

October 26, 2004

William D. Hacker, M.D.
Commissioner
Cabinet for Health and Family Services
Department for Public Health
275 East Main Street
Frankfort, KY 40621-0001

Dear Dr. Hacker:

On October 12, 2004, 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 protect public health and safety and compatible with the Nuclear Regulatory Commission's program.

Section 5.0, page 18 of the enclosed final report presents the IMPEP team's recommendations for the Commonwealth of Kentucky. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years. However, the review team recommended, and the MRB agreed, that a periodic meeting take place with the Commonwealth approximately one year from the date of the IMPEP review to assess the Commonwealth's progress in implementing the action plan that resulted from the radiation control program's self-audit.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the radiation control program and the excellence in program administration demonstrated by your staff, as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director
for Materials, Research and State Programs
Office of the Executive Director for Operations

Enclosure:
As stated

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Alice Rogers, TX
OAS Liaison to the MRB

William D. Hacker, M.D.

bcc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF KENTUCKY AGREEMENT STATE PROGRAM

July 19-23, 2004

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Kentucky Agreement State program. The review was conducted during the period July 19-23, 2004, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement States of Ohio and Texas. 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 February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of July 22, 2000 to July 23, 2004, were discussed with Kentucky management on July 23, 2004.

A draft of this report was issued to Kentucky for factual comment on August 25, 2004. The State responded by letter dated September 24, 2004. The Management Review Board (MRB) met on October 12, 2004 to consider the proposed final report. The MRB found the Kentucky radiation control program adequate to protect public health and safety and compatible with NRC's program.

The Kentucky Agreement State program is administered by the Radiation Health and Toxic Agents Branch (the Branch). The Radioactive Materials Section (the Section) along with Radiation Producing Machines and Radiation/Environmental Monitoring Sections comprise the Branch. The Branch is part of the Division of Public Health Protection and Safety within the Department for Public Health (the Department). The Department is part of the Cabinet for Health and Family Services (the Cabinet). The Branch Manager reports to the Division Director who in turn reports to the Commissioner of the Department. Organization charts are included in Appendix B. At the time of the review, the Kentucky Agreement State program regulated approximately 430 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 April 27, 2004. The Branch provided a response to the questionnaire on July 9, 2004. A copy of the questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML042110358.

The review team's general approach for conduct of this review consisted of: (1) examination of Kentucky's responses to the questionnaire; (2) review of applicable Kentucky statutes and regulations; (3) analysis of quantitative information from the Branch licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of four Branch inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review 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 Kentucky Agreement State program's performance.

Section 2 below discusses the Commonwealth's actions in response to recommendations made following the previous IMPEP review and the review team's conclusion regarding close out of the recommendations. 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. Recommendations made by the review team are comments that relate directly to performance by the Commonwealth. A response is requested from the Commonwealth to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on July 21, 2000, four recommendations were made and transmitted to Jimmy D. Helton, Secretary of the Cabinet of Health Services, on October 27, 2000. The team's review of the current status of the recommendations are as follows:

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 Inspection Manual Chapter (IMC) 2800. (Section 3.1)

Current Status: The Branch revised their inspection manual to eliminate the listing of multiple, individual field offices on licenses. The Branch issued a separate license to each field office and treat each as an individual licensee. This recommendation is closed.

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

Current Status: The Branch now inspects reciprocity licensees in accordance with the frequency criteria specified in the Branch's inspection manual. The Branch's reciprocity inspection frequencies are more frequent than the frequencies identified in IMC 1220. This recommendation is closed.

3. The review 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).

Current Status: The Branch has revised their training program to include supervisory sign-off to demonstrate staff's equivalent experience and training. Although the team noted that documentation in some cases was limited, the Branch Manager and Section Supervisor committed to improving the documentation for staff as the Branch's policy and procedures are revised. This recommendation is closed.

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

Current Status: Since the last IMPEP review, two of the 11 registrations were amended, and updated information on the remaining registration certificates were received in May 2004. The Branch staff will be re-evaluating the submitted information as their workload permits. This matter is further discussed in Section 4.2.2, Technical Quality of the Product Evaluation, and the review team has made a new recommendation. This recommendation is closed.

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) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the program'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 Branch management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Branch is located in the Department for Public Health offices in Frankfort. There are no field offices. The Branch Manager is responsible for the Section, Radiation Producing Machines Section, and the Radiation/Environmental Monitoring Section. The Radioactive Materials Section Supervisor (Section Supervisor) is primarily responsible for materials licensing and compliance activities. There is one dedicated administrative support position.

The Section experienced a complete turnover in staff during the review period. The four individuals currently in the Section and the Branch Manager have been hired since the last IMPEP review. Three former staff members left the Branch upon retirement from the Commonwealth. The other two former staff members were transferred to other Branches within the Department. Although there was a complete staff turnover, the team found little or no evidence of transfer of knowledge between the former Branch Manager and the current one. Between June and November of 2002, the Branch operated with neither a Branch Manager nor Section Supervisor. The new management was unaware of some practices of the former management. For example, the former management maintained a separate database to track initial inspections that compensated for some of the limitations in the Department-wide system (see Section 3.2). In order to assess the condition of the radioactive materials program, the current Branch Manager performed a self-audit of the program. The audit identified a number of weaknesses in performance that the review team confirmed during this review. The identified performance weaknesses also served as a basis for two new positions in the Section that were recently authorized. Finally, the Branch developed an action plan with specific goals identified and time frames to achieve satisfactory performance. For example, the action plan addresses

the need to revise the Branch's policy and procedure manuals to reflect current inspection and licensing practices.

At the time of the review, there were five technical staff members with various degrees of involvement in the radioactive materials program. The review team determined that currently a total of 3.25 full time equivalents (FTE) is dedicated to the materials licensing and inspection programs, and 0.3 FTE to emergency response, reciprocity, and transportation. With the one current vacant position and the authorization of two new positions, the radioactive materials program will have approximately 7 FTE once the positions are filled.

There was at least one vacant position for all but nine months of the review period, due to the Commonwealth's budgetary problems and an associated hiring freeze. Additional vacant positions remained unfilled for an average of approximately six months. At the time of the review, the Section had one vacancy, which the Branch had recently been given authority to fill. Applicants had been interviewed, and the Branch is waiting for a response from the selected candidate. In addition, the Section recently received authorization for two new positions, for which position descriptions were under development. The Branch is seeking approval to make one of the positions a senior position. If approved, the Section will have two senior and four junior positions under the Supervisor.

The technical staff members are classified as Materials Specialists (MS). Currently, MSIII is the entry/junior level, and MSIV is the senior level. Minimum qualifications are specified in the MSIII position description, and require a bachelor's degree or equivalent experience in the physical sciences. Equivalency determinations are made by the Commonwealth's Department of Human Resources prior to listing the candidate for interview by the program. Most current staff members have equivalent training through the military or health career speciality training and working experience. The team did not identify any performance issues that could be related to a lack of a formal degree.

The Branch has a documented training and qualification program for licensing and inspection staff that is consistent with the NRC/Organization of Agreement States Joint Working Group report on training for Agreement State staff. Qualification is established through a combination of education and experience. In house and on-the-job training may be substituted for formal classroom training. The Section considers both attendance at NRC-sponsored courses and alternate resources for training.

The review team observed that Branch management has exhibited a strong commitment to training. The Branch has developed an in-house training program featuring monthly sessions with topics selected through management assessment of staff needs. The Section maintains a training and qualification binder with a sign-off qualification record for each technical staff member. Staff members must complete each module and receive management sign-off on the qualification record prior to being authorized to independently perform the tasks associated with that module. All staff members review licenses and conduct inspections. At management direction, training starts with licensing activities, then proceeds to inspection activities when the individual's licensing knowledge is demonstrated to be adequate.

Management sign off on a module is granted only after successful completion of the inspection portion of the module, and indicates qualification in both licensing and inspection. Memoranda in the training binder documented inspection participation, and recommended granting of qualification in most cases where management had signed off. Similar documentation of training and experience for the licensing portion of the module is not retained in the binder. Training requirements can be waived by the Branch Manager for sufficient reason. However, the review team did not find documentation of the basis for the waivers granted in the training binder.

The previous review team recommended 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 a supervisory sign off for each completed area of training. A supervisory sign off is now performed, but documentation of training and experience is limited. In view of the recent high staff turnover, the review team concluded that the Branch should improve their documentation of training and experience. The Branch Manager and Section Supervisor committed to improve the documentation as the Branch's policy and procedures are revised.

The Branch is authorized to charge annual fees for specific licenses and for the registration of radiation machines. All fees are deposited in a Division fund, then appropriated back to the Branch. The fee structure was increased during the review period, and is posted on the Kentucky web site. The Branch currently obtains approximately 80 percent of its radioactive materials funding through fees.

The Branch does not have a standing advisory committee, but does have authority to empanel an advisory committee to provide advice on specific issues. The establishment of a permanent committee under statutory authority was considered during the review period, but is not being pursued currently.

The review team considered a finding of satisfactory, but needs improvement for this indicator based on the complete turnover of staff and the number of identified weaknesses. However, the review team notes that the Branch identified a number of needed improvements, developed and in some cases implemented action plans to correct specific performance issues. In addition, the Branch continued to perform the core inspection and licensing functions and has recently received authorization to fill one vacant position and to add two new positions. The review team concluded that the Branch has an adequate plan to sufficiently staff the Section and make the necessary improvements to the program. Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

3.2 Status of Materials Inspection Program

The review team focused on five factors in reviewing the status of the material inspection program: inspection frequency, overdue inspections, initial inspections of new licensees, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections.

The review team's evaluation is based on the Branch's questionnaire response 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 management and staff.

The team's review of the Branch's inspection priorities verified that inspection frequencies for various types of Kentucky material licenses are generally the same as those listed in NRC Manual Chapter (MC) 2800. However, there are some categories of licenses that were assigned inspection priority codes that prescribe a more frequent inspection schedule than those currently prescribed in MC 2800. These reduced inspection intervals are assigned to activities the Branch has determined to be of higher risk, or for licensees who have demonstrated poor performance.

In their response to the questionnaire, the Branch indicated that there were 10 core licenses currently overdue by more than 25 percent of the NRC inspection frequency. This information was verified during the inspection casework reviews. However, the team also noted that several initial license inspections exceeded the one year frequency specified in MC 2800. Out of 398 core and initial licenses inspected by the Branch during the review period, a total of 38 inspections (9.6 percent) were performed overdue or are overdue now. Nearly all of the 38 overdue inspections were new licenses requiring an initial inspection. The previous Branch Manager maintained a separate database for initial licenses, but this information was not conveyed to the new Branch Manager. The Branch believes that not knowing about the Branch's initial licensee database was a significant contributor to the higher than normal number of initial license inspections that were not performed timely. The review team noted that over the last year of the review period, the number of overdue initial inspections has been reduced by the Branch.

The review team determined that Branch staff members prior to calendar year 2002 did not have access to the Department's database and maintained records of inspections manually. In 2003, the Branch was granted limited access to the Department's database and has been in the process of building a workable database to accurately maintain inspection data. The Branch indicated that many of the overdue initial inspections identified by the review team and other omitted licensee data could be attributed to issues with the databases. The review team recommends that the Branch upgrade their database so that all relevant licensee data are incorporated and maintained to ensure that inspections can be scheduled and performed in accordance with the requirements of MC 2800.

The timeliness of the issuance of inspection findings was also evaluated. The Branch has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. The Branch's procedures require that inspection findings be issued to the licensee within 30 days. Of the 27 inspection files reviewed, all inspection correspondence was issued to the licensee within 30 days.

Based on records available to the review team, for the period of January 1, 2002 to July 19, 2004, the Branch granted 49 core reciprocity licenses. The Branch exceeded the minimum 20 percent criteria prescribed in MC 1220 by inspecting 16 licensees.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Status of the Materials Inspection Program, was satisfactory.

3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for a total of 27 inspections conducted during the review period. The casework reviewed included each of the Branch's current and former materials inspectors. The review covered inspections of various types as follows: industrial radiography, academic broad scope, medical broad scope, medical institution with written directive required, nuclear cardiology, nuclear pharmacy, gamma knife, brachytherapy, blood irradiators, well logging, portable and fixed gauges, and research and development. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of each licensee's radiation protection program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that each licensee's performance with respect to health and safety was acceptable. The review team found that routine inspections adequately cover each licensee's radiation protection program, include a written summary of the scope of the licensed activities and categorize violations into severity levels which can later be used for escalated enforcement if necessary. The documentation adequately supported the cited violations. Exit interviews were held with appropriate licensee personnel.

The current Branch Manager conducted formal, unannounced accompaniments of materials inspectors in calendar year 2004, and prior to the calendar year 2002 staff turnover, annual accompaniments were conducted by the previous Branch Manager. However in the interim period between calendar years 2002 and 2004 during the staff turnover, there was a period of five months when the Branch did not have a Branch Manager and an additional 15 months where the Branch did not have a Section Supervisor. During this period, no formal accompaniments were conducted, however the staff improvised an accompaniment program where more experienced inspectors accompanied less experienced inspectors while conducting inspections. The current Branch Manager indicated that the staff is stable now and annual unannounced accompaniments will continue on a routine basis.

The review team noted that out of 27 inspection files examined, there were two instances where licensees failed to respond to the Branch's inspection correspondence. In both of these instances the Branch did not follow up on the failure of the licensee to respond to the inspection correspondence. There were no safety issues identified by the team due to the licensee's failure to respond. Both of these instances occurred during a transition period of high staff turnover.

Members of the review team accompanied four Kentucky inspectors from June 1 to 4, 2004, and observed their activities during inspections of an industrial radiography facility, a small medical facility licensed for diagnostic nuclear medicine and radiopharmaceutical therapy, a broad scope medical facility, and a Type A Broad Scope academic licensee which are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate

inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their review of each of the licensee's radiation safety programs. The inspections were adequate to assess radiological health and safety at each of the licensed facilities.

The Branch has an adequate number and selection of survey instruments to support the inspection program. Each inspector is assigned a calibrated dual function (GM and micro-R) survey meter that is carried with them at all times to facilitate a rapid response in emergency situations. The meters are calibrated by the manufacturer or a properly licensed facility. The Branch Manager indicated that the Branch has plans to set up a calibration facility to calibrate their meters. 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 analytical laboratory. Members of the review team toured the facility. The laboratory has broad analytical capability including liquid scintillation counters, gas proportional counters, intrinsic germanium detectors, multichannel analyzers, alpha spectroscopy, and radiochemistry. The laboratory is capable of analyzing a broad range of environmental media.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 16 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. 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 which were completed during the review period. The cross-section sampling focused on the new licenses, amendments, renewals, and licenses terminated during the review period. The sampling included the following types: medical broad scope, general license distribution, manufacturing and distribution, medical (institution and private practice), research and development, nuclear pharmacy, industrial radiography, self-shielded irradiator, laboratory analysis and source material. Licensing actions reviewed included three new, seven renewals, five amendments and one termination file. A listing of the casework 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 high quality with health and safety issues properly addressed. License tie-down conditions were 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. The review team confirmed that there were no exemptions issued as indicated on the Branch's questionnaire response.

The team reviewed three licenses which had possession limits that required financial assurance for decommissioning but the licensees had not provided either a decommissioning funding plan or financial assurance. This matter was discussed with the Branch Manager who indicated that the Branch discussed the need for financial assurance with one of the licensees, but not with the other two licensees. The Branch Manager indicated that there may be additional licensees that require financial assurance for decommissioning. The review team recommends that the Branch identify those licensees who require financial assurance and take appropriate action to have them comply with the Commonwealth's decommissioning and financial assurance requirements.

Licensing actions are assigned to one of the Branch's license reviewers. Once the reviewer completes the action, the Branch Manager signs each licensing action. Licensing checklists are used for each type of program and are included in the license file. The status of all licensing actions are tracked using a log book. The Branch generates licenses and correspondence with standardized conditions and formats. The Branch issues licenses for a one-year period based on the collection of an annual fee. A comprehensive technical renewal is performed every five to seven years. The Branch utilizes appropriate licensing guides, standard licensing conditions, and issues a complete license for each licensing action.

The review team noted that some license conditions still in use have been superseded either by regulations or change in policy and consequently, were no longer required. The review team discussed this matter with the staff and the Branch Manager. The Branch Manager indicated that the Branch's procedures and standardized license conditions are in need of review. The update and revision of the licensing procedures and standard license conditions are included in the Branch's action plan. This matter is discussed further in Section 4.1.2, "Program Elements Required for Compatibility."

The review team found that terminated licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records. In discussions with Branch staff, the review team noted that there were no major decommissioning efforts underway with regard to Agreement material in the Commonwealth.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents, the review team examined the Section's responses to the questionnaire relative to this indicator, reviewed the incident reports for Kentucky in the Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated reports and supporting documentation for ten incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The review team also reviewed the Section's response to eight allegations involving radioactive material. Three allegations were referred to the Section by the NRC during

the review period.

The incidents selected for review included the following categories: medical event, lost/stolen material, overexposure, leaking source, and damaged equipment. The review team found that the documentation of the Section's response to incidents was deficient. Section procedures specifying documentation requirements were not followed. This had been identified as a corrective action item by the Branch's self assessment prior to the review. For seven of the ten incidents, the only documentation was a copy of the NMED report.

Based on the limited documentation available in the NMED reports, the initial responses to the incidents appeared prompt and well coordinated, and the level of effort appeared commensurate with the health and safety significance. The Section dispatched inspectors for on-site investigations when appropriate. However, follow up and enforcement actions were fully documented in only three cases.

Six license files were examined for documentation of the incidents and follow up during the next inspection. Documentation of the incidents was limited or missing in all six files. Three of the files had no documentation of follow up to the incident or review of licensee's corrective actions during the next inspection.

Notification of an incident or allegation may be received by any staff member. When a notification is received, the Branch Manager or Section Supervisor determines what level of initial response is appropriate and assigns appropriate staff. After the investigation is completed, the pertinent information is forwarded to NMED.

The review team identified 32 incidents in NMED for Kentucky during the review period, including 10 incidents that required reporting. For incidents that require immediate notification, Section procedures require reporting to the NRC within 24 hours of receiving notification from the licensee. Reports to NMED are to be submitted when the initial investigation is finished, and follow-up reports are made as needed to close the incident and NMED report. During the period of staff turnover, these procedures were not consistently followed as those staff members assigned this task departed from the Branch. This was identified by the Section as a corrective action item. Currently, cases requiring follow up and closure are tracked by the Section Supervisor.

During the review period, the Branch received eight allegations, three of which were referred to the Branch by NRC. The casework for all allegations was reviewed. The review of the casework and the Section's files indicated that the Section took prompt and appropriate action in response to the concerns raised. All of the allegations were appropriately closed except one that was still under investigation. The team noted that Branch procedures call for allegations to be treated and documented internally in the same manner as incidents. Based on the review of the casework documentation, the team found that the documentation procedures were not followed since the staff turnover in 2002. This was discussed with the Branch Manager and Section Supervisor who were aware of the situation and have plans to address it through in-house training.

The review team recognizes that the Section has identified the need to document responses to incidents and allegations through their self assessment and included this item in their corrective action plan. Documentation of the Section's responses will also facilitate the follow up to the

incident or review of licensee corrective actions during the next inspection. The review team recommends that the Branch document incident and allegation responses in accordance with their procedures and provide training on the procedures to all technical staff.

Although the Branch makes an effort to protect the identity of an alleged, 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 the Branch Administrative Manual provides guidance to the staff on handling public documents. Legal council is available in the Department to assist the staff in deciding whether or not to release information.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Compatibility Requirements

4.1.1 Legislation

In addition to their response to the questionnaire, the Branch provided the review team with the opportunity to review copies of legislation that effect the radiation control program. The current effective statutory authority for the Branch is contained in Kentucky's Revised Statutes (KRS) Title XVIII, Chapter 211, which names the Cabinet as the radiation control agency of the Commonwealth. The Branch is designated as the Commonwealth's radiation control agency. Chapter 211 also authorizes the Cabinet to regulate the registration and licensing for the possession or use of any sources or ionizing or machine produced radiation, handling and disposal of radioactive waste, and establishing and assessing fees. The review team noted that no legislation affecting the Branch was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Kentucky Regulations for Control of Radiation, found in 902 Kentucky Administrative Regulations (KAR) Chapter 100, Regulations for Radioactive Materials, apply to all ionizing radiation, whether emitted from radionuclides or machine sources. 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 Commonwealth's administrative rulemaking process and found that the process takes approximately 12 months after the Branch submits the drafted amendment for Cabinet review. The public and other interested parties are provided an

opportunity to comment on proposed rules. The NRC is provided with proposed rules for comments during the promulgation process. The Commonwealth can adopt other agency's regulations by reference and has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. The regulations are not subject to sunset provisions.

The review team evaluated the Branch's response 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' State Regulation Status Data Sheet. Since the previous IMPEP review, the Branch adopted six amendments that became effective in March 2001, February 2002, and June 2004.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. The review team found that the Branch currently has the following six overdue NRC amendments:

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995. The Branch submitted proposed revisions to their regulations for this amendment for NRC review in a letter dated September 27, 2004.
- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998.
- "Respiratory Protection and Controls to Restrict Internal Exposure," 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 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.
- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. The Branch has amended the appropriate licenses with license conditions compatible with the requirements in 10 CFR 32.52 (a) and (b). The Branch has not adopted the remainder of the amendment.

The Branch will need to address the following four regulations in upcoming rulemakings or by adopting alternate legally binding requirements:

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002. The Branch submitted proposed

revisions to their regulations for this amendment for NRC review in a letter dated September 27, 2004.

- “Financial Assurance for Materials Licensees,” 10 CFR Parts 30, 40 and 70 amendments (68 FR 57327) that became effective on December 3, 2003.
- “Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments,” 10 CFR Part 71 amendment (69 FR 3697) that becomes effective October 1, 2004.

The team discussed the status of overdue NRC amendments with the Branch Manager and Section Supervisor. As discussed in Section 3.1, the Branch self-audit identified the need to adopt overdue NRC amendments. The Branch’s action plan specifies schedules for the adoption of overdue NRC amendments during 2005. In addition, the Branch also recognized the need to update their various policy and procedure manuals to reflect changes in the regulations. These planned revisions are also reflected in the Branch’s action plan with planned completion in late 2005. Since the Branch has already developed an action plan to adopt the overdue NRC amendments, the review team determined that a specific recommendation was not needed.

Based on IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky’s performance with respect to the indicator, Compatibility Requirements, was satisfactory, but needs improvement.

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

In conducting this review, three sub-indicators were used to evaluate the Branch’s performance regarding their SS&D Evaluation Program. These sub-indicators include: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

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. A review of two amended SS&D registration evaluations and supporting documents covering the review period was conducted. The review team interviewed the Section Supervisor and Branch Manager and assessed the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

During the review period, the former Section Supervisor performed the initial reviews for amendments issued during the review period. Two members of the current Branch staff each performed one concurrence review of the amendments.

In April 2001, one concurrence reviewer attended the NRC/State SS&D Workshop and received management approval for performing SS&D reviews. This reviewer is presently the only reviewer with management approval to perform SS&D reviews. A second reviewer attended the SS&D workshop in September 2003, but does not have documented management approval to perform SS&D reviews, yet signed as a concurrence reviewer for one of the amended

registration certificates in May 2002. This reviewer stated that verbal approval to be a qualified reviewer was given by the former Branch Manager in 2002 prior to signing as a concurrence reviewer. A third staff member also attended the September 2003 workshop, but has not attained management approval for performing SS&D reviews.

The review team determined that the Branch did not establish a training program with qualification criteria or maintain documentation indicating that SS&D reviewers met the qualifying criteria specified in Management Directive 5.6. Additionally, the team could not identify any documented training review experience for the Branch's two concurrence reviewers. The review team recommends that the Branch establish, implement and document a training program for SS&D reviewers.

4.2.2 Technical Quality of the Product Evaluation

There is currently one device manufacturer in the Commonwealth with 11 registration certificates. During the review period, the Branch performed three amendments which included the review of two device registration certificates including one of which was amended twice. The review team examined all three amendments and supporting documentation and the manufacturer's license. The SS&D registration certificates examined by the review team are listed with case-specific comments in Appendix F.

A review of the files and interviews with staff confirmed that the Branch has available for use the recommended guidance from the NRC/State SS&D Workshop and NUREG 1556, Volume 3, Revision 1. This includes ANSI 43.8-2001 "Classification of Industrial Ionizing Radiation Gauging Devices," ANSI N43.6-1997 "Sealed Radioactive Sources, Classification," and NRC Regulatory Guide 6.9. Various National Council Radiation Protection reports were also available.

The amendments reviewed by the Branch were minor amendments to use additional sealed source models within the devices and to increase the activity and shielding on another device. The team found the amended information in the registration certificates was satisfactory. However, for all three amendments issued, there was no documentation of the scope of the reviews and only the amendment request and the completed registration were in the Branch's files. The team did find sufficient documentation of prior reviews in the files, but not of device reviews conducted during the current review period.

The review team could not determine if the review checklist from NUREG-1556, Volume 3, was used for amendments issued during the current review period. The amendment evaluations performed by the Branch did not update and review the existing information in the registrations to conform to current guidance found in NUREG 1556, Volume 3. The review team did review the contents of the entire registration certificates and identified a number of issues detailed in the comments of Appendix F. These included (1) the consistency and justification between prototype testing, ANSI ratings, and normal conditions of use; (2) verification that listed sealed sources are still active and applicable to be used in a device, and/or indicate when sealed sources no longer have an active registration; and (3) commitments made by the manufacturer in their applications and referenced in the registration certificates are consistent and enforceable with Kentucky regulations.

The review team and the Branch staff discussed the need to review the contents of the entire

certificate and follow the format for documenting the product evaluations since the registration certificates are used nationally. The review team recommends that the registration certificate evaluation criteria and document format be consistent with NUREG 1556, Volume 3.

The team identified three registration certificates for products manufactured outside Kentucky for specifically licensed custom users in the Commonwealth. None of the three custom users were identified as current licensees. There is also a device manufacturer that is no longer located in the Commonwealth but in an adjacent Agreement State that still has 12 active Kentucky registration certificates. The review team recommends that the Branch review and determine the status of SS&D registrations issued to non-Kentucky manufacturers and take appropriate action to either update or inactivate the registration certificates.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team identified eight reported incidents related to the use of registration certificates issued by the Branch during the review period. Two incidents were related to accident conditions unrelated to the device. The remaining six incidents involved leaking sealed sources and sealed sources becoming disconnected from the device and falling into the user source well. These six device failures are listed under Appendix E. Four of the five incidents were for multiple source disconnects with the same devices at the same location. The review team concluded that for the four incidents at the one facility indicated that there may have been other factors to consider in the device failures.

The six device failures occurred prior to current Branch management who were unaware of the scope of the incidents. The review team identified little documentation that the Branch fully evaluated the root causes of all defects and incidents involving the devices covered by the registration certificates. For example, the review team did identify a note involving a discussion between the NRC and the Branch regarding one of the incidents that the NRC would investigate the incident and contact the Branch if the Branch was to perform any additional action. Any knowledge of the events, reports, personal notes or undocumented follow-up actions relating to device failures and defects were lost to the current staff when the previous Branch management retired.

The review team did discuss the need for the Branch to periodically review the NMED database for incident reports that may be related to potential design and manufacturing SS&D issues for follow up and root cause analysis during license renewals, license inspections, and device registration amendments. The review team also determined that there is no requirement for manufacturers in the Commonwealth to report failures of safety-related systems and document follow-up actions. The review team recommends that the Branch implement an enforceable mechanism (e.g., rule or license condition) to have the manufacturers report defects, deviations or non-conformance of safety-related systems, structures, or components and document follow-up actions.

During the MRB meeting, NRC management discussed the potential implications of having Agreement States requiring manufacturers under their jurisdiction report defects, deviations and items of non-conformance for devices which they have issued SS&D registry sheets without the benefit of a compatibility requirement. During the MRB's discussion, it was noted that some Agreement States apply this requirement as either a regulation or legally binding requirement. The MRB recommended that the NRC's Office of Nuclear Materials Safety and Safeguards,

Office of State and Tribal Programs, and Office of the General Counsel review the basis for the lack of a compatibility requirement for reporting defects, deviations and items of non-conformance for devices registered by Agreement States and make appropriate recommendations if the lack of such a requirement results in gaps in the collective national effort to regulate materials under the Atomic Energy Act.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was satisfactory, but needs improvement.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

The Maxey Flats site is located in eastern Kentucky near Hillsboro in Fleming County. The site operated as a commercial LLRW disposal facility authorized by the Commonwealth from May 1963 through December 1977. The site was listed on the National Priority list in 1986 and a Record of Decision was issued in September 1991 by the Environmental Protection Agency (EPA) under its Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) authority to stabilize the site and treat contaminated leachate (mainly tritium) from tanks and trenches. Dewatering and leachate treatment was initiated in 1988 and was completed in 2000. The remaining activities over the last few years were the construction of a cap, erosion control measures, perimeter drainage system and groundwater intercept channel.

Currently, the Natural Resources and Environmental Protection Cabinet (NREPC) is responsible for monitoring and maintaining the site. NREPC assumed responsibility for the site in 1978. NREPC is licensed by the Branch.

4.3.1 Technical Staffing and Training

The Branch staff, whose qualifications and training are discussed in Section 3.1, serve as license reviewers and inspectors. Since the facility is closed and operations at the site are limited to environmental sampling and monitoring, the Branch's radioactive materials qualification and training requirements are adequate for technical staff to perform LLRW licensing actions and inspections. The laboratory technical staff in the Radiation/Environmental Monitoring Section involved with the Maxey Flats site consist of five professional chemists, who have been trained in radiochemistry, environmental sampling, and analysis and evaluation. The review team discussed the qualifications of the laboratory technical staff with the Branch Manager and determined that their qualifications are commensurate with expertise needed to regulate the closed LLRW disposal site.

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

The Branch's inspection frequency for the site is every two years. NRC has not established an inspection frequency for closed LLRW sites. The Branch conducted an inspection of the site in January 2004. The previous inspection was conducted in February 2000. No formal inspection was conducted in 2002 due to staffing issues discussed in Section 3.1. Despite the lack of a formal radioactive materials inspection in 2002, the Branch Manager stated that other oversight activities are routinely conducted at the site including on-site sample collection on a monthly and quarterly basis. Quarterly and monthly site visits for environmental sampling and monitoring are conducted by the laboratory technical staff. In addition, NREPC conducts

quarterly inspections at the site and provides detailed reports to the EPA and the Branch. The Branch Manager committed to continue the two-year inspection frequency for the site.

Regarding the timeliness of the Branch inspection reports, the review team noted that for the inspection conducted in January 15, 2004, the report was issued to NRECP on July 12, 2004. The Branch Manager and Section Supervisor indicated that the delay was due to higher priority activities.

4.3.3 Technical Quality of Inspections

The inspection of the NRECP license is handled in the same manner as the other radioactive materials licensees. The review team reviewed the January 2004 inspection report and interviewed select members of the inspection staff. The inspection was conducted as a team and included the Section Supervisor who accompanied the inspection team for training purposes. Branch management also participated in preparation, review and approval of the inspection report. The review team concluded that the scope and quality of the inspection was appropriate. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments.

As discussed in Section 3.3, the review team visited the Radiation/Environmental Monitoring Section laboratory and found the facility equipped to support monitoring activities at the site. Periodic site visits are made by the laboratory technical staff on at least a monthly basis and also during major rainfall for environmental sampling and monitoring purposes. Sampling includes surface water from creeks and storm water runoff from the site. Results of environmental monitoring are maintained at the laboratory. The Branch maintains an adequate variety of calibrated radiation survey instruments as discussed in Section 3.3. Survey instruments are also available at the laboratory.

4.3.4 Technical Quality of Licensing Actions

NREPC's license authorizes the possession of the wastes previously disposed of at the site, management and maintenance of the site, and possession and treatment of radioactive solids and liquids generated as a result of management and maintenance activities at the site. The license covers the on-site radiation control program, occupational exposure of individuals, and control of radioactive materials as it affects occupational exposures.

The review team examined a total of eight licensing actions, including one renewal and seven amendments. A listing of the casework evaluated with case-specific comments can be found in Appendix D. In examining the technical quality of completed licensing actions, the review team found that all correspondence including deficiency letters related to the issuance of the license was well documented and the license meets standard licensing practices such as possession, activities, location, Radiation Safety Officer qualifications, compliance with regulations, and tie-downs. The tie-down condition cites the renewal application, health and safety plan, radiation protection program, Consent Decree Statement of Work, and other letters as appropriate. All tie-down documents were on file. Applicable guidance documents related to licensing actions are available and used as needed.

4.3.5 Technical Quality of Incident and Allegation Activities

There was one allegation received by the Branch since the last review, but the concern raised was not in the Branch's jurisdiction. There were no incidents at the site since the last review.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Kentucky's performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, was satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Kentucky's performance to be satisfactory for five performance indicators and satisfactory, but needs improvement, for three performance indicators. Accordingly, the review team recommended and the MRB agreed on finding the Kentucky Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. The team considered a finding of adequate, but needs improvement, but noted that the Branch identified a number of needed improvements, developed and in some cases implemented action plans to correct specific performance issues and has been approved to expand the Section's staff. The team also recommended and the MRB agreed that the next periodic meeting be conducted in approximately one year to assess the Branch's progress with implementing their action plan. The status of the Branch's progress with the action plan will be reported to the MRB to determine if any changes in the program finding is needed. Based on the results of the current IMPEP review, the review team recommends that the next full review should be in approximately four years.

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

RECOMMENDATIONS:

1. The review team recommends that the Branch upgrade their database so that all relevant licensee data are incorporated and maintained to ensure that inspections can be scheduled and performed in accordance with the requirements of MC 2800. (Section 3.2)
2. The review team recommends that the Branch identify those licensees who require financial assurance and take appropriate action to have them comply with the Commonwealth's decommissioning and financial assurance requirements. (Section 3.4)
3. The review team recommends that the Branch document incident and allegation responses in accordance with its procedures and provide training on their procedures to all technical staff. (Section 3.5)
4. The review team recommends that the Branch establish, implement and document a training program for SS&D reviewers. (Section 4.2.1)
5. The review team recommends that the registration certificate evaluation criteria and document format be consistent with NUREG 1556, Volume 3. (Section 4.2.2)
6. The review team recommends that the Branch review and determine the status of SS&D registrations issued to non-Kentucky manufacturers and take appropriate action to either

update or inactivate the registration certificates. (Section 4.2.2)

7. The review team recommends that the Branch implement an enforceable mechanism (e.g., rule or license condition) to have the manufacturers report defects, deviations or non-conformance of safety-related systems, structures, or components and document follow-up actions. (Section 4.2.3)

Below is a recommendation, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by NRC staff:

1. The MRB recommended that NMSS/STP/OGC review the basis for the lack of a compatibility requirement for reporting defects, deviations and items of non-conformance for devices registered by Agreement States and make appropriate recommendations if the lack of such a requirement results in gaps in the National Materials Program.

LIST OF APPENDICES AND ATTACHMENT

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 and Device Casework Reviews
Attachment	September 24, 2004 Letter from William D. Hacker Kentucky's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Duncan White, Region I	Team Leader Technical Quality of Licensing Actions Compatibility Requirements
Richard Blanton, STP	Technical Staffing and Training Technical Quality of Incident and Allegation Activities
Randy Erickson, Region IV	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Sheri Minnick, Region I	Inspector Accompaniments
Muhammadali Abbaszadeh, Texas	Low-Level Radioactive Waste Disposal Program
Karl Von Ahn, Ohio	Sealed Source and Device Evaluation Program

APPENDIX B
KENTUCKY ORGANIZATION CHARTS

ADAMS: ML042170062

COMMONWEALTH OF
KENTUCKY

Ernie Fletcher
Governor

CABINET FOR HEALTH &
FAMILY SERVICES

James W. Holsinger, Jr., M.D.
Secretary

DEPARTMENT FOR PUBLIC
HEALTH

William D. Hacker, M.D.
Commissioner

DIVISION OF PUBLIC HEALTH
PROTECTION & SAFETY

Clyde Bolton
Director

RADIATION HEALTH & TOXIC
AGENTS BRANCH

Robert L. Johnson
Manager

RADIOACTIVE MATERIALS
SECTION

Matthew McKinley
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RADIATION PRODUCING
MACHINES SECTION

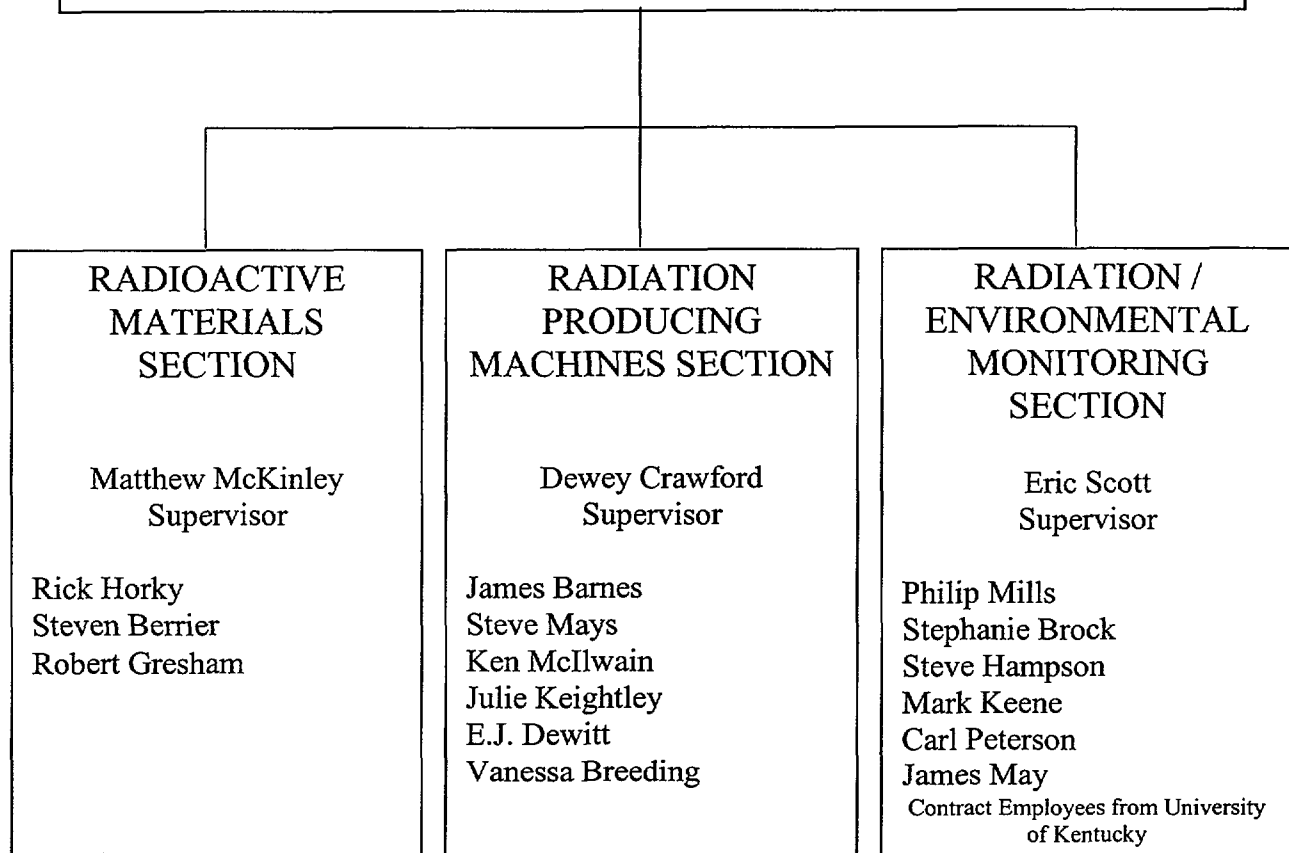
Dewey Crawford
Supervisor

RADIATION /
ENVIRONMENTAL
MONITORING SECTION

Eric Scott
Supervisor

RADIATION HEALTH & TOXIC AGENTS BRANCH

Robert L. Johnson
Manager



ATTACHMENT

September 24, 2004 Letter from William D. Hacker
Kentucky's Response to the Draft IMPEP Report

ADAMS: ML042780161



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SECRETARY

September 24, 2004

Mr. Duncan White, C.H.P.
Regional State Agreements Officer
Division of Nuclear Materials Safety
Region I
475 Allendale Rd.
King of Prussia, PA. 19406

RE: Kentucky Integrated Materials Performance Evaluation Program (IMPEP) Review

Dear Mr. White

We have received the draft Kentucky IMPEP report and reviewed the findings it outlines. The contents are as briefed on your departure, are consistent with what we agreed as the status of all areas reviewed, and we have no questions, corrections or challenges at this time.

We appreciated the visit, staff felt it to be a valuable tool for our program, and we are moving vigorously with internal program action plans based on the recommendations outlined in your draft program evaluation. It is our intent to have Mr. Robert L. Johnson, Radiation Safety Branch Manager attend the Management Review Board where the report will be finalized.

Thank you for this opportunity to provide comments. Should there be questions or further clarification we can provide, Mr. Johnson will be available or you can contact my office any time at 502-564-3671.

Sincerely,

WILLIAM D. HACKER, M.D.
Acting Commissioner

Cc: Mr Bolton
Mr Johnson