STATE OF KANSAS

DEPARTMENT OF HEALTH AND ENVIRONMENT
DIVISION OF PUBLIC HEALTH
CURTIS STATE OFFICE BUILDING
1000 SW JACKSON ST., SUITE 330
TOPEKA, KS 66612-1365

PHONE: (785) 296-1560
FAX: (785) 559-4251
WWW.KDHEKS.GOV/RADIATION

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.	

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.	