee's root cause analysis or its corrective actions for an inspection regarding a Yttrium-90 (Y-90) contamination event that occurred the previous month; and (4) not documenting another medical event in which a patient received approximately 24 percent of the prescribed dose of Y-90 microspheres. For the Y-90 microsphere medical event, the inspection documentation did not contain any information on the Program's assessment or confirmation of the licensee's root cause analysis and corrective actions.

A complete list of inspection casework reviewed by the team can be found in Appendix C. Below is a synopsis of risk significant inspections where the team identified performance issues:

> On June 29, 2015, a licensee reported that a declared pregnant woman had a measured dose to the embryo fetus of greater than 500 millirem during the gestation period. The Program conducted a reactive inspection on September 3,

2015, and cited the licensee for a failure to report the event in a timely manner, but did not cite the licensee for the overexposure or the non-uniform exposure over the gestation period. The inspection report did not provide any information indicate that the Program followed up on a discrepancy between the dose reported by the licensee and the dose identified in monthly dosimetry reports. The team reviewed the dosimetry records in the case file and identified that the total doses summed to 579 millirem for the gestation period, and not 535 millirem as reported by the licensee. The team questioned Program staff about this discrepancy and the Program explained that according to the licensee, one of the monthly dosimetry reports was incorrect. However, the dosimetry records did not confirm the error, and the team could not find any conclusive evidence to support the 535 millirem dose reported by the licensee. The Program accepted the licensee's corrective action for the overexposure, but failed to request corrective actions for the failure to report within 30 days.

The Program did not cite the licensee for a reported radiographer's extremity overexposure. There also was not any documentation of the Program's review of this event during the next routine inspection. There also was no indication that the Program adequately reviewed the licensee's evaluation of the event or that the Program conducted an independent assessment to confirm the overexposure.

During an inspection of a medical licensee, the Program reviewed a contamination event involving Y-90, but did not document the review of a medical event at the same facility where a patient received an under dose of Y-90 microspheres. The Program indicated that it reviewed the other Y-90 medical under dose event that occurred 2 years earlier, but failed to document the review. There was no documentation to indicate a review of the licensee's root cause analysis and corrective actions for the two under dose medical events.

Based on its findings, the team determined that there was a supervisory and management over-reliance on the inspectors' ability to fully assess, evaluate, follow-up, and document violations and licensee responses to specific events. The team determined that supervisory and management personnel missed opportunities to provide inspector guidance for further evaluation of events or improved reporting. Through interviews with staff, the team found that the Program's inspectors do not routinely review the relevant NRC inspection procedures, or an equivalent procedure as part of their inspection preparation. Additionally, the team determined that the Program's inspection procedures are not equivalent to the NRC's Inspection Procedure 87100 series. Procedures lacked the detail and specificity to ensure proper review of root causes and/or poor licensee performance.

The team determined that the performance issues described in this section of the IMPEP team report are also indicative of the Program's inappropriate and inadequate handling of reactive inspections as described in Section 3.5 of this report.

A team member accompanied three inspectors on April 10–12, 2018. The inspector accompaniments are identified in Appendix B. The inspectors conducted routine

unannounced inspections. During the accompaniments, no items of licensee non-compliance were found by the Program inspectors, and no issues of inspector concern were determined by the team member performing the accompaniments. The team noted that during the inspection accompaniments, the routine inspections appeared to be properly performed and led to clear inspections.

The Program provided licensees with the results of its inspections within 30 days of the exit. The Program performed annual supervisory accompaniments for all inspectors each year during this review period. The Program maintained an adequate supply of calibrated and operable survey instruments available to support the inspection program.

c. Evaluation

The team determined that, except as noted below, during the review period the Kansas program met the performance indicator objectives listed in Section 3.3.a.

- Inspection findings are neither consistently well-founded nor properly documented in reports.
- Procedures do not help identify root causes and poor licensee performance.
- Inspections do not consistently address previously identified open items and violations.
- Inspection findings do not, in all cases, lead to appropriate and prompt regulatory action.
- Inspection guides are not consistent with NRC guidance.

The team determined that inspection findings were often not well-founded or properly documented in the inspection reports reviewed. In its inspection findings, the Program did not clearly communicate the specific regulation that caused the licensee to be in non-compliance. The Program's inspection documentation often did not adequately address previously identified open violations. Although supervisory and management reviews of the inspection documentation were timely, they did not include an adequate assessment of, or address, the inspector's evaluation of the licensee's root cause analysis, extent of condition review, evaluation of the effectiveness of corrective actions, or ensure the clear communication of inspection findings in inspection reports. Although inspection procedures were in place, they lacked the detail and specificity to ensure proper review of root causes and/or poor licensee performance.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Kansas' performance with respect to the indicator, Technical Quality of Inspections, be found unsatisfactory.

d. MRB Decision

The MRB acknowledged the IMPEP team's finding, yet concluded that Kansas' performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory, but needs improvement. The MRB took into consideration that the Program's inspectors performed well on the inspection accompaniments, and that the

frequency of the issues identified in the casework review did not meet the criteria for an unsatisfactory finding.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the Kansas licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Kansas' performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, Kansas performed 854 radioactive materials licensing actions. The team evaluated 34 of those actions. The licensing actions selected for review included 4 new applications, 21 amendments, 5 renewals, and 4 terminations. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, portable and fixed gauges, self-shielded irradiators, well-logging, service providers, decommissioning actions, bankruptcy actions, changes of ownership, and

financial assurance. The casework sample represented work from nine license reviewers.

As noted in Section 2.0 of this report, the team concluded that the recommendation from the previous IMPEP review should be closed. The team reviewed medical licenses to verify that the Program's corrective actions in response to this recommendation were effective. The Program's database uses a new function that allows the Program staff to enter information about each authorized users' training and experience. If an authorized user requests permission to use material that it is not authorized for, a message flags the reviewer of the discrepancy. In addition, the Program changed its licensing format from authorizing by exception (e.g., 35.300 except for the treatment of thyroid carcinoma) to authorizing by individual use (e.g., 35.392, 35.394).

In eight of the licensing actions reviewed, the team identified examples of deficiencies with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing licensing guidance and procedures. For example, during its evaluation of license amendment requests to add new authorized users, the team found an instance of an addition of an authorized user for 10 CFR 35.600, where the preceptor was not verified. When the team interviewed the license reviewers regarding the verification of the preceptor, the team learner that a license reviewer was not verifying the authorized user, authorized medical physicist, or radiation safety officer qualifications of the preceptor for licenses that were issued by another Agreement State or by the NRC. The team found that the reviewer would verify that the preceptor was adequately qualified for the modalities for which the proposed user was seeking authorization, as long as the license listed for the preceptor was issued in Kansas. The license reviewer assumed that he could only verify authorized users who were listed on a Kansas license, and the Program did not have a process to reach out to other Agreement States or to the NRC to obtain preceptor license confirmation and verification. Once this was brought to the Program's attention, the Program indicated that it would contact all of the affected licensees and obtain documentation to verify that all of the preceptors were properly qualified. The Program further committed to revise procedures to ensure that the qualifications of preceptors are properly verified to attest to the training for new authorized users, authorized medical physicists, or radiation safety officers that are to be added to the licenses.

For a licensing amendment request to change a Radiation Safety Officer, the team could not find any documentation that this individual's training and experience met the requirements. In addition, the team found that an authorized user was added to the license with an incomplete preceptor statement, as well as a license renewal that had not been signed by the licensee.

The team identified issues with the Program's application of financial assurance program requirements. At the time of the review, the Program had identified four licensees that were authorized for possession of radioactive materials in excess of the quantities that would require financial assurance. The team verified that for these four licensees the proper financial assurance documentation was on file and that the information was appropriately secured. The team found an additional three licensees that were authorized to possess radioactive materials in excess of the financial assurance

quantities; however, in these cases the Program did not possess the required financial assurance documentation. All three of the licensees were State universities that the Program later confirmed met the financial assurance requirements because they were government entities.

The team found that the Program added a license condition to some medical licenses that allowed visiting authorized users to be able to work under a Kansas radioactive materials license for up to 60 days as long as they were already listed on another Agreement State or NRC license. This condition was not submitted to the NRC for a compatibility review. Based on the team's review, the Program decided to remove this condition from all licenses. This issue is further described in Section 4.1 of this report.

The team examined the Program's licensing practices with respect to requests for "Risk Significant Radioactive Material." The team determined that the Program has a licensing procedure to identify new and amended licenses that should be subject to additional security measures, and that it is implementing the procedure correctly. In addition, the team assessed the Program's implementation of the pre-licensing guidance. The team determined that the Program had the documentation to support a basis of confidence that the radioactive material would be used as requested.

c. Evaluation

The team determined that, except as noted below, during the review period Kansas met the performance indicator objectives listed in Section 3.4.a.

- Licensing action reviews are not consistently thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications were not consistently submitted and elements were not always consistent with current regulatory guidance (e.g., financial assurance).

A review of the licensing casework indicated repeat examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing licensing guidance and procedures. As noted above, the Program had a misunderstanding on obtaining preceptor verification from other Agreement States and the NRC for 10 CFR 35.300 users. The Program also did not understand that State government licensees still needed to provide financial assurance based on the limits authorized on the license. In addition, the Program utilized a license condition on several licenses without first submitting the condition to the NRC for a compatibility review.

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

d. MRB Decision

The MRB agreed with the team's recommendation and found Kansas' performance with respect to this indicator to be satisfactory, but needs improvement.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and follow-up actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Kansas' performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 32 incidents were reported to Kansas. The team evaluated 19 radioactive materials incidents, which included seven lost/stolen/abandoned radioactive materials, two overexposures, three medical events, four reports of damaged equipment, two contamination events, and one unauthorized transfer of radioactive material. The Program dispatched inspectors for onsite follow-up for five of the cases reviewed. The onsite responses ranged from 2 days to 65 days after notification of the event.

For this indicator, the team focused on the completeness of the incident review by the Program, the timeliness of the Program's response to the incident, and the Program's actions taken in response to the incidents. In evaluating the effectiveness of the

Program's response to incidents, the team conducted interviews, examined case files, and reviewed the Program's response to the IMPEP questionnaire.

The Program's procedure for incident response requires "an onsite investigation for all incidents, medical and industrial, within 5 days of the notice." If the Program Director determines that an onsite response is not warranted, the justification must be documented. The Program uses an event database to document all incidents, allegations, and miscellaneous reports or queries. The Program uploads this information to the NMED using a transfer file built into the Program's event database. As noted in Appendix D of this report, the Program reported incidents in a timely manner to the Headquarters Operations Center except in two cases.

In the response to the IMPEP questionnaire, the Program addressed the previous rating of satisfactory, but needs improvement, for this indicator and provided an explanation for the Program's performance, the results of its determination of root causes, and the corrective actions taken. The Program identified that the root causes were insufficient management oversight of the event investigation, and that the Program's procedures did not provide enough guidance on when to conduct an onsite investigation. The Program's corrective actions included management providing greater oversight of incidents and investigations, and revising the incident and investigation procedure to include a preliminary priority evaluation, based on initial information, to determine when an onsite investigation would be warranted. As part of this procedure revision, the Program modified its internal policy to investigate all medical events within 5 days.

The team determined that during the review period, the lack of management oversight of incidents continued to occur. The Program's response to risk significant incidents during the review period was in many cases incomplete, inappropriate, and/or not timely. The team identified frequent examples of performance deficiencies involving responses to incidents. As a result, health and safety risks may persist. A complete list of incident casework reviewed by the team can be found in Appendix D. Below is a synopsis for five risk significant incidents that occurred at three Kansas licensees' facilities during this review period:

> On May 6, 2015, a radiography licensee reported a potential overexposure to a radiographer during licensed activities being performed at a refinery that occurred earlier that day. According to the information reported, a radiographer's assistant misinterpreted radio communications from the refinery's quality control lead as the signal to start radiographic operations and cranked the source out while the radiographer was adjusting the source collimator. Based on the information in NMED, when the radiographer felt the vibration of the source, he dropped the collimator, exited the area, and retracted the source. On May 29, 2015, the licensee provided updated dose measurements and calculations to the Program. The licensee reported that the radiographer's whole body dosimeter read 33 millirem, the year-to-date dose was 262 millirem, and the extremity dose was between 50 and 100 rad. The Program did not perform an onsite investigation of this incident. The Program's event database indicated that the Program responded by telephone and e-mail. Since the staff that documented this incident in the Program's event database was no longer employed by the

Program at the time of the review, the team was not able to conduct an interview and gather additional information. The next routine inspection of the licensee was performed on July 27, 2015, and the incident was not reviewed. The incident was uploaded to the NMED on June 20, 2016, but was not reported to the NRC. A subsequent inspection was performed on July 6, 2016, and the incident was not reviewed. Based on the documentation in the files, it appears that there was no review of this incident other than a telephone call and e-mail exchange between the Program and licensee. The Program did not respond to the licensee's facility to interview the persons involved, perform a dose re-enactment to validate the dose estimates, and determine if an overexposure occurred. The Program did not issue any violation for the extremity overexposure, and the Program did not report the overexposure to the NRC.

On April 30, 2015, a medical licensee received a declared pregnant woman's final monthly fetal badge dosimetry results, which indicated the fetal dose had exceeded 500 millirem for the gestation period. On June 29, 2015, the licensee reported to the Program that the total fetal dose received during the gestation period was 535 millirem. The licensee's notification was past the 30-day reporting requirement for overexposures. The Program reported the incident to NMED on July 16, 2015. The team considered this timely because it was within 30 days of receiving the report from the licensee. The Program conducted a reactive inspection on September 3, 2015. The Program issued a violation for the late reporting of the incident, but failed to issue violations for the overexposure and the variance in dose distribution. The Program accepted the licensee's corrective actions for the overexposure, which included closer monitoring of fetal exposure and reviews at 10 and 30 percent of the dose limit, but did not request corrective actions for the late reporting. As noted in Section 3.3 of this report, there was a discrepancy in the dose reported to NMED. The team noted that at the time of the review, the Program had not updated the NMED report with the correct exposure data.

The team identified issues with multiple events involving Y-90 microspheres. On September 30, 2015, a medical licensee reported an under dose of Y-90 microspheres administered to a patient the day before. This event was reported to the NRC on October 1, 2015. The licensee determined that the root cause for the event was a weak battery in the digital electronic radiation dosimeter. The licensee's procedure for this type of administration requires the use of a digital electronic radiation dosimeter to confirm post-injection, that the microspheres were no longer in the vial. The licensee's corrective actions included changing batteries in the electronic dosimeter prior to each microsphere administration to ensure optimum power. The Program's records did not indicate if an onsite investigation was conducted, and the next inspection following the event did not appear to independently evaluate and confirm that the licensee's root cause analysis of the event was acceptable. This medical event was not reviewed until an inspection was conducted in September 2017.

At this same facility, on July 19, 2017, another incident occurred where a patient received an under dose of Y-90 microspheres. The licensee later discovered

that the microspheres had collected in the catheter and not in the patient; even though a digital electronic radiation dosimeter read “zero” at the conclusion of the administration. The Program did not perform an onsite investigation for this medical event. There was no documentation of exposures to personnel or patients from the microspheres that remained outside of the patient. There was no validation of the licensee’s root cause analysis of the event or its corrective actions and, in this case, the corrective actions noted by the licensee were not commensurate with the determined root cause. The Program reported this event to the NRC on July 19, 2017.

On August 25, 2017, the same medical licensee reported a contamination event involving Y-90 microspheres which occurred the day before. A technologist did not follow the proper procedure and became contaminated. This technologist tracked contamination down a hallway and into several rooms. The Program reported the incident to the NRC on the same day that is was notified by the licensee, and conducted an onsite investigation on August 28, 2017, to evaluate the incident and contamination, and a routine inspection on September 27, 2017. An interview with the technologist revealed that she was distracted. The event was closed by the Program; however, the information in NMED indicates an additional review was being conducted. The licensee’s corrective actions were reviewed as part of the routine inspection; however, the corrective actions do not appear to match the causes of the event.

As described in Section 3.1 of this report, the team determined that management did not provide sufficient oversight of reactive and follow-up inspections to ensure a prompt response to incidents.

During the review period, eight allegations were received by Kansas. The team evaluated three allegations, including two allegations that the NRC referred to Kansas during the review period. The team determined that the Program was adequately responding to allegations, following procedures, maintaining documentation to close the allegation, and was able to protect the identity of concerned individuals. In one of the cases referred to the Program by the NRC, the team identified that a concerned individual was not notified about the Program’s investigation results. The Program performed an onsite investigation within 6 days of referral, and determined that the concerns could not be substantiated. While the allegation response was prompt and thorough, there was no indication that the concerned individual was notified of the results. Once the team raised this question, the Program committed to notify the concerned individual about the results of the investigation. With the exception of this one isolated case, the Program followed its allegation response procedure.

c. Evaluation

The team determined that, except as noted below, during the review period Kansas met the performance indicator objectives listed in Section 3.5.a.

- In one isolated case, the concerned individual was not notified of investigation conclusions.

- Incident response and investigation procedures are not consistently followed.
- Response actions are not always appropriate, well-coordinated, or timely.
- Onsite responses are not consistently performed when incidents have potential health, safety, or security significance.
- Appropriate follow-up actions are not always taken to ensure prompt compliance by licensees.
- Follow-up inspections are not consistently scheduled and completed, as necessary.
- Notifications are not always made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.

From its evaluation, the team identified frequent examples in which responses to incidents were incomplete, inappropriate, poorly coordinated, or not timely. As a result, potential health and safety problems persisted. The team also identified two instances where the Program failed to notify the NRC of incidents, as appropriate.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Kansas' performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found unsatisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found Kansas' performance with respect to this indicator to be unsatisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State

Agreements procedure SA-200, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements,” that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, “Reviewing the Non-Common Performance Indicator: Compatibility Requirements,” and evaluated Kansas’ performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC website at the following address: https://scp.nrc.gov/regtoolbox.html.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State’s regulations.

b. Discussion

Kansas became an Agreement State on January 1, 1965. The Kansas regulations governing radiation protection requirements are found in Kansas Administrative Regulations 28-35-133 through 28-35-505, and apply to all ionizing radiation, whether emitted from radionuclides or produced by machines. No legislation affecting the Program was passed during the review period except a new bill was approved on June 7, 2018, that now requires the review and approval by the Kansas Division of Budget, in addition to the Department of Administration, and the Attorney General for all rulemakings.

Kansas’ administrative rulemaking process takes approximately 2 to 3 years from drafting to finalizing a rule. The public, the NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Kansas Attorney General. Based on the

new bill that was approved on June 7, 2018, the Program could not estimate the additional time that will be added to the legislative process, but it believes it could be significant. The team noted that the State's rules and regulations are not subject to "sunset" laws.

During the review period, the Program submitted one proposed regulation amendment (Regulation Amendment Tracking System Identification Number (RATS ID) (2013-1)), nine final regulation amendments (RATS IDs 2001-1, 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2012-4, 2013-1, and 2013-2), and one legally binding license condition (10 CFR Part 37) to the NRC for a compatibility review. Eight final regulation amendments (RATS IDs 2001-1, 2011-1, 2011-2, 2012-2, 2012-3, 2012-4, 2013-1, and 2013-2) were overdue for State adoption at the time of submission. Based on its review of these amendments, the NRC identified provisions in which the Kansas rules were not written essentially identical to the NRC's regulations. On June 7, 2018, the Program submitted its revised final regulations incorporating some of the NRC's comments, and indicated that a rulemaking package to address the remainder of the comments is undergoing Kansas' legislative review.

At the time of this IMPEP review, the following two amendments were overdue and had not been submitted to the NRC for a compatibility review:

- RATS ID 2015-1: Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments Part 70 (79 FR 57721, 80 FR 143) that was due for State adoption on January 26, 2018.

- RATS ID 2015-2: Safeguards Information - Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73 and 150 (79 FR 58664, 80 FR 3865) that was due for State adoption on January 28, 2018.

The team questioned the Program as to why the regulations were submitted overdue, and why the Program did not issue legally binding requirements in the interim. The Program indicated that the eight final regulation amendments that were overdue for State adoption at the time of submission were undergoing legislative review, and that resources were not available to address all of the rulemakings through legally binding requirements. The Program noted that the legislative review process is outside of its control.

As described in Section 3.4 of this report, the team found that the Program issued a license condition that was not previously reviewed and approved by the NRC. The license condition was added to some medical licenses that allowed the licensees to approve visiting authorized users. Since this license condition is a legally binding requirement, which may not be compatible with NRC regulations, the Program should have submitted the proposed license condition to the NRC for a compatibility review prior to placing the condition on any licenses. After a discussion with the team, the Program decided to remove this license condition immediately from the medical licenses, contact the affected licensees to determine whether any authorized users were added using this license condition, and, if so, request the training and experience documentation of these visiting authorized users for the Program's review and approval.

c. Evaluation

The team determined that, except as noted below, during the review period Kansas met the performance indicator objectives listed in Section 3.5.a.

- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were, in some cases, adopted greater than 3 years after the effective date of the NRC regulation.

Several regulations adopted by Kansas for purposes of compatibility, or health and safety, were adopted later than 3 years after the effective date of the NRC regulation. The team took into consideration that Kansas' administrative rulemaking process can take 3 years from drafting to finalizing a rule and any delay would lead to an overdue submission. The team discussed whether a finding of satisfactory, but needs improvement, versus unsatisfactory would be appropriate. Due to the following, the team concluded that a finding of satisfactory, but needs improvement would be appropriate: (1) although amendments were submitted late to the NRC for compatibility review, Kansas has final regulations adopted and effective as of this review, and has a rulemaking package to address all outstanding NRC comments in process; (2) the legislative process is outside the control of the Program; and (3) new Program management is committed to ensuring that all efforts will be made to promulgate regulations on time, and, if not, will issue legally binding requirements. The team determined that the Kansas radiation control program is compatible with the NRC's program at this time.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that Kansas' performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

d. MRB Decision

The MRB agreed with the team's recommendation and found Kansas' performance with respect to this indicator to be satisfactory, but needs improvement.

4.2 Sealed Source and Device (SS&D) Evaluation Program

The Kansas Agreement State Program has authority to conduct sealed source and device (SS&D) evaluations for byproduct, source, and certain special nuclear materials; however, Kansas did not conduct any SS&D evaluations during the review period. There are currently no SS&D manufacturers in Kansas. If Kansas were to receive an application for an SS&D action, it has a procedure in place to outsource or contract the action. Accordingly, the team did not review this indicator. The Program manager indicated that the Program is considering returning this portion of the Agreement to the NRC.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need for an amendment. Although Kansas has such authority to regulate a LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for LLRW disposal. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Kansas. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Kansas' performance was found to be satisfactory for the performance indicators: Technical Staffing and Training, and Status of Materials Inspection Program. Kansas' performance was found to be satisfactory, but needs improvement, for the performance indicators: Technical Quality of Inspections, Technical Quality of Licensing Actions, and Compatibility Requirements. Kansas' performance was found to be unsatisfactory for the performance indicator: Technical Quality of Incident and Allegation Activities. The indicator, Technical Quality of Inspections was found unsatisfactory by the IMPEP team. However, the MRB determined this indicator should be found satisfactory, but needs improvement.

The team did not make any recommendations and the MRB agreed that the recommendation from the 2014 IMPEP review should be closed.

The team determined that the declining performance from the previous 2014 IMPEP review was mainly due to: (1) inadequate management oversight of inspection and event reports as described in Sections 3.3 and 3.5 of this report; (2) poorly documented inspection findings to licensees as described in Section 3.3; and (3) the pattern of untimely and insufficient responses to events (e.g., overexposure to an embryo fetus, extremity overexposure to a radiographer, medical events, etc.) as described in Section 3.5.

Based on the criteria in MD 5.6 and the findings of this IMPEP review, the team recommended, and the MRB agreed, to place the Kansas Agreement State Program on Heightened Oversight. Heightened Oversight is an increased monitoring process used by the NRC to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate Kansas Agreement State Program and NRC staffs. The team discussed placing the Kansas Agreement State Program on Probation versus Heightened Oversight based on the

findings; however, the team determined that Probation is not appropriate at this time because of the following:

- The last IMPEP review was satisfactory and the Program was not on any level of enhanced oversight (e.g., monitoring or heightened oversight) during the review period;
- The Program was receptive to the team's findings and committed to addressing the performance issues identified by the team; and
- The team is confident that the Program can resolve these issues in an expeditious manner.

Accordingly, the team recommended, and the MRB agreed, that the Kansas Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. Based on the results of this IMPEP review, the team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 2 years with a periodic meeting in approximately 1 year.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Michelle Beardsley, NMSS	Team Leader Compatibility Requirements
Kathy Modes, NMSS	Team Leader in Training Technical Staffing and Training Inspection Accompaniments
Binesh Tharakan, Region IV	Status of Materials Inspection Program Technical Quality of Incident and Allegation Activities
James Cassata, Region I	Technical Quality of Inspections
Brian Goretzki, Arizona	Technical Quality of Licensing Actions

APPENDIX B

INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1	License No.: 18-C753-01
Licensee: Via Christi Hospitals Wichita	Priority: 1
License Type: Medical Broad-scope (with HDR)	Inspector: JH
Inspection Date: 4/10/2018	

Accompaniment No.: 2	License No.:21-B165-01
Licensee: Coder X-ray Service	Priority1:
License Type: Industrial Radiography	Inspector JU:
Inspection Date: 4/11/2018	

Accompaniment No.: 3	License No.:38-C011-01
Licensee: Kansas State University	Priority: 1
License Type: Academic Broad-scope (with R&D)	Inspector: AS
Inspection Date: 4/12/2018	

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS

File No.: 1	
Licensee: Prime Health Care Services – Providence	License No.: 19-C182-01
Inspection Type: Medical Institution – Diagnostics – Special	Priority: 2
Inspection Date: 9/3/2015; Report Date 12/21/2015	Inspector: JAH
Comment: This reactive inspection included a review of an overexposure to an embryo fetus for a declared pregnant woman. The Program cited a violation for the failure to file a 30 day report notifying the Program of the overexposure, but the Program did not cite the licensee for the overexposure. The inspection documentation was not thorough for a reactive inspection (e.g., there was no documentation that the inspector validated the dose received). There was no indication that the Program followed up on a discrepancy in the dose reported by the licensee of 535 mrem for the overexposure that differed from the summation of the monthly dosimetry reports that totaled 579 mrem. Described in Section 3.3 of this report.	

File No.: 2	
Licensee: Prime Health Care Services – Providence	License No.: 19-C182-01
Inspection Type: Medical Institution – Diagnostics – Routine	Priority: 2
Inspection Date: 12/9/2015; Report Date 12/30/2015	Inspector: JAH
Comment: The inspection documentation did not close the previous violation from the September 3, 2015 inspection. On the Program's internal computer inspection database report, it was stated that not enough time had elapsed to determine the overall effect of the licensee's policy changes.	

File No.: 3	
Licensee: Prime Health Care Services – Providence	License No.: 19-C182-01
Inspection Type: Medical Institution – Diagnostics – Routine	Priority: 2
Inspection Date: 12/6/2017; Report Date 12/12/2017	Inspectors: JW, JAH
Comment: The inspection documentation did not address the previous violation from the September 3, 2015, inspection report which remained open. This inspection documentation did not address the evaluation of the licensee's policy changes that went into effect in 2015 as a result of the failure to report an overexposure to an embryo fetus.	

File No.: 4	
Licensee: DBI Inc.	License No.: 21-B805
Inspection Type: Industrial Radiography – Routine	Priority: 1
Inspection Date: 7/27/2015; Reported on 8/17/2015	Inspector: DL
Comment: None	

File No.: 5	
Licensee: DBI Inc.	License No.: 21-B805
Inspection Type: Industrial Radiography – Routine	Priority: 1
Inspection Date: 7/6/2016; Reported on: 7/14/2016	Inspector: JW
Comment: The Program issued a clear safety and security inspection, despite the overexposure event. On May 6, 2015, the licensee notified the Program of an extremity overexposure of 50 – 100 rad to a radiographer. However, the Program did not address this matter during this inspection. There was no documentation to show that the Program reviewed the licensee's dosimetry results or the evaluation of the event. There was no indication that the Program did an independent assessment and validation of the dose.	

File No.: 6	
Licensee: DBI Inc.	License No.: 21-B805
Inspection Type: Industrial Radiography – Routine	Priority: 1
Inspection Date: 4/18/2017; Reported on: 4/20/2017	Inspector: JU
Comment: The Program cited the radiography licensee for using a dark room truck with an inoperable pin sensor. A pin sensor is used as part of their security system. The Program wrote in their internal database "the error was not serious enough to stop the alarm, but merely delay it." This statement does not convey a clear picture of the problem encountered. The report does not indicate if the radioactive material was left unattended in the dark room truck. In the Program's inspection report, this is noted as a non-cited violation, but in the letter to the licensee it was identified as "either a minor violation or corrected at the time of the inspection." The inspection report and letter to the licensee are inconsistent. The citation is vague and ambiguous in the letter to the licensee.	

File No.: 7	
Licensee: DBI Inc.	License No.: 21-B805
Inspection Type: Industrial Radiography – Routine	Priority: 1
Inspection Date: 5/4/2018; Report Date: 5/22/2018	Inspector: DL
Comment: This was a clear inspection. There was no inspection documentation describing the licensee's corrective actions to prevent recurrence and achieve compliance in regards to the previous violation of 10 CFR 37.49.	

File No.: 8	
Licensee: University of Kansas Hospital Authority	License No.: 18-C801
Inspection Type: Type A Medical Broad Scope with Self-Shielded Irradiator – Routine	Priority: 1
Inspection Date: 9/27/2017; Reported on: 10/5/2017	Inspector: JW
Comment: The Program performed an inspection of a medical licensee on September 27, 2017. The inspection report addressed a Y-90 contamination event that occurred on August 24, 2017, but the inspection report did not confirm that the licensee's corrective actions were effective or	

their root cause was correct. The incident caused the department to restrict access for more than 24 hours due to contamination. The inspection documentation did not address a medical event that occurred on July 18, 2017, where a patient received approximately 24 percent of the prescribed dose of Y-90 microspheres. The inspection documentation contained no information on the Program's assessment or confirmation of the licensee's root cause and corrective actions of the medical event. The inspection documentation did not address another medical event where a patient was administered 64 percent of the prescribed dose of Y-90 microspheres in September 2015. The Program indicated that they reviewed the 2015 Y-90 medical under dose event, but failed to document the review. There was no documentation to indicate a review of the licensee's root cause analysis and corrective actions for the two under dose events. Additional details are described in Sections 3.3 and 3.5 of this report.

File No.: 9	
Licensee: Wesley Medical Center, LLC	License No.: 19-C041-01
Inspection Type: Type A Medical Broad Scope – Routine	Priority: 1
Inspection Date: 4/26/2016; Reported on 5/4/2016	Inspector: JAH, JW
Comment: None.	

File No.: 10	
Licensee: Wesley Medical Center, LLC	License No.: 19-C041-01
Inspection Type: Type A Medical Broad Scope – Routine	Priority: 1
Inspection Date: 5/3/2017; Reported on 5/19/2017	Inspector: JU
Comment: The inspection documentation did not address and did not close the previous seven violations. The Program issued three new violations during this inspection. However, there was a discrepancy between the report issued to the licensee and the documentation in the database inspection report. Two of the three new violations are identified as violations in the report to the licensee, but they were identified as non-cited violations in the database inspection report. The inspection documentation for these two violations was vague and ambiguous.	

File No.: 11	
Licensee: Wesley Medical Center, LLC	License No.: 19-C041-01
Inspection Type: Type A Medical Broad Scope – Routine	Priority: 1
Inspection Date: 5/15/2018; Reported on 5/31/2018	Inspector: JAH
Comment: The previous 2017 violation was properly closed on this inspection. The 2016 violations were marked as closed in the database (drop-down label), but there was no documentation as to how the licensee addressed these violations. The focus of this inspection was a review of an incident where the incorrect radioactive material was administered to a patient.	

File No.: 12	
Licensee: Chanute Manufacturing Co.	License No.: 21-B189-01
Inspection Type: Industrial Radiography – Fixed Location – Routine	Priority: 1
Inspection Date: 10/20/2017; Reported on 10/31/2017	Inspector: JU
Comment: Two security violations cited for access authorization program requirements (10 CFR 37.23) and access authorization program review (10 CFR 37.33). The regulations were poorly paraphrased and non-specific as to the subsection in the regulation resulting in unclear communication with the licensee. As written in the report, 10 CFR 37.23, implied a failure for trustworthiness and reliability determinations, a failure to perform background screenings, and a failure to remove from the access authorization list within seven days. For the citation against 10 CFR 37.33, it was unclear if the annual access authorization program review was completed and not documented, or if the annual review was not performed.	

File No.: 13	
Licensee: Coder X-Ray Service, Inc.	License No.: 21-B165-01
Inspection Type: Industrial Radiography – Routine	Priority: 1
Inspection Date: 5/3/2016; Reported on 6/21/2016	Inspector: DL
Comment: The inspection report with a violation for failure to perform leak tests was issued beyond 30 days due to the Program waiting on information from the licensee.	

File No.: 14	
Licensee: Coder X-Ray Service, Inc.	License No.: 21-B165-01
Inspection Type: Industrial Radiography – Routine	Priority: 1
Inspection Date: 5/9/2017; Reported on 5/19/2017	Inspector: AS
Comment: None	

File No.: 15	
Licensee: Coder X-Ray Service, Inc.	License No.: 21-B165-01
Inspection Type: Industrial Radiography –- Routine	Priority: 1
Inspection Date: 4/11/2018; Reported on 4/18/2018	Inspector: JU
Comment: None	

File No.: 16	
Licensee: Taylor Forge Engineering	License No.: 21-B108-01
Inspection Type: Industrial Radiography and Portable Gauge – Routine	Priority: 1
Inspection Date: 2/17/2015; Reported on: 2/18/2015	Inspector: JW
Comment: The inspection documentation noted one non-cited violation for the failure of conspicuous visible and audible warning signals to warn of the present of radiation. There was ambiguous language used in the Program's report to the licensee such as, "checked until bell sounded." This language could infer that the audible signal was operational and may be the visible signal was not working. The report stated that there was a similar problem with this system in 2014, but did not explain the similarities or why the problem persisted if the licensee had implemented effective corrective actions. Since this may have been a repetitive violation, there was no justification to issue a non-cited violation in lieu of a violation.	

File No.: 17	
Licensee: Taylor Forge Engineering	License No.: 21-B108-01
Inspection Type: Industrial Radiography and Portable Gauge – Routine	Priority: 1
Inspection Date: 2/28/2018; Reported on 3/2/2018	Inspector: AS
Comment: None	

File No.: 18	
Licensee: Saint Francis Health Center Medical Institution	License No.: 19-B272-04
Inspection Type: Radiopharmacy – Routine	Priority: 1
Inspection Date: 9/7/2017; Reported on 9/29/2017	Inspector: JU
Comment: None	

File No.: 19	
Licensee: VIA Christi Hospitals – Pittsburg	License No.: 18-C753-01
Inspection Type: Type A Medical Broad Scope and Self-Shielded Irradiator – Routine	Priority: 2
Inspection Date: 4/13/2017; Reported on 4/29/2017	Inspector: JU, AS, JH
Comment: The inspector cited two security violations (10 CFR 37.23 and 37.41), but the citations were vague and ambiguous. Described in Section 3.3 of this report.	

File No.: 20	
Licensee: VIA Christi Hospitals – Pittsburg	License No.: 18-C753-01
Inspection Type: Type A Medical Broad Scope and Self-Shielded Irradiator – Routine	Priority: 2
Inspection Date: 4/10/2018; Reported on: 4/26/2018	Inspector: JAH
Comment: None	

File No.: 21	
Licensee: Front Range Nuclear Services	License No.: 12-B860
Inspection Type: Medical Mobile Service – Diagnostics – Routine	Priority: 2
Inspection Date: 1/11/2017; Reported on 1/31/2017	Inspector: DL
Comment: None	

File No.: 22	
Licensee: Gemini Wireline, LLC	License No.: 27-B928
Inspection Type: Well Logging – Routine	Priority: 2
Inspection Date: 11/16/2017; Reported on 12/4/2017	Inspector: DL
Comment: None	

File No.: 23	
Licensee: Rural Health Resources	License No.: 12-B1024
Inspection Type: Medical Institution – Unsealed Diagnostic – Initial Inspection	Priority: 3
Inspection Date: 5/20/2018; Reported on 5/21/2018	Inspector: JAH
Comment: None	

File No.: 24	
Licensee: Heartland Oncology, LLC	License No.: 12-B1007
Inspection Type: Medical Institution – Diagnostic – Initial Inspection	Priority: 3
Inspection Date: 8/23/2016; Reported on 9/6/2016	Inspector: JAH
Comment: None	

File No.: 25	
Licensee: SOFIE Bioscience Inc.	License No.: 10-C0122
Inspection Type: Cyclotron – Initial Inspection	Priority: 1
Inspection Date: 2/15/2018; Reported on 2/18/2018	Inspector: JU
Comment: None	

APPENDIX D

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS

File No.: 1	License No.: 19-C041-01
Licensee: Wesley Medical Center	NMED Item No: 180223/KS180004
Incident Date: 5/4/18	Incident Type: Potential Medical Event
Investigation Date: 5/7/18	Investigation Type: Site
Comment: None	

File No.: 2	License No.: Unknown
Licensee: Unknown	NMED Item No: KS180003
Incident Date: 4/24/18	Incident Type: Abandoned RAM
Investigation Date: 4/24/18	Investigation Type: Site
Comment: None	

File No.: 3	License No.: 18-C800-01
Licensee: Kansas University Medical Center	NMED Item No: KS180001
Incident Date: 2/6/18	Incident Type: Lost RAM
Investigation Date: 2/6/18	Investigation Type: Site
Comment: None	

File No.: 4	License No.: 18-C801-01
Licensee: University of Kansas Hospital Authority	NMED Item No: 170410/KS170008
Incident Date: 8/24/17	Incident Type: Contamination
Investigation Date: 9/27/17	Investigation Type: Site
Comment: Personnel and room contamination during Y-90 treatment. Described in Section 3.5 of this report.	

File No.: 5	License No.: 18-C801-01
Licensee: University of Kansas Hospital Authority	NMED Item No: 17035/KS170006
Incident Date: 7/18/17	Incident Type: Medical Event
Investigation Date: None	Investigation Type: Phone/Email
Comment: Medical Event involving Y-90 microspheres. Described in Section 3.5 of this report.	

File No.: 6	License No.: NA
Licensee: Feralloy Corporation	NMED Item No: KS170005
Incident Date: 2/15/17	Incident Type: Unauthorized transfer
Investigation Date: 2/15/17	Investigation Type: Phone/Email
Comment: None	

File No.: 7	License No.: 22-B683-01
Licensee: Kirkham Michael & Associates	NMED Item No: 170185/KS170004
Incident Date: 4/3/17	Incident Type: Damaged Equipment
Investigation Date: 4/5/17	Investigation Type: Phone/Email/Site
Comment: None	

File No.: 8	License No.: 22-B580-01
Licensee: Bartlett & West Engineers	NMED Item No: 160332/KS160006
Incident Date: 8/1/16	Incident Type: Stolen Gauge
Investigation Date: 12/22/16	Investigation Type: Phone
Comment: None	

File No.: 9	License No.: GL 2016-052 (AL 1266)
Licensee: Building & Earth Sciences	NMED Item No: 160308/KS160005
Incident Date: 7/19/16	Incident Type: Damaged Equipment
Investigation Date: 7/19/16	Investigation Type: Phone
Comment: None	

File No.: 10	License No.: GL-878
Licensee: Pace Analytical Services, Inc.	NMED Item No: KS160004
Incident Date: 4/1/16	Incident Type: Damaged Equipment
Investigation Date: 5/9/16	Investigation Type: Phone
Comment: None	

File No.: 11	License No.: NA
Licensee: Advantage Metals Recycling (non-licensee)	NMED Item No: 160003
Incident Date: 4/29/16	Incident Type: Abandoned RAM
Investigation Date: 6/23/16	Investigation Type: Site
Comment: None	

File No.: 12	License No.: 38-C011-01
Licensee: Kansas State University	NMED Item No: KS160002
Incident Date: 1/19/16	Incident Type: Lost RAM
Investigation Date: NA	Investigation Type: Phone
Comment: None	

File No.: 13	License No.: 18-C753-01
Licensee: Via Christi Regional Medical Center Wichita	NMED Item No: Not Reported
Incident Date: 1/15/16	Incident Type: Contamination
Investigation Date: 1/28/16	Investigation Type: Phone
Comment: Unreported I-131 patient room contamination. On January 15, 2016, a medical licensee reported that a patient had contaminated a hospital room after being treated with 159.8 millicuries (mCi) of Iodine-131 on January 13, 2016. The room was isolated for approximately 60 hours over the weekend to allow for decay and to reduce exposure of individuals decontaminating the room. The room was decontaminated and released back into service on Monday morning, January 18, 2016. The Program did not perform an onsite investigation. The incident was closed on January 28, 2016, with no additional actions by the Program. The Program reported this incident to the NRC on July 2, 2018, after the IMPEP team identified that this was a reportable incident due to the room being isolated for more than 24 hours for radiation safety reasons. The Program has not entered this information into NMED.	

File No.: 14	License No.: 18-C801-01
Licensee: University of Kansas Hospital Authority	NMED Item No: 150545/KS150009
Incident Date: 9/29/15	Incident Type: Medical Event
Investigation Date: 9/30/15	Investigation Type: Phone/Email
Comment: Medical Event involving Y-90 microspheres. Described in Section 3.5 of this report.	

File No.: 15	License No.: 19-C182-01
Licensee: Prime Healthcare Services	NMED Item No: 150427/KS150006
Incident Date: 4/30/15	Incident Type: Overexposure
Investigation Date: 9/03/15	Investigation Type: Site
Comment: Declared Pregnant Woman Fetus Overexposure. Described in Section 3.5 of this report.	

File No.: 16	License No.: 22-B952-01
Licensee: Cornejo and Sons	NMED Item No: 150413/KS 150008
Incident Date: 7/16/15 at 0100	Incident Type: Damaged Equipment
Investigation Date: 7/16/15 afternoon	Investigation Type: Phone/Email
Comment: None.	

File No.: 17	License No.: 21-B805-01
Licensee: DBI, Inc.	NMED Item No: 160272/KS150004
Incident Date: 5/6/15	Incident Type: Overexposure
Investigation Date: None	Investigation Type: Phone/Email
Comment: Radiographer extremity overexposure. Described in Section 3.5.	

File No.: 18	License No.: GL-281
Licensee: Mid-America Trucking Equipment, Inc.	NMED Item No: 140617/KS140014
Incident Date: 9/2/14	Incident Type: Lost RAM
Investigation Date: 9/22/14	Investigation Type: Phone/Email
Comment: None.	

File No.: 19	License No.: GL-750
Licensee: Bonanza Bioenergy, LLC	NMED Item No: 140616/KS140013
Incident Date: 8/25/14	Incident Type: Lost RAM
Investigation Date: 9/17/14	Investigation Type: Phone/Email
Comment: None.	