

May 2, 2003

MEMORANDUM TO: Management Review Board Members:  
Carl J. Paperiello, EDO  
Paul H. Lohaus, STP  
Martin J. Virgilio, NMSS  
Karen D. Cyr, OGC

FROM: Kathleen N. Schneider, Senior Project Manager  
Office of State and Tribal Programs */RA/*

SUBJECT: FINAL MINUTES: NOVEMBER 22, 2002  
KANSAS MRB MEETING

Attached are the final minutes of the Management Review Board (MRB) meeting (Attachment 1) and the revised "Kansas Response to the Draft IMPEP Report - Resolution of Comments Document" (Attachment 2). If you have comments or questions, please contact me at 415-2320.

Attachments:  
As stated

cc: Thomas Conley, KS  
William Sinclair, UT

Management Review Board

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MINUTES: MANAGEMENT REVIEW BOARD MEETING OF NOVEMBER 22, 2002

These minutes are presented in the same general order as the items were discussed in the meeting. The attendees were as follows:

Paul Lohaus, MRB Chair, STP  
Martin Virgilio, MRB Member, NMSS  
Richard Blanton, Team Leader, STP  
Kathleen Schneider, STP  
Lance Rakovan, STP  
Marissa Bailey, NMSS  
Cardelia Maupin, STP

Karen Cyr, MRB Member, OGC  
Carl Paperiello, MRB Member, OEDO  
Brian Smith, OEDO  
Brenda Usilton, STP  
John Zabko, STP  
Shelley Cole, OGC

By teleconference:

William Sinclair, OAS Liaison, UT  
James Harris, KS  
David Whitfill, KS  
Scott Bangert, KS

Ken Weaver, Team Member, CO  
James Johnson, KS  
Kim Steves, KS

By video:

Thomas Conley, KS  
Chuck Layman, KS  
Greg Morell, Team Member, RIV  
Ken Brockman, RIV

Vic Cooper, KS  
Vivian Campbell, Team Member, RIV  
Richard Leonardi, Team Member, RIV

1. **Convention.** Paul Lohaus, Chair of the Management Review Board (MRB) convened the meeting at 10:10 a.m. Introductions of the attendees were conducted. Note: Carl Paperiello joined the MRB approximately 10:30 a.m.
2. **New Business - Kansas Review.** Mr. Richard Blanton, STP, led the Integrated Materials Performance Evaluation Program (IMPEP) team for the Kansas review.

Mr. Blanton summarized the events that took place during the preparation for the review by the State, the change in State personnel, and mis-communications between State and IMPEP review team which resulted in additional inspector accompaniments being conducted June 12-14, 2002 and July 18, 2002.

Mr. Blanton summarized the review and noted the findings. Preliminary work included a review of Kansas' response to the IMPEP questionnaire. The onsite review was conducted April 23-26, 2002. The on-site review included an entrance interview, detailed audits of a representative sample of completed licensing actions and inspections, inspector accompaniments and follow-up discussions with staff and management. Following the supplementary accompaniments, an additional close-out meeting was held September 5, 2002. The team issued a draft report on September 23, 2002; received Kansas' comment letter dated October 30, 2002; and submitted a proposed final report to the MRB on November 15, 2002.

**Common Performance Indicators.** Mr. Ken Weaver reviewed the common performance indicator, Status of the Materials Inspection Program. His presentation corresponded to Section 3.1 of the IMPEP report. The review team found Kansas's performance with respect to this indicator "satisfactory." Mr. Conley discussed with the MRB the use of their database as a management tool as a good practice. Both the State and the review team noted that the database has maximized efficiency and effectiveness of the program. However, the review team did not recommend this as a good practice because a very similar good practice had been identified during a previous review. The MRB and Mr. Conley discussed the desirability to maintain a list of software and databases utilized by States to share with both NRC and other Agreement States. The MRB directed staff to investigate a means of maintaining a list of those States that have effective database systems that could be publicly available. The MRB agreed that Kansas' performance met the standard for a "satisfactory" rating for this indicator.

Mr. Greg Morell presented the common performance indicator, Technical Quality of Inspections. His presentation corresponded to Section 3.2 of the report. The team found that Kansas' performance was "satisfactory" for this indicator. The MRB discussed with the review team and the State the inspection report documentation issues identified on page 8 of the proposed final report and whether a recommendation was warranted. The MRB directed that the final IMPEP report should be revised to indicate that those items not covered in the inspection reports were areas the State expected staff to obtain information. The review team stated that they believe that the reduced staffing drove the inspectors to minimize the documentation of the inspection reports. The MRB agreed that Kansas' performance met the standard for a "satisfactory" rating for this indicator.

Ms. Campbell presented the findings regarding the common performance indicator, Technical Staffing and Training. Her presentation corresponded to Section 3.3 of the IMPEP report. The team found that Kansas' performance with respect to this indicator was "satisfactory with recommendations for improvement" and made one recommendation involving adequate resources and staffing for the program. After a brief discussion regarding the significance of the finding for this indicator, the MRB agreed that Kansas' performance met the standard for a "satisfactory with recommendations for improvement" rating for this indicator.

Ms. Campbell presented the findings regarding the common performance indicator, Technical Quality of Licensing Actions. She summarized the findings in Section 3.4 of the report. The team found Kansas' performance to be "satisfactory" for this indicator and made one recommendation involving financial assurance. The MRB agreed that Kansas' performance met the standard for a "satisfactory" rating for this indicator.

Mr. Weaver presented the findings regarding the final common performance indicator, Response to Incidents and Allegations. As discussed in Section 3.5 of the report, the team found Kansas' performance relative to this indicator to be "satisfactory" and made no recommendations. The State indicated that their experience with the Nuclear Material Events Database (NMED) has been excellent. The MRB agreed that Kansas' performance met the standard for a "satisfactory" rating for this indicator.

**Non-Common Performance Indicators.** Mr. Blanton led the discussion of the non-common performance indicator, Legislation and Program Elements Required for Compatibility, which is summarized in Section 4.1 of the report. The team found that Kansas' performance with respect to this indicator was "satisfactory with recommendations for improvement" and made two recommendations involving submitting legally binding requirements and adoption of two overdue regulations. The MRB discussed precedents and proposed guidance with the review team and STP staff. The MRB directed the finding be revised that Kansas' performance met the standard for a "satisfactory" rating for this indicator.

**MRB Consultation/Comments on Issuance of Report.** Mr. Blanton concluded, based on the discussion and direction of the MRB, that Kansas' performance was satisfactory with recommendations for improvement for the indicator, Technical Staffing and Training and satisfactory for all remaining indicators. The review team recommended and the MRB concurred that the Kansas Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program. The review team recommended that the next IMPEP review be scheduled in 2 years due to the impacts of staffing on the program. The MRB discussed with the team the benefits of a full review versus an alternate mechanism of maintaining communications as to the status of the program. Ms. Campbell noted that at the request of Kansas, monthly teleconferences occur between Region IV and Kansas. STP staff noted that in Rhode Island, Tennessee, and Oklahoma, regional and headquarter staff maintained closer contact through monitoring the status of the program with the State and briefing the MRB after each contact whether monthly or quarterly. The MRB directed that the staff monitor the Kansas program until the periodic meeting and directed that the next full review be conducted in approximately four years, unless the program experiences difficulties which would dictate completing an earlier IMPEP review.

3. **Comments.** Mr. Conley thanked the review team for their performance and noted that the process was a learning experience both for his organization and NRC as to what works and does not work. He appreciated the team's approach on returning to the State to perform additional accompaniments. He agreed that resources and staffing are their greatest challenge. Mr. Conley also indicated that Kansas is attempting to get dedicated funds for their programs.

Mr. Weaver was thankful for the opportunity to participate on the review team. He commented briefly on the Kansas program's limited resources and their database.

4. **Status of IMPEP Reviews and Heightened Oversight/Monitoring Activities.** Lance Rakovan briefly discussed current and upcoming reviews. He also noted that there were no periodic meeting summaries issued since the last MRB meeting.

5. **Adjournment.** The meeting was adjourned at approximately 11:25 a.m.

## **Kansas Response to the Draft IMPEP Report Resolution of Comments Document**

Comment 1: 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.

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.

### Response

The team reviewed this question again and similarly concluded that the Kansas database does not meet the current criteria to be identified as a "Good Practice." The criteria for the designation of a practice as a "Good Practice," is that neither the practice nor a substantially similar practice has been observed in a previous IMPEP. The team notes that a substantially similar database was previously found to be a good practice and is discussed in All Agreement States Letter SP-96-081, "Identification of Good Practices in 1994-1995 Integrated Materials Performance Evaluation Program Reviews," dated July 17, 1996. There will be no change to the report based on this comment.

Comment 2: 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.

### Response

The review team agrees with this comment. The language in the report will be clarified.

ATTACHMENT 2

Comments 3 through 6: Technical Quality of Inspections (referring to the original accompaniment conducted April 22 and 23) - 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.

#### Response

**As described in the report, the team learned after the first accompaniment that the junior inspector, although qualified by training, was inexperienced in performing inspections of this type. The observations and comments of the NRC IMPEP reviewer, as stated in the draft report, were valid. However, the team concluded in retrospect that the observations were consistent with the experience level of the inspector. Further, during the follow-up**



**accompaniments, the performance of the inspector was adequate when conducting inspections of the type he normally does. Given the circumstances, the team concluded that the observations and comments from the first accompaniment do not contribute to the overall evaluation of the program, and should be removed from the final report. This removal does not, however, reduce the accuracy of the observations, nor signify that the team fully concurs with the Bureau's comments.**

Comment 7: Technical Quality of Inspections - 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.

Response: The review team agrees that the description "use a combination of compliance and performance based inspection techniques" is a more complete description of the inspector's performance and that the proportion of effort may reasonably change depending on the circumstances encountered in individual inspections. The language in the report will be clarified, but documentation of the performance as evaluated will be retained.

Comment 8: Technical Quality of Inspections - Section 3.2, page 8, 2<sup>nd</sup> 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.

#### Response

Factual documentation of reviewer observations in the report does not presume significant deficiencies in the reviewed program. The team noted, discussed, and documented certain observations, but did not conclude that a programmatic deficiency existed and therefore did not offer any recommendations on the observations.

The team notes that under certain conditions, NRC inspectors may issue a Form 591 for a clear inspection. However, other documentation may be required in the inspection file. While the pilot project referenced, TI 2800/033, does seek in part to reduce documentation requirements, States are not required to use it. A State wishing to use TI 2800/033 should

adopt temporary procedures and documentation similar to those in the TI. In any case, where checklists guide an inspector to document an observation, the checklist should be completed or an explanation given. There will be no change to the report based on this comment.

Comment 9: 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.

#### Response

The comment offers two criteria (sound basis and adequate assessment) and two data points (no enforcement action overturned and a favorable review). The team adds data points for past reviews, and the mis-assignment of a junior inspector to an inspection which the Bureau does not consider him qualified to perform. While unusual circumstances may contribute to an error, ultimately it is the regulatory program's responsibility to assure that an inspector is qualified for the inspection to be conducted, just as it is a licensee's responsibility to assure that a materials user is qualified for the evolution undertaken. Finally, considering the inevitable effect of staff shortage on program quality, the team does not agree that the review is unreasonably biased, or that the report is unfair. Other than as previously described, the final report is unchanged.

Comment 10: 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.

#### Response

The review team browsed through all incident reports and selected specific files for in-depth reviews. Thus the comment is based on more than just the cases summarized for the IMPEP report. The team's observation is minor, however, since in some of the cases reviewed a simple statement detailing the reason for not having a dose estimate or calculation might well have been sufficient. This language will be removed from the report.

Comment 11: 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.

Comment 12: 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.

#### Response to Comments 11 & 12

See Response to Comment 8.

Comment 13: Appendix C, File # 9 comment “c” regarding the Nebraska inspection is not relevant to the Kansas IMPEP

Response

The State of Nebraska inspected the licensee under reciprocity on 1/12/01 and cited eight violations. The review team initially included this comment in the report because it may be reflective of the licensee's performance in-State. However, the licensee is not overdue for their next inspection according to NRC Priority. The comment will be removed from the report.

Comment 14: Appendix C, 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.

Response

See Response to Comment 8.

Comment 15: 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.

Comment 16: Inspector accompaniment No. 1 (page C.4)

- 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.

Comment 17: Inspector accompaniment No. 1 (page C.4)

- 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.

Comment 18: Inspector accompaniment No. 1 (page C.4)

- e) My independent discussions with both inspectors indicate these took place in the presence of the reviewer.

Comment 19: Inspector accompaniment No. 1 (page C.4)

- 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.

Response to Comments 15 - 19

See Response to Comments 3-6.

Comment 20: 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.

Response

The report will be revised to include this information.

Comment 21: 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.

Response

See Response to Comment 8.

Comment 22: 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.

Response

The report will be revised to include this information.

Comment 23: 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.

Response

The team chooses not to distinguish between an "expanded NMED" and a database similar to NMED. There will be no change to the report due to this comment.