Mr. Clyde D. Graeber, Secretary Kansas Department of Health and Environment 1000 SW Jackson Topeka, KS 66612-1366

Dear Mr. Graeber:

On November 22, 2002, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Kansas Agreement State Program. The MRB found the Kansas program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendations for the State of Kansas. We request your response to the recommendations within 30 days of your receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years. While the Bureau has acted to alleviate the short-term staffing problem, the team and the MRB are concerned that long-term stability in hiring, training and retaining staff has not been achieved. Therefore, the MRB requested that periodic conference calls take place with the appropriate Kansas and NRC staffs to discuss the status of the program and that the results of these calls be presented at MRB meetings.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. We appreciate your continued support for the Radiation Control Program and I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello Deputy Executive Director for Materials, Research and State Programs

Enclosure: As stated

cc: Ronald Hammerschmidt, Division Director
Division of Environment
Department of Health and Environment

Thomas A. Conley, KS

William Sinclair, UT OAS Liaison to MRB

Mr. Clyde D. Graeber, Secretary Kansas Department of Health and Environment 1000 SW Jackson Topeka, KS 66612-1366

Dear Mr. Graeber:

On November 22, 2002, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Kansas Agreement State Program. The MRB found the Kansas program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendations for the State of Kansas. We request your response to the recommendations within 30 days of your receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years. While the Bureau has acted to alleviate the short-term staffing problem, the team and the MRB are concerned that long-term stability in hiring, training and retaining staff has not been achieved. Therefore, the MRB requested that periodic conference calls take place with the appropriate Kansas and NRC staffs to discuss the status of the program and that the results of these calls be presented at MRB meetings.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. We appreciate your continued support for the Radiation Control Program and I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello

Deputy Executive Director

for Materials, Research and State Programs

Enclosure: As stated

cc: Ronald Hammerschmidt, Division Director

Thomas A. Conley, KS

Division of Environment

Department of Health and Environment

_

William Sinclair, UT OAS Liaison to MRB

Distribution:

DIR RF

KSchneider, STP

LRakovan, STP

DCD (SP01) PDR (YES/) bcc: Chairman Meserve

Commissioner Dicus

Commissioner Diaz

JZabko, STP/ASPO FCameron, OGC Commissioner McGaffigan DCool, NMSS/IMNS VCampbell, RIV Commissioner Merrifield

RStruckmeyer, NMSS/IMNS GMorell, RIV

KWeaver, CO RLeonardi, RIV STreby, OGC JLieberman, OGC

Kansas File ML023400619

DOCUMENT NAME: G:\IMPEP\2002 KS Final Report and Letter2.wpd

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	STP	STP:DD	STP:D	DEDMRS	
NAME	RBlanton:kk	JMPiccone	PHLohaus	CJPaperiello	
DATE	12/2/02	12/5/02	12/5/02	12/13/02	

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF KANSAS AGREEMENT STATE PROGRAM

April 23 - 26, 2002

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Kansas Agreement State program. The review was conducted during the period April 23 - 26, 2002, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Colorado. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of June 20, 1998 to April 26, 2002, were discussed with Kansas management on April 26, 2002. Subsequent to additional inspector accompaniments conducted June 12-14, and July 18, 2002, revised preliminary results were discussed with Kansas management in a telephone conference on September 3, 2002.

A draft of this report was issued to Kansas for factual comment on September 23, 2002. The State responded by letter dated October 30, 2002. The Management Review Board (MRB) met on November 22, 2002 to consider the proposed final report. The MRB found the Kansas radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Kansas Agreement State program is administered by the Department of Health and Environment (the Department). The Secretary of Health and Environment manages the Department and reports directly to the Governor. The day-to-day operations of the program are managed by the Bureau of Air and Radiation (Bureau). Radiation control program staff are located in the Radiation and Asbestos Control Section (the Section) of the Bureau, under the Materials Supervisor. Organization charts for the Department are included as Appendix B. At the time of the review, the Kansas Agreement State program regulated 325 specific licenses authorizing Agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Kansas.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the Bureau on January 29, 2002. The Bureau provided its response to the questionnaire on April 4, 2002. A copy of the completed questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML022550488.

The review team's general approach for conduct of this review consisted of: (1) examination of the Bureau's responses to the questionnaire; (2) review of applicable Kansas statutes and regulations; (3) analysis of quantitative information from the Bureau's licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniment of two Bureau inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the program's performance.

Section 2 below discusses the program's actions in response to recommendations made following the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on June 19, 1998, the review team made 18 recommendations. These were transmitted to Mr. Gary Mitchell, the Department Secretary, on September 23, 1998. During the follow-up review, which concluded June 17, 1999, the review team closed three recommendations and made one new recommendation.

The team's review of the current status of the recommendations is as follows:

1. Based on the record of overdue inspections during the review period, the review team recommends: (1) that Kansas heighten its management oversight of the inspection due dates of core licenses (Priority 1, 2, and 3 licensees) to ensure inspections are performed at the required frequencies; and (2) that the new inspection tracking system then under development include provisions for flagging initial inspections at an early date to ensure they are inspected within 6 months of date of license issuance. In addition, Kansas should consider updating procedure RHS-7 to incorporate procedures on initial inspections as stated in NRC Inspection Manual Chapter (IMC) 2800, Section 04.03 a. (Section 3.1)

Current Status: (1) A written policy for increased management oversight was developed and implemented. The backlog of overdue inspections was eliminated and has not recurred. (2) The Bureau developed a radioactive materials licensing information database which incorporates the recommended provisions for flagging new inspections. The procedure RHS-7 was revised. This recommendation is closed.

2. The review team recommends that the State's "Inspection Priority System" be revised for reciprocity inspections to correspond to the inspection goals in IMC 1220. (Section 3.1)

Current Status: The Bureau has revised the procedure and incorporated the IMC 1220 goals. This recommendation is closed.

3. The review team recommends the State conduct reciprocity inspections at intervals equal to those stated in IMC 1220. (Section 3.1)

Current Status: The 1998 team noted that Kansas procedure RHS-7 listed reciprocity inspections as a Priority 5, to be conducted as resources allowed. The Bureau changed the procedure such that reciprocity inspections now have priorities based on the license type, as does IMC 1220. This recommendation is closed.

4. The review team recommends that the inspection report form be strengthened by including names of individuals contacted and interviewed in greater detail. (Section 3.2)

Current Status: Bureau staff implemented an inspection tracking program in the radioactive materials database. The database generates inspection reports and stores inspection data. The Bureau developed an electronic inspection form with fields for listing the persons interviewed and those present at the exit meeting. Inspection data is entered directly from the form into the database. This recommendation is closed.

5. The review team recommends that Kansas provide direction to the inspection staff to help them identify poor licensee performance, identify when licensee root cause evaluations should be conducted, and to help them assess licensee root cause evaluations. Staff members' skills could also be improved by attending a training course that teaches these techniques as part of the inspector qualification process. (Section 3.2)

Current Status: The radioactive materials database incorporates features to track and trend specific items of noncompliance. This facilitates identification of poor licensee performance and assists in determining when to perform root cause evaluations. The two fully qualified inspectors have completed root cause training. This recommendation is closed.

6. The review team recommends that the State continue to maintain management oversight of the inspection program. (Section 3.2)

Current Status: The radioactive materials database significantly strengthened oversight of the program. The Materials Supervisor receives timely status reports, and reviews and initials the inspection reports and compliance letters. This recommendation is closed.

7. The review team recommends that the State document a training and qualifications program equivalent to that contained in the "NRC/OAS Training Working Group Recommendations for Agreement State Training Programs," as appropriate, assess the current training needs of all radioactive materials staff, and provide the necessary training to ensure that all staff are properly trained to complete assigned tasks. (Section 3.3)

Current Status: The Bureau adopted, documented, and implemented a training and qualifications program consistent with the recommendations in the Working Group Report. Training is provided through a combination of NRC courses, and workshops and courses arranged using other resources. Staff attend these courses as funds are available. The Bureau developed a database to monitor training status, which the team reviewed. All Kansas staff, except one recent hire, meet the qualifications criteria for their primary assignments. This recommendation is closed.

8. The review team recommends that program management consider increasing supervisory oversight to ensure that all pertinent items are adequately and properly

addressed during the review process to provide quality assurance and to improve the technical quality of licenses. (Section 3.4)

Current Status: The Bureau has increased supervisory oversight by using a two-tier supervisory review of all licensing actions. The Materials Supervisor and the Section Chief review completed licensing actions. Both sign the license document. This recommendation is closed.

- 9. The review team recommends that the State conduct a self-evaluation of all existing licenses to determine the technical quality and to identify potential health and safety issues. This evaluation should be accomplished as soon as possible to identify and correct other possible license deficiencies. In addition, the State should ask the licensee to supply copies of any missing documents that should be included with the application. (Section 3.4)
 - Current Status: The comprehensive review of all licenses was completed. No health and safety issues were identified by the review. This recommendation is closed.
- 10. The review team recommends that the Radiation Control Program update the license guidance to address and parallel the current Kansas Radiation Protection Regulations to assist in the consistency and accuracy of the license review process. (Section 3.4)
 - Current Status: This recommendation was closed in the 1999 follow-up IMPEP report.
- 11. The review team recommends that licensing check lists be developed, used, and retained in the file to ensure that all elements of the application have been submitted and that the license is complete. (Section 3.4)
 - Current Status: This recommendation was closed in the 1999 follow-up IMPEP report.
- 12. The review team recommends that the State place documentation of any pre-licensing visits in the appropriate licensing file. (Section 3.4)
 - Current Status: This recommendation was closed in the 1999 follow-up IMPEP report.
- 13. The review team recommends that the State revise their incident response procedure to conform with the NRC Office of State and Tribal Programs (STP) Procedure SA-300, including medical events. (Section 3.5)
 - Current Status: The team reviewed Kansas procedure RHS-35, "Investigation Procedures," dated April 3, 2002. The procedure outlines actions and establishes responsibilities for the investigations. It directs staff to follow STP Procedure SA-300 for NRC reportable events. This recommendation is closed.
- 14. The review team recommends that a system be established to track the progress of incident investigations and to verify that each investigation is evaluated by management, that all reporting requirements are met, that follow-up actions and close-out information are documented. (Section 3.5)

Current Status: The Section developed and implemented a database program similar to the NRC Nuclear Material Events Database (NMED). The team determined that the Kansas events database satisfies the 1998 recommendation. The recommendation is closed.

- 15. The review team recommends that the inspection procedure be revised to include narrative documentation of the inspector's review of incidents and description of the licensee's corrective actions. (Section 3.5)
 - Current Status: With the implementation of the inspections database, the inspection checklist now includes a specific item for documenting the inspector's review of incidents and corrective actions. This recommendation is closed.
- 16. The review team recommends the State send copies of final close-out reports to the NRC in accordance with the STP Procedure, "Reporting Material Events SA-300." (Section 3.5)
 - Current Status: The 1998 team found that four reportable events were initially reported to NRC. However, close-out information was not provided unless NRC specifically asked. The Section responded to this recommendation by sending final close-out reports to NRC on August 20, 1998. The current team found that the State database prompts close-out reports to NRC and NMED. This recommendation is closed.
- 17. The review team recommends that the State review and amend all remaining industrial radiography licenses with license conditions necessary to meet the "Safety Requirements for Industrial Radiographic Equipment" requirement, and expedite adoption of the rule which was due January 10, 1994. (Section 4.1.2)
 - Current Status: The recommended review is complete. In addition, all industrial radiography licenses were amended to include a license condition requiring the two-man rule. This recommendation is closed.
- 18. The review team recommends that the State compare the Kansas regulations involved with the "Low-Level Waste Shipment Manifest Information and Reporting" and "Radiation Protection Requirements: Amended Definitions and Criteria" amendments against the final NRC rules and make any necessary changes to ensure compatibility. (Section 4.1.2)

Current Status: The Kansas staff reviewed the regulations and found no compatibility issues. The team notes, however, that the comparison was made to Part 20 Appendix F rather than Appendix G. Appendix F was removed and Appendix G became effective and required for compatibility on March 1, 1998. The Department is adopting Appendix G in their current rulemaking, and implementing the requirements by license condition in the interim. This recommendation is closed.

One new recommendation was added in the 1999 follow-up IMPEP report:

The review team recommends that the State complete a thorough review as well as a supervisory or quality assurance review of all licensing actions to ensure that each license is complete in accordance with Kansas guidance. (Section 2.1)

Current Status: As noted in regard to recommendation 8, above, the Bureau developed a two-tier supervisory review of all licensing actions. This recommendation is closed.

During the 1998 review, two suggestions were made for the Bureau to consider. The team determined that the Bureau considered the suggestions and took appropriate actions.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on the Bureau's questionnaire responses relative to this indicator, data gathered independently from the radioactive materials database, the examination of complete licensing and inspection casework, and interviews with managers and staff.

The team's review of the inspection priorities list verified that priorities for material licenses are the same as, or higher than, those listed in IMC 2800. The Bureau occasionally adjusted the inspection frequency based on the compliance history of the license, more often to increase rather than decrease inspection frequency. The team confirmed that deviations from inspection schedules are coordinated between staff and management. Routine inspections in western Kansas, which come due during November through March, are intentionally deferred to avoid travel during winter weather conditions.

In their response to the questionnaire, the Bureau indicated that there were four overdue inspections of core licensees. Two of those inspections were intentionally delayed by the Bureau as candidates for accompaniment during the review. At the time of the review, the team noted six overdue core inspections. Examination of the radioactive materials database revealed that 18 of 183 core inspections were overdue when completed, but only seven of these were in the last two years.

The review team also determined that all initial inspections of new licenses were performed in a timely manner. For new licensees, the Bureau designated the initial inspections as Priority 0.5. This resulted in a due date appearing in the radioactive materials database for the second calendar quarter following license issuance.

The team calculated the percentage of overdue inspections to be 12.7% by the usual formula. Although this number exceeds the nominal 10% overdue criterion for a satisfactory finding, the team considered three mitigating factors. First, the Bureau intentionally deferred inspections to avoid travel in winter weather conditions, and two inspections were deferred for use as accompaniments by the review team. Second, the team notes an improving trend after the implementation of the radioactive materials database. Third, the team identified the staffing problem discussed in Section 3.3 as a root cause for the six core inspections overdue at the time of the review. The team concludes that the Program should be given credit for factors one and two, and that the third factor should be addressed in Section 3.3.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. The Bureau has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. A monthly report by the Materials Supervisor indicates the average time required to mail out inspection letters. For 2000-2002, inspection letters were sent within a few days. For example, in March 2002, the average time to issue inspection findings was one day.

During the review period, the Bureau granted reciprocity permits to 101 core licensees based on IMC 1220. The core licensees consisted of 82 Priority 1 licensees including 16 service licensees performing teletherapy and irradiator source installations or changes, and 19 Priority 2 licensees. Kansas met the IMC 1220 criteria only in 1999. In the year 2000, they met the criteria for Priority 1 licensees, but not service licensees or Priority 2. The Bureau attributed the shortfall to the difficulty of reaching sites in Western Kansas where the majority of activities under reciprocity are conducted. The team notes that the Bureau did meet the revised criteria in Temporary Instruction 1220/001 for each year except 2001, when six inspections were due but only two were completed. The review team believes this shortfall was primarily due to the Bureau's limited staffing.

Based on the IMPEP evaluation criteria, the review team recommends that Kansas' performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.2 <u>Technical Quality of Inspections</u>

The team evaluated the inspection field notes, inspection reports, enforcement documentation and interviewed inspectors for 14 radioactive materials inspections conducted during the review period. The casework covered four materials' inspectors, including one inspector that left the program during the review period. The casework included inspections of various types as follows: industrial radiography, medical broad scope, nuclear pharmacy, limited medical, well logging and portable gauging licensees. Appendix C lists the inspection casework files reviewed, with case-specific comments.

On April 21 and 22, 2002, the team accompanied two Bureau inspectors to a large medical licensee with a radiopharmacy. The accompaniment focused primarily on the junior inspector, who had not previously been accompanied during an IMPEP review. The team learned later, however, that the inspector was not qualified by the Bureau to inspect large medical programs. He normally inspected fixed and portable gauges, and other small industrial licensees. The team concluded that the inspector's performance was not accurately reviewed because he was

assigned an inspection for which he was not qualified. The team determined that this inspection resulted from a mis-communication between the team and the Bureau.

The review team, therefore, determined that additional inspector accompaniments should be conducted to evaluate the inspectors' performance. On June 12-14, 2002, the team accompanied the senior inspector at a medical center. On July 18, 2002, the team accompanied the junior inspector at a portable gauge licensee and a licensee using an industrial x-ray analyzer. The facilities inspected are identified in Appendix C. Both of the Bureau's inspectors followed the Bureau's procedures and guidance during these inspections. Each inspector demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were trained, well prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. Each inspector conducted confirmatory measurements, and utilized good health physics practices. Their inspections were adequate to assess radiological health and safety at the licensed facilities. The team evaluated the performance of both inspectors on these inspections as very good. The team noted that the inspectors used a combination of compliance and performance based inspection techniques. The team discussed with the inspector, the benefits of conducting performance-based inspections.

The casework review found that inspection reports were in checklist format and had space for narrative information in all inspection areas. Completed inspection reports were entered into the Bureau's radioactive materials database. The database was used to generate the inspection reports that are issued to licensees. The team observed documentation deficiencies in these inspection reports. Of the 14 database inspection reports reviewed, four did not document inspector observation of licensed activities. Three did not document interviews with personnel authorized to use licensed material. Two reports did not list licensee personnel attending the entrance or exit briefing and two did not indicate that independent and confirmatory surveys were conducted. None of these inspection reports discussed the relative safety significance or root causes of the violations. Bureau hard-copy documentation addressed some deficiencies in the database. The team discussed the documentation issues with the Bureau staff.

The team believes that the Bureau's staffing level was a root cause of the inspection program issues, including the documentation issues. Because of the short staffing, inspectors tend to economize on documentation of observations of licensee performance in order to maintain inspection frequencies. The team noted that the Bureau's radioactive materials database was a significant resource for improving the efficiency and effectiveness of the inspection program when the data was complete. Staffing is discussed further in Section 3.3.

The Materials Supervisor accompanied each materials inspector annually, and adequately documented the accompaniments. The team noted that at the time of the review, the Bureau had three experienced materials inspectors. One was the Materials Supervisor, and the other was a recently hired inspector in training. Team inspections were conducted when appropriate.

The Bureau had an adequate number and types of survey meters to support the inspection program, as well as for responding to incidents and emergency conditions. Appropriate calibrated survey instruments such as GM meters and micro-R meters were observed.

Based on the IMPEP evaluation criteria, the review team recommends that Kansas' performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.3 <u>Technical Staffing and Training</u>

Issues central to the evaluation of this indicator include the Bureau's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Bureau's questionnaire responses relative to this indicator, interviewed the Materials Supervisor and staff, and considered any possible workload backlogs.

The Section Chief supervises three administrative staff and three unit supervisors. The Materials Supervisor is responsible for the radioactive material and x-ray programs, and supervises technical staff members classified as radiation control inspectors.

License fees are collected and deposited in the State general fund, from which the Bureau's budget is allocated. This is significant to the performance of the program, since the Kansas general fund is facing a significant shortfall. Programs budgeted from the general fund are restricted from travel outside the State.

The review team found that the Section, when fully staffed, devotes approximately 4 full time equivalents (FTE) of staff effort to the Agreement Materials Program. Of this, 1.25 FTE is administrative and supervisory consisting of one Section Chief (0.3 FTE); the Materials Supervisor (0.8 FTE); one Program Consultant (0.15 FTE). The staff effort consists of three Radiation Control Inspectors (with a combined level of 2.70 FTE).

There were a total of six turnovers during the review period. The earlier vacancies were filled quickly. As of April 26, 2002, the Section had two vacancies. The Section Chief position became vacant April 19, 2002 and the Program Consultant position in March 2002. The Bureau Chief expected to fill the positions within two months. However, the team learned after the review that the Materials Supervisor was promoted to the Section Chief position, and that the newest inspector resigned from the program. In addition, the supervisor for Emergency Planning left the Department.

The decommissioning of the Coleman facility in Wichita has been a significant resource drain on the Section. The Materials Supervisor spent at least 0.15 FTE in FY 2002 on oversight and technical review of the decommissioning activities at this facility. In addition, the newest inspector's time was almost exclusively dedicated to the project.

The Bureau developed and implemented a training and qualification program consistent with the recommendations in the NRC/OAS Training Working Group Report. They also established a database tracking system for staff training. Materials inspectors are required to have bachelor's degrees or equivalent training in the physical and/or life sciences. Before

performing assigned tasks independently, new hires work with senior staff and under the guidance of the Materials Supervisor until appropriate training and experience is received. However, due to staffing constraints and the Coleman decommissioning in FY 2002, the newest inspector participated in only a small amount of on the job training.

The Bureau uses non-NRC training courses to supplement the training curriculum so that individuals may broaden their work areas. Training courses are provided by device manufacturers and academic institutions within the State. Department management is aware that the inability to participate in out-of-State NRC training courses may further degrade the technical quality of the program over time.

During the review, the Bureau had only two staff members fully qualified to perform license reviews and inspections. One of the staff members functions primarily as license reviewer and conducts approximately five inspections per year. The other conducts the majority of the inspections, occasionally as many as 15 - 20 inspections per month. The team concluded that the lack of adequate staff was a root cause of issues observed in other indicators. The team noted that the Kansas staff, with 2.7 FTE for licensing and inspection of 325 licensees, was unusually small even at full strength.

Since a third technical staff member (the newest inspector) was in training, the team determined that the Bureau had a marginally adequate number of qualified personnel to carry out the Agreement Materials Program. The team discussed with the Department management the problems observed as related to the staffing shortage. Shortly after the completion of the onsite portion of the review, the third technical staff member departed from the Program. At that point, the team became concerned that absent strong corrective action, the Kansas Agreement Materials Program would be unable to protect public health and safety. Subsequently, the Bureau received authorization to fill the positions despite a statewide hiring freeze. As of August 17, 2002, the Bureau has interviewed and filled three of the vacant positions.

The team remains concerned that the Bureau may not be able to complete the training and qualification of the new staff in an appropriate period of time, due to continuing fiscal constraints. The team discussed, with Bureau and Department management, fiscal strategies that have been successful in other States. The Department requested legislative approval of similar strategies in prior years, and plans to request them again. The team recommends the State ensure that the Agreement Materials Program has adequate resources and an adequate complement of qualified staff.

Based on the IMPEP evaluation criteria, the review team recommends that Kansas' performance with respect to the indicator, Technical Staffing and Training, be found satisfactory with recommendations for improvement.

3.4 <u>Technical Quality of Licensing Actions</u>

The review team examined completed licensing casework and interviewed the staff for 15 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for

licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data.

Licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following types: academic (limited specific and broad scope), medical (institution, mobile, and private practice), gauge (fixed and portable), industrial radiography, well logging, radiopharmacy, and veterinary nuclear medicine. Licensing actions included two new licenses, five renewals, four amendments, and four terminations. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were usually stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. Reviewers appropriately used the Bureau's licensing guides, license templates, standard conditions and checklists. No potentially significant health and safety issues were identified.

Licensing actions were tracked via the amendment tracking system in the radioactive materials database. The Office Assistant initially entered the appropriate information for each licensing action into the database. The actions were then assigned to a license reviewer. The amendment tracking system followed the status of licensing actions throughout the process. Good communication between staff was realized via the amendment tracking system. The license reviewer documented issues in the database during the review process. This system enabled other staff to efficiently address licensees' questions regarding the status of actions when the assigned reviewer was not available.

The review team found that staff followed appropriate licensing guides to ensure that licensees submit information necessary to support the request. The review team found the generic checklists to be comprehensive, and when used in conjunction with the appropriate guidance documents, provided consistency between staff. Letters and documented telephone conversations contain appropriate regulatory language and address deficiencies. The use of license templates by the staff also results in consistency between reviewers. Bureau staff identified changes resulting from each licensing action to the licensee by bolding text in the license document.

The team found that terminated licensing actions were well documented. The files included the appropriate material transfer records and survey records. Confirmatory surveys for license terminations were conducted when appropriate. An evaluation of selected termination records revealed excellent communication between staff to prevent abandonment of radioactive material. The files showed that documentation of proper disposal or transfer was provided.

Licenses have two year terms. A simple renewal is granted every two years. However, licenses are renewed in their entirety either after ten years or after five amendments. Licenses under timely renewal are amended as necessary to assure that public health and safety issues are addressed. Deficiencies are addressed by letters and documented telephone conferences, which use appropriate regulatory language. Licensing actions undergo a two-tier management review prior to issuance. All licenses are reviewed and signed by both the Materials Supervisor and the Section Chief.

The review team determined that the Bureau had not fully implemented the financial assurance requirements adopted by the State in 1996. The team's examination of licenses disclosed that several licenses authorized radioactive material in the types and quantities requiring financial assurance documents. However, the licensees had not addressed the financial assurance requirements. The review team recommends that the Section review all Kansas' licenses to ascertain if they require financial assurance, and take appropriate action on each affected license to ensure that all licenses meet the State's financial assurance requirements.

Based on the IMPEP evaluation criteria, the review team recommends that Kansas' performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Bureau's actions in responding to incidents, the review team examined the Bureau's response to the questionnaire relative to this indicator, and evaluated selected incidents reported for Kansas in NMED against those contained in the Kansas files, and evaluated the casework and supporting documentation for 11 material incidents. A list of the incidents examined is included in Appendix E. The team also reviewed the Program's response to six allegations involving radioactive materials including two allegations referred to the Program by the NRC during the review period.

The 11 incidents selected for review included the following categories: overexposure, loss or theft of radioactive material, release of radioactive material, misadministration, contamination event, equipment failure, and deliberate misconduct. The review team found that the Bureau's response to incidents was generally complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Bureau dispatched inspectors for onsite investigations when appropriate, and took suitable enforcement and follow-up actions.

The review team discussed the Bureau's event and allegation procedures, tracking system, file documentation, the NMED, and notification of incidents to the NRC Operations Center with Program management and staff. The Bureau's event procedures include the reporting requirements to NRC from STP Procedure SA-300, "Reporting Material Events."

Kansas' incident and allegation response procedure appropriately lists steps to be followed by professional staff while conducting an investigation in RHS-35, *Investigation Procedures*, April 3, 2002. Kansas staff took appropriate actions to ensure that response to incidents or

allegations was coordinated and timely, including initial response by the person receiving notice, investigation, and review by supervisory staff prior to closeout.

As noted in Section 2.0, the Bureau developed and implemented a database program similar to the NRC NMED. The information provided by the Kansas events database was generally complete and accurate. However, in several instances data were missing, for example, selection boxes were not checked. This occurred, in part, because a database entry was made prior to having complete data. The team discussed, with the Materials Supervisor, the flagging of records with missing information for completion prior to incident closeout.

The Bureau documented 44 Agreement materials events during the review period. Event records were in files for 1998 and 1999, and in the Kansas events database for 2000-2002. For the review period, 19 of the 44 events were required to be reported to the NRC NMED system in accordance with STP Procedure SA-300, "Reporting Material Events." All required reports were submitted.

In a few cases, the Kansas events database records were missing key information. For example, in four of the 44 cases, the record did not indicate the radionuclide involved, or alternatively contain a finding that the radionuclide was unknown.

During the review period, the Bureau received six allegations involving Agreement material, two of which were from the NRC. The team reviewed the casework for all six allegations. The casework indicated that the Bureau's level of effort in responding to allegations was commensurate with potential health and safety significance. The Bureau took prompt and appropriate action in response to the concerns raised and appeared to have appropriately protected the alleger's identity. The allegations were treated and documented internally in the same manner as events. No performance issues were identified in the team review of allegation files and documentation.

Based on the IMPEP evaluation criteria, the review team recommends that Kansas' performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Kansas' Agreement State Program does not cover uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

The Bureau gave the review team copies of legislation affecting the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in Article 16 - Nuclear Energy Development and Radiation Control Act, Kansas Statutes, K.S.A. 48-1601 to 48-1619. The Department Secretary is responsible by law for radiation control. There has been no legislation passed since the last IMPEP review that affected the radiation control program.

4.1.2 Program Elements Required for Compatibility

The Kansas Regulations for Control of Radiation, found in KAR 28-35-133 through KAR 28-35-363, apply to all ionizing radiation, whether emitted from radionuclides or devices. Kansas requires a license for possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. Kansas also requires registration of all equipment designed to produce x-rays or other ionizing radiations. To the extent practical, the Kansas regulations follow the Suggested State Regulations (SSRs) of the Conference of Radiation Control Program Directors, Inc.

Kansas has a 12 step regulation promulgation process which includes a 60-day notice for public comment prior to a public hearing. The entire process nominally takes about 36 weeks from regulation drafting to full effect. The Materials Supervisor has responsibility for maintaining the regulations.

Kansas did not promulgate any revisions to the regulations during the review period. The Department is promulgating a complete revision of the regulations with an expected effective date in December 2002. The amendments are drafted, and are under review by Agencies outside the Department. Bureau management chose to revise the regulations in whole rather than adopt individual NRC amendments partly because the required amendments entail conforming changes to a significant number of references. They also chose to address the x-ray program regulations first because those regulations were more out of date than the radioactive materials regulations.

The team reviewed the status of the regulations required for adoption by the State under the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (Policy Statement). The team compared the adoption of regulations by the State with data obtained from the STP Regulation Assessment Tracking System, and NRC Chronology tables. Interviews conducted with the staff confirmed that the Bureau uses license conditions when regulations were not adopted within the 3-year time frame. The team noted that license conditions or other legally binding requirements were being used for the following rules:

- ! "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995.
- ! "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The

Agreement States were expected to promulgate their regulations no later than March 1, 1998 so that NRC and the State would require this national system to be effective at the same time.

- ! "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995.
- ! "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- ! "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995.
- ! "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- ! "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.
- ! "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1996.
- ! "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.
- ! "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997.
- ! "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.
- ! "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28948) that became effective June 27, 1997.
- ! "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.
- ! "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.
- ! "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.

! "License for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.

- ! "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 393477 and 63 FR 45393) that became effective October 26, 1998.
- ! "Transfer for Disposal and Manifest; Minor Technical Conforming Amendments," 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998.
- ! "Radiological Criteria for License Termination of Uranium Recovery Facilities," 10 CFR Part 40, Appendix A (64 FR 17506) that became effective June 11, 1999.
- ! "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543) that became effective February 2, 2000.
- ! "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.
- ! "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001.

The review team examined eight licenses selected at random. All eight contained the appropriate license conditions required as alternatives for applicable regulations. The team concluded that the Bureau satisfactorily uses license conditions as alternatives to regulations. However, these legally binding requirements have not been submitted for NRC review. The team recommends that, when the Bureau uses legally binding requirements as alternates to rules, it submit the text of the requirements to NRC for review.

The Bureau believed that the following two regulations were found compatible at the last IMPEP. Because of this belief, license conditions were not used. This team found that the State regulations were older versions that did not incorporate the requirements added by the amendments. The 1998 IMPEP found the State's performance satisfactory based on the rule adoption extension granted through the implementation of the Commission Policy until September 3, 2000, not based on the content of the State regulations.

- ! "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994.
- ! "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767 and 65243) that became effective January 1, 1995.

The review team recommends the Bureau adopt the regulations "Timeliness in Decommissioning of Materials Facilities," and "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," or adopt generally applicable legally binding alternatives to the regulations.

The Department has not addressed the regulation "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," (65 FR 79162) parts of which were due for adoption by the Agreement States by August 16, 2001. However, the Materials Supervisor stated that currently there are no Kansas licensees authorized to distribute generally licensed devices. The remaining portions of the regulation are due by February 16, 2004.

Based on the IMPEP evaluation criteria, the review team recommended that Kansas' performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory with recommendations for improvement. At the November 22, 2002 MRB meeting, the MRB concluded that a rating of satisfactory was appropriate for this indicator due to the State's performance involving this indicator and past IMPEP precedent.

4.2 Sealed Source and Device (SS&D) Evaluation Program

At the time of the review, Kansas had no sealed source or device manufacturers nor were any applicants anticipated in the near future. The State, however, does not wish to relinquish the authority to regulate SS&D manufacturers in the future. The State has committed in writing in a memorandum to their files to have a program in place prior to performing evaluations. Accordingly, the review team did not review this indicator.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Kansas has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Kansas. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, Kansas' performance was found to be satisfactory for five common performance indicators, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Response to Incidents and Allegations, and Legislation and Program Elements Required for Compatibility. The Kansas' performance was found satisfactory with recommendations for improvement for the common performance indicator, Technical Staffing and Training. The review team recommended and the MRB concurred in finding the Kansas Agreement State program adequate to protect public health and safety and compatible with NRC's program. Although the review team recommended that the next full review be in approximately two years, the MRB directed that the next IMPEP

review be in approximately four years. While the Bureau has acted to alleviate the short-term staffing problem, the team and the MRB are concerned that long-term stability in hiring, training and retaining staff has not been achieved. Therefore, the MRB requested that periodic conference calls take place with the appropriate Kansas and NRC staffs to discuss the status of the program and that the results of these calls be presented at MRB meetings.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State.

RECOMMENDATIONS:

- 1. The team recommends the State ensure that the Agreement Materials Program has adequate resources and an adequate complement of qualified staff. (Section 3.3)
- 2. The review team recommends that the Program review all Kansas' licenses to ascertain if they require financial assurance, and take appropriate action on each affected license to ensure that all licenses meet the State's financial assurance requirements. (Section 3.4)
- 3. The team recommends that, when the Bureau uses legally binding requirements as alternates to rules, it submit the text of the requirements to NRC for review. (Section 4.1.1)
- 4. The review team recommends the Bureau adopt the regulations "Timeliness in Decommissioning of Materials Facilities," and "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," or adopt generally applicable legally binding alternatives to the regulations. (Section 4.1.1)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A **IMPEP Review Team Members**

Appendix B Kansas Organization Chart

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E **Incident Casework Reviews**

October 30, 2002 Letter from Thomas A. Conley Kansas' Response to Draft IMPEP Report Attachment

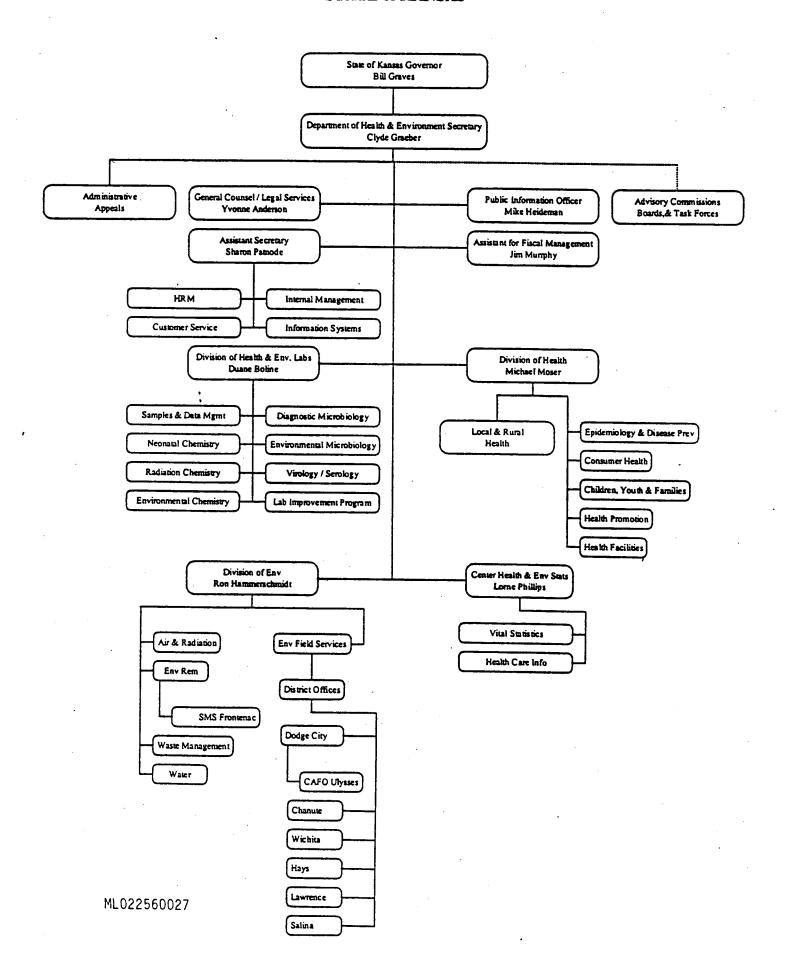
APPENDIX A

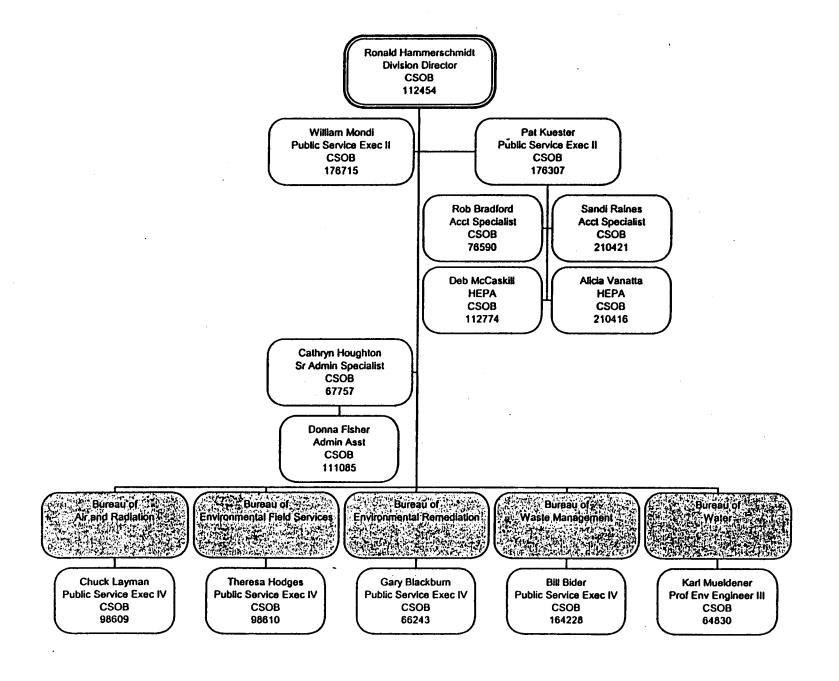
IMPEP REVIEW TEAM MEMBERS

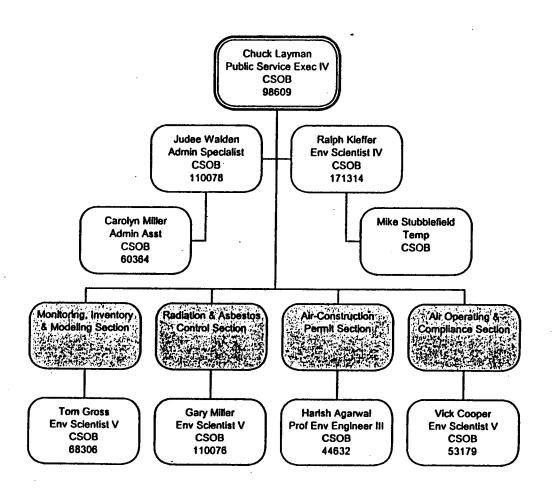
Name	Area of Responsibility
Richard Blanton, STP	Team Leader Legislation and Program Elements Required for Compatibility
Vivian Campbell, RIV	Technical Quality of Licensing Actions Technical Staffing and Training
Gregory Morell, RIV	Technical Quality of Inspections Inspector Accompaniments
Richard Leonardi, RIV	Additional Inspector Accompaniments
Kenneth Weaver, CO	Status of Materials Inspection Program Response to Incidents and Allegations

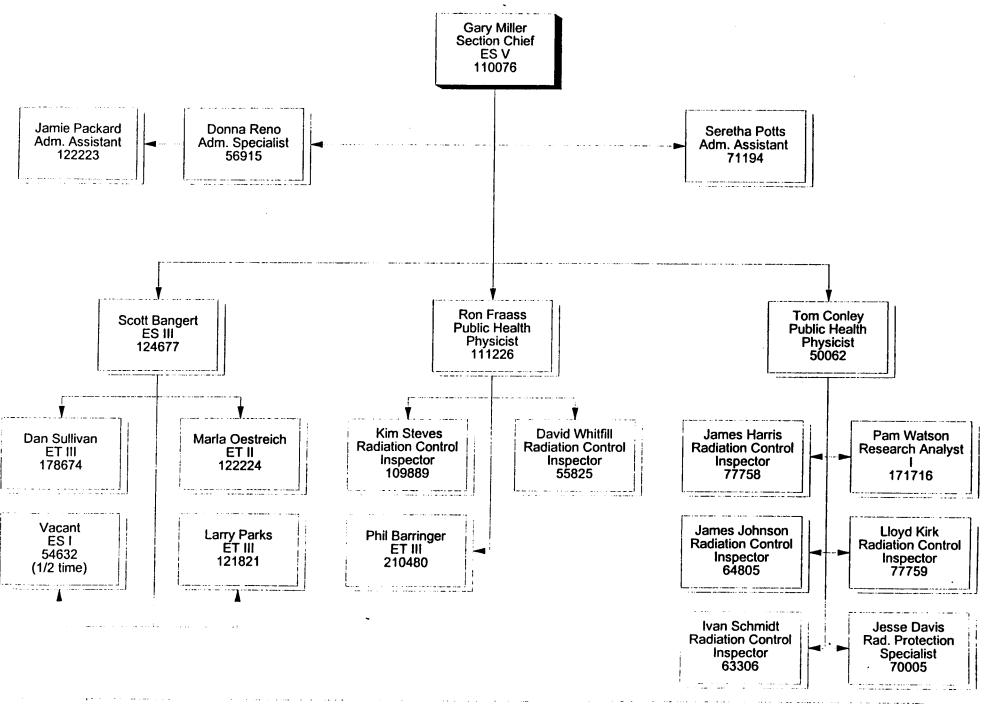
APPENDIX B KANSAS ORGANIZATION CHART ML022560027

STATE of KANSAS













ATTACHMENT

October 30, 2002 Letter from Thomas A. Conley Kansas' Response to Draft IMPEP Report

ML023100186



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. Section 1.1.

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 personhours. 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 many the second s อ้าน วาวจะระบาท 5 ค.วรทา ยา ว.วทา ยา ค.การกรณา น้ำการกมุรายหาย เจอ และเรารถแระ กรรกษายาม

Division of Environment, Bureau of Air and Radiation 'Radiation Control Program, 1000 SW Jackson, Suite 310 Topeka, Kansas 66612-1366

(785) 296-1560° FAX (785) 296-0984 http://www.kdhe.state.ks.us/radiation/

Printed on Recycled Paper



IMPEP Draft Report Comments Page 2 of 5

.:

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.

IMPEP Draft Report Comments
Page 3 of 5

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 dicensee 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.

IMPEP Draft Report Comments
Page 5 of 5

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 teonley@kdhe.state.ks.us.

Sincerely,

Thomas A. Conley, RRPT, CHP-

Section Chief, Radiation and Asbestos Control

cc: C. Layman