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Robert Moser, MD, Secretary

Sam Brownback, Governor

August 12, 2014

Duncan White, Chief
Agreement State Programs Branch
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11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. White:

Thank you for the opportunity to provide comments on the draft Integrated Materials Performance Evaluation Program (IMPEP) report we received on August 18, 2014. IMPEP reports serve as an extremely valuable tool that Radiation Control Programs (RCPs) and NRC Regions use to continuously improve their efforts to protect the public health from the harmful effects of radiation. As such, it is essential that the report contain detailed and constructive information which an RCP can use to achieve the common goal that all Agreement States and the Nuclear Regulatory Commission have of protecting the health and safety of the public.

We'd like to take this opportunity to commend NRC and the Agreement States on their on-going efforts to improve the IMPEP process and make it an even more useful tool for improvement. To that end we offer the following feedback on our latest IMPEP review with the hopes that this will be passed on to the IMPEP working group for consideration:

1. We commend the team as a whole on their professionalism and thoroughness of their review which has resulted in significant improvements to our program. Even though some of the findings of an IMPEP team may be distressing, it is only through such professionalism that the program and review team can work together to find the causes and improve the program.
2. We commend Ms. Shirley Xu specifically for taking the time to explain the nuances of 10 CFR 35.300 to our staff. Her explanation made it very clear where we had gone wrong and allowed us to determine the best way to correct these problems.
3. The listings of the case studies are very useful to the program being reviewed as it provides us the opportunity to look at exactly what the reviewer did so we can fully understand what the reviewer found. However, the use of generic statements in the comments defeats the purpose of listing the case studies. These comments should be general in nature but contain enough detail that the program can extract the example from the file.

In the interest of accuracy and detail we offer the following comments, suggestions and updates which will be addressed in the order in which they appear in the report.

Section 3.1 Technical Staffing and Training Comments
Page 3 Paragraph 3

The first two sentences of this paragraph contain an error in the number of full-time equivalents and should be replaced with:

> "At the time of the review, five technical staff members, plus the supervisor, totaling 5.5 full-time equivalents (FTE) had direct involvement in the daily operations of the radioactive materials program. All of the technical staff members are allocated 5 percent of their FTE for nuclear power plant emergency response with one allocated an additional 20 percent to perform asbestos program activities."

Section 3.2 Status of Materials Inspection Program Comments
Paragraph 3 Sentence 4

Because Kansas is an Agreement State, this sentence should be more appropriately worded as follows:

"Section procedures, in agreement with IMC 2800, state initial inspections should be conducted within 12 months of license issuance."

Page 4 Paragraph 1

References in this paragraph to transmitting inspection reports should be changed to transmitting inspection findings. The actual inspection reports are not transmitted to the licensee except upon request. A letter is sent transmitting the inspection findings. In addition it is suggested that to address a contributing factor the last sentence be replaced with the following which addresses the improvement of monitoring these transmissions:

"Section management determined that computer generated reports used to monitor the timeliness of inspection activities were not providing sufficient detail to monitor the transmittal of inspection findings. This has been addressed by modifying the reports and section management will be more closely monitoring the timely transmittal of inspection findings."

Section 3.3 Technical Quality of Inspections Comments
Page 5 Paragraph 4

The IMPEP report should address not only the areas needing improvement but those areas where the team noted strengths. It is suggested that the following sentence be added to this paragraph:

"The review team noted that the computer generated inspection reports supported a good format for a narrative of the inspectors observations and findings. Examples of these reports were taken by two of the review team members."

Section 3.4 Technical Quality of Licensing Actions Comments
Page 6 Paragraph 5 Last Sentence

To more accurately represent the licensing guidance used by the Section this sentence should be replaced with the following:

"The Section has Kansas specific guidance documents for the common types of licenses issued but also uses the NRC's NUREG-1556 series for additional licensing guidance."

Page 7 Paragraph 1

The following paragraph is implies a much broader scope of an issue than what the team discussed during the review and doesn't clearly convey the findings of the review team:

"The review team identified repeated examples of problems with respect to thoroughness, completeness, consistency, and adherence to existing guidance for medical licensing actions. The review team recommends that the State review all active medical licenses and verify that previously approved authorized users, authorized medical physicists, radiation safety officers, and authorized nuclear pharmacists 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."

The following suggested replacement paragraph conveys the findings of the review team as discussed during the review and in the body of draft report:

"The review team identified repeated examples of problems authorizing users for 10 CFR 35.300 (KAR 28-35-264) uses with respect to thoroughness, completeness, consistency, and adherence to existing guidance for medical licensing actions. The review team recommends that the State review all active medical licenses and verify that previously approved authorized 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. While no problems were identified during the review with respect to authorized medical physicists, radiation safety officers, and authorized nuclear pharmacists, as a result of subsequent discussions the Section may feel it is prudent to review a sampling of the training and experience of these individuals."

Update

Root causes:

- After review of all of the active licenses authorizing 10 CFR 35.300 uses it has been determined that issues identified by the review team and Section staff are related to a significant paradigm shift in licensing when the new Part 35 was adopted. The prior paradigm for training and experience was focused on patient release criteria as opposed to a specific procedure based paradigm. As a result, the Section did not correctly transition to this new paradigm.
- Licensing by restriction has been the historical format, particularly for medical licenses. This has resulted in a confusing array of inconsistent wording and erroneous authorizations.

The following corrective actions have been or are being taken:

- Each of the 10 CFR 35.300 medical licensees were contacted to determine if any users were performing procedures that they were not qualified for. No users performing unqualified procedures have been identified.
- An audit of all active medical licenses authorizing 10 CFR 35.300 uses has been completed. An additional two license actions were found to be in error similar to those found by the review team.
- An audit of all other active medical licenses is currently underway.
- Changes to the database have been completed which will allow license reviewers to enter information about training and experience. When an attempt is made to authorize a user for uses they are not qualified for a message will be given stating the user is not qualified and give the reviewer an opportunity to update that persons record. This will apply to all users not just medical. At this time the qualification data is being populated. Upon completion, licenses with improperly authorized users will be amended.
- Section procedures are being revised to adopt a new license format. Licensing by restriction will be the exception rather than the rule for medical licenses. Instead of authorizing a user for 35.300 except X, Y and Z they will be authorized for the uses referenced in 35.392, 35.394 or 35.396 as appropriate. This change has already been incorporated into the database.

Section 3.5 Technical Quality of Incident and Allegation Activities

Update

An investigation team of one supervisor and three inspectors was sent to the licensee's facility where reenactments and time and motion studies were performed. Employees and management were interviewed both together and separately. The team then observed a well logging operation in the field noting that the operation was conducted using the licensee's revised procedures. The investigation is complete and two individual's received overexposures, one received 5.122rem TEDE and the other received 50.14rem SDE to the extremity. There was no public exposure. We are currently evaluating potential enforcement actions.

Root Causes:

- There was insufficient management oversight of this particular investigation.
- The Section's procedure on incidents and allegations did not have guidance on when an onsite investigation should be conducted.

The following corrective actions are being taken:

- There will be closer management oversight of incidents in the future.
- The incident and investigation procedure has been revised to include a preliminary priority evaluation, based on initial information, using our severity level tool to determine when an onsite investigation is warranted.

Section 4.1.2 Program Elements Required for Compatibility
Paragraph 3 Sentence 2

The IMPEP report should address not only the areas needing improvement but those areas where the team noted strengths. We suggest this sentence be changed to read:

> "Kansas is up to date on the adoption of regulation packages, which the review team noted was not a common finding during IMPEP reviews."

Update on the three previously submitted regulation packages
"Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," RATS 2001-1, has been closed with no comments 07/29/2014, ML14162A452
"Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material; Licensing and Reporting Requirements," and "Requirements for Expanded Definition of Byproduct Material," are addressed in our regulatory process database and are included in the next regulatory package to be submitted.

Recommendations
To be consistent with the comment made in Section 3.4 "Technical Quality of Licensing Actions" the recommendation should be reworded as follows:

> "The review team recommends that the State review all active medical licenses and verify that previously approved authorized 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."

Appendix E "Incident Casework Reviews" Comments
File number 12

The comment should be changed to read as follows to ensure it is clear the investigation was still open at the time of the review:

> "At the time of the review an on-site investigation had not yet been performed by the State, in spite of evidence of a significant exposure to an untrained individual, and potential overexposures to members of the public."

Thank you for the opportunity to comment on the draft IMPEP report and we look forward to discussing the draft final report with the Management Review Board on September 4, 2014.

Sincerely,

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cc: James Lynch
Binesh Tharakan