

**Comment Resolution for the September 8, 2010 letter from KDHE (ML102520077)
regarding the July 14, 2010, draft IMPEP report**

Comment 1: Page 4 paragraph 3

This paragraph should be stricken from the report as it makes an uninformed comparison between an NRC course and a course provided by one of the most respected radiation oncologists in the state at a facility second only to one of the top rated medical schools in the country. The team had no firsthand knowledge of the quality or content of this course and is not in a position to adequately judge its quality.

Response 1:

Paragraph 4 on page 3 does not discuss the quality of the course, the qualifications of its instructor, or the credentials of any affiliated facility. The paragraph only states that the course contained approximately 18 hours of formal classroom and laboratory training compared to approximately 37 hours in the NRC's course. The data regarding length of time spent on the subject matter was obtained through a review of the course outline which was provided to the team during the IMPEP review. The team did not render a judgment on the quality of the course. No changes to the report are necessary.

Comment 2: Page 4 paragraph 4

While we do not argue that the Kansas staff and the safety of Kansas citizens will benefit from the recommendation made in this paragraph, the paragraph itself is derogatory and counterproductive to the IMPEP process. The paragraph should be reworded as follows: "Because the more senior technical staff would benefit from additional experience in performing inspections of therapeutic modalities, it is possible the more junior inspectors may not have received the benefit of this additional experience during on-the-job training for reviewing 10 CFR Part 35-related requirements during inspections. As discussed in greater detail in Section 3.3, the review team determined that the Section's inspectors performed thorough reviews of requirements related to occupational radiation safety, inventories, receipt and transfer of materials, surveys, and postings; however, the inspectors should place more emphasis on reviewing 10 CFR Part 35-related requirements for risk significant activities involving therapeutic modalities. The review team recommends that the State ensure that inspectors gain increased familiarity with the regulations in 10 CFR Part 35, as well as be provided appropriate formal training in addition to mentoring and/or on-the-job training to ensure familiarity with various therapeutic modalities involving byproduct materials such that these areas will be appropriately reviewed during inspections."

Response 2:

The first and second sentences will be revised using the wording suggested by the Section Chief. Changes to the third sentence (recommendation) are not necessary.

Comment 3: Page 7 paragraph 4

Sensitive and security-related information is a very important aspect of the licensing program and must be balanced between the public's right to an open and transparent government and their own personal security. It is essential that state and federal governments have clear and concise expectations as to what information belongs in the public domain and what must be kept from public release in the name of security. Such determinations cannot be made lightly. When asked, the team leader was not able to

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either clearly define sensitive information or cite a regulatory reference to support what the team considered sensitive or security-related information.

The Kansas Open Records Act is very clear in the expectation that any record not specifically exempted from release shall be treated as a public document and if there is a question about an exemption, the act requires us to err on the side of transparency and treat the record as a public document. In the absence of specific regulatory citations clearly defining what sensitive or security-related information is, we will have great difficulty in justifying the denial of a request for documents.

Therefore, statements regarding what the team considered sensitive or security-related information should be stricken from the report and replaced with specific regulatory citations clearly defining the criteria for classification of sensitive or security-related information.

Response 3:

During the IMPEP review, the Section Chief asked the team leader for a specific list of documents or items that should be considered as sensitive or security-related information. The team leader did not provide such a specific list but instead directed the Section Chief and Unit Supervisor to NRC Regulatory Issue Summary (RIS) 2005-31. Although this RIS provides guidance to NRC licensees, it provides useful screening criteria for sensitive and security-related information. As the team leader noted during the IMPEP review, the RIS describes sensitive (but unclassified, non-safeguards) information as a range of information for which the loss, misuse, modification, or unauthorized access can reasonably be foreseen to harm the public interest, commercial or financial interests of an entity, the conduct of NRC and federal programs, or the personal privacy of individuals. The RIS further describes security-related information as information, which if released, could cause harm to the public interest as it could be useful, or reasonably be expected to be useful, to a terrorist in a potential attack.

As was explained by the team during the IMPEP review, the purpose of identifying, marking, properly handling, transmitting, and storing documents that contain sensitive or security-related information is not to prohibit them from being withheld. The recommendation does not suggest or imply that the Section should not follow the Kansas Open Records Act. The recommendation, if implemented, will help prevent inadvertent release of sensitive information. Just because a record or document can be released to the public does not mean that the record or document should not be protected from inadvertent disclosure.

No changes to the report are necessary.

Comment 4: Page 9 paragraph 2

“The Section’s administrative staff receives” should be changed to read “The Section’s Research Analyst receives....”

Response 4:

Thank you for this clarification. This sentence will be revised in the report.

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Comment 5: page 10 paragraph 1

This paragraph was thoroughly covered in Section 3.3 of the report and should be stricken as repetitive. This paragraph does not add any meaningful value to the report and is detrimental to the effectiveness of the IMPEP program.

Response 5:

The recommendation was placed into Section 3.3 of the draft report, "Technical Quality of Inspections." Paragraph 1 on page 10 is in Section 3.4 of the draft report, "Technical Quality of Licensing Actions." This paragraph was meant to convey that potentially sensitive or security-related information was located in licensing actions in addition to the inspection records described in Section 3.3 of the draft report. The paragraph will be revised as follows: "As noted in Section 3.3, the review team made a recommendation regarding sensitive or security-related information. This recommendation also applies to documents related to licenses, outgoing licensing actions, and incoming licensing action requests."

Comment 6: Page 11 paragraph 4

This paragraph is repetitive and as written adds little value to the report. The paragraph should be revised as follows: "As previously discussed in Sections 3.1 and 3.3 of this report, the review team identified a recommendation for improvement in performing inspections of medical licensees. The review team noted that the technical staff adequately pursued the issue regarding the lost source; however, the technical staff did not fully pursue the potential of a medical event. The review team believes that by addressing the recommendation in Section 3.1 of this report the Section's technical staff will increase their skills and knowledge to better identify and pursue potential medical events in the future."

Response 6:

Per SA-100, "Implementation of the Integrated Materials Performance Evaluation Program," the review team identified a weakness and its root causes. This served as the basis for the team's recommendation. The paragraph will be revised as follows: "As previously discussed in Sections 3.1 and 3.3 of this report, the review team identified a weakness in the area of performing inspections of medical licensees and made a recommendation in this area. Regarding the Section's review of the above incident, the review team noted that the technical staff adequately pursued the issue regarding the lost source; however, the technical staff failed to recognize a potential medical event. The review team believes that by addressing the recommendation in Section 3.1 of this report the Section's technical staff will increase their skills and knowledge to better identify and pursue potential medical events in the future."

Comment 7: Section 4.1.2 update

The regulation package referenced in this section has entered the public comment period. A hearing before the Joint Committee on Administrative Rules and Regulations was held on August 16, 2010. The regulation package was submitted to the NRC for comment via e-mail and a receipt was received by the Kansas Radiation Control Program on August 19, 2010. A public hearing is scheduled on October 7, 2010, after the public comment period has ended.

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Response 7:

Thank you for this update. The first full paragraph on Page 14 will be revised as follows: “At the time of the onsite IMPEP review, the review team found that the Section had prepared a regulatory package that included the single overdue regulation amendment (minor changes not resulting in a significant compatibility issue as a result of the delay in adoption) as well as the five regulatory amendments that are coming due for adoption. The Section submitted the regulatory package to the Kansas Attorney General’s office for legal review. On May 28, 2010, the Section received the Kansas Attorney General’s legal review and began the process of publishing the proposed notice in the *Kansas Register* for public comment. Following the IMPEP review, on August 16, 2010, a hearing was held before the Kansas Joint Committee on Administrative Rules and Regulations. The regulatory package was submitted to the NRC, and on August 19, 2010, was assigned to an NRC staff member for compatibility review. In accordance with its processes and procedures, Kansas has scheduled a public hearing to be held on October 7, 2010, after the public comment period has ended.”

Comment 8: “Inspection Casework Reviews”

The comments provided on casework reviews should add value to the report giving the program adequate information to assess what the reviewer saw during their review and take action to improve the program. Generic statements without detail add no value to the report and should be stricken.

Response 8:

The comments in the Appendix of the draft report were based not just on a review of the inspection records but also on discussions with the technical staff and managers. The reviewer discussed specific comments with individuals as appropriate. Per SA-102, “Reviewing the Common Performance Indicator, Technical Quality of Inspections,” comments in regard to inspection casework that will appear in the report’s appendix should be factual, concise, and concentrate on casework deficiencies and their root cause(s). In the team’s effort to be concise, and because the specific comments were reviewed during the IMPEP review as appropriate, the team did not enumerate or reiterate the specific comments in the appendix.

Comment 8a: File No. 14

Kansas City Cancer Center inspection date 2/5/09 – The comment states the inspection did not cover relevant requirements related to 10 CFR Part 35 for various therapeutic modalities, however, it fails to note that the inspector reported that there had been no HDR or manual Brachytherapy performed to date nor that the facility had not performed unsealed therapies. It also fails to note that these requirements were adequately reviewed in the following inspection after the licensee had begun conducting these therapies. The comment should be stricken.

Response 8a:

See Response 8. The comment will be removed.

Comment 8b: File No. 16

Providence Medical Center inspection date 3/26/09 – The comment should be stricken. The inspector noted on the report that there had been no HDR therapies performed or

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scheduled to date and that manual Brachytherapy was performed on a very limited basis and that a thorough review of the documentation had been performed.

Response 8b:

See Response 8. The comment will be removed.

Comment 8c: File No. 19

University of Kansas Hospital inspection date 5/12/08 – This inspection was of a satellite facility which had recently been opened. The inspection report clearly states that there had been no therapeutic procedures performed at this location. This comment should be stricken.

Response 8c:

See Response 8. The comment will be removed.

Comment 8d: File No. 22

Wesley Medical Center, LLC inspection date 2/14/07 –

Comment “a” is misleading in that it fails to note that the 75 day delay was due to the fact that a civil penalty was imposed and that such a delay is expected and acceptable. The licensee was aware of the inspection results and that a civil penalty was to be imposed.

Comment “b” should be stricken because the inspection report clearly indicates that these requirements were reviewed for all therapeutic modalities. The inspector noted that patient charts, written directives, follow up etc. were reviewed.

Response 8d:

The following sentence will be added to Comment (a): “The 75-day delay was due to the processing of enforcement action.”

See Response 8. Comment (b) will be removed and comments (c) and (d) will become (b) and (c), respectively.

Comment 8e: Accompaniments Comments

Accompaniment No. 1 Via Christi Medical Center

Comment “a” – The inspector’s report states that the following were reviewed for unsealed I-131 therapy:

- source receipt and package survey,
- dose assay,
- dose administration,
- patient, room and area survey data with diagram,
- written directive and dose order signed by physician,
- patient release calculations,
- final area survey with wipes, and
- facility’s follow-up checklist.

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Please include more detail as to what relevant requirements related to 10 CFR 35 for unsealed iodine-131 therapy were not reviewed.

Comment “b” – It should be noted that while the team reviewer accompanied the inspector at the facility, the inspection is not limited to on-site activities. The inspector noted that the self-shielded irradiator was moved from one side of the room to another and that an additional barrier had been constructed around it. Being familiar with the security controls on the irradiator the inspector also noted that this action did not in any way affect the security controls and in fact enhanced them by providing an additional barrier. Upon return to the office the inspector reviewed the relocation and discussed it with management in detail. The determination was made that this relocation was performed within the scope of the licensee’s broad scope license. With regard to potential industrial safety issues it should also be noted that in discussions during the review the team leader commented that the inspector should have evaluated the floor loading of the irradiator. Our inspectors are not structural engineers and evaluating such issues is not within their authority. Kansas law prohibits such evaluations being performed by non-licensed engineers. This comment should be stricken.

Response 8e:

See Response 8. Comment (a) will be removed.

Regarding Comment (b), regrettably, there must have been miscommunication because the account provided in the response differs from what was discussed during the IMPEP review. Comment (b) will be removed. Furthermore, there must have been some additional miscommunication because the team leader did not comment that the inspector should have evaluated the floor loading of the irradiator. The team leader asked the inspector if the licensee had considered the floor loading prior to the relocation of the irradiator.

Comment 9: Section 4.0 comments

One major problem RCPs have is when a violation is identified at a licensee, how is the violation characterized with respect to severity and what level of enforcement action is warranted. When taking enforcement action it is necessary to be consistent, fair and reproducible. It may be necessary to defend decisions on enforcement action in court and if the RCP is not consistent they may open themselves up to liabilities that are unacceptable. For example, if one licensee is fined for a violation while another is not fined for the same or similar violation then the RCP may at best lose credibility or at worst find itself the target of lawsuits that could devastate the program.

To address this problem, the Kansas staff has developed an evaluation tool that analyzes the cause and effect of a violation in a very consistent and reproducible manner. Once the bounds of severity of the cause and effect are identified then it is a simple matter to use the tool to determine the severity level of any violation and therefore the level of enforcement action to be taken. After development this tool was applied to a large number of historical violations and it correctly identified the severity level and enforcement action in all cases. An example of this tool and its use to classify the severity level of a violation resulting in a medical event is attached.

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Kansas staff use this tool for classifying violations not only in the materials program but also the x-ray program. Due to the ease of use of this tool, it has been incorporated into the RCP's database. When an inspector identifies a violation the database shows the tool and the inspector simply selects a radio button for the cause and effect. The database then assigns the severity level and enforcement action as appropriate.

It was encouraging that one team member recognized the value of this tool and requested a copy of it be provided. However, we were disappointed to see that this valuable tool was not mentioned in the draft report. We believe that due to the versatility, ease of use, reproducibility and defensibility of the tool that it should be considered a good practice to be shared with other states and NRC regions.

Response 9:

The tool was first provided by the Unit Supervisor to a team member prior to the onsite IMPEP review. During the onsite IMPEP review, the team was provided with a revised version of the tool. The entire team was impressed with the level of effort extended by the Section to develop the tool and believes that it will be a valuable enforcement aid to help the Section to determine the severity level of violations. During the onsite IMPEP review, the team leader spent considerable time one-on-one with the Unit Supervisor who was largely responsible for the development of the tool and discussed the tool in great detail. During discussions with the team leader, the Unit Supervisor indicated that the tool was still being tested, honed, and improved. The example provided as Attachment 1 to the State's response demonstrates that the tool has been further refined since the IMPEP review. With respect to enforcement, the team's review was limited to whether violations as written could be substantiated, whether violations were appropriately documented and dispatched in a timely manner, and whether enforcement actions resulted in licensee compliance with health, safety, and security requirements. The team will defer to the Management Review Board (MRB) for consideration of the tool as a good practice.

Comment 10: Conclusion

As indicated above, an analysis of the inspection casework files reviewed by the team indicates that the inspections identified as being deficient in the review of relevant requirements of 10 CFR 35 either did include reviews of patient charts, written directives, follow up of treatments, etc., or no therapies had been performed at the licensee at the time of the inspection. At two of the four licenses identified with deficient inspections no therapy using radioactive material had been performed. At one, no HDR had been performed and the inspection report clearly indicated a thorough review of unsealed therapy. The final inspection also clearly indicated a review of 10 CFR 35 requirements for all types of therapeutic modalities performed.

We agree that the Kansas staff should have additional training and experience in the areas of radioactive material therapeutic modalities as stated in recommendation 1. As stated in the report Kansas strongly supports the training of its staff and is committed to ensuring they receive the training and experience they need to protect the public health. However, we feel that the supporting evidence does not support elevating the Technical Quality of Inspections indicator to needs improvement as described in Management Directive 5.6 "Integrated Materials Performance Evaluation Program."

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With a regulatory citation clearly defining what is sensitive or security-related information we will be able to resolve the concerns expressed in Recommendation 2.

Response 10:

See Responses 8, and 8a-e regarding the specific comments related to the inspection casework files.

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommended that Kansas' performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory, but needs improvement. During the MRB meeting, the MRB will make a final determination based on the team's report and input from the State of Kansas.

See Response 3 regarding Recommendation 2.