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

September 11, 2018

MEMORANDUM TO: Daniel H. Dorman
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Office of the Executive Director for Operations

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SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF KANSAS

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of Kansas. The review was conducted by a team of U.S. Nuclear Regulatory Commission (NRC) and Agreement State technical staff during the period of June 25–29, 2018. The team's preliminary findings were discussed with Kansas on the last day of the review. Additionally, a follow-up call was held on July 25, 2018. The team issued a draft report to Kansas on August 1, 2018, for factual comment. Kansas responded to the draft report by email dated August 29, 2018, from Kimberly Steves, Director, Kansas Radiation Control Program Kansas Department of Health and Environment (Enclosure 2). The team created a Comment Resolution Document (Enclosure 3).

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Overall, the team is recommending that Kansas' performance be found satisfactory for two common performance indicators: Technical Staffing and Training and Status of Materials Inspection Program; satisfactory, but needs improvement, for two indicators: Technical Quality of Licensing Actions and Compatibility Requirements; and unsatisfactory for two indicators: Technical Quality of Inspections and Technical Quality of Incident and Allegation Activities. Accordingly, the team recommends 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 findings and the criteria in Management Directive 5.6, the team recommends that the Kansas Agreement State Program be placed on Heightened Oversight. The team recommends that the next IMPEP review take place in approximately 2 years (April/May 2020 timeframe) with a periodic meeting in approximately 1 year.

The MRB meeting to consider the Kansas report is scheduled for **Tuesday, September 18, 2018, from 1:00 p.m. to 4:00 p.m. ET**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 4).

Enclosures:
1. Kansas Proposed Final Report
2. Kansas Response to Draft IMPEP Report
3. Kansas Response to Draft IMPEP Report Comment Resolution Document
4. Agenda for MRB Meeting

cc: Kimberly Steves, Director
Radiation Control Program
Kansas Department of Health and Environment

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

SUBJECT: KANSAS FY2018 PROPOSED FINAL IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE KANSAS PROGRAM

JUNE 25–29, 2018

PROPOSED 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 two indicators: Technical Quality of Licensing Actions and Compatibility Requirements; and unsatisfactory for two indicators: Technical Quality of Inspections and Technical Quality of Incident and Allegation Activities. The team did not make any recommendations and determined 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 findings and the criteria in Management Directive 5.6, the team recommends 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 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 recommends 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. The team recommends that the next IMPEP review take place in approximately 2 years (April/May 2020 timeframe) 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. This updated response is available in in ADAMS using the Accession Number ML18186A683.

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 Kansas the 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 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 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 were not repeated. Additional information can be found in Section 3.4. The team determined that this recommendation should be 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 FTE supervisory/management; 4.2 FTE for technical; and 0.6 FTE for administrative. 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 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 to items of non-compliance; the documentation of reactive and followup 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 recommends that Kansas's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

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

3.2 Status of Materials Inspection Program

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

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated 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) 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 contributed to an insufficient number of reciprocity inspections; 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 these shortfalls is to inspect more candidates at the beginning of each year, which should increase the overall number of reciprocity inspections conducted annually. 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 recommends that Kansas's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

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

3.3 Technical Quality of Inspections

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

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated 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 to include placeholders for each area of concern and the ability of the inspector to enter observation information specific to that section. 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 adequately evaluate or address the inspector's determinations of the licensee's root cause, extent of condition review, evaluation of effectiveness of corrective actions, or ensure the clear communication of inspection findings on 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 contained no 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 with 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 provided no information to support the thoroughness of the reactive inspection, and no indication 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 correction 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 no documentation of the review of this event during the next routine inspection. There was no indication that the Program adequately reviewed the licensee's evaluation of the event or that the Program did an independent assessment to confirm the overexposure.

During a routine 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 they 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 the team's findings, the team determined that there was a supervisory and management over-reliance on the inspectors' ability to fully assess, evaluate, followup, and document violations and licensee's response to specific events. The team determined that supervisor and management personnel missed opportunities to provide inspector guidance for further evaluation 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 identified in this section of the report are also exemplified by 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 their 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 adequately identify or address the inspector's evaluation of the licensee's root cause analysis, extent of condition review, evaluation of effectiveness of corrective actions, or ensure the clear communication of inspection findings on 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 recommends that Kansas' performance with respect to the indicator, Technical Quality of Inspections, be found unsatisfactory.

d. MRB Decision

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

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the 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 believes 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 user to enter information about each authorized users' training and experience. If an authorized user is given a use 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, etc.).

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 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, it was identified that license reviewers were 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 reviewers would verify that the preceptor was adequately qualified for the modalities that the proposed user was seeking authorization, as long as the license listed for the preceptor was issued in Kansas. License reviewers assumed that they 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 get documentation to verify that all of the preceptors had the proper qualifications. 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 who was added with an incomplete preceptor, 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 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 the proper financial assurance documentation was on file, and that the information was appropriately secured for these four licensees. The team found an additional three licensees that were authorized for 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 believed already met the financial assurance requirements because they were government entities.

The team found that the Program added a license condition that allowed visiting authorized users to be able to work on 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 submitting it to the NRC for a compatibility review.

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

d. MRB Decision

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

3.5 Technical Quality of Incident and Allegation Activities

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

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated 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 followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 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 followup 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 review of the incident, 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 questionnaire.

The Program's procedure 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 questionnaire, the Program addressed the previous rating of satisfactory, but needs improvement, for this indicator and provided an explanation, a determination of root causes, and the corrective actions taken. The Program identified that the root causes were insufficient management oversight of the 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 five 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 response was by telephone and email. 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 except a telephone call and e-mail exchange. 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 the root cause to be a weak battery in the digital electronic radiation dosimeter. The licensee's procedure 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 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 they were notified by the licensee, and conducted an onsite investigation on September 27, 2017, as part of the routine inspection of this licensee. 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 followup 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 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 followup actions are not always taken to ensure prompt compliance by licensees.
- Followup 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.

The team's evaluation 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 recommends that Kansas' performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found unsatisfactory.

d. MRB Decision

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery 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. The NRC's review of these amendments 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 submit 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 by legally binding requirements. The Program noted that the legislative review process is outside of their 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 allows specific medical 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, will 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 recommends that Kansas' performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

d. MRB Decision

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

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 a 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. Kansas' performance was found to be satisfactory, but needs improvement, for the performance indicators: Technical Quality of Licensing Actions and

Compatibility Requirements. Kansas' performance was found to be unsatisfactory for the performance indicators: Technical Quality of Inspections and Technical Quality of Incident and Allegation Activities. The team did not make any recommendations, and determined that the recommendation from the 2014 IMPEP review should be closed.

Accordingly, the team recommends 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. 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 recommends placing the Kansas Agreement State Program on Heightened Oversight. Heightened Oversight is an increased monitoring process used by 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 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, based on the results of the current IMPEP review, the team recommends that the next full IMPEP review take place in approximately 2 years (April/May 2020 timeframe), 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.	

STATE OF KANSAS

DEPARTMENT OF HEALTH AND ENVIRONMENT
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GOVERNOR JEFF COLYER, M.D.
JEFF ANDERSEN, SECRETARY

August 29, 2018

Paul Michalak
Chief, Agreement State Programs Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission

Dear Mr. Michalak:

The following comments are provided by the Kansas Department of Health and Environment (KDHE)/Kansas Radiation Control Program in response to the draft IMPEP report for Kansas dated August 1, 2018:

1. For all the Kansas management, this was our first IMPEP. Accordingly, we want to extend our thanks and appreciation for the professionalism of the IMPEP team. The team members were all very patient and helpful in explaining the issues and areas of concern and guiding us through this process.

2. Section 3.1 "Technical Staffing and Training", under the discussion section it stated that the Program Director has been in the position since July 2015. It is important to note that the previous program director resigned effective July 24, 2015, but the new program director served as "acting" program director from that time until she was officially hired as the program director effective September 28, 2015. There was essentially a vacancy in the program director position for that time period, and as the new program director did not have a radioactive materials background, there was a growth period time after that date when heavy reliance on the supervisor of the radioactive materials unit occurred. This transition time especially has bearing on our responses to Section 3.3 and 3.5. In addition, the unit supervisor for the radioactive materials unit changed four times during the four-year review period, which also had impact.

3. Section 3.2 "Status of Materials Inspection Program", under the discussion section the fourth paragraph states the statistics of reciprocity inspections during the IMPEP period. We believe it is important to note that a good faith effort was made by inspection staff during 2015 and 2017 to reach the 20 percent inspections. Unfortunately, because of the way reciprocity assignments were assigned to staff, each inspector was independently accomplishing reciprocity inspections without realizing that some of their inspections would not count toward the 20%. Though the draft letter correctly identifies one of 22 in 2015 and three 17 in 2017, in actuality five reciprocity inspections occurred in 2015 and five in 2017. Additional training on the NRC requirements for reciprocities was provided to all inspectors. After reviewing the last 15 years of reciprocity candidates a goal of a minimum of five inspections has been identified which should meet the requirement of 20% inspections. We are pushing to accomplish the five reciprocity inspections accomplished during the first two quarters of the year, and we changed the process to making one individual in charge of all reciprocities for a given year, to ensure that there is someone tracking to reach

the 20% goal. This change has already demonstrated success in 2018 where we currently stand at 36.4 percent for the first half of the year.

4. Section 3.3 "Technical Quality of Inspections", under the discussion section the statement "When issues of non-compliance were identified, inspectors did not clearly communicate the specific regulations(s) that caused the licensee to be in non-compliance" we believe is an incorrect conclusion drawn by the IMPEP team. Kansas materials inspectors perform a very detailed close-out discussion with licensees at the end of any inspection and all findings are discussed in detail regarding the specific regulations involved. Citations and non-cited issues are adjusted and discussed with licensees prior to the letter being sent. The database used by Kansas to document inspections is limited to only referencing sections of the regulations. We are in the process of improving the clarity in our inspection letter, however, the licensee is always aware of the specific subsections when violations occurred. Because the database used to document inspections does not include Email or telephone communications, this leads to less documentation of these activities in the inspection report, but the clear and detailed communication did and does occur.

5. Section 3.3 "Technical Quality of Inspections" under the discussion section there were three examples listed "…where inspection findings were not well-founded or properly documented…these were (1) the Program performed a routine inspection of a medical licensee and cited the licensee for a failure to train, but the inspection report noted that there were no gaps in training; this language contradicts the violation (2) the inspection report addressed a Y-90 contamination event that occurred the previous month, but the inspection report did not confirm whether the licensee's corrective actions were effective or its root cause was correct; and (3) the Program did not address a medical event in which the 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…" Regarding item (1), we believe this statement is caused by a misunderstanding by the IMPEP team for how the Kansas database documents inspection reports. The citation was listed under the "Training and Practices" section of the inspection report in the database which addresses specific training such as in the use and handling of Y-90, but there is also a "General Training" section which addresses general radiation safety training. The report noting no gaps in training was referring to the "General Training" but the citation was correctly noted under the "Training and Practices". Regarding item (2), we want to clarify that our inspector did confirm that the licensee's corrective actions were effective, and its root cause was correct. Unfortunately, this was not well- documented in the report. Regarding item (3), we do not believe stating that the program did not "address" a medical event in which the patient received approximately 24 percent of the prescribed dose of Y-90 microspheres is accurate. The incident was addressed and investigated, though we did not perform an onsite reactive inspection.

6. Section 3.3"Technical Quality of Inspections", references Appendix C for the list of inspection casework reviewed by the IMPEP team. Please refer to Attachment A of this letter where we have provided comments and corrections to information provided in your Appendix C. Please note that in some cases we do not agree with the conclusions drawn by the IMPEP team, and that some of those incorrect conclusions appear to be from a misunderstanding for how our database works to track inspections and issues.

7. Section 3.3 "Technical Quality of Inspections", on page 8 under the description of the accompanied inspections, the statement "During the accompaniments, no items of licensee non-compliance were found by the Program inspections…" is incorrect. During the inspection of Kansas State University, which was accompanied by an IMPEP team member, it was identified that the doses received from the pharmacy were being labeled with a previous Authorized User who was no longer employed. This error was not cited to the university but was addressed with the shipper of the material who was not verifying the label was correct before they shipped the doses. This example highlights that the issue was detected, a root cause was determined, and was addressed with both the licensee shipping and the licensee receiving the material. The conclusion at the end of this paragraph that "… the team questions whether Program inspectors would have identified specific conditions of poor performance and critiqued the licensee's root cause evaluations and corrective actions…"is answered in the positive by this example of the inspector identifying and addressing issues thoroughly and correctly. We believe that a statement such as provided in this letter is a subjective opinion and is inconsistent with the concept of a performance-based process, and that it

should be removed. If there were concerns that our inspectors could not identify specific conditions of poor performance and critique the root cause and corrective actions, then additional accompaniments should have been performed rather than drawing such a conclusion. In addition, the conclusion that "…inspections often did not adequately address previously identified open violations…" is incorrect. The Kansas database uses a drop-down system to track violations, as well as open and closed items. The text portion provides the details from the observations. Using the drop-down system makes it easier to sort and run queries on open and closed items. The database will leave an issue open and labeled as "RVW" for "Review" until an inspector reviews it at the next inspection and then the drop-down menu will be used to "close" the item by changing the label to "SA" for "satisfactory. The actual words "closed" are not typically used in the narrative because it is intuitive from the database for our inspectors. Our database handles these differently than for what the IMPEP team looking, but they are handled and kept open until the next inspection identifies that area as "satisfactory".

8. The final recommendation of the team for Section 3.3 "Technical Quality of Inspections", is unsatisfactory. On Page 8 the statement "The team determined that the root causes of the performance issues identified in this section of the report led to the Program's inappropriate and inadequate handling of reactive inspections as described in Section 3.5 of this report." Section 3.5 deals with Technical Quality of Incident and Allegation Activities. By referencing the root cause as being a different Performance Indicator, we believe this is a case of "double-dinging" whereby the same issue is used to justify two unsatisfactory findings. With the data we are providing with this letter, we believe that a finding of Unsatisfactory for Technical Quality of Inspections is not justified.

9. Section 3.4 "Technical Quality of Licensing Actions", on page 10 and again on page 12, the vague statement "…The team identified repeated examples of deficiencies with respect to thoroughness, completeness, consistence, clarify, technical quality, and adherence to existing licensing guidance and procedures..." is a very vague and unprecise statement. Please be more specific. What are the repeated examples? We would like to address the examples provided in this paragraph on page 10-11 as follows:

   - Regarding the example of missing financial assurance by three state university entities. All staff in the program had previously been told that financial assurance was not required because these were state universities, and state agencies will provide the necessary funds for decommissioning costs through the self- insurance requirements for all state agencies. These licenses had been previously reviewed during other IMPEP audits with this issue never previously identified. Examples of the fact that the state self-insurance was sufficient financial assurance had been demonstrated by previous decommissioning activities which have occurred at all three of the Kansas university entities in question. We stand by the statement that there was never any risk in place that one of the universities possessing the radioactive material in quantities requiring the financial assurance statement, were ever at risk of not possessing the funding required. However, all state agency licensees requiring financial assurance have now signed the financial assurance statement of intent.
   - There was a license condition added to a few Kansas licenses allowing visiting authorized users to work under a license for up to 60 days as long as they were already listed on another agreement state or NRC license. This license condition was added by our predecessors in Kansas Radiation Control management and we do not have any data on from where it came. However, we have removed it from the 16 licenses on which it was contained. We contacted each specific licensee to request information on if that condition had ever been exercised and learned that it was never used, which means there was no impact on health and safety or risk to radioactive materials security from that license condition, and it is no longer contained on any Kansas licenses.
   - There is a comment on Page 11 that "…License reviewers assumed that they 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…" This only happened one time by one inspector. There was not a misunderstanding of the process by all our license reviewers, there was an error and oversight one time by one inspector. The process and training is in place with our inspectors to verify preceptors regardless of whether they are in Kansas, another Agreement State, or the NRC. The wording used in this draft report makes it appears that this is a wide spread issue with our program when it is actually just one error one time. One page 12 where it states that "…the Program had a

misunderstanding on obtaining preceptor verification from other Agreement States and the NRC for 10 CFR 35.300 users…" please reword this to state that one inspector made an error one time and failed to verify a preceptor for a 10 CFR 35.300 user.

10. Section 3.5 "Technical Quality of Incident and Allegation Activities", the finding included an ongoing lack of management oversight of the investigation. We do not contest this finding though we strongly believe that the Kansas program is not as weak in this area as the draft IMPEP report indicates. We would like to provide additional insight into the five risk significant incidents which occurred at three Kansas licensees' facilities during the review period, with a final message being that these five were someone unique cases and do not show the capabilities and knowledge and skills of our program staff to their full extent:
    - May 6, 2015 radiography incident: The report of this incident was received on May 6, 2015 by a program director who has not been employed by KDHE since July 24, 2015. This individual received the report off hours and made the notification to the NRC and filled out the NMED report. As far as we can tell, this individual did not involve any other program staff in the response. After that program director was no longer employed, the unit supervisor for radioactive materials (who also is no longer employed by KDHE) finalized an inspection report for the incident, signing both his name and the previous program directors' as the inspectors. The new radiation program director was named September 28, 2015, and this investigation slipped through the cracks of the transition. This is not the norm for this Program, but an example of lack of transferring of information when changes in management occur. It was handled inadequately by Kansas and we do not dispute this.
    - April 30, 2015 fetal overexposure event. This report was received by the Kansas Program on June 29, 2015, which is just prior to the departure of the previous program director who left on July 24, 2015. We do not know why this incident was not investigated via an onsite inspection until September 3, 2015, as this time period was during the transfer of program management and neither the program director from the time of incident report receipt nor the radioactive materials unit supervisor are currently employed by the Kansas program. An onsite inspection of this incident was performed. Notes from one of the two inspectors who performed the onsite inspection were obtained, and they document a questioning attitude pulling the threads to a root cause including a reenactment, and a review of the dosimeter reports. We did not have access to those notes during the IMPEP audit, but do believe that they show a thorough investigation, if not a timely response.
    - September 30, 2015 under dose of Y-90 microspheres. This root cause was a mechanical failure of the dosimeter. Our program did not perform an onsite investigation, and we believe this is partly due to the transition of program management occurring with the new program director becoming effective on September 28, 2015, and partly due to the known entity of the RSO for this licensee, who was the previously program director for the Kansas program. We believe that the root case was acceptable, and that the previous program director for Kansas now serving as the RSO for the licensee, was qualified and correct in that conclusion. However, we do concur that an onsite investigation should have occurred.
    - July 19, 2017 under dose of Y-90 microspheres. This incident took place at the same licensee as the previous Y-90 incident described above, with the previous Kansas program director as RSO. It was not, however, a "similar" incident as described in the draft letter, and we request that wording be revised. The first incident was due to mechanical failure of the dosimeter, and the second incident was due to patient anatomy causing the physician to infuse the microspheres at a slower rate allowing them to accumulate in the catheter. The only similarity is the fact that they were both underexposures. In addition, we request clarification or re-wording of the statement "The corrective actions noted by the licensee were not commensurate with the root cause which indicates that the root cause was not correct". The conclusion was that the incident was caused by an emergent patient condition due to patient anatomy, and the corrective actions implemented included a review of the case by all interventional radiologists to train them on this type of unique situation, and the additional step of confirmation of the electronic dosimeter readings to confirm delivery of the TheraSpheres. The corrective actions implemented also include if the full dose is not delivered, then the physician flushes the catheter enough times to deliver the entire dose. These corrective actions were appropriate for this situation and commensurate with addressing cases where patient anatomy affects the delivery of the medication. We did not perform an onsite investigation and that was an error on our part which will not be made again for this

licensee or any other licensee, but we do believe this incident was handed satisfactorily by the licensee and is not "similar" to the previous incident described above except that they both resulted in under-exposures.

- August 25, 2017 contamination event involving Y-90 microspheres. This incident took place at the same licensee as the previous two Y-90 incidents described above. The information contained in this section is incorrect. This incident was reported to the Kansas Program on August 25, 2017 (a Friday), and the Kansas program performed an onsite investigation of the incident on Monday, August 28, 2017. The corrective actions for this event involve training and the licensee was cited by Kansas for inadequate training.
- Regarding the one allegation discussed on page 15 of the report, we wish to emphasize that the program has contacted concerned individual and reported the results of the investigation into his allegation. This delayed notification of the concerned individual was not a failure to act by the Kansas program, but was partly a misunderstanding of the acronym "CI" used by the NRC. In our world, "CI" means "Confidential Informant", and we were using that meaning and assuming that the individual wished to remain confidential. In addition, item 16 of the report sent to us by the NRC regarding this incident stated "…recommend that Region IV provide a response to the CI and reach out to the state of Kansas to determine…", and this statement caused some confusion on the part of our inspector that it was the NRC who would be communicating with the CI. We believe that the root cause of this lack of final contact to the concerned individual by the Kansas Program is the use by NRC of an acronym which with a meaning which is not standard or typical and a misunderstanding of the wording used in the NRC report which was provided to us. It is our normal process to report back any findings of allegations to the individual making the allegation.

As a conclusion to this discussion, we feel it is important to emphasize that this report only discusses five investigations out of 32 total reported incidents from the time period (19 of which were reviewed by the NRC). These five specific incidents targeted by the NRC IMPEP team are unique in that they occurred during a time of management transition and/or were specifically by a licensee who has as their RSO the previous Kansas program director. We do not believe these five investigations reflect the true response activities or competency of our staff during the past four years or ongoing. We are not as weak in this area as these specific examples make us appear. We have attached to this letter as Attachment B, the incident casework reviews performed by the IMPEP team with additional comments and clarifications for a few of the files.

11. Summary. We do not agree with the item (2) in the summary that there is "poorly communicated inspection findings to licensees". Out inspectors have very detailed in person close-out discussions with our licensees following each inspection, and frequently communicate via telephone and Email to discuss inspection findings and corrective actions. Our database currently does not have allowance for much of the documentation of these communications to be included, but they do occur. We also do not agree with item (3) in the summary, that there is a "pattern of untimely and insufficient responses to events". As discussed above, we believe that the *pattern* is adequate response, though there were a small percentage of incidents which occurred during a unique time of transition which did not receive an adequate onsite response. The pattern we continue to demonstrate in Kansas is adequate onsite responses to incidents and allegations. We acknowledge that there was an "inadequate management oversight of inspection and event reports" during the transition time of program director and radioactive materials unit supervisor transitioning, but that did not occur throughout the whole four- year IMPEP period and is no longer currently an issue in our program. We believe our primary weakness with regards to the success of the IMPEP audit is the lack of documentation of activities which took place. Documentation appears to be an over-arching issue with much of the items identified by the IMPEP Team. I can state with confidence that the Kansas program is better than how it is portrayed in this draft letter, and many of the critical activities which are

assumed to not have occurred, actually were done correctly but were not documented.We look forward to presenting additional information on corrective actions which have been implemented in our program to address the IMPEP Findings during the Management Review Board meeting on September 18, 2018.

Thank you for consideration of our comments.

Sincerely,

Kimberly Steves, Director
Kansas Radiation Control Program
Kansas Department of Health and Environment

Attachment A – Kansas Comments on Inspection Casework reviewed by the IMPEP team
Attachment B – Kansas comments on Incident Casework reviewed by the IMPEP team

ATTACHMENT A - Kansas Comments on Inspection Casework reviewed by the IMPEP team

Kansas comments on the files are listed immediately following the casework information.

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 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.	

Kansas comments: The Program did follow-up with Landauer to verify the 535 mrem overexposure and we have copies of the communications with Landauer on this topic.

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. The Program did not decrease the inspection frequency in order to perform a review of the licensee's policy changes.	

Kansas comments: This licensee is on a two-year inspection frequency and for an issue such as implementation of additional policy requirements for declared pregnant workers we believe it required two years. The three months of the timing of the next routine inspection was too soon to fully evaluate the implementation. In the database this issue remained clearly identified as "open" for review until following the next two-year inspection.

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.	

Kansas comments: Our documentation in the Kansas database does clearly address this previous violation and any previous violations. They are marked as "RVW" which means open for review, and are not changed to "SA" which means satisfactory, until an inspector has specifically inspected that specific item. This inspection did look at the previous violation specifically and was changed to "SA" in the database.

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.	

Kansas comments: We use "non-cited violation" and "minor violation" wording interchangeably. The pin sensor discussed in this case is an extra layer of security above the minimum requirements We are very familiar with this licensee and all our inspectors have inspected them before. Our inspectors did understand clearly what was encountered due to their familiarity with this licensee, and the licensee understood clearly what was meant by the citation.

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. The previous minor violation for 10 CFR 37.49 was not reviewed and not closed.	

Kansas comments: The comment is incorrect. This issue was reviewed and closed as shown in our database.

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 Program cited the licensee for a failure to train, but the inspection report noted that there were no gaps in training. This language contradicts the violation. 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 conducted on September 27, 2017, 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. A reactive inspection for the medical event was not performed. Described in Sections 3.3 and 3.5 of this report.

The inspection conducted on September 27, 2017 did not address a similar medical event where a patient was administered 64 percent of the prescribed dose of Y-90 microspheres in September 2015. Since this licensee had a similar medical event in 2015, the Program could have reviewed the licensee's root cause and corrective actions from the 2015 event to determine if the root cause and corrective actions were valid and effective. There was no indication in the documentation that the Program had ever properly evaluated the licensee's root cause for the 2015 medical event. Described in Section 3.3 of this report.

Kansas comments: As previously described in item #5 of this letter, the citation for failure to train was listed under the "Training and Practices" section of the inspection report in the database which addresses specific training such as in the use and handling of Y-90, but there is also a "General Training" section which addresses general radiation safety training. The report noting no gaps in training was referring to the "General Training" but the citation was correctly noted under the "Training and Practices".

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 Program did not address and did not close the previous seven violations. The Program issued three new violations during this inspection. 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. However, both of these violations were vague and ambiguous.	

Kansas comments: The comment for this file is incorrect. Five of the seven previous violations were closed out and documented in our database. Our database maintains open issues by labeling them as "RVW" for review, and when then are closed out by the inspector that label is changed to "SA" for satisfactory. The violations as documented in the database may be vague or brief due to limitations of the database, but they are thoroughly discussed in detail by the inspector during the exit meeting with the licensee, and via any additional communications which occur between the inspector and the licensee as corrective actions are developed.

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 seven violations from the 2016 inspection remain open. The focus of this inspection was a review of an incident where the incorrect radioactive material was administered to a patient.	

Kansas comments: Those 2016 violations were all closed in the database during the 2017 inspection. Our database maintains open issues by labeling them as "RVW" for review, and when then are closed out by the inspector that label is changed to "SA" for satisfactory.

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.	

Kansas comments: We do have clear communication with the licensee in person at the conclusion of an inspection when the inspector clearly describes any findings. However, we concur that our database options for the Part 37 issue do need to be improved to add additional detail and explanation.

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: The previous 2016 violation for failure to perform leak tests was not mentioned in this inspection report and was not closed.	

Kansas comments: In our database that violation was changed to satisfactory to close the issue, and the dates when leak tests were performed was included to confirm review of that issue. Our database maintains open issues by labeling them as "RVW" for review, and when then are closed out by the inspector that label is changed to "SA" for satisfactory.

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	

ATTACHMENT B - Kansas comments on Incident Casework reviewed by the IMPEP team

Kansas comments on the files are listed immediately following the casework information.

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: Phone/Email
Comment: None	

Kansas comments: Investigation Type is "Site". An onsite investigation of this incident occurred on 5/8/18 and the routine inspection was moved up and conducted on 5/15/18.

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: Phone/Email
Comment: None	

Kansas comments: Investigation Type is "Site". An onsite investigation of this incident occurred on 2/7/18.

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	

Kansas comments: The lack of an onsite investigation was a deliberate decision by the program director in this case because of the extreme distance from the Kansas office. This event occurred in southwestern Kansas which is about an eight-hour drive from the Kansas office in Topeka. This event involved a grass fire burning the truck and the gauge. The licensee came up from Oklahoma quickly to perform the surveys and pack up the remains of the equipment for transporting. The licensee employees would have had to wait in the very high heat in the field where the fire occurred for many hours to give the Kansas inspector time to arrive. Surveys to ensure the sources were intact and shielded were conducted by the licensee and communicated to the Kansas program.

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 Worker Fetus Overexposure. Described in Section 3.5 of this report.	

Kansas Response to Draft IMPEP Report
Comment Resolution Document

Kansas' response to the draft IMPEP report dated August 29, 2018, from Kimberly Steves, Director of the Kansas Radiation Control Program, Kansas Department of Health and Environment for the State of Kansas is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML18248A091. Below are the comments from Kansas and the responses from the IMPEP team.

1. For all the Kansas management, this was our first IMPEP. Accordingly, we want to extend our thanks and appreciation for the professionalism of the IMPEP team. The team members were all very patient and helpful in explaining the issues and areas of concern and guiding us through this process.

   RESPONSE: Thank you. No additional response needed.

2. Section 3.1 "Technical Staffing and Training", under the discussion section it stated that the Program Director has been in the position since July 2015. It is important to note that the previous program director resigned effective July 24, 2015, but the new program director served as "acting" program director from that time until she was officially hired as the program director effective September 28, 2015. There was essentially a vacancy in the program director position for that time period, and as the new program director did not have a radioactive materials background, there was a growth period time after that date when heavy reliance on the supervisor of the radioactive materials unit occurred. This transition time especially has bearing on our responses to Section 3.3 and 3.5. In addition, the unit supervisor for the radioactive materials unit changed four times during the four-year review period, which also had impact.

   RESPONSE: Agree. The team has revised the language in Section 3.3, Discussion, to indicate the management changes over the review period.

3. Section 3.2 "Status of Materials Inspection Program", under the discussion section the fourth paragraph states the statistics of reciprocity inspections during the IMPEP period. We believe it is important to note that a good faith effort was made by inspection staff during 2015 and 2017 to reach the 20 percent inspections. Unfortunately, because of the way reciprocity assignments were assigned to staff, each inspector was independently accomplishing reciprocity inspections without realizing that some of their inspections would not count toward the 20%. Though the draft letter correctly identifies one of 22 in 2015 and three 17 in 2017, in actuality five reciprocity inspections occurred in 2015 and five in 2017.

   Additional training on the NRC requirements for reciprocities was provided to all inspectors. After reviewing the last 15 years of reciprocity candidates a goal of a minimum of five inspections has been identified which should meet the requirement of 20% inspections. We are pushing to accomplish the five reciprocity inspections accomplished during the first two quarters of the year, and we changed the process to making one individual in charge of all reciprocities for a given year, to ensure that there is someone tracking to reach the 20% goal. This change has already demonstrated success in 2018 where we currently stand at 36.4 percent for the first half of the year.

RESPONSE: The information provided is consistent with the IMPEP report. No change is needed. The Program can discuss their good faith effort with the Management Review Board (MRB) at the September 18, 2018, meeting.

4. Section 3.3 “Technical Quality of Inspections”, under the discussion section the statement “When issues of non-compliance were identified, inspectors did not clearly communicate the specific regulations(s) that caused the licensee to be in non-compliance” we believe is an incorrect conclusion drawn by the IMPEP team. Kansas materials inspectors perform a very detailed close-out discussion with licensees at the end of any inspection and all findings are discussed in detail regarding the specific regulations involved. Citations and non-cited issues are adjusted and discussed with licensees prior to the letter being sent. The database used by Kansas to document inspections is limited to only referencing sections of the regulations. We are in the process of improving the clarity in our inspection letter, however, the licensee is always aware of the specific subsections when violations occurred. Because the database used to document inspections does not include Email or telephone communications, this leads to less documentation of these activities in the inspection report, but the clear and detailed communication did and does occur.

   RESPONSE: Communication can be either verbal or written. Based upon casework reviewed by the team, the written communication contained in the database and other inspection documentation did not clearly document the specific regulation that caused the licensee to be in non-compliance. Additionally, the Program, noted that the database did not provide enough details. The team revised Section 3.3 of the report to emphasize that the team’s conclusion was based on both the casework reviewed as well as from interviews with inspectors.

5. Section 3.3 “Technical Quality of Inspections” under the discussion section there were three examples listed “…where inspection findings were not well-founded or properly documented…these were (1) the Program performed a routine inspection of a medical licensee and cited the licensee for a failure to train, but the inspection report noted that there were no gaps in training; this language contradicts the violation (2) the inspection report addressed a Y-90 contamination event that occurred the previous month, but the inspection report did not confirm whether the licensee’s corrective actions were effective or its root cause was correct; and (3) the Program did not address a medical event in which the 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…” Regarding item (1), we believe this statement is caused by a misunderstanding by the IMPEP team for how the Kansas database documents inspection reports. The citation was listed under the “Training and Practices” section of the inspection report in the database which addresses specific training such as in the use and handling of Y-90, but there is also a “General Training” section which addresses general radiation safety training. The report noting no gaps in training was referring to the “General Training” but the citation was correctly noted under the “Training and Practices”. Regarding item (2), we want to clarify that our inspector did confirm that the licensee’s corrective actions were effective, and its root cause was correct. Unfortunately, this was not well- documented in the report. Regarding item (3), we do not believe stating that the program did not “address” a medical event in which the patient received approximately 24 percent of the prescribed dose of Y-90 microspheres is accurate. The incident was addressed and investigated, though we did not perform an onsite reactive inspection.

RESPONSE: In regards to (1) above, the IMPEP team understands that the database has two entries for training. However, the inspection documentation did not identify that the non-compliance dealt with the specialized training and not the general training. The documentation stated "the licensee failed to provide radiation safety training to personnel commensurate with the individual's duties as required." This is an example of the issues identified with the inspection documentation and clarity of inspection findings.

In regards to (2) above, the team identified that documentation was lacking for the Y-90 contamination event. The team was not provided documentation at the time of the onsite review to indicate that the medical event, such as an evaluation of the licensee's root cause and corrective actions, was adequately reviewed by the Program.

In regards to (3) above, the IMPEP team was not provided documentation showing the closure of the Y-90 under dose medical event.

6. Section 3.3 "Technical Quality of Inspections", references Appendix C for the list of inspection casework reviewed by the IMPEP team. Please refer to Attachment A of this letter where we have provided comments and corrections to information provided in your Appendix C. Please note that in some cases we do not agree with the conclusions drawn by the IMPEP team, and that some of those incorrect conclusions appear to be from a misunderstanding for how our database works to track inspections and issues.

   RESPONSE: See resolution of Appendix comments below.

7. Section 3.3 "Technical Quality of Inspections", on page 8 under the description of the accompanied inspections, the statement "During the accompaniments, no items of licensee non-compliance were found by the Program inspections…" is incorrect. During the inspection of Kansas State University, which was accompanied by an IMPEP team member, it was identified that the doses received from the pharmacy were being labeled with a previous Authorized User who was no longer employed. This error was not cited to the university but was addressed with the shipper of the material who was not verifying the label was correct before they shipped the doses. This example highlights that the issue was detected, a root cause was determined, and was addressed with both the licensee shipping and the licensee receiving the material. The conclusion at the end of this paragraph that "… the team questions whether Program inspectors would have identified specific conditions of poor performance and critiqued the licensee's root cause evaluations and corrective actions…"is answered in the positive by this example of the inspector identifying and addressing issues thoroughly and correctly. We believe that a statement such as provided in this letter is a subjective opinion and is inconsistent with the concept of a performance-based process, and that it should be removed. If there were concerns that our inspectors could not identify specific conditions of poor performance and critique the root cause and corrective actions, then additional accompaniments should have been performed rather than drawing such a conclusion. In addition, the conclusion that "…inspections often did not adequately address previously identified open violations…" is incorrect. The Kansas database uses a drop-down system to track violations, as well as open and closed items. The text portion provides the details from the observations. Using the drop-down system makes it easier to sort and run queries on open and closed items. The database will leave an issue open and labeled as "RVW" for "Review" until an inspector reviews it at the next inspection and then the drop-down menu will be used to "close" the item by changing the label to "SA" for "satisfactory. The actual words "closed" are not

typically used in the narrative because it is intuitive from the database for our inspectors. Our database handles these differently than for what the IMPEP team looking, but they are handled and kept open until the next inspection identifies that area as “satisfactory”.

RESPONSE: As noted above, the inspection at Kansas State University was a clear inspection, like the other inspection accompaniments. The issue with the shipper was not part of the inspection accompaniment. The IMPEP team did not observe inspectors convey violations to the licensee. However, we do agree that the sentence in the report is subjective and we have removed the sentence: “However, given the issues the team identified during the review of inspection files, the team questions whether Program inspectors would have identified specific conditions of poor performance, and critiques the licensee’s root cause evaluations and corrective actions.”

Regarding adequately addressing previously identified open violations, the team was not told to note the label in the database. Changing a label from “RVW” to “SA” does not address what actions the licensee took to achieve compliance. The team based its findings on the information that was provided during the on-site review. No change was made to the report regarding adequately addressing previously identified open violations.

8. The final recommendation of the team for Section 3.3 “Technical Quality of Inspections”, is unsatisfactory. On Page 8 the statement “The team determined that the root causes of the performance issues identified in this section of the report led to the Program’s inappropriate and inadequate handling of reactive inspections as described in Section 3.5 of this report.” Section 3.5 deals with Technical Quality of Incident and Allegation Activities. By referencing the root cause as being a different Performance Indicator, we believe this is a case of “double-dinging” whereby the same issue is used to justify two unsatisfactory findings. With the data we are providing with this letter, we believe that a finding of Unsatisfactory for Technical Quality of Inspections is not justified.

   RESPONSE: The same licensee inspections were reviewed in two indicators: Technical Quality of Inspections (TQI) and Technical Quality of Incident and Allegations Activities (TQIAA). However, the focus of the review for each indicator was different. The team member that reviewed the TQI indicator focused on well-founded documented inspection findings, identification of root causes and poor licensee performance, proper address of previous open items and violations, appropriate and prompt regulatory action, and consistent application of inspection guidance. The team member that reviewed the TQIAA indicator focused on timely reporting, followup and adherence with your procedure. Because of this difference in foci, the team does not see this as “double-dinging.” No change was made to the report.

9. Section 3.4 “Technical Quality of Licensing Actions”, on page 10 and again on page 12, the vague statement “…The team identified repeated examples of deficiencies with respect to thoroughness, completeness, consistence, clarify, technical quality, and adherence to existing licensing guidance and procedures...” is a very vague and unprecise statement. Please be more specific. What are the repeated examples? We would like to address the examples provided in this paragraph on page 10-11 as follows:

   - Regarding the example of missing financial assurance by three state university entities. All staff in the program had previously been told that financial assurance was not required because these were state universities, and state agencies will provide the necessary funds for decommissioning costs through the self- insurance requirements for

all state agencies. These licenses had been previously reviewed during other IMPEP audits with this issue never previously identified. Examples of the fact that the state self-insurance was sufficient financial assurance had been demonstrated by previous decommissioning activities which have occurred at all three of the Kansas university entities in question. We stand by the statement that there was never any risk in place that one of the universities possessing the radioactive material in quantities requiring the financial assurance statement, were ever at risk of not possessing the funding required. However, all state agency licensees requiring financial assurance have now signed the financial assurance statement of intent.

- There was a license condition added to a few Kansas licenses allowing visiting authorized users to work under a license for up to 60 days as long as they were already listed on another agreement state or NRC license. This license condition was added by our predecessors in Kansas Radiation Control management and we do not have any data on
on from where it came. However, we have removed it from the 16 licenses on which it was contained. We contacted each specific licensee to request information on if that condition had ever been exercised and learned that it was never used, which means there was no impact on health and safety or risk to radioactive materials security from that license condition, and it is no longer contained on any Kansas licenses.

- There is a comment on Page 11 that "…License reviewers assumed that they 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…" This only happened one time by one inspector. There was not a misunderstanding of the process by all our license reviewers, there was an error and oversight one time by one inspector. The process and training is in place with our inspectors to verify preceptors regardless of whether they are in Kansas, another Agreement State, or the NRC. The wording used in this draft report makes it appears that this is a wide spread issue with our program when it is actually just one error one time. One page 12 where it states that "…the Program had a misunderstanding on obtaining preceptor verification from other Agreement States and the NRC for 10 CFR 35.300 users…" please reword this to state that one inspector made an error one time and failed to verify a preceptor for a 10 CFR 35.300 user.

RESPONSE: The team found repeated examples of improper licensing. The team identified three State licensees that had no financial assurance, and license reviewers indicated that they were not aware of the need for financial assurance. Additionally, the team identified 16 licenses that featured a license condition that was not submitted to the NRC for a compatibility review. The team did not find documentation supporting an individual's training and experience to be named as the Radiation Safety Officer. Also the team found a license renewal that had not been signed by the Program manager.

With regard to the out-of-State preceptor verification, the team received this information from interviews with license reviewers. The report was revised to indicate that the information was based on interviews with license reviewers.

10. Section 3.5 "Technical Quality of Incident and Allegation Activities", the finding included an ongoing lack of management oversight of the investigation. We do not contest this finding though we strongly believe that the Kansas program is not as weak in this area as the draft

IMPEP report indicates. We would like to provide additional insight into the five risk significant incidents which occurred at three Kansas licensees' facilities during the review period, with a final message being that these five were someone unique cases and do not show the capabilities and knowledge and skills of our program staff to their full extent:

- May 6, 2015 radiography incident: The report of this incident was received on May 6, 2015 by a program director who has not been employed by KDHE since July 24, 2015. This individual received the report off hours and made the notification to the NRC and filled out the NMED report. As far as we can tell, this individual did not involve any other program staff in the response. After that program director was no longer employed, the unit supervisor for radioactive materials (who also is no longer employed by KDHE) finalized an inspection report for the incident, signing both his name and the previous program directors' as the inspectors. The new radiation program director was named September 28, 2015, and this investigation slipped through the cracks of the transition. This is not the norm for this Program, but an example of lack of transferring of information when changes in management occur. It was handled inadequately by Kansas and we do not dispute this.

  RESPONSE: Agree. No change needed to the report. The Program can provide additional information at the MRB.

- April 30, 2015 fetal overexposure event. This report was received by the Kansas Program on June 29, 2015, which is just prior to the departure of the previous program director who left on July 24, 2015. We do not know why this incident was not investigated via an onsite inspection until September 3, 2015, as this time period was during the transfer of program management and neither the program director from the time of incident report receipt nor the radioactive materials unit supervisor are currently employed by the Kansas program. An onsite inspection of this incident was performed. Notes from one of the two inspectors who performed the onsite inspection were obtained, and they document a questioning attitude pulling the threads to a root cause including a reenactment, and a review of the dosimeter reports. We did not have access to those notes during the IMPEP audit, but do believe that they show a thorough investigation, if not a timely response.

  RESPONSE: Thank you for the clarification. The notes from the inspector were not in the inspection file which was provided to the team. The inspector was not interviewed because he was no longer with the Kansas Program. The report is a reflection of the information provided to the team during the onsite review for the review period ending on June 29, 2018.

- September 30, 2015 under dose of Y-90 microspheres. This root cause was a mechanical failure of the dosimeter. Our program did not perform an onsite investigation, and we believe this is partly due to the transition of program management occurring with the new program director becoming effective on September 28, 2015, and partly due to the known entity of the RSO for this licensee, who was the previously program director for the Kansas program. We believe that the root case was acceptable, and that the previous program director for Kansas now serving as the RSO for the licensee, was qualified and correct in that conclusion. However, we do concur that an onsite investigation should have occurred.

  RESPONSE: By not performing an onsite investigation, it is difficult to accept the root

cause. The IMPEP team agrees with the Program that an onsite investigation should have occurred and that the management turnover was a contributing factor.

 July 19, 2017 under dose of Y-90 microspheres. This incident took place at the same licensee as the previous Y-90 incident described above, with the previous Kansas program director as RSO. It was not, however, a "similar" incident as described in the draft letter, and we request that wording be revised. The first incident was due to mechanical failure of the dosimeter, and the second incident was due to patient anatomy causing the physician to infuse the microspheresat a slower rate allowing them to accumulate in the catheter. The only similarity is the fact that they were both underexposures. In addition, we request clarification or re-wording of the statement "The corrective actions noted by the licensee were not commensurate with the root cause which indicates that the root cause was not correct". The conclusion was that the incident was caused by an emergent patient condition due to patient anatomy, and the corrective actions implemented included a review of the case by all interventional radiologists to train them on this type of unique situation, and the additional step of confirmation of the electronic dosimeter readings to confirm delivery of the TheraSpheres. The corrective actions implemented also include if the full dose is not delivered, then the physician flushes the catheter enough times to deliver the entire dose. These corrective actions were appropriate for this situation and commensurate with addressing cases where patient anatomy affects the delivery of the medication. We did not perform an onsite investigation and that was an error on our part which will not be made again for this licensee or any other licensee, but we do believe this incident was handed satisfactorily by the licensee and is not "similar" to the previous incident described above except that they both resulted in under-exposures.

RESPONSE: The word similar has been removed and replaced with the word "another."

 August 25, 2017 contamination event involving Y-90 microspheres. This incident took place at the same licensee as the previous two Y-90 incidents described above. The information contained in this section is incorrect. This incident was reported to the Kansas Program on August 25, 2017 (a Friday), and the Kansas program performed an onsite investigation of the incident on Monday, August 28, 2017. The corrective actions for this event involve training and the licensee was cited by Kansas for inadequate training.

RESPONSE: The information contained in the Technical Quality of Inspection Indicator was based on interviews with inspectors and review of casework files. If the Program has information that was not provided to the IMPEP team, they can address this matter with the MRB.

 Regarding the one allegation discussed on page 15 of the report, we wish to emphasize that the program has contacted concerned individual and reported the results of the investigation into his allegation. This delayed notification of the concerned individual was not a failure to act by the Kansas program, but was partly a misunderstanding of the acronym "CI" used by the NRC. In our world, "CI" means "Confidential Informant", and we were using that meaning and assuming that the individual wished to remain confidential. In addition, item 16 of the report sent to us by the NRC regarding this incident stated "…recommend that Region IV provide a response to the CI and reach out to the state of Kansas to determine…", and this

statement caused some confusion on the part of our inspector that it was the NRC who would be communicating with the CI. We believe that the root cause of this lack of final contact to the concerned individual by the Kansas Program is the use by NRC of an acronym which with a meaning which is not standard or typical and a misunderstanding of the wording used in the NRC report which was provided to us. It is our normal process to report back any findings of allegations to the individual making the allegation.

RESPONSE: Regarding the allegation, the NRC defines the acronym at the first occurrence. "CI" should have been properly identified as a "concerned individual." It is important to ensure proper followup and follow through when handling sensitive information.

As a conclusion to this discussion, we feel it is important to emphasize that this report only discusses five investigations out of 32 total reported incidents from the time period (19 of which were reviewed by the NRC). These five specific incidents targeted by the NRC IMPEP team are unique in that they occurred during a time of management transition and/or were specifically by a licensee who has as their RSO the previous Kansas program director. We do not believe these five investigations reflect the true response activities or competency of our staff during the past four years or ongoing. We are not as weak in this area as these specific examples make us appear. We have attached to this letter as Attachment B, the incident casework reviews performed by the IMPEP team with additional comments and clarifications for a few of the files.

RESPONSE: The team focused its review on the most risk-significant examples: two overexposures, two medical events, and one contamination event.

11. Summary. We do not agree with the item (2) in the summary that there is "poorly communicated inspection findings to licensees". Out inspectors have very detailed <u>in person</u> close-out discussions with our licensees following each inspection, and frequently communicate via telephone and Email to discuss inspection findings and corrective actions. Our database currently does not have allowance for much of the documentation of these communications to be included, but they do occur. We also do not agree with item (3) in the summary, that there is a "pattern of untimely and insufficient responses to events". As discussed above, we believe that the *pattern* is adequate response, though there were a small percentage of incidents which occurred during a unique time of transition which did not receive an adequate onsite response. The pattern we continue to demonstrate in Kansas is adequate onsite responses to incidents and allegations. We acknowledge that there was an "inadequate management oversight of inspection and event reports" during the transition time of program director and radioactive materials unit supervisor transitioning, but that did not occur throughout the whole four- year IMPEP period and is no longer currently an issue in our program. We believe our primary weakness with regards to the success of the IMPEP audit is the lack of documentation of activities which took place. Documentation appears to be an over-arching issue with much of the items identified by the IMPEP Team. I can state with confidence that the Kansas program is better than how it is portrayed in this draft letter, and many of the critical activities which are assumed to not have occurred, actually were done correctly but were not documented.

RESPONSE: The word "communicated" has been replaced with "documented" for clarification.

The Program's procedure stated that the Program will respond to all medical events within 5 days. This was not performed. The Program failed to follow their own procedure. Overexposures, medical events, and wide-spread contamination are examples of risk-significant events that require prompt regulatory action. During interviews and review of casework, the team did not get the sense of urgency of these matters from the staff. The team acknowledged that some staff are no longer with the Program and their inspection documentation was lacking.

ATTACHMENT A - Kansas Comments on Inspection Casework reviewed by the IMPEP team

Kansas comments on the files are listed immediately following the casework information.

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 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.	

Kansas comments: The Program did follow-up with Landauer to verify the 535 mrem overexposure and we have copies of the communications with Landauer on this topic.

RESPONSE: Thank you for finding additional information. The inspection documentation should contain this information and an explanation as to why the higher calculated dose was not accepted. The discrepancy with the dose is one issue, but the more risk significant issue is that the Program did not cite the overexposure and did not provide an explanation as to why this was not cited. No change was made to the 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. The Program did not decrease the inspection frequency in order to perform a review of the licensee's policy changes.	

Kansas comments: This licensee is on a two-year inspection frequency and for an issue such as implementation of additional policy requirements for declared pregnant workers we believe it required two years. The three months of the timing of the next routine inspection was too soon to fully evaluate the implementation. In the database this issue remained clearly identified as "open" for review until following the next two-year inspection.

RESPONSE: The information provided in the comment section has been modified to remove the last sentence. The information remaining aids the reader for understanding comments on File No. 3.

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.	

Kansas comments: Our documentation in the Kansas database does clearly address this previous violation and any previous violations. They are marked as "RVW" which means open for review, and are not changed to "SA" which means satisfactory, until an inspector has specifically inspected that specific item. This inspection did look at the previous violation specifically and was changed to "SA" in the database.

RESPONSE: As noted above, the team was not afforded an explanation of this labelling practice. However, in accordance with the NRC's Inspection Manual Chapter 2800 "Materials Inspection Program" inspection documentation should contain sufficient information to support cited violations, non-cited violations, and closed violations identified during a previous inspection. Changing a label from "RVW" to "SA" is not a sufficient explanation as to why the violation can be closed. No change was made to the report.

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.	

Kansas comments: We use "non-cited violation" and "minor violation" wording interchangeably. The pin sensor discussed in this case is an extra layer of security above the minimum requirements. We are very familiar with this licensee and all our inspectors have inspected them before. Our inspectors did understand clearly what was encountered due to their familiarity with this licensee, and the licensee understood clearly what was meant by the citation.

RESPONSE: As noted above, the wording used in the inspection database read: "The error was not serious enough to stop the alarm, but merely delay it." This wording makes it appear that an alarm had sounded and this would be significant for a security inspection. The team believes that management oversight of inspection documentation is needed. No change was made to the report.

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. The previous minor violation for 10 CFR 37.49 was not reviewed and not closed.	

Kansas comments: The comment is incorrect. This issue was reviewed and closed as shown in our database.

RESPONSE: The report does not provide verbiage to indicate closure of the 10 CFR 37.49 violation. The team clarified the 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." The Program can provide further explanation at the MRB.

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 Program cited the licensee for a failure to train, but the inspection report noted that there were no gaps in training. This language contradicts the violation. 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 conducted on September 27, 2017, 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. A reactive inspection for the medical event was not performed. Described in Sections 3.3 and 3.5 of this report.

The inspection conducted on September 27, 2017 did not address a similar medical event where a patient was administered 64 percent of the prescribed dose of Y-90 microspheres in September 2015. Since this licensee had a similar medical event in 2015, the Program could have reviewed the licensee's root cause and corrective actions from the 2015 event to determine if the root cause and corrective actions were valid and effective. There was no indication in the documentation that the Program had ever properly evaluated the licensee's root cause for the 2015 medical event. Described in Section 3.3 of this report.

Kansas comments: As previously described in item #5 of this letter, the citation for failure to train was listed under the "Training and Practices" section of the inspection report in the database which addresses specific training such as in the use and handling of Y-90, but there is also a "General Training" section which addresses general radiation safety training. The report noting no gaps in training was referring to the "General Training," but the citation was correctly noted under the "Training and Practices".

RESPONSE: The IMPEP team understands that the database has two entries for training. However, the inspection documentation did not identify that the non-compliance dealt with the specialized training and not the general training. The documentation stated "the licensee failed to provide radiation safety training to personnel commensurate with the individual's duties as required." This is an example of the issues identified with the inspection documentation and clarity of inspection findings. The Program can provide further explanation at the MRB. No change was made to the 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 Program did not address and did not close the previous seven violations. The Program issued three new violations during this inspection. 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. However, both of these violations were vague and ambiguous.	

Kansas comments: The comment for this file is incorrect. Five of the seven previous violations were closed out and documented in our database. Our database maintains open issues by labeling them as "RVW" for review, and when then are closed out by the inspector that label is changed to "SA" for satisfactory. The violations as documented in the database may be vague or brief due to limitations of the database, but they are thoroughly discussed in detail by the inspector during the exit meeting with the licensee, and via any additional communications which occur between the inspector and the licensee as corrective actions are developed.

RESPONSE: The IMPEP team agrees that the documentation in the database may be vague. The reliance on drop-down labels (e.g., RVW or SA) does not provide clarity. In some cases, the team noted the documentation to include the statement: "the previous violation is closed." This statement was not in this report. There was no statement to indicate the two violations were remaining open. It is important that the written documentation clearly indicates the justification for closing previous violations. The Program can provide further explanation at the MRB. The comment was changed to indicate that the inspection documentation did not contain information regarding the previous seven violations and noting the discrepancy between the licensee report and the inspection database report.

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 seven violations from the 2016 inspection remain open. The focus of this inspection was a review of an incident where the incorrect radioactive material was administered to a patient.	

Kansas comments: Those 2016 violations were all closed in the database during the 2017 inspection. Our database maintains open issues by labeling them as "RVW" for review, and when then are closed out by the inspector that label is changed to "SA" for satisfactory.

RESPONSE: The report was revised to read: "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 team noted that the documentation should include the actions taken by the licensee to prevent reoccurrence and a notation as to when the licensee achieved compliance. This information was not included in the inspection documentation. The Program can provide further explanation at the MRB.

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.	

Kansas comments: We do have clear communication with the licensee in person at the conclusion of an inspection when the inspector clearly describes any findings. However, we concur that our database options for the Part 37 issue do need to be improved to add additional detail and explanation.

RESPONSE: The team agrees that the database needs to be improved to add additional detail and explanation. The team also believes that additional management oversight is needed. The Program can provide further explanation at the MRB. No change was made to the report.

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: The previous 2016 violation for failure to perform leak tests was not mentioned in this inspection report and was not closed.	

Kansas comments: In our database that violation was changed to satisfactory to close the issue, and the dates when leak tests were performed was included to confirm review of that issue. Our database maintains open issues by labeling them as "RVW" for review, and when then are closed out by the inspector that label is changed to "SA" for satisfactory.

RESPONSE: Since the dates of the leak test were provided, we will remove this comment.

ATTACHMENT B - Kansas comments on Incident Casework reviewed by the IMPEP team

Kansas comments on the files are listed immediately following the casework information.

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: Phone/Email
Comment: None	

Kansas comments: Investigation Type is "Site". An onsite investigation of this incident occurred on 5/8/18 and the routine inspection was moved up and conducted on 5/15/18.

RESPONSE: Agree. Change made.

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: Phone/Email
Comment: None	

Kansas comments: Investigation Type is "Site". An onsite investigation of this incident occurred on 2/7/18.

RESPONSE: Agree. Change made.

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	

Kansas comments: The lack of an onsite investigation was a deliberate decision by the program director in this case because of the extreme distance from the Kansas office. This event occurred in southwestern Kansas which is about an eight-hour drive from the Kansas

office in Topeka. This event involved a grass fire burning the truck and the gauge. The licensee came up from Oklahoma quickly to perform the surveys and pack up the remains of the equipment for transporting. The licensee employees would have had to wait in the very high heat in the field where the fire occurred for many hours to give the Kansas inspector time to arrive. Surveys to ensure the sources were intact and shielded were conducted by the licensee and communicated to the Kansas program.

RESPONSE: The Program's justification to not respond onsite as soon as possible can be provided to the Management Review Board. The team stands by its conclusion. No change was made to the report.

Agenda for Management Review Board Meeting
September 18, 2018, 1:00 p.m. – 4:00 p.m. (ET), OWFN-17B04

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.

2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other participants.

3. Consideration of the Kansas IMPEP Report.

   A. Presentation of Findings Regarding Kansas' Program and Discussion.

      - Technical Staffing and Training
      - Status of Materials Inspection Program
      - Technical Quality of Inspections
      - Technical Quality of Incident and Allegation Activities
      - Compatibility Requirements
      - Technical Quality of Licensing Actions

   B. IMPEP Team Recommendations.

      - Recommendation for Adequacy and Compatibility Ratings
      - Recommendation for Heightened Oversight
      - Recommendation for Next IMPEP Review

   C. MRB Consultation/Comments on Issuance of Report.

4. Request for comments from Kansas representatives, OAS Liaison, and State IMPEP team members.

5. Questions/comments from members of the public.

6. Adjournment.