October 27, 2000

Mr. Jimmy D. Helton
Secretary
Cabinet for Health Services
275 East Main Street, 4th Floor West
Frankfort, Kentucky 40621

Dear Mr. Helton:

On October 24, 2000, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Kentucky Agreement State Program. The MRB found the Kentucky program adequate to assure public health and safety and compatible with NRC's program.

Section 5.0, pages 15 and 16, of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to the recommendations within 30 days from the receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. 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 and Tribal Programs

Enclosure:
As stated

cc: See next page

cc: Rice C. Leach, M.D.
Commissioner
Department for Public Health

David Klee, Division Director
Public Health Protection and Safety Division

John A. Volpe, Ph.D.
Manager
Radiation Health and Toxic Agents Branch

Steve Collins, IL
Agreement State Liaison to
Management Review Board

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF KENTUCKY AGREEMENT STATE PROGRAM

July 17-21, 2000

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Kentucky radiation control program. The review was conducted during the period July 17-21, 2000, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of South Carolina. 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 April 20, 1996 to July 21, 2000 were discussed with Kentucky management on July 21, 2000.

A draft of this report was issued to Kentucky for factual comment on August 21, 2000. The Commonwealth responded in a letter dated September 8, 2000. The Management Review Board (MRB) met on October 24, 2000 to consider the proposed final report. The MRB found the Kentucky radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Commonwealth of Kentucky program is administered by the Radiation Health and Toxic Agents Branch (the Branch) and is located within the Cabinet for Health Services (the Cabinet). An organization chart for the Branch is included as Appendix B. At the time of the review, the Kentucky program regulated 396 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 Commonwealth of Kentucky.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Branch on March 16, 2000. The Branch provided a response to the questionnaire on June 19, 2000. During the review, discussions with the Branch staff resulted in the responses being further developed. A copy of the questionnaire responses is included as Appendix G to the proposed final report.

The review team's general approach for conduct of this review consisted of: (1) examination of the Branch's response to the questionnaire; (2) review of applicable Kentucky statutes and regulations; (3) analysis of quantitative information from the Branch's licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of three Kentucky 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 non-common performance indicator and made a preliminary assessment of the Branch's performance.

Section 2 below discusses the Branch's actions in response to recommendations made following the previous IMPEP 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 program performance by the Branch. A response is requested from the Branch to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 19, 1996, three recommendations were made and transmitted to Mr. John H. Morse, Secretary, Cabinet for Health Services, on August 12, 1996. The team's review of the current status of these recommendations is as follows:

1. The review team recommends that the Branch maintain its policy of annual supervisory accompaniments of all inspectors.

   Current Status: Annual accompaniments are performed for all inspectors. In some cases, these accompaniments are performed more frequently than annually. This recommendation is closed.

2. The review team recommends that the Branch determine the specific isotope in all incidents rather than assuming the source to be naturally occurring and accelerator produced radioactive material (NARM).

   Current Status: The Branch uses a portable germanium gamma spectroscopy system and an Exploranium GR-130 portable multichannel analyzer to perform quantitative analyses in the field. This recommendation is closed.

3. The review team recommends that the Branch continue with their plan to reassess all previously issued sealed source and device (SS&D) sheets under their regulatory jurisdiction to assure that the files contain all current background information and drawings applicable to the device safety review and to verify and document that generally licensed devices meet the current dose requirements. This is a recommendation from the 1995 review visit.

   Current Status: The Branch continued with their plan to reassess all previously issued SS&D sheets by completing the review of one device and anticipates having another device application forwarded for review in July 2000. However, because of staff turnovers and the need to train new employees for routine and reactive type inspections, the Branch elected to evaluate only the applications for device amendments that were needed to stay current with the device workload and to schedule the re-evaluations as time and resources permitted. This recommendation is closed.

During the 1996 review, one suggestion was made concerning the Cabinet obtaining necessary statutory authority to apply civil penalties as an additional enforcement action. The team determined that the Branch considered the suggestion and took appropriate action.

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 Kentucky questionnaire responses relative to this indicator, data gathered independently from the Branch's licensing and inspection data tracking system, the examination of complete licensing and inspection casework, and interviews with managers and staff.

A review of the Branch's inspection priorities revealed that the inspection frequencies for the various types of licenses are the same or more frequent than similar license types listed in NRC Inspection Manual Chapter (IMC) 2800. The Branch may also extend the inspection frequency based on the compliance history of the licensee. The Branch has a procedure whereby every three months a listing of inspections due during the next three months is provided to each inspector. The inspectors use these lists to determine their inspection schedules.

In their response to the questionnaire, the Branch indicated they had only one core inspection overdue by more than 25% of the NRC frequency and this inspection was completed prior to the team's arrival to conduct the current IMPEP review. The team determined that 41 of 250 core inspections completed since the last IMPEP review had been overdue by more than 25% of the NRC frequency. The Branch Manager explained that staffing shortages during calendar years 1996 and 1997 had prevented the Branch from completing their inspection goals. The team noted that only four overdue inspections had occurred since the first quarter of calendar year 1998.

IMC 2800 states that if a license authorizes activities to be conducted from multiple permanent field offices (satellite locations of use identified on the license), at least 50% of the field offices should be inspected at the frequency specified in IMC 2800. The review team's examination of inspection casework and the Branch's inspection manual revealed that the Branch has no written procedure to inspect permanent field offices and therefore no permanent field offices had ever been inspected by the Branch. The impact of this is minimal since the license review indicated that less than five licensees maintain permanent field offices. The review team recommends that the Branch revise their inspection manual to ensure that core licenses authorizing the conduct of activities from multiple permanent field offices are inspected at the same frequency as specified in IMC 2800.

With respect to initial inspections of new licensees, the team evaluated a list of licensing actions and determined that there were 44 new licenses issued during the review period. Although the license review determined that 19 of the initial inspections were conducted more than six months after issuance of the licenses, the team determined that only two of these instances had occurred in the last two years. The hiring of additional staff and the Branch's procedure noted

above to identify the inspections due have been highly effective in improving this aspect of the materials inspection program.

The timeliness of the issuance of inspection findings was evaluated during the inspection casework review. Of the 20 cases reviewed by the team, 18 letters transmitting inspection findings were transmitted to the licensees within 30 days following the inspection. The internal audit conducted by the Branch determined that 250 core inspections had been completed since the previous IMPEP review and identified only five cases in which inspection findings were issued greater than 30 days following the inspection. The two cases reviewed by the team were also identified in the Branch's audit.

To evaluate the Branch's reciprocity inspection program, the review team obtained a computer printout of data for the years of 1996 through May 2000. With regard to core licensees, the Branch received 16 requests for reciprocity in 1996; 11 requests for reciprocity in 1997; 14 requests for reciprocity in 1998; 14 requests for reciprocity in 1999; and 7 requests for reciprocity in 2000 (through May). The Branch performed two core reciprocity inspections in 1996, one in 1997, one in 1998, and none in 1999 and 2000. To meet the goals established in IMC 1220, the Branch was required to have completed at least 25 core reciprocity inspections. As noted above, the Branch completed only 4 core reciprocity inspections, and none since 1998. The Branch Manager explained that staffing shortages during calendar years 1996 and 1997 had prevented the Branch from completing their inspection goals and that reciprocity inspections were of lower priority relative to other inspections. He also indicated that an action plan (dated June 12, 2000) for performing the required number of reciprocity inspections had been written. The review team recommends that the Branch ensure that reciprocity licenses are inspected in accordance with the frequency criteria specified in the Branch's inspection manual.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 20 radioactive materials inspections conducted during the review period. The casework included five of the Branch's materials license inspectors, and covered inspections of various types including radiography, medical, academic, portable and fixed gauges, well logging, mobile nuclear medicine, and nuclear pharmacy. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

The inspection procedures utilized by the Branch are consistent with the inspection guidance outlined in IMC 2800. The Branch has specific inspection forms for the various types of licensees and the inspection reports are in a checklist format that adequately cover all inspection areas. Narrative reports are completed for all broad scope licensee inspections. The Radioactive Materials Section Supervisor (the Supervisor) reviews all inspection reports, and a letter documenting the inspection findings is signed by the Supervisor and issued after each inspection.

It was noted that Kentucky has an adequate number and types of survey meters to support the current inspection program. Calibrated survey instruments such as GM meters, scintillation detectors, ion chambers and micro-R meters were observed in the meter cabinet. Inspectors are not assigned meters, but check out an appropriate meter for the inspection they are performing. The meters are calibrated by the manufacturer or a properly licensed facility. The task of ensuring the survey meters are calibrated has been assigned to a senior member of the inspection staff. The Branch also oversees a Radiation/Environmental Monitoring Section which maintains a well equipped and adequately staffed radiochemistry laboratory facility.

Based on casework, the review team noted that the routine inspections covered all aspects of the licensee's radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety were acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

During the review period, inspector accompaniments were performed by the Supervisor on each member of the inspection staff at least annually during calendar years 1996, 1998, 1999 and 2000. The Branch Manager stated that staff shortages did not permit accompaniments during calendar year 1997. The inspectors employed by the Branch during 1997 were experienced and had all been accompanied during 1996. The Branch Manager re-initiated accompaniment efforts in January 1998. The review team considered this approach acceptable.

Three Radioactive Materials Section inspectors were accompanied during inspections by a review team member during the period of April 24-27, 2000. The accompaniments included a nuclear pharmacy, one institutional nuclear medicine, and one broad nuclear medicine licensee. These accompaniments are also identified in Appendix C.

During the accompaniments, each inspector demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were trained, prepared, and thorough in their audits of the licensees' radiation safety programs. Overall, each inspector utilized good health physics practices, their interviews with licensee personnel were performed in an effective manner, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

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

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Branch'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 Branch's questionnaire response relative to this indicator, interviewed program management and staff, and considered any possible workload backlogs. The team noted that Kentucky does not have a radiation oversight board.

The Branch Manager supervises the activities of the Radioactive Materials Section, the Radiation

Producing Machines Section, and the Environmental Monitoring Section. Information provided by the Branch indicates that 3 of the 4 staff in the Radioactive Materials Section departed during the review period. The three positions were filled within 9, 13, and 2 months of becoming vacant. The Branch Manager also informed the team that a new Branch position, approved in 1999, is not yet filled because he is determining how to integrate the position into one or more of the Branch's sections.

The review team found that the current staffing level is adequate to administer the basic regulatory program, as evidenced by the significant reduction of backlogs in inspections and lack of backlogs in licensing. However, according to the Branch Manager, providing support on issues concerning the Paducah Gaseous Diffusion Plant currently requires approximately 50% of his time. Furthermore, complex licensing and compliance cases, complicated investigations, specialized training needs, and frequent revisions to regulations continue to require the use of overtime and delayed leave usage by the supervisors and staff. The Branch Manager indicated that he anticipates the Supervisor becoming a part-time employee (4 days per week) in the near future and retiring in the latter part of 2001. He also stated that a senior Materials Specialist retired from the Branch on July 31, 2000 and that the vacancy was immediately filled by a junior Materials Specialist from within the Branch. The resulting junior Materials Specialist vacancy is expected to be filled by the end of 2000.

The licensing and inspection functions of the program are integrated such that all Materials Specialists perform duties in licensing, inspection, and event response. Balance between the licensing and inspection functions is achieved by basing staff assignments on program needs. Technical staffing and training for the SS&D program is addressed in Section 4.2.2. Technical staffing and training for the low-level radioactive waste disposal program is addressed in Section 4.3.3.

From Branch Manager interviews and review of the job descriptions, the team determined that successful candidates for technical positions are required to have a Bachelor's degree in science, or an equivalent, for entry level positions and a Master's degree and/or additional radiation-related work experience for steps beyond the entry level. From review of the technical qualifications of the current Radioactive Materials Section staff, the team concluded that the Branch has been able to recruit qualified individuals. All of the Materials Specialists and the Supervisor have Bachelor's degrees in science; and the Branch Manager has a Ph.D.

The Branch has a written training program for license reviewers and inspectors which is based upon the requirements specified in IMC 1246 and the Final Report of the NRC/OAS Training Working Group Recommendations for Agreement State Training Programs (the NRC/OAS Report). The Branch's documentation of training does not include supervisory sign off for completed areas of training as required in the NRC/OAS Report. The documentation also indicates that, with one exception, all Section staff members have taken the required basic training courses and continue to take specialized training courses as available. The exception noted was that the training documentation for a junior Materials Specialist, who appeared to have the training and experience equivalent to two of the basic courses, did not indicate that the Specialist had completed the two basic courses or their equivalent. The team recommends that the Branch revise their training program to include documentation of staff's equivalent training and experience in lieu of completing a required basic training course, including supervisory sign off for each completed area of training.

New staff are assigned independent inspections after demonstrating competence during accompaniment evaluations and by use of written and oral examinations by the Supervisor. New staff are assigned increasingly complex licensing duties under the direction of senior staff and accompany experienced inspectors during increasingly complicated inspections. The Supervisor reviews the licensing work performed by the junior personnel and accompanies them during inspections to assure regulatory consistency and quality of work performed. The team determined that the program has a well balanced staff, confirmed the qualifications of the staff hired since the l996 IMPEP review, and verified staff performance through licensing and compliance casework and inspection accompaniments. The Branch Manager expressed a strong commitment to training.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed staff for 18 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.

The 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: industrial radiography, medical (institution and private practice), nuclear pharmacy, medical and academic broad scope, portable and fixed gauge, teletherapy, well logging, mobile nuclear medicine, and a self-shielded irradiator. Types of licensing actions selected for evaluation included four new licenses, six amendments to existing licenses, six license renewals, and two license terminations. In discussions with the Supervisor, it was noted that there were no major decommissioning efforts underway with regard to agreement material in Kentucky. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

The casework evaluation indicated that the staff follows appropriate licensing guides during the review process to ensure that licensees submit information necessary to support their request. The review team found the licensing checklists used for each type of program to be comprehensive with the exception that the requirement for alarming ratemeters was not in the industrial radiography checklist. The Branch revised the checklist accordingly during the week of the review. Deficiencies were addressed by letters and documented telephone conversations containing appropriate regulatory language. License templates are currently under development and were not yet available for use by the staff, however, notable consistency between reviewers was observed. The Branch Manager signs each licensing action. The review team found that the licensing actions were thorough, complete, consistent, of high quality and properly addressed

health and safety issues.

The questionnaire listed nine major licenses that had been amended (or are now in the process of being amended) in their entirety during the review period, two of which were identified by the Branch as requiring financial assurance for decommissioning. The review team identified a third license, which had already been renewed, as needing financial assurance and there was no such assurance in place. This was discussed with the Supervisor who indicated that there had been verbal communication with the licensee on the financial assurance requirements and that Kentucky is in the process of assessing the need for a decommissioning funding plan.

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky's 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 Branch's actions in responding to incidents, the review team examined the Branch's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Kentucky in the Nuclear Material Events Database (NMED) against those contained in the Kentucky files, and evaluated the casework and supporting documentation for ten material incidents. A list of the incident casework examined with the case-specific comments is included in Appendix E. The team also reviewed the Branch's response to 17 allegations involving radioactive materials including six allegations referred to the Commonwealth by NRC during the review period.

The review team discussed the Branch's incident and allegation procedure, file documentation, the Commonwealth's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with the Branch Manager and selected staff.

Event calls or reports are handled by the individual receiving the notification, or are assigned to another staff member by the Supervisor. The Supervisor is informed of the initial call and any subsequent follow up or resolution of the case. A tracking form is utilized for tracking the status of incidents and allegations and to record information on the initial report, any additional information or action needed, closure date, and the Supervisor's signature.

The Branch had 18 significant radioactive materials incidents (those that are reportable immediately or within 24 hours) during the review period and 10 were selected for review. The incidents included: loss of radioactive material, damaged devices, misadministrations and contamination events. The review team found that the Branch's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated. The level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the Branch took suitable enforcement action including coordination with the license reviewers, other agencies, and follow up, as appropriate.

The Branch has been submitting event information to NRC via hard copy to the Office of State and Tribal Programs as event information is developed. The Branch has the current software and a computer system to submit event data directly to NMED; however, the person trained for the NMED data entry left the Branch in 1999 and a replacement has not been trained. The team

discussed the upgrade to the NMED system software scheduled for later this fiscal year and the benefits of direct entry of incident data into the system with the Branch Manager and the Supervisor. The team encouraged the Branch to install the NMED software and to train staff to enter the event data.

During the review period, the Branch received 17 allegations/complaints, six of which were referred to the Branch by NRC. The casework for all allegations was reviewed. The review of the casework and the Branch's files indicated that the Branch took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed and the team noted that allegations were treated and documented internally in the same manner as incidents. There were no performance issues identified from the review of the casework documentation. Although the Branch makes an effort to protect the identity of an alleger, the team noted that Kentucky law requires that all public documents be made available for inspection and copying unless specifically exempted from disclosure under Kentucky's Open Records Act. The Branch procedure, "Availability of Files to the Public," Section 414, Title 400, of their Administrative Manual provides guidance to the staff on public documents.

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky's 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. Kentucky's Agreement does not cover uranium recovery, 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

Along with their response to the questionnaire, the Branch provided the review team with the opportunity to review copies of legislation that affects the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in Kentucky Revised Statutes (KRS) Title XVIII, Chapter 211, which names the Cabinet as the radiation control agency of the Commonwealth of Kentucky. Chapter 211 also authorizes the Cabinet to regulate the registration and licensing of the possession or use of any sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste and to fix fees and charges.

The Branch is designated as the Commonwealth's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed since being found adequate during the previous review, and found that the Commonwealth's legislation is adequate.

4.1.2 Program Elements Required for Compatibility

The Kentucky Regulations for Control of Radiation are located in 902 Kentucky Administrative

Regulations (KAR) Chapter 100, Regulations for Radioactive Materials, and apply to all ionizing radiation, whether emitted from radionuclides or devices. Kentucky requires a license for possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the procedures used in the Branch's regulatory process and found that the public and other interested parties are offered an opportunity to comment on proposed rules throughout the process. The NRC is provided with drafts for comment on the proposed rules early in the promulgation process. The proposed rules are forwarded to the Legislative Research Commission for review and approval. The regulations are then implemented by the Cabinet. Typically, rule promulgation requires 9 to 12 months, including drafting of revisions. The Cabinet's regulations are not the subject of "sunset" laws.

The team evaluated Kentucky's responses to the questionnaire, reviewed the status of regulations required to be adopted by the Commonwealth under the Commission's Adequacy and Compatibility Policy, and verified the adoption of regulations with data obtained from the Office of State and Tribal Programs Regulation Assessment Tracking System.

The team identified the following regulation changes and adoptions that will be needed in the future.

- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995.

- "Clarification of Decommissioning Funding Requirements" - 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.

- "10 CFR Part 71: Compatibility with the International Atomic Energy Agency" - 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724) that became effective April 1,1996.

- "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.

- "Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947) 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.

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61amendments (60 FR 15649 and 25983) that became effective March 1, 1998.

- "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.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change" - 10 CFR Parts 20, 35, and 36 amendments (63 FR 39347 and 63 FR 45393) that became effective October 26, 1998.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment" - 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 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.

- "Termination of Transfer of Licensed Activities: Recordkeeping Requirements" - 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1999.

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications" - 10 CFR Part 39 amendment (65 FR20337) that became effective May 17, 2000.

The team reminded the Branch Manager that, in accordance with Management Directive 5.9, Handbook, Part V, (1)(C)(III), and the Commission Policy Statement on Adequacy and Compatibility, that the first seven regulations listed above should be adopted by the Commonwealth as expeditiously as possible to comply with the September 3, 2000 deadline. Three of the seven regulations have been submitted to NRC in a proposed form. The Supervisor indicated that the other four regulations have been drafted, or are in the process of being drafted, and anticipates their adoption no later than December 31, 2000. The Branch plans to adopt the other eight regulations, which are due during the period of January 2001 through May 2003, in a timely manner. The Branch Manager related to the team that the revisions to the regulations would tax the staff and require significant overtime to complete.

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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

In assessing the Branch's SS&D evaluation program, the review team examined information provided by the Branch in response to the IMPEP questionnaire on this indicator. The team observed the staff's use of guidance documents and procedures, interviewed the Supervisor and Branch Manager involved in SS&D evaluations, and verified the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The Branch reviewed two new devices and issued SS&D sheets, as generally licensed devices. The team noted that the Branch currently has only one device manufacturer with 11 registrations, and that the processing of the two new registrations and one amended registration from the same manufacturer would provide a regulatory assessment of the manufacturer's overall safety and quality control program. The Branch will continue their re-evaluation of the seven other registrations as their workload permits, and the Branch Manager estimated that two re-evaluations could be accomplished per year. The team recommends that the Branch commit the necessary resources to complete all the SS&D registry re-evaluations prior to the next IMPEP review period.

The review team selected the one amendment and the two new SS&D applications for review. The review included all amendments, supporting documentation, licenses, and inspections associated with each of the registrations selected. The three certificates reviewed covered the period since the last program review in April of 1996 and represented cases completed by the principal reviewer.

Analysis of the files and interviews with the staff confirmed that the Branch follows the recommended guidance from the NRC SS&D training workshops and the NUREG-1556, Volume 3, issued September 1997. The SS&D review checklist from the NRC SS&D workshop and NUREG-1556 are used to assure all relevant information has been submitted and reviewed. The checklists were contained in the registration files. All pertinent ANSI Standards, Regulatory Guides, and references were confirmed to be available and are used when performing SS&D reviews. The Branch's SS&D reviewer related that non-AEA material reviews would be performed in the same procedural manner using the same references as used for AEA sources and devices.

The registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license possession and use of the product. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The team determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of an accident.

4.2.2 Technical Staffing and Training

The Supervisor reviews and signs all registration sheets and a concurrence review is performed by the Branch Manager. The Supervisor has a Bachelor of Science Degree, several years experience in health physics and in performing SS& D reviews, and has attended the NRC/State SS&D workshop. The Branch Manager has a Ph.D. in Chemistry, several years experience in the regulatory program, serves as the Commonwealth's consultant on radiation matters, and has also attended the NRC/State SS&D workshop. The Branch Manager and the Supervisor are committed to maintaining a high degree of quality in their SS&D reviews. The team determined that the reviewers meet the technical training required for SS&D reviews as described under the guidance. The Branch Manager indicated that a Branch staff member would be trained for SS&D reviews, and that an additional SS&D workshop is needed.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

There were two incidents related to the use of Ronan devices during the review period. These events are listed under Appendix E. The team believes that these incidents were isolated and there is no evidence that the events were generic in nature. An NMED system search of the manufacturer was conducted by the team and no other incidents were identified that were related to any malfunctioning devices or products during this review period.

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

Background information on the Maxey Flats Disposal Site (the site) was detailed in the previous 1996 IMPEP review. The site was opened in January 1963 and operated through December of 1977. In 1978, the Commonwealth of Kentucky's Natural Resources and Environmental Protection Cabinet (NREPC) assumed responsibility for management and operations of the site. Regulatory responsibility for the site's radiation safety program rests with the Cabinet. On October 7, 1991, Kentucky was notified by the U.S. Environmental Protection Agency (EPA) that the site had been approved for remedial action under the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund).

4.3.1 Status of Low-Level Radioactive Waste Disposal Inspection

The Branch's frequency of inspection for the site is every two years, and the team noted that NRC does not have an inspection frequency for closed LLRW sites. Following the April 1996 IMPEP review, the Branch conducted formal inspections of the site in July of 1996 and again on February 24, 2000. No formal inspection was conducted in 1998 due to staffing issues, however, the Branch Manager emphasized that other oversight activities such as on-site sample collection were being performed on a monthly basis. The Branch Manager committed that the inspection frequency would remain on two year frequency. Bi-monthly site visits for environmental sampling and monitoring purposes are conducted by the Radiation/Environmental Monitoring Section laboratory staff and the Branch Manager accompanies the laboratory staff at least once a quarter. In addition, NREPC conducts quarterly inspections at the site and provides detailed reports to the EPA and the Branch. The Branch Manager related that he personally reviews the reports in detail. These monthly and quarterly reports were reviewed by the team for content and the full inspection reports conducted by the Branch were reviewed in detail.

4.3.2 Technical Quality of Inspections

Inspection and enforcement is handled in the same manner as the other Branch licensees. In addition to the laboratory equipment discussed under Section 3.2, the Branch maintains a variety of calibrated instrumentation, including micro R meters, and a portable multichannel analyzer, which are used at the site. The laboratory has the capability of analyzing all required types of environmental media.

The inspection reports covered the scope, completeness, and technical accuracy necessary to determine compliance with regulations, license conditions, and available guidance. The reports provided details on the licensee organization, work performed under licensed procedures,

personnel and training of on-site personnel, access control, personnel monitoring, contamination control, protective equipment, environmental monitoring, trench cap inspections, and site emergencies and incidents. The review team found that the inspection reports were thorough, complete, consistent and of high quality, with sufficient documentation to ensure that the site's performance with respect to health and safety was acceptable.

Branch inspectors communicated inspection findings to the licensee in a timely fashion, documented licensee responses to inspection findings, and closed outstanding inspection issues. The Branch Manager participated in preparation, review and approval of the inspection reports.

4.3.3 Technical Staffing and Training

The Branch Manager and the Supervisor, whose training and experience are discussed in Section 3.3, also serve as the LLRW site reviewers and inspectors. They have many years of experience regulating this licensee. The review team believes they are both fully qualified for their responsibilities.

The six laboratory technical staff involved with the site project consist of a Ph.D. biochemist, a mechanical engineer, a hydrologist, and three chemists, all who have been trained in radiochemistry, environmental sampling, and analysis and evaluation. Based on the previous 1996 IMPEP and the team's discussion with the Branch manager, it was determined that the qualifications of the technical staff are commensurate with expertise identified as necessary to regulate a LLRW disposal facility. The Branch Manager has developed and conducted health and safety training for the staff and other personnel involved in the daily operations at the site.

4.3.4 Technical Quality of Licensing Actions

The license was revised on July 19, 2000 and will be due for amendment in its entirety by June 30, 2001. In examining the license and background information in the file, the review team found that the license: (1) meets standard licensing practices (activity, location, RSO, regulations, tie-downs, etc.); (2) ties the license to Kentucky regulations, including the equivalent Part 61; (3) limits operations to maintenance, remedial, and monitoring activities;
(4) precludes receipt or disposal of waste; (5) limits possession to existing material and addresses possible form changes; and (6) requires qualified personnel to be designated in writing before working on site.

The tie down conditions properly cite the renewal application, the radiological protection program, specified radiological procedures, the Superfund consent decree Statement of Work, and other documents as appropriate. The license file was complete with all background documents.

Applicable guidance documents such as the NUREG that support 10 CFR 61 are available and used as needed. Overall, the team found that the DRWM licensing actions were very thorough, complete, consistent, of high quality and properly addressed health and safety issues.

4.3.5 Response to Incidents and Allegations

There were no reportable incidents or allegations pertaining to the Branch's LLRW program

activities during the review period. The Branch Manager explained to the review team that incidents and allegations relating to the site would be handled in the same manner as those pertaining to any materials licensee.

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky's performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Kentucky's performance to be satisfactory with recommendations for improvement in the Status of Materials Inspection Program performance indicator and satisfactory for the remaining eight performance indicators. Accordingly, the review team recommended and the MRB concurred in finding the Kentucky Agreement State program to be adequate to protect public health and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately four years.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the Commonwealth.

RECOMMENDATIONS:

1. The review team recommends that the Branch revise their inspection manual to ensure that core licenses authorizing the conduct of activities from multiple permanent field offices are inspected at the same frequency as specified in IMC 2800. (Section 3.1)

2. The review team recommends that the Branch ensure that reciprocity licenses are inspected in accordance with the frequency criteria specified in the Branch's inspection manual. (Section 3.1)

3. The team recommends that the Branch revise their training program to include documentation of staff's equivalent training and experience in lieu of completing a required basic training course, including supervisory sign off for each completed area of training. (Section 3.3)

4. The team recommends that the Branch commit the necessary resources to complete all the SS&D registry re-evaluations prior to the next IMPEP review period. (Section 4.2.1)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Kentucky Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source & Device Casework Reviews
Attachment	September 8, 2000 letter from Jimmy D. Helton Kentucky Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Thomas O'Brien, STP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
Richard Woodruff, Region II	Response to Incidents and Allegations Sealed Source and Device Evaluation Program LLRW Disposal Program
Jeffrey Cruz, Region IV	Technical Quality of Inspections Status of Materials Inspection Program
James Peterson, SC	Technical Quality of Licensing Actions

APPENDIX B

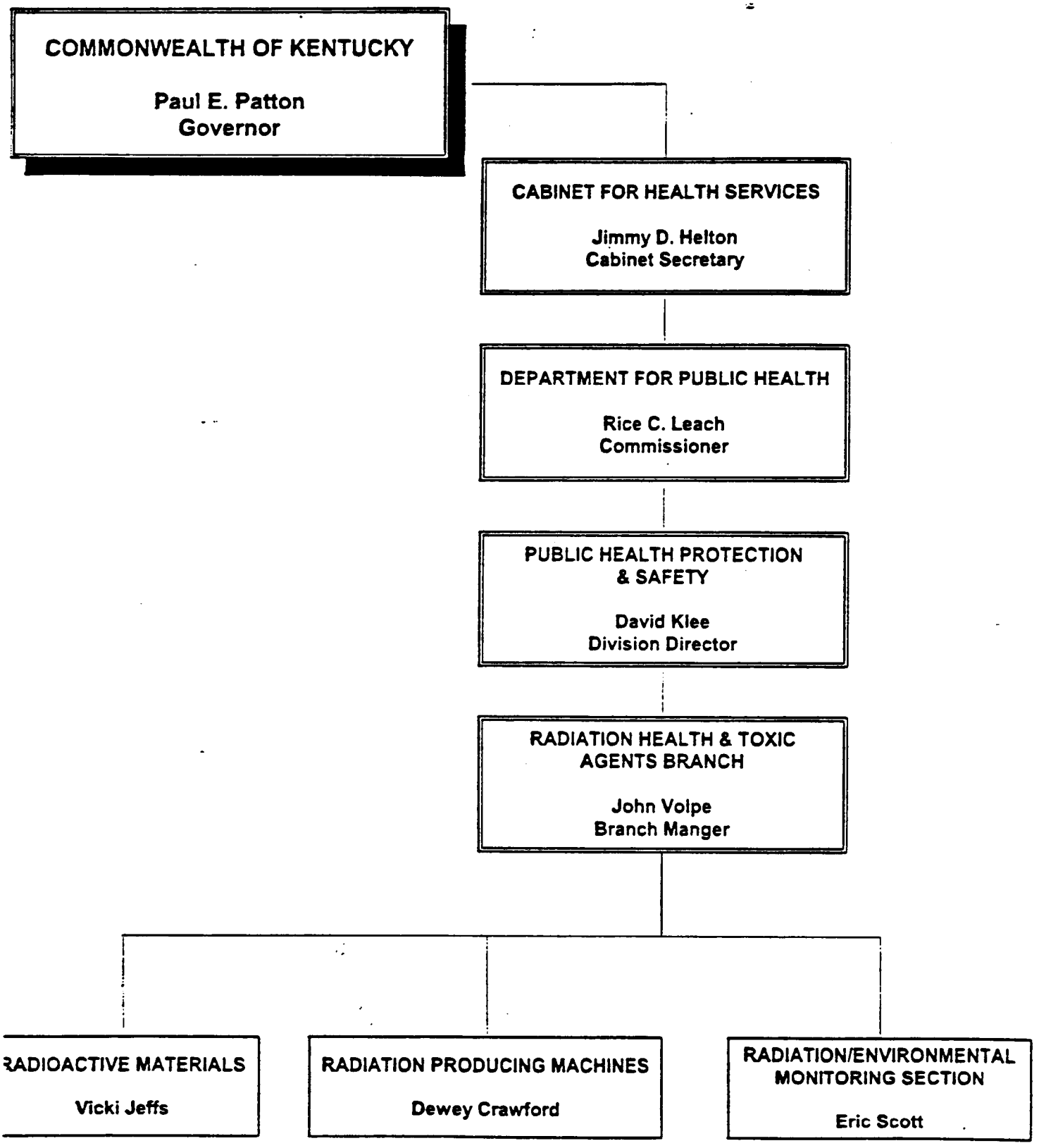
KENTUCKY DEPARTMENT FOR PUBLIC HEALTH

and

RADIATION HEALTH AND TOXIC AGENTS BRANCH

ORGANIZATION CHARTS
(ML003742489)

Kentucky Department for Public Health



July 1, 2000

RADIATION HEALTH & TOXIC AGENTS BRANCH

John Volpe, Ph.D.
Branch Manger

RADIOACTIVE MATERIALS

Vicki Jeffs, Supervisor

Mike Cleaver
Ed Lohr
Jan Jasper

RADIATION PRODUCING MACHINES

Dewey Crawford, Supervisor

RADIATION/ENVIRONMENTAL MONITORING SECTION

Eric Scott, Supervisor

Phil Mills - MF
Todd Adams - PGDP
* Steve Hampson - MF/PGDP
Mark Keene - PGDP
Gerald Morford - MF
* Carl Peterson - MF
* William Sewell - PGDP
James Mays - MF/PGDP

* Contract Employees from University of Kentucky

July 18, 2000

ATTACHMENT
ML003760456

SEPTEMBER 8, 2000 LETTER FROM JIMMY D. HELTON
KENTUCKY RESPONSE TO DRAFT IMPEP REPORT

THE SECRETARY FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
275 EAST MAIN STREET
FRANKFORT 40621-0001
(502) 564-7042
(502) 564-7091 FAX

PAUL E. PATTON
GOVERNOR

JIMMY D. HELTON
SECRETARY

00 SEP 19 PM 3:16

OSP

September 8, 2000

PAUL LOHAUS DIRECTOR
STATE AND TRIBAL PROGRAMS
U S NUCLEAR REGULATORY COMMISSION
WASHINGTON DC 20555

Dear Mr. Lohaus:

The Radiation Health and Toxic Agents Branch and the Commissioner, Department for Public Health, have reviewed the draft report issued by the review team resulting from the evaluation of our program under the Integrated Materials Performance Evaluation Program (IMPEP). There are a few minor corrections to be made to the report as noted below:

1. Page 4 - We feel it should be noted that an action plan, dated June 12, 2000, for performing the required number of reciprocity inspections, had been written prior to the review. This plan should allow the Branch to meet the required criteria.
2. Page 4, Item 3.2 - The second paragraph of the section states the Branch Manager reviews all inspection reports and signs the inspection letters. This is incorrect. The inspection reports are reviewed by the Supervisor of the Radioactive Materials Section and the letters are signed by the Section Supervisor.
3. Page 5 - It is stated in the second paragraph of this page that inspector accompaniments are performed by the Branch Manager. This is incorrect. Inspector accompaniments are performed by the Supervisor of the Radioactive Materials Section. Although technically stated correctly, one inspector accompaniment was performed on January 22, 1998 which was due by December 4, 1997. This was done with the intent of performing a second accompaniment in the latter part of the year for 1998: however, the employee resigned October 31, 1998 before this could be done. Only one other employee required an accompaniment in 1997 because other employees had resigned before their next annual accompaniment date was due.

EDUCATION PAYS

AN EQUAL OPPORTUNITY EMPLOYER M/F/D

4. Page 5, Item 3.3 - The second paragraph states "The three positions were filled within 9, 12, and 2 months....". The 12 months should be 13 months since an employee left approximately May 12, 1998 and the vacancy was not filled until June 16, 1999.
5. Page 7, Item 3.4 - The third paragraph states license templates were not available for use by the staff. This project was commenced prior to the review. One template has been prepared and will be distributed to staff when other basic license templates are completed.
6. Appendix E, File No.8 - This states the contamination occurred when the stomach tube was removed. This should be clarified by stating a smaller tube was inserted into the existing stomach tube in order to administer the I-131. The contamination occurred when this smaller tube was removed.
7. Appendix F, File No. 3 - Upon further review this registration sheet is correct. The original registration was issued February 3, 1999. The registration issued July 19, 1999 was an amendment.

The Cabinet appreciates the IMPEP team's professional review of our Agreement State Radioactive Materials Program. Their evaluation and critique provided a valuable service to the Commonwealth in our efforts to protect worker and public health. If you have questions, feel free to contact program staff.

Sincerely,

Jimmy D. Helton, Secretary
Cabinet for Health Services

c: Rice C. Leach, M.D.
John A. Volpe, Ph.D.