



KANSAS
DEPARTMENT OF HEALTH & ENVIRONMENT
BILL GRAVES, GOVERNOR
Clyde D. Graeber, Secretary

October 30, 2002

U.S. Nuclear Regulatory Commission
ATTN: Paul Lohaus, Director
Office of State and Tribal Programs
Mail Stop O-3C10
Washington, DC 20555-0001

Dear Mr. Lohaus:

Thank you for the opportunity to comment on the draft Kansas Integrated Materials Performance Evaluation Program (IMPEP) report. This is an important and vital step in the IMPEP process to ensure the accuracy and effectiveness of the evaluations. IMPEP is a valuable tool for both the Nuclear Regulatory Commission (NRC) and the Agreement States to help achieve our common goal of protecting the health and safety of the public, radiation workers and environment. Our staff has reviewed the draft report in detail and to help produce the highest quality product possible we offer the following comments: These comments are arranged by report section and if you have any questions or need further clarification please do not hesitate to contact me.

Good Practices

The report states in a number of locations that Kansas has an effective and efficient process to ensure inspection findings are communicated to licensees and the database was a significant resource for improving efficiency. The team also stated in the exit meetings that the database was an integral reason for the Kansas program accomplishing what it has. We feel we have not been given adequate credit for the efficiencies we have realized and which were recognized in the exit meetings. The database should be cited as a Good Practice. A review of the annual summaries of good practices and trends indicates this database is unique in that it fully integrates licensing, inspection, and reciprocity. It is flexible and has the ability to quickly integrate new requirements and practices. For example, when the "Advisory for Materials Licensees on Security of Licensed Materials" was issued, the Kansas inspection checklist was immediately updated to include the items in this advisory. As a result, the contents of the advisory became part of our routine inspections the day it was received. Another example is when NRC requested we provide listings of our licensees by interim compensatory measures (ICM) categories we were able to quickly add the ICM categories to our database. This allowed us to examine and categorize each licensee using only 35 person-hours. These categories are now part of the database and will be maintained current as licenses are written and amended. As stated during the exit meetings, without this database the Kansas program would not have been able to meet licensing and inspection goals.

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The value and uniqueness of the Kansas database is further evidenced by the fact that NRC and the state of California went to the time and expense of sending teams to Kansas for the sole purpose of reviewing it and that other states including Wisconsin, Oklahoma, Nevada and New Hampshire have requested and received copies for evaluation and/or use.

Technical Quality of Inspections

It should be noted the first inspection accompaniment was of a large specific medical licensee with a radiopharmacy, not a broad scope medical licensee.

There are a number of negative comments regarding the first inspector accompaniment which we feel can be attributed to the reviewer's lack of experience (this was his first IMPEP) and expressing his personal opinion rather than using the criteria in NRC procedures. The following are specific comments:

In Section 3.2 paragraph 2, sentences 3, 4 & 5, should be stricken from the report. They are inaccurate, not supported by data provided in the report and represent the personal opinions of an inexperienced reviewer. During discussions with the reviewer it was apparent these observations reflected his personal opinion and were not the way he would have conducted the inspection. The report states the inspector did not use performance based techniques, did not observe activities, missed observation opportunities and did not follow procedures.

This was a large licensee and would normally take an inspection team 2 - 3 days to complete an accurate assessment and inspection of the licensed activities. It was discussed with the reviewer that this inspection would focus on radioactive material usage for all groups, but mainly V, IV (unsealed therapy) and intravascular brachytherapy; the Radiation Safety Committee; Radiation Safety Officer; administration and the nuclear pharmacy. During the initial entrance meeting, it was determined after talking with the physicist, RSO and nuclear medicine director, that there were no therapy procedures involving I-131 (there was an in-patient that had received I-131) or brachytherapy to be performed that week. The pharmacy, which operates from 3 am to noon, was available to inspect during actual working conditions. This was proposed to the reviewer as a substitute for observing hospital operations. The inspectors were scheduled to arrive at 6 am, but the reviewer did not wish to arrive until about 8 am (as a result the inspectors missed most of the dose preparation, set up and tear down).

By training and experience Kansas inspectors utilize both compliance and performance based inspection techniques. The inspection checklist is developed to allow leeway to the inspector to perform qualitative as well as quantitative inspections. In addition, the inspectors observed the care and radiation safety precautions for the I-131 therapy patient, calculation of molybdenum breakthrough, preparation and transport of radioactive material as well as other aspects of licensee use, the reviewer chose to focus on one inspector and therefore missed opportunities to observe several uses.

As director of the Kansas Radiation Control Program I discussed the details of the inspection as well as reviewed the documentation and have determined that the inspectors followed appropriate Bureau procedures.

Section 3.2, page 8 first full paragraph. This paragraph appears to be somewhat contradictory. It is stated that the inspectors "demonstrated appropriate inspection techniques and knowledge of the regulations," then implies only compliance based techniques were used. As stated above, Kansas inspectors use a combination of compliance and performance based inspection techniques. It has been found that compliance techniques give the inspectors valuable information on where to focus performance based inspection activities. For example, the inspector and reviewer "dressed" out and observed an IVB procedure. They also observed an I-131 patient during the treatment phase. The reviewer was also taken to a gauge user licensee. During these inspections, the licensee was observed and demonstrated the use of devices, radioactive materials, emergency procedures, and what and how they were to operate under the limits of the license.

Section 3.2, page 8 2nd full paragraph. The statements regarding documentation of inspector observation, confirmatory surveys, and relative significance or root cause of violations should be stricken. Discussions with the reviewer indicated these were personal preferences of the reviewer and not a strict evaluation based on IMPEP criteria. Some information is incorporated in the database by reference and when there are no problems or significant comments then sometimes a narrative description is not included or needed. This is consistent with NRC's current practice of issuing a checklist form to the licensee at the time of the inspection which only states there were no violations. It is also consistent with the inspection pilot project NRC is conducting where only violations will be documented.

In an unbiased performance based review, the standard should be, does the inspection provide a sound basis for taking appropriate enforcement action and does it adequately assess the radiation protection program of the licensee. Since Kansas has not had any enforcement action overturned and the second seasoned experienced reviewer stated the "inspections were adequate to assess radiological health and safety at the licensed facilities," the report should be amended as indicated to properly reflect the quality of the Kansas inspection program.

Incident response and allegations

Paragraph 4 page 13, states that in "several cases" dose estimates were not recorded. However, in the incident casework reviews only one case was noted. The licensee in question had conducted a dose assessment and conservatively determined the dose to be 6.75 mrem to the individual. Since this was a licensee this documentation was located in the license file not in the incident file.

Inspection casework reviews - appendix C

The statement "documentation missing in database inspection record" should be stricken from each. As stated above based on my discussions with the reviewer these are personal preferences of the reviewer. In addition, the statements add no value to the report.

In each case the statements regarding violations and their documentation should be stricken as personal opinions of the reviewer. It should be noted that in the 37 years of the Kansas Agreement program there has not been one case of a violation being overturned. As such the level of documentation we provide meets Kansas requirements and allows us to take appropriate enforcement action.

File # 9 comment "c" regarding the Nebraska inspection is not relevant to the Kansas IMPEP

File # 13 comment "a"

The comment that there is no documentation that workers receive notification of dose should be stricken as the personal opinion of the reviewer. If there was a problem with the requirement to notify workers of their dose there would have been a violation cited.

Inspector accompaniment No. 1 (page C.4)

- a) During walk throughs and surveys a good inspector will be looking at and observing all activities. This may not have been obvious to an inexperienced reviewer. This comment should be stricken.
- b) Inspectors observed an I-131 therapy patient, calculation of moly breakthrough, preparation and transport of RAM as well as other aspects of licensee use, the reviewer missed opportunities to observe several uses. In addition, the inspectors were prepared to arrive at the facility early to observe pharmacy operations but the reviewer did not want to observe these operations. This comment should be stricken.
- c & d) My independent discussions with both inspectors indicate these took place. My discussions with the reviewer indicated they did not take place to the level he would have done. These are good comments but personal opinions do not belong in the report.
- e) My independent discussions with both inspectors indicate these took place in the presence of the reviewer.
- g) (note there is no comment "f") While one inspector's experience with brachytherapy is limited this statement is refuted by the additional inspector accompaniments by an experienced seasoned reviewer. This comment should be stricken.

License casework reviews (appendix D)

File No. 6

It should be noted the issue with the logging supervisor's training had been corrected on the next amendment.

File no. 9 (line medical)

The issues raised by the comments were discussed with the team at length during the review. At the time of the review these issues were addressed to the satisfaction of the reviewer and team leader. It is agreed this license could have been written better, however, between the license, radiation regulations and Kansas pharmacy regulations this issue was closed. Note: the license has since been amended to better reflect the requirements.

Incident casework review (appendix E)

File no. 4

The licensee had conducted a dose assessment and conservatively determined the dose to be 6.75 mrem to the individual. This documentation was located in the license file not in the incident file.

One last minor comment. In several places it is stated that Kansas developed a database similar to NMED. This is incorrect, we are using a local copy of NMED as it is designed to be used. We have expanded its use to include all incidents such as non AEA material, NORM, and Xray.

Again, we appreciate the opportunity to comment on the draft report. If you wish to discuss any of these comments or need further clarification or information please contact me at (785) 296-1565 or email tconley@kdhe.state.ks.us.

Sincerely,



Thomas A. Conley, RRPT, CHP
Section Chief, Radiation and Asbestos Control

cc: C. Layman