

To: Miller, FSME



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DEDMRT  
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Adams

**CABINET FOR HEALTH AND FAMILY SERVICES**  
**Department for Public Health**

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**Janie Miller**  
Secretary

**Steven L. Beshear**  
Governor

December 8, 2008

Martin J. Virgilio, Deputy Executive Director  
Materials, Waste, Research, State, Tribal, and Compliance Programs  
Office of the Executive Director for Operations  
11555 Rockville  
Rockville, MD 20852

RE: 2008 Kentucky Integrated Materials Performance Evaluation Program (IMPEP) Review

Dear Mr. Virgilio:

We have received the final Kentucky IMPEP report and evaluated the six (6) recommendations along with the good practice action identified by the review team. We are in agreement that they are as expected and discussed throughout the IMPEP process.

Matt McKinley, Supervisor, Radioactive Materials Section, has informed me that the findings were discussed with the panel during the review board in Rockville, MD. It is my understanding that five (5) of the recommendations have been addressed, with the sixth scheduled for completion prior to the NRC visit expected during the summer of 2009. We look forward to demonstrating the implementation of these recommendations at that time.

Thank you for your candor and professionalism throughout this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Wm D. Hacker".

William D. Hacker, M.D., FAAP, CPE, Commissioner  
Department for Public Health

c: Guy Delius, Director, Division of Public Health Protection & Safety  
Dewey Crawford, Manager, Radiation Health Branch



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

November 20, 2008

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 28, 2008, 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 Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB requested that the period of monitoring of the Kentucky Agreement State Program continue. Monitoring is an informal process that allows NRC to maintain an increased level of communication with an Agreement State program. As part of the Monitoring process, NRC will conduct quarterly calls with the appropriate representatives from the Kentucky Radiation Health Branch.

Section 5.0, page 21 of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. 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, NRC will conduct a periodic meeting with the Kentucky Agreement State Program approximately 1 year from the date of review. During this meeting, NRC will assess the Commonwealth's progress in addressing the review team's recommendations.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and wish to acknowledge your continued support for the Agreement State Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

A handwritten signature in black ink, appearing to read "M. J. Virgilio".

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

Enclosure:  
Kentucky Final IMPEP Report

cc w/encl.: See next page

W. Hacker

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cc w/encl.: Dewey Crawford, Manager  
Kentucky Radiation Health Branch

Matthew McKinley, Supervisor  
Kentucky Radioactive Materials Section

Thomas Conley, Kansas  
Organization of Agreement States  
Liaison to the MRB



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM  
REVIEW OF THE KENTUCKY AGREEMENT STATE PROGRAM

July 28-August 1, 2008

**FINAL REPORT**

Enclosure

## 1.0 INTRODUCTION

This report presents the results of the review of the Kentucky Agreement State Program. The review was conducted during the period of July 28 - August 1, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida. 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 Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of July 24, 2004, to August 1, 2008, were discussed with Kentucky managers on the last day of the review.

The review team issued a draft of this report to Kentucky for factual comment on August 28, 2008. The Commonwealth responded via letter from Dr. William D. Hacker, Commissioner, Department for Public Health (the Department), on October 6, 2008. A copy of the Commonwealth's response is included as the attachment to this report. The Management Review Board (MRB) met on October 28, 2008, to consider the proposed final report. The MRB found the Kentucky Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with NRC's program. The MRB requested that the period of monitoring of the Kentucky Agreement State Program continue.

The Kentucky Agreement State Program is administered by the Radiation Health Branch (the Branch). The Radioactive Materials Section (the Section), the Radiation Producing Machines Section, and the Radiation/Environmental Monitoring Section comprise the Branch. The Branch is part of the Division of Public Health Protection and Safety within the Department. The Department is part of the Cabinet for Health and Family Services (the Cabinet). Organization charts for the Branch and Section are included in Appendix B.

At the time of the review, the Kentucky Agreement State Program regulated 446 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive 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 applicable non-common performance indicators was sent to the Branch on March 20, 2008. The Branch provided its response to the questionnaire on July 11, 2008, with a revised response provided on August 8, 2008. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML082240074.

The review team's general approach for conduct of this review consisted of: (1) examination of Kentucky's response to the questionnaire; (2) review of applicable Kentucky statutes and regulations; (3) analysis of quantitative information from the Branch's database; (4) technical review of selected regulatory actions; (5) field accompaniments of eight inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance

indicator and made a preliminary assessment of the Kentucky Agreement State Program's performance.

Section 2.0 of this report covers the Commonwealth's actions in response to recommendations made during the previous review. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, covering the period of July 22, 2000, to July 23, 2004, the review team made seven recommendations regarding program performance. The current status of the recommendations is as follows:

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 Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program" (Section 3.2 of the 2004 IMPEP report).

Current Status: The Branch identified a database limitation in which all new licenses were automatically assigned an initial inspection due date based on its inspection interval instead of 12 months after license issuance, as prescribed by IMC 2800. The Branch addressed this limitation by manually entering the initial inspection due date upon initial entry of the license into the existing database. This process allows for the Branch to manually alter dates, if needed, based on the actual timing of the issuance of the license. To ensure the accuracy of tracking inspection and licensing data, the Branch performs an audit of all tracking logs and the database through a monthly review by the Radioactive Materials Section Supervisor (the Section Supervisor) and subsequently, by the Branch Manager via a monthly report. This recommendation is closed.

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 of the 2004 IMPEP report).

Current Status: The Branch has completed a review of its licenses, identified the licensees who require financial assurance, and took appropriate action. This recommendation is closed.

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 of the 2004 IMPEP report).;

Current Status: The Branch has a centralized binder that includes Kentucky's policy and guidance, as well as NRC guidance: Nuclear Materials Events Database (NMED)

instructions: and other information pertinent to incident and allegation administration. The information and procedures included in the binder, along with a review of past incidents and allegations, are reviewed by all staff annually. The review team noted that, in some cases, the supervisory sign off indicating completion of annual training was limited. The Branch also identifies a specific Radiation Health Specialist to ensure all events are appropriately documented and addressed in accordance with all available guidance, on an annual basis. The Section Supervisor reviews this process monthly to verify compliance. This recommendation is closed.

4. The review team recommends that the Branch establish, implement, and document a training program for Sealed Source and Device (SS&D) reviewers (Section 4.2.1 of the 2004 IMPEP report).

Current Status: The Branch has expended substantial effort in improving the Kentucky Agreement State Program, including the SS&D program. In particular, 0.5 full-time equivalents (FTE) were dedicated to managing the SS&D program. The primary SS&D reviewer, the Section Supervisor, and several additional staff have attended the NRC SS&D Workshop, inactivated registries, addressed amendment requests, and performed new device reviews. Additionally, the Commonwealth contracted a consulting company to provide a comprehensive 1-week SS&D training course to the Section staff. This recommendation is closed.

5. The review team recommends that the registration certificate evaluation criteria and document format be consistent with NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration" (Section 4.2.2 of the 2004 IMPEP report).

Current Status: The Branch utilizes NUREG-1556, Volume 3, Revision 1 for all SS&D evaluations. This recommendation is closed.

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 of the 2004 IMPEP report).

Current Status: The Branch inactivated non-Kentucky and outdated registries to the extent practical. This recommendation is closed.

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 followup actions (Section 4.2.3 of the 2004 IMPEP report).

Current Status: The Branch added a license condition to its sole manufacturer's license to require reporting of defects, deviations, or non-conformances of safety-related systems, structures, or components and documentation of followup actions. This recommendation is closed.

### 3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials 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, the Radiation Producing Machines Section, and the Radiation/Environmental Monitoring Section. The Section Supervisor is primarily responsible for materials licensing and compliance activities. The Branch has 9.0 FTE dedicated to the Agreement State program.

The performance weaknesses and the complete staff turnover that were identified during the previous IMPEP review period served as a basis for management's focused attention on filling positions with qualified and motivated staff. During the review period, the Radiation Producing Machines Section Supervisor from the previous review period received a promotion as the new Branch Manager, which became a vacant position after the resignation of the previous Branch Manager. Three additional staff left the Section during the review period; however, two of those individuals left the Section due to promotional opportunities, one of which was within the Branch. One additional Section staff member was deployed with the National Guard for a period of time, but has since returned to his position in the Section. To address the vacancies within the Section during the review period, six technical staff members were hired. Additionally, in 2007, a consultant (approximately 0.6 FTE) was contracted to assist in preparing necessary regulation changes in order to maintain compatibility with NRC. At the time of the review, the Section was fully staffed.

The technical staff members are classified as Radiation Health (RH) Specialists. Currently, RH II is the entry/junior level, and RH III is the senior level. Minimum qualifications for an RH II position include a bachelor's degree, certification, or year-for-year equivalent experience in the physical sciences. The review 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 and Organization of Agreement States Training Working Group Recommendations for Agreement State Training Programs. Qualification is established through a combination of education and experience, and formal classroom, in-house, and on-the-job training. The Section considers both attendance at NRC-sponsored courses and alternate resources for training.



The review team observed that Branch management exhibited a strong commitment to training. The Section maintains a training and qualification binder with a signoff qualification record for each technical staff member and the Section Supervisor. Staff members must complete each module and receive management signoff on the qualification record prior to being authorized to independently perform the tasks associated with that module. In an effort to obtain qualification in a particular modality, staff members review licenses and conduct inspections under the direction and supervision of an experienced and qualified license reviewer and inspector. The Section heavily focuses on the completion of this on-the-job training in order for the Section Supervisor to certify and document that an individual is qualified as both a license reviewer and inspector in a particular modality. Usually, training begins with licensing activities, and then proceeds to inspection activities when the individual's licensing knowledge is demonstrated as adequate. The review team observed that all current staff members have met the qualification requirements in at least one modality. The review team also discussed with the Section Supervisor a formalized program the Branch has in place, in which staff and managers are assigned to various collateral duties within the Branch on an annual basis. These collateral duties are essential in ensuring that various administrative functions, such as maintaining staff training and qualification records, within the Branch are kept up to date and organized. Through the annual rotation of collateral duty assignments among the staff, the staff is able to be a more integral part of the administrative functions of the Branch. The review team concluded that the Section's staffing and training is adequate to carry out its regulatory duties.

The Branch does not have dedicated revenue from licensee fees. Licensee fees are deposited in a general fund; a portion of which is appropriated back to the Branch. The last fee increase occurred during the last review period in 2003.

The Commonwealth of Kentucky does not have a radiation advisory board.

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 while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Branch's questionnaire response relative to this indicator, data gathered from the Branch's database, examination of completed inspection casework, and interviews with the Section Supervisor and staff.

The review team verified that the Branch's inspection frequencies for various types of licenses are generally the same as those prescribed by IMC 2800. There are some categories of licenses that the Branch inspects more frequently, including: private practice medical, broad medical, nuclear pharmacy, and portable gauge licenses. 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 its initial response to the questionnaire, the Branch indicated that there were no high priority (Priority 1, 2, and 3), initial, or Increased Controls licenses currently overdue by more than 25 percent of the inspection priorities prescribed by IMC 2800. With the exception of the Increased Controls inspections, this information was verified during the review of the inspection casework, database printouts, and administrative controls put in place by the Section Supervisor. The review team identified 64 of the 213 Priority 1, 2, and 3 and initial inspections the Branch completed during the review period as performed overdue. The review team calculated the Branch performed approximately 30 percent of the inspections overdue. The review team found that during the previous IMPEP review, the number of core inspections reported was incorrect due to the fact that the calculation included all licenses inspected. In 2004, the Branch appeared to exceed the 25 percent metric of inspections performed overdue or were presently overdue, not the 9.6 percent calculation as noted in the report. The Branch expended considerable effort in completing all overdue inspections from the 2004 review period and managed the backlog during this review period in order to achieve no overdue Priority 1, 2, and 3, and initial inspections at the time of this review. The Section Supervisor maintains supplemental database information to verify the Department's database for accurate inspection information. With the Branch fully staffed and trained and the inspection schedules maintained by the Section Supervisor, the review team believes that the Branch is in the position to maintain this level of performance for future inspections.

The review team determined that the Branch had 19 licensees subject to the Increased Controls, which are additional security requirements. At the time of the review, the Branch had conducted 12 inspections and 24 visits to these 19 licensees. The Branch did not develop and implement a documented and auditable prioritization methodology for ranking licensees for inspections of the Increased Controls, as requested in the 2006 NRC guidance for implementing the Increased Controls. Branch management interpreted the guidance to mean that the Branch had 3 years to verify that Increased Controls licensees were fully compliant, consistent with the requirement that all initial Increased Controls inspections should be completed within 3 years from the date of implementation of the controls. The review team noted that Branch inspection staff visited all of the Increased Controls licensees at least once since the issuance of the Increased Controls. During the visits, Branch inspection staff reviewed all applicable aspects of the Increased Controls requirements; however, due to database limitations with assigning multiple inspection due dates to one licensee, the inspection staff was unable to properly document the visits as inspections. Because the visits could not be properly documented as inspections in the database, the Branch had to use a less reliable mechanism to followup on and enforce violations that the inspectors identified during the visits. At the time of the review, the Branch had not officially performed initial inspections of seven Increased Controls licensees. On August 25, 2008, the review team was notified that the remaining seven initial Increased Control inspections were completed and appropriately documented.

The review team evaluated the timeliness of the issuance of inspection findings to licensees. The Branch's procedures require that inspection findings be issued to the licensee within 30 days of the date of the inspection. Of the 30 health and safety inspection files reviewed, 7 inspection findings were issued to the licensee beyond the 30 days ranging from several days to 4 months. The three inspection findings issued 2, 3, and 4 months late had significant violations identified, and the Section Supervisor was aware of the delays. Of the 12 initial Increased Control inspections conducted, 9 inspection findings were issued within 30 days; however, 3 inspection findings, ranging from 1.5 to 13 months, had not been issued at the time

of the on-site portion of the IMPEP review. The Section Supervisor informed the review team that the inspection findings were issued on August 1, 2008.

During the review period, the Branch granted 187 reciprocity licenses that were candidates for inspection based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Branch met the criterion of inspecting at least 20 percent of candidate reciprocity licensees, as prescribed by IMC 1220, in each of the three years prior to 2008. For 2008, the Branch inspected 15 percent of the candidate reciprocity licensees as of July 1, 2008.

Based on the criteria in Management Directive 5.6, the review team considered a finding of unsatisfactory because of the high percentage of inspections that the Branch performed overdue during the review period. The review team determined that the overdue inspections were a legacy issue and that the Branch expended considerable effort during the review period to eliminate the backlog. The review team concluded that the Branch's considerable efforts to eliminate the inspection backlog, the efforts to complete the Increased Controls inspections, and the performance of reciprocity inspections was justification for a finding of satisfactory, but needs improvement.

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 Materials Inspection Program, was satisfactory, but needs improvement.

### 3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes and interviewed the responsible inspectors for 41 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by all eight current inspectors and covered a wide variety of inspection types. These included academic broadscope, medical broadscope, medical institutions, nuclear cardiology, nuclear pharmacy, gamma knife, brachytherapy, self-shielded blood irradiators, industrial radiography, service provider, positron emission tomography, well logging, portable gauges, fixed gauges, manufacturers, and reciprocity licensees. Appendix C lists the inspection casework files reviewed and includes case-specific comments.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety program. The review team noted that inspection reports were generally thorough, complete, and consistent, with sufficient documentation to support that the licensees' performances with respect to health, safety, and security were acceptable. In general, inspection report documentation supported violations and recommendations made to licensees. The review team found that routine inspections adequately covered each licensee's radiation protection program; included a written summary of the scope of the licensed activities; and categorized violations into severity levels, which can later be used for escalated enforcement, if necessary. The documentation adequately supported the cited violations.

The Branch's inspection procedures are consistent with the inspection guidance found in IMC 2800. The Branch requires licensees to respond to any violation within 30 days of issuance of a Notice of Violation. All responses are reviewed for adequacy by the inspector. In several of the casework files reviewed, the inspection field notes did not document the closure of previous violations. The review team recommends that the Commonwealth revise its inspection procedures to require documentation of the closure of any previous violation, verification of corrective actions, and evaluation of preventive measures implemented by the licensee both in the inspection documentation and during the exit with the licensee.

The review team determined that documents involving Increased Controls inspections were protected, segregated from the electronic file storage system, and maintained in a locked file cabinet with limited access. Files were kept in visually distinct folders, identifying the 19 licensees subject to the Increased Controls. The review team determined that documents were sufficiently marked as sensitive information to be withheld from public disclosure.

As part of the preparation of the initial site visit to a licensee's facility, the inspector would suggest that the licensee invite the respective local law enforcement agency's representative to attend the initial on-site visit. The review team observed this practice during the inspector accompaniments and determined it was very productive in communicating the intent and clarifying the requirements of the Increased Controls between the licensee and local law enforcement agency. This practice would be particularly beneficial to new licensees that meet the criteria for implementing the Increased Controls. The review team recommended, and the MRB agreed, that the Branch's practice of requesting that the licensees extend an invitation to the local law enforcement agency during initial on-site visits/inspections for Increased Controls is a good practice.

The review team verified that the Branch maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, as well as to respond to radioactive materials incidents and emergency response events. Each inspector is assigned a calibrated dual function (Geiger-Mueller 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 includes the Radiation/Environmental Monitoring Section, which maintains a well-equipped and adequately staffed analytical laboratory. 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.

The Branch performs staff accompaniments annually. Due to the hiring of new staff in Calendar Years 2005 and 2006, annual accompaniments did not occur during the training period for the new inspectors. The Section Supervisor conducted formal, announced accompaniments of all radioactive materials inspectors in Calendar Years 2007 and 2008. The Section Supervisor indicated that the inspector accompaniments will continue on a routine basis.

The review team accompanied all of the Branch's radioactive materials inspectors during the weeks of May 12, 2008 and June 9, 2008, at a hospital, a nuclear pharmacy, an industrial radiography jobsite, facilities with portable and fixed gauges, and a facility using a self-shielded irradiator. Appendix C lists the inspector accompaniments and includes observations. During

the accompaniments, the review team noted that the inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

The inspectors held entrance and exit meetings with the appropriate level of licensee management. During the accompaniments, the review team noted that the inspectors did not discuss previous inspection findings and the licensees' corrective actions with the licensees during the entrance or exit meetings. The review team also observed that inspectors do not communicate any potential violations to the licensees at the exit meetings. Discussions with the Section Supervisor and staff revealed that it is standard practice not to communicate to the licensee whether the inspection findings during an inspection are actual violations or potential violations during the exit meeting. The Section does not contact the licensee before the issuance of the final Notice of Violation. The review team recommends that the Commonwealth discuss previous inspection findings, corrective actions, and any violations with the licensee during inspections.

Although each inspector is provided an appropriate, calibrated radiological survey instrument, the review team noted that, on several accompaniments, the inspectors used the licensees' radiological survey instruments to perform independent confirmatory surveys. The review team recommends that the Commonwealth use its own calibrated radiological survey equipment to perform independent confirmatory surveys during inspections.

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, but needs improvement.

### 3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined the licensing casework for 16 specific licenses, which included 32 licensing actions. Licensing actions were reviewed for completeness, consistency, proper possession authorizations, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 1 new license, 4 renewals, 25 amendments, and 2 license terminations. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy, brachytherapy, gamma knife, industrial radiography, nuclear pharmacies, manufacturing and distribution, and academic and industrial broadscope. The casework sample represented work from each of the

license reviewers. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

Licensing actions are assigned to one of the Branch's radioactive materials license reviewers. Once the reviewer completes the action, the action undergoes a peer review, a management review by the Section Supervisor, and then the license is signed by the Branch Manager. The license reviewers and Section Supervisor do not have signatory authority for licensing actions. Licensing checklists are used for each type of program and are included in the license file. The status of licensing actions is tracked using a log book. The Branch generates licenses and correspondence with standardized conditions and formats using program codes listed in a Department database. The use of the current database to generate licensing actions permits errors to enter the license documents when unique licensing types, sealed sources models, or license conditions are needed. The Branch utilizes appropriate licensing guides, standard licensing conditions, and issues a complete license for each licensing action. Overall, the review team found that the licensing actions were of adequate quality and generally consistent with the Branch's procedures, the Commonwealth's regulations, and good health physics practices.

The Branch issues licenses for a 1-year period based on the collection of an annual fee. The Commonwealth's regulations and the Branch's licensing guidance documents require a comprehensive technical renewal to be performed every 5-7 years; however, the review team found that the Department's database did not contain the data to identify that renewals were performed and does not have the capability to identify and track licenses that are required to have a comprehensive technical renewal. The review team recommends that the Commonwealth develop and implement a reliable mechanism to identify when a license is in need of a comprehensive renewal, identify these licenses, and develop and implement a plan to perform these renewals.

The review team evaluated the Branch's application of the Commonwealth's financial assurance requirements. The review team's evaluation revealed that the license reviewers use checklists to appropriately identify licensees required to maintain financial assurance and have taken appropriate steps to ensure compliance with the financial assurance requirements.

The review team examined the Branch's licensing practices regarding the Increased Controls and Fingerprinting requirements. The review team noted that the Branch added legally binding license conditions to the licenses that met the criteria for implementing the Increased Controls, including fingerprinting, as appropriate. The review team analyzed the Branch's methodology for identifying those licenses and found the rationale was thorough and accurate.

The Branch performs pre-licensing checks of all new applicants to verify their identity and need for radioactive materials. The Branch performs pre-license visits on all new applicants that meet the criteria for Increased Controls. In the evaluation of the pre-licensing checks, the review team found copies of corporation registrations from a variety of States and verifications that certain applicants are known to possess NRC or Agreement State licenses in the license files. At the time of the review, the Branch was unaware of the pre-license guidance requirements specified in the Office of Federal and State Materials and Environmental Management Programs (FSME) letter issued March 20, 2007, FSME 07-026. Although the Branch did not formally implement the pre-licensing guidance requirements, the essential objectives of this

program element were addressed. The Section Supervisor indicated that the Branch will implement the remaining requirements of FSME 07-026, as soon as possible. The review team recommends that the Commonwealth integrate the pre-licensing requirements of FSME 07-026 into their licensing program and reevaluate new licenses issued since September 2007 for implementation of these requirements.

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 Branch's actions in responding to incidents and allegations, the review team examined the Branch's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Kentucky in NMED against those contained in the Branch's files, and evaluated the casework for 12 of the 32 radioactive materials incidents listed in the Branch's incident database. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Branch's response to six allegations involving radioactive materials reported directly to the Branch during the review period and one allegation that NRC referred to the Branch during the review period.

When notified of an incident or an allegation, the Section Supervisor and staff discuss the event and determine the level of initial response based on the health and safety risk associated with the incident or allegation. The Branch maintains a database for tracking the status of all incidents and allegations. The actions taken in response to an incident are documented and filed. If the incident meets the reporting thresholds established in the NRC's FSME Procedure SA-300 "Reporting Material Events," the Branch notifies NRC. If an investigation is complex and extends over a period of time, NMED is appropriately updated, using the NMED software. The review team verified the staff's understanding of NMED through a demonstration of a data search and generation of specific reports. During the review period, the review team identified 20 incidents in NMED for Kentucky, of which 12 required reporting to NRC. The review team evaluated the Branch's timeliness in reporting incidents to NRC's Headquarters Operations Center, and determined that, following notification from the licensee, the Branch reported incidents within the required time frame.

The incidents selected for review included medical events; lost, stolen, or abandoned radioactive material; overexposures; damaged equipment; equipment failures; and transportation incidents. The review team determined that the Branch's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The review team noted that at the conclusion of investigations, inspectors documented the investigations.

The review team discussed the reporting of incidents involving certain naturally occurring and accelerator-produced material (NARM) with the Section Supervisor. A review of the Branch's tracking database verified that no incidents involving NARM have occurred since the November 30, 2007 waiver termination date for expansion of the definition of "byproduct

material," as established by the Energy Policy Act of 2005. The Section Supervisor was aware of the requirement to report NARM events to NRC and include the events in NMED.

In evaluating the effectiveness of the Branch's response to allegations, the review team evaluated the casework for seven allegations, one of which NRC referred to Kentucky. The review team concluded that the Branch consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Branch thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations; however, in four of the casework reviews, the allegation files contained no documentation that the allegeders had been notified of the disposition of the allegations at the conclusion of the Branch's investigations. The Branch is currently revising its allegation procedure and will include specific guidance in the procedure to require documentation of contact with allegeders at the conclusion of an investigation of an allegation. The review team determined that the Branch adequately protected the identity of allegeders.

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, was satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review 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 relinquish authority for a uranium recovery program; therefore, only the first three non-common performance indicators were applicable to this review.

##### 4.1 Compatibility Requirements

###### 4.1.1 Legislation

Kentucky became the first Agreement State in 1962. The 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 NARM.



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 until it is submitted to NRC for a final compatibility review. The public and other interested parties are provided an opportunity to comment on proposed rules. 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 relative to this indicator, 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 State Regulation Status sheet that FSME maintains.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. The following 16 amendments are overdue, some significantly longer than 3 years from the effective date. The current status for each amendment is included:

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendment (60 FR 15649 and 60 FR 25983), that was due for Agreement State implementation on March 1, 1998.

Status: This is one of 12 amendments that was sent to the Commonwealth's Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendment (60 FR 38235), that was due for Agreement State implementation on November 24, 1998.

Status: The Commonwealth adopted a final rule that addressed NRC's comments transmitted on June 1, 2000, on the proposed rule, but did not submit the package for NRC review as a final rule. The Commonwealth plans to include the final rule with the package of 12 amendments that was being prepared for public comment within the Commonwealth's regulation process as soon as the package is ready to be sent for NRC review of the final rules.

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendment (60 FR 48623), that was due for Agreement State implementation on October 20, 1998.

Status: The Commonwealth's adoption of the overdue amendments, "Medical Use of Byproduct Material" and "Medical Use of Byproduct Material – Recognition of Specialty Boards," will supersede this amendment.

- “10 CFR Part 71: Compatibility with the International Atomic Energy Agency,” 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724), that was due for Agreement State implementation on April 1, 1999.

Status: The Commonwealth’s adoption of the overdue amendment, “Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments,” will supersede this amendment.

- “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 35, and 36 amendment (63 FR 39777 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Transfer for Disposal and Manifests: Minor Technical Conforming Amendment,” 10 CFR Part 20 amendment (63 FR 50127), that was due for Agreement State implementation on November 20, 2001.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Respiratory Protection and Controls to Restrict Internal Exposure,” 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524), that was due for Agreement State implementation on February 2, 2003.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment (65 FR 20337), that was due for Agreement State implementation on May 17, 2003.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “New Dosimetry Technology,” 10 CFR Parts 34, 36, and 39 amendment (65 FR 63749), that was due for Agreement State implementation on January 8, 2004.

Status: This is one of 12 amendments was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, and 32 amendment (65 FR 79162), that was due for Agreement State implementation on February 16, 2004.

Status: While on site, the review team examined a revised license condition that the Section Supervisor drafted that addressed the three comments submitted by NRC on March 16, 2004, on the Commonwealth’s proposed license condition. The Section Supervisor committed to incorporating the revised license condition on its sole manufacturer’s license and submitting the revised license condition to NRC for final review.

- “Revision of the Skin Dose Limit,” 10 CFR Part 20 amendment (67 FR 16298), that was due for Agreement State implementation on April 5, 2005.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Medical Use of Byproduct Material,” 10 CFR Parts 20, 32, and 35 amendment (67 FR 20250), that was due for Agreement State implementation on October 24, 2005.

Status: The Commonwealth adopted a final rule that addressed the comments submitted by the NRC on October 28, 2004, on the proposed rule. The Commonwealth plans to include the final rule with the package of 12 amendments that was being prepared for public comment within the Commonwealth’s regulation process, as soon as the package is ready to be sent for NRC review of the final rules.

- “Financial Assurance for Materials Licensees,” 10 CFR Parts 30, 40, and 70 amendment (68 FR 57327), that was due for Agreement State implementation on December 3, 2006.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments,” 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 1, 2007.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Medical Use of Byproduct Materials - Recognition of Specialty Boards - Part 35,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR Part 30 amendment (70 FR 2001), that was due for Agreement State implementation on October 1, 2007.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

The review team identified the following NRC amendments that the Commonwealth will need to address in the future. The Section Supervisor related that the amendments would be addressed in upcoming rulemakings or in the adoption of alternate legally binding requirements:

- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65865), that is due for Agreement State adoption by January 31, 2009.

Status: While on site, the review team provided the Section Supervisor a copy of an example license condition for the amendment. The Section Supervisor committed to addressing the amendment via license condition and submitting it to the NRC for review in the near future.

- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005), that is due for Agreement State adoption by March 27, 2009.

Status: This is one of 12 amendments that was sent to the Commonwealth’s Legislative Research Commission for publication as a final rule and was being prepared for public comment.

- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32 and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

The review team recognized the amount of progress since the last review to address the number of overdue regulations. With the submittal of the previously mentioned rulemaking package and several additional amendments to NRC for final review, the Commonwealth will be up to date with regulation development. The Branch implemented a plan to help ensure that the Commonwealth continues to adopt and maintain compatibility with the NRC by addressing upcoming regulation changes and adoptions.

Based on the 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 Evaluation Program

In reviewing this indicator, the review team used three subelements to evaluate the Branch's performance regarding the SS&D Evaluation Program. These subelements were: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Branch's SS&D evaluation activities, the review team examined information contained in the Branch's response to the IMPEP questionnaire for this indicator. The review team evaluated all SS&D evaluations and supporting documents processed during the review period. The Branch conducted 1 new SS&D evaluation, issued 2 amendments to existing registrations, and inactivated 14 registrations since the last review. The review team noted the staff's use of guidance documents and procedures, interviewed staff members involved in SS&D evaluations, and verified the use of regulations and inspections to enforce commitments made in the applications.

##### 4.2.1 Technical Staffing and Training

The Branch has six reviewers who are qualified to perform safety evaluations of SS&D applications. All have degrees in a physical science or engineering and have attended the NRC's SS&D Workshop or the Branch's week-long training discussed in Section 2.0. The review team evaluated the independent training program materials and found it to be comparable in content and quality to NRC's workshop. The review team interviewed staff members involved in the reviews and determined that they were familiar with the procedures used in the evaluation of a device or source and had access to applicable reference documents.

##### 4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated 2 of the 3 SS&D actions and 2 of the 14 SS&D registration inactivations issued during the review period. One of the actions was a significant amendment and the other was a new registration. The casework reviewed represented the efforts of two of the Branch's six SS&D reviewers. These were the only two reviewers who performed

evaluations during the review period. A list of SS&D casework examined, with case-specific comments, can be found in Appendix F.

Analysis of the casework and interviews with staff members confirmed that the Branch follows the recommended guidance from the NRC's SS&D Workshop and NUREG-1556, Volume 3, Revision 1. The review team confirmed that all applicable and pertinent American National Standards Institute standards, NUREG-1556 Series guides, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews. The Branch also follows a documented internal process when performing an SS&D review that includes a round-table discussion with the manufacturer and physically inspecting the prototype device.

The Commonwealth currently has one device manufacturer who has active registrations. Registrations clearly summarized the product evaluations to provide license reviewers with adequate information to license the possession and use of the products. Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. Overall, the review 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 under accident conditions.

The review team found that the Branch does not have a legal means (e.g., regulations, license conditions, etc.) to enforce any commitments a manufacturer makes in its application and does not list the SS&D commitments in the manufacturer's radioactive materials possession license. Subsequent to the review, the Branch added a license condition to the manufacturer's license that ties the active SS&D registries to the license, providing a legal means to enforce any commitments made in the applications.

The review team also found that while the Branch performs a review of the submitted quality assurance and quality control program used with the SS&D registry, the Branch does not have a mechanism to verify whether the approved quality assurance and quality control program is implemented by the manufacturer. The review team recommends that the Commonwealth develop and implement a mechanism to verify the implementation of the approved quality assurance and quality control program.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&D defects involving sources or devices registered by the Commonwealth were reported during the review period. Incident procedures are in place should an SS&D-related incident occur. The Branch Manager and Section Supervisor were aware of the need to look at such incidents as potentially generic issues with possible wide-ranging effects.

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.

#### 4.3 Low-Level Radioactive Waste Disposal Program

In reviewing this indicator, the review team used five subelements to evaluate the Branch's performance regarding the low-level radioactive waste (LLRW) disposal program. These subelements were: (1) Technical Staffing and Training, (2) Status of Low-Level Radioactive Waste Disposal Inspection, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

The LLRW program consists of oversight at one facility, the Maxey Flats site, which 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.

The license for the site authorizes maintenance activities related to the closed LLRW disposal site. The license is issued to the Energy and Environment Cabinet (EEC), who is responsible for carrying out regulatory requirements. Since the facility is closed and has no on-site activity or operations, the activities at the site are limited to a radiological environmental monitoring program consisting of soil, surface water, and ground water monitoring.

##### 4.3.1 Technical Staffing and Training

The Branch staff, whose qualifications satisfy the RH Specialist III level of training discussed in Section 3.1, serves as license reviewers and inspectors. The laboratory technical staff in the Radiation/Environmental Monitoring Section involved with the Maxey Flats radiological environmental monitoring program consists of five individuals, who have been trained in radiochemistry, environmental sampling, and analysis and data evaluation. The review team discussed the qualifications of the laboratory technical staff with the Section Supervisor and determined that their qualifications are commensurate with expertise needed to regulate and monitor the closed LLRW disposal site. The review team found that the Branch's radioactive materials qualification and training requirements are adequate for technical staff to perform LLRW licensing actions and inspections.

##### 4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

The Branch's inspection frequency for the site is every 2 years. NRC has not established an inspection frequency for closed LLRW sites. The Branch conducted an inspection of the site on June 18, 2008. The previous inspection was conducted in January 2004. No formal inspection was conducted in 2006 due to staffing issues and prioritization of overdue inspections identified during the last review. Despite the lack of a formal radioactive materials inspection in 2006, the Branch Manager stated that other oversight activities are routinely conducted at the site through radiological environmental monitoring program. The laboratory technical staff conducts monthly and quarterly site visits. In addition, the licensee conducts quarterly inspections at the site and provides detailed reports to EPA and the Branch. The Section Supervisor committed to continue the 2-year inspection frequency for the site based on discussions with the review team.

Regarding the timeliness of the Branch inspection reports, the review team noted that for the inspection conducted in June 18, 2008, the inspection results and report had not been issued at the time of this review. The Section Supervisor indicated that the delay was due to higher priority activities and that the inspection format has changed from an inspection checklist to a formal narrative report.

#### 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. No inspection casework from the review period was available for review, as noted in Section 4.3.2.

The review team visited the Radiation/Environmental Monitoring Section laboratory and found the facility was well equipped to support the radiological environmental monitoring program at Maxey Flats. The laboratory staff makes use of written approved procedures, instrument control charts, participates in an interlaboratory quality control program, and conducts independent review and assessment of data. The laboratory has a wide array of analytical equipment, as described in Section 3.3. Both the licensee and laboratory staff collect soil and water samples at prescribed frequencies. Split sampling is conducted on all compliance point sampling locations. Action levels for reporting unusual sample analysis results are based on historical knowledge. If a sample result is returned as elevated or high, the State Environmental Contractor is notified. Following the notification to the contractor, the Radiation/Environmental Monitoring Section Supervisor reports the result to the Branch Manager, who in turn, sends the report to the Section Supervisor all within a 5-day period.

In addition, laboratory analysis activities include wipe analysis and analysis of samples from items found in the public domain. Sample results are provided in a timely manner. 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, radiological environmental monitoring program data are maintained at the laboratory. The Branch maintains an adequate number and type of calibrated radiation survey instruments to support the materials program, as discussed in Section 3.3. Survey instruments are also available at the laboratory.

#### 4.3.4 Technical Quality of Licensing Actions

EEC'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 Section Supervisor is the reviewer for all license amendment actions.

The review team examined four licensing actions related to the EEC license issued during the review period, as indicated in Appendix D. Applicable guidance documents related to licensing actions were available and used, as needed. The review team found that the licensing actions were thorough, complete, consistent, and of high quality, with health, safety, and security issues properly addressed.



#### 4.3.5 Technical Quality of Incident and Allegation Activities

The review team found that the Branch has procedures in place for handling incidents and allegations. During the review period, the Branch received no reports of incidents or allegations pertaining to the LLRW disposal program.

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 3.0 and 4.0, Kentucky's performance was found satisfactory, but needs improvement, for the performance indicators, Status of Materials Inspection Program, Technical Quality of Inspections, and Compatibility Requirements. Kentucky's performance was found satisfactory for all other performance indicators reviewed. The review team made six recommendations regarding program performance and identified one good practice. Accordingly, the review team recommended, and the MRB agreed, that the Kentucky Agreement State Program was adequate to protect public health and safety, but needs improvement, and compatible with NRC's program. The review team also recommended, and the MRB agreed, that the period of monitoring will continue, including quarterly conference calls and a periodic meeting in approximately 1 year to assess the Branch's progress in addressing the review team's recommendations.

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

1. The review team recommends that the Commonwealth revise its inspection procedures to require documentation of the closure of any previous violation, verification of corrective actions, and evaluation of preventive measures implemented by the licensee both in the inspection documentation and during the exit with the licensee (Section 3.3).
2. The review team recommends that the Commonwealth discuss previous inspection findings, corrective actions, and any potential violations with the licensee during inspections (Section 3.3).
3. The review team recommends that the Commonwealth use its own calibrated radiological survey equipment to perform independent confirmatory surveys during inspections (Section 3.3).
4. The review team recommends that the Commonwealth develop and implement a reliable mechanism to identify when a license is in need of a comprehensive renewal, identify these licenses, and develop and implement a plan to perform these renewals (Section 3.4).
5. The review team recommends that the Commonwealth integrate the pre-licensing requirements of FSME 07-026 into their licensing program and reevaluate new licenses issued since September 2007 for implementation of these requirements (Section 3.4).

6. The review team recommends that the Commonwealth develop and implement a mechanism to verify the implementation of the approved quality assurance and quality control program (Section 4.2.2).

Below is a good practice, as mentioned earlier in the report:

The review team recommends that the Branch's practice of requesting that the licensees extend an invitation to the local law enforcement agency during initial on-site visits/inspections for Increased Controls be identified as a good practice. (Section 3.3)

## LIST OF APPENDIXES 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 & Device Casework Reviews
Attachment	October 6, 2008, Letter from William D. Hacker Kentucky's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

<b>Name</b>	<b>Area of Responsibility</b>
Kathleen Schneider, FSME	Team Leader Status of Materials Inspection Program
Kim Lukes, FSME	Technical Staffing and Training Compatibility Requirements
James Kottan, Region I	Technical Quality of Incident and Allegation Activities
Michael Stephens, FL	Technical Quality of Licensing Actions Sealed Source and Device Evaluation Program
Ricardo Munoz, RIV	Technical Quality of Inspections Low-Level Radioactive Waste Disposal Program Inspector Accompaniments

APPENDIX B

KENTUCKY ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML082410026

COMMONWEALTH OF  
KENTUCKY

Steven L. Beshear  
Governor

CABINET FOR HEALTH &  
FAMILY SERVICES

Janie Miller  
Secretary

DEPARTMENT FOR PUBLIC  
HEALTH

William D. Hacker, M.D.  
Commissioner

DIVISION OF PUBLIC HEALTH  
PROTECTION & SAFETY

Guy Delius  
Acting Director

RADIATION HEALTH BRANCH

Dewey Crawford  
Manager

RADIOACTIVE MATERIALS  
SECTION

Matthew McKinley  
Supervisor

RADIATION PRODUCING  
MACHINES SECTION

Robert Gresham  
Supervisor

RADIATION /  
ENVIRONMENTAL  
MONITORING SECTION

Stephanie Brock  
Supervisor

# RADIATION HEALTH BRANCH

Dewey Crawford  
Manager

## RADIOACTIVE MATERIALS SECTION

Matthew McKinley  
Supervisor

Rick Horky  
Steven Berrier  
Angela Shryock (Britton)  
Curt Pendergrass  
Brian Parsley  
Mel Goodfriend  
Nathan Garner  
Michele Greenwell

## RADIATION PRODUCING MACHINES SECTION

Robert Gresham  
Supervisor

James Barnes  
Steve Mays  
Ken McIlwain  
Julie Keightley  
James Royalty  
Vacant position

OPERATOR  
CERTIFICATION  
Vanessa Breeding

## RADIATION / ENVIRONMENTAL MONITORING SECTION

Stephanie Brock  
Supervisor

Philip Mills  
Mark Keene  
James May  
Christopher Keffer  
Contract Employees from University  
of Kentucky and URS

## APPENDIX C

### INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Schlumberger Technology  
Inspection Type: Special, Announced  
Inspection Date: 6/14/07

License No.: 201-665-40  
Priority: 1  
Inspector: AB

Comment:

Inspection findings were dispatched to the licensee 13.5 months after the date of the inspection.

File No.: 2

Licensee: Jewish Hospital of Shelbyville  
Inspection Type: Routine, Unannounced  
Inspection Dates: 6/4/05, 5/15/08

License No.: 202-198-25  
Priority: 3  
Inspector: BP

Comments:

- a) The inspection report for the 2005 violation did not document the date of violation or the length of time the violation occurred.
- b) Inspector notes for the 2008 inspection did not document the closeout of the previous inspection's violations.
- c) Documentation in the file stated that there is no "Return to Compliance" letter.

File No.: 3

Licensee: Springview Hospital  
Inspection Type: Routine, Unannounced  
Inspection Date: 6/13/08

License No.: 202-311-24  
Priority: 3  
Inspector: RH

Comment:

The inspection report did not document that the corrective actions for the violations from the 2004 inspection were verified.

File No.: 4

Licensee: Mays Suddereth & Etheredge  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/14/08

License No.: 201-207-51  
Priority: 4  
Inspector: NG

Comment:

Previous inspection identified repeat violations. The inspection report did not document how the corrective action for these violations was verified during the 2008 inspection.



File No.: 5

Licensee: Radiopharmacy of Paducah, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 6/10/08

License No.: 202-211-32  
Priority: 1  
Inspectors: MMG, AB

File No.: 6

Licensee: University of Kentucky  
Inspection Type: Special, Announced  
Inspection Date: 6/3/08

License No.: 212-024-31  
Priority: 2  
Inspector: CP

File No.: 7

Licensee: Flaget Memorial Hospital  
Inspection Type: Routine, Unannounced  
Inspection Date: 5/13/08

License No.: 202-193-25  
Priority: 3  
Inspector: RH

File No.: 8

Licensee: American Red Cross Blood Services  
Inspection Type: Special, Announced  
Inspection Date: 5/12/08

License No.: 202-216-96  
Priority: 3  
Inspectors: AB, SB

Comment:

Inspection findings were dispatched to the licensee 80 days after the date of the inspection.

File No.: 9

Licensee: University of Kentucky  
Inspection Type: Special, Announced  
Inspection Date: 6/3/08

License No.: 212-266-96  
Priority: 2  
Inspector: CP

Comment:

Sensitive information was incorrectly filed.

File No.: 10

Licensee: Kentucky Blood Center  
Inspection Type: Special, Announced  
Inspection Date: 5/24/08

License No.: 202-243-96  
Priority: 3  
Inspector: CP

Comment:

Inspection findings were dispatched to the licensee 68 days after the date of the inspection.

File No.: 11

Licensee: Acuren Inspection  
Inspection Type: Special, Announced  
Inspection Date: 5/20/08

License No.: 201-666-05  
Priority: 1  
Inspector: CP

File No.: 12

Licensee: Logan Aluminum  
Inspection Type: Special, Announced  
Inspection Date: 4/30/08

License No.: 201-419-57  
Priority: 1  
Inspector: CP

File No.: 13

Licensee: Huntington Testing & Technology  
Inspection Type: Special, Announced  
Inspection Date: 3/25/08

License No.: 201-551-05  
Priority: 1  
Inspector: CP

File No.: 14

Licensee: Stupp Bridge  
Inspection Type: Special, Announced  
Inspection Date: 5/1/08

License No.: 201-674-05  
Priority: 1  
Inspector: CP

File No.: 15

Licensee: Integrity Testing  
Inspection Type: Special, Announced  
Inspection Date: 6/11/08

License No.: 201-692-05  
Priority: 1  
Inspector: CP

File No.: 16

Licensee: Integrity Testing & Inspection  
Inspection Type: Routine, Unannounced  
Inspection Date: 2/19/08

License No.: 201-692-05  
Priority: 1  
Inspector: CP

File No.: 17

Licensee: El DuPont DeNemours & Company  
Inspection Type: Routine, Unannounced  
Inspection Date: 6/12/08

License No.: 201-028-57  
Priority: 5  
Inspector: MG

File No.: 18

Licensee: American Red Cross Blood Services  
Inspection Type: Routine, Announced  
Inspection Date: 5/12/08

License No.: 202-216-96  
Priority: 3  
Inspectors: AB, SB

File No.: 19

Licensee: St. Luke Hospital West  
Inspection Type: Routine, Unannounced  
Inspection Date: 1/26/08

License No.: 202-003-25  
Priority: 3  
Inspector: BP

File No.: 20

Licensee: Lake Cumberland Regional Hospital  
Inspection Type: Routine, Unannounced  
Inspection Date: 10/10/07

License No.: 202-123-26  
Priority: 3  
Inspector: RH

File No.: 21

Licensee: Norton Suburban Hospital  
Inspection Type: Routine, Unannounced  
Inspection Dates: 1/25-26/07

License No.: 202-099-26  
Priority: 3  
Inspector: RH

Comment:

Ten violations noted during the inspection. The notice of violation/inspection findings correspondence was issued approximately 5 months after the inspection.

File No.: 22

Licensee: Owensboro Medical Health System  
Inspection Type: Routine, Unannounced  
Inspection Date: 3/19/08

License No.: 202-161-26  
Priority: 3  
Inspector: BP

File No.: 23

Licensee: Cardiac & Vascular Imaging  
Inspection Type: Routine, Unannounced  
Inspection Date: 12/13/07

License No.: 202-317-29  
Priority: 2  
Inspector: BP

Comment:

The Section has not yet issued a "Return to Compliance" letter in response to licensee's February 15, 2008 correspondence.

File No.: 24

Licensee: StanTec Consulting  
Inspection Type: Routine, Unannounced  
Inspection Date: 9/19/07

License No.: 201-142-51  
Priority: 4  
Inspector: CP

File No.: 25

Licensee: West Kentucky Well Surveys  
Inspection Type: Routine, Unannounced  
Inspection Date: 3/27/07

License No.: 201-056-41  
Priority: 3  
Inspector: CP

File No.: 26

Licensee: Lourdes Medical Pavilion, LLC  
Inspection Type: Routine, Unannounced  
Inspection Date: 11/8/08

License No.: 202-302-24  
Priority: 4  
Inspector: RH

File No.: 27

Licensee: Hayes Testing Laboratory  
Inspection Type: Special, Announced  
Inspection Date: 6/9/08

License No.: 211-168-05  
Priority: 1  
Inspectors: CP, SB

File No.: 28

Licensee: Hayes Testing Laboratory  
Inspection Type: Routine, Announced  
Inspection Date: 6/9/08

License No.: 201-168-05  
Priority: 1  
Inspectors: CP, SB

File No.: 29

Licensee: Kentucky State University  
Inspection Type: Routine, Unannounced  
Inspection Date: 9/11/07

License No.: 202-029-22  
Priority: 5  
Inspector: MG

Comments:

- a) Status of previous non-compliance items not addressed in the inspection report.
- b) Licensee's response to notice of violation findings was not in the file.

File No.: 30

Licensee: Bluegrass Regional Imaging  
Inspection Type: Routine, Unannounced  
Inspection Date: 7/12/08

License No.: 202-367-24  
Priority: 1  
Inspector: AB

File No.: 31

Licensee: PetNet Solutions, Inc.  
Inspection Type: Routine, Unannounced  
Inspection Date: 3/13/08

License No.: 202-281-32  
Priority: 1  
Inspector: BP

File No.: 32

Licensee: St. Elizabeth Medical Center  
Inspection Type: Routine, Unannounced  
Inspection Date: 1/26/06

License No.: 202-152-26  
Priority: 3  
Inspector: BP

Comment:

Inspection findings were dispatched to the licensee approximately 2 months after the date of the inspection.

File No.: 33

Licensee: Cardinal Health Services  
Inspection Type: Routine, Unannounced  
Inspection Dates: 3/18/08, 7/9/08

License No.: 202-204-32  
Priority: 1  
Inspectors: BP, AB

File No.: 34

Licensee: Bluegrass Cardiology  
Inspection Type: Routine, Unannounced  
Inspection Date: 12/19/05

License No.: 202-256-26  
Priority: 4  
Inspector: RH

File No. 35

Licensee: Ronan Engineering Company  
Inspection Type: Routine, Announced  
Inspection Date: 6/28/07

License No. 201-260-95  
Priority: 3  
Inspector: MG

File No. 36

Licensee: Grand Eagle Mining  
Inspection Type: Routine, Announced  
Inspection Date: 11/15/07

License No. 201-660-56  
Priority: 4  
Inspector: CP

File No.: 37  
Licensee: TEI Analytical Services  
Inspection Type: Reciprocity, Unannounced  
Inspection Date: 5/9/07

License No.: NRC 37-28004-01  
Priority: 1  
Inspector: CP

Comment:

The special inspection requirements were not covered during the safety inspection.

File No.: 38  
Licensee: Jan-X Integrity Group  
Inspection Type: Reciprocity, Unannounced  
Inspection Dates: 8/22/07, 2/18/08

License No.: NRC 21-16560-01  
Priority: 1  
Inspectors: CP, MG

Comment:

The special inspection requirements were not covered during the safety inspection.

File No.: 39  
Licensee: Tracerco  
Inspection Type: Reciprocity, Unannounced  
Inspection Date: 6/12/08

License No.: NRC 07-28386-01  
Priority: 4  
Inspector: MG

File No.: 40  
Licensee: Appalachian Well Surveys, Inc.  
Inspection Type: Reciprocity, Unannounced  
Inspection Date: 3/17/08

License No.: OH 03111300001  
Priority: 1  
Inspector: MG

File No.: 41  
Licensee: NDC Infrared Engineering  
Inspection Type: Reciprocity, Unannounced  
Inspection Date: 3/17/08

License No.: CA 1451-19  
Priority: 4  
Inspector: BP

### INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1  
Licensee: American Red Cross/River Valley Region  
Inspection Type: Routine, Announced  
Inspection Date: 5/12/08

License No.: 202-216-96  
Priority: 3  
Inspectors: AB, SB

Comment:

During the exit briefing with the licensee, the inspector did not discuss any inspection findings or potential violations.

Accompaniment No.: 2

Licensee: American Red Cross/River Valley Region

Inspection Type: Special, Announced

Inspection Date: 5/12/08

License No.: 212-216-96

Priority: 1

Inspectors: AB, SB

Comment:

The inspectors needed to pursue additional queries into the requirements of continuous monitoring and communication among component systems were not addressed during the initial site visit.

Accompaniment No.: 3

Licensee: Flaget Memorial Hospital

Inspection Type: Routine, Unannounced

Inspection Date: 5/13/08

License No.: 202-193-25

Priority: 3

Inspector: RH

Comment:

Although inspectors carry their own survey instruments, during the inspection, the inspector used the licensee's radiological survey equipment to perform independent confirmatory surveys.

Accompaniment No.: 4

Licensee: Mayes Sedderth & Ethridge

Inspection Type: Routine, Unannounced

Inspection Date: 5/14/08

License No.: 201-207-51

Priority: 3

Inspector: NG

Comments:

- a) The inspector did not perform independent confirmatory surveys.
- b) During the exit briefing with the licensee, the inspector did not discuss any inspection findings or potential violations.

Accompaniment No.: 5

Licensee: Jewish Hospital of Shelbyville

Inspection Type: Routine, Unannounced

Inspection Date: 5/15/08

License No.: 202-198-25

Priority: 3

Inspector: BP

Comment:

Although inspectors carry their own survey instruments, during the inspection, the inspector used the licensee's radiological survey equipment to perform independent confirmatory surveys.

Accompaniment No.: 6

Licensee: Hays Testing Laboratory, Inc

Inspection Type: Routine, Announced

Inspection Date: 6/9/08

License No.: 211-168-05

Priority: 1

Inspector: CP

Accompaniment No.: 7

Licensee: Hays Testing Laboratory, Inc.

Inspection Type: Special, Announced

Inspection Date: 6/9/08

License No.: 201-168-05

Priority: 1

Inspector: CP

Comments:

- a) The inspector needed to pursue additional queries into the requirements of continuous monitoring and communication among component systems that were not addressed during the initial site visit.
- b) The inspector did not identify violations related to line-cut detection at the facility and on the licensee's transport vehicles.

Accompaniment No.: 8

Licensee: Radiopharmacy of Paducah, Inc

Inspection Type: Routine, Unannounced

Inspection Date: 6/10/08

License No.: 202-221-32

Priority: 1

Inspectors: MMG, AB

Comment:

During the exit briefing with the licensee, the inspector did not discuss any inspection findings or potential violations.

Accompaniment No.: 9

Licensee: Integrity Testing & Inspection

Inspection Type: Routine, Announced

Inspection Date: 6/11/08

License No.: 201-692-05

Priority: 1

Inspector: CP

Accompaniment No.: 10

Licensee: Integrity Testing & Inspection

Inspection Type: Special, Announced

Inspection Date: 6/11/08

License No.: 211-692-05

Priority: 1

Inspector: CP

Comments:

- a) The inspector needed to pursue additional queries into the requirements of continuous monitoring and communication among component systems that were not addressed during the initial site visit.
- b) The inspector did not identify violations related to line-cut detection at the facility and on the licensee's transport vehicles.

Accompaniment No.: 11

Licensee: Tracerco

Inspection Type: Reciprocity, Unannounced

Inspection Date: 6/12/08

License No.: NRC 07-28386-01

Priority: 3

Inspector: MG

Comment:

The inspector did not observe the licensee set up or conduct of licensed activities.

Accompaniment No.: 12

Licensee: DuPont

Inspection Type: Routine, Unannounced

Inspection Date: 6/12/08

License No.: 201-028-33

Priority: 3

Inspector: MG

Comments:

- a) The inspector did not review issues related to receipt and disposal of licensed material to the manufacturer.
- b) The inspector had not prepared by reviewing the entire license file. Previous violations were not reviewed or verified during the inspection.
- c) During the exit briefing with the licensee, the inspector did not discuss any inspection findings or potential violations.

Accompaniment No.: 13

Licensee: Western Kentucky Energy, D.B. Wilson Plant

Inspection Type: Incident Investigation

Inspection Date: 6/11/08

License No.: 201-277-56

Type of Incident: Equipment Failure

Inspector: CP



APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: E.I. Dupont De Nemours & Company

Type of Action: Amendments

Dates Issued: 7/21/05, 7/24/06, 12/15/06

License No.: 201-028-57

Amendment Nos.: 77, 79, 80

License Reviewers: SB, CP, AB

File No.: 2

Licensee: Bluegrass Cardiology

Type of Action: Amendment

Date Issued: 1/8/08

License No.: 202-256-24

Amendment No.: 15

License Reviewers: MMG, RH

File No.: 3

Licensee: Kentucky State University

Type of Action: Amendments

Dates Issued: 1/10/06, 6/4/07

License No.: 203-037-83

Amendment Nos.: 30, 33

License Reviewer: AB

Comment:

License expired on May 31, 2008 for non-payment of annual fees and licensee still possesses radioactive materials.

File No.: 4

Licensee: PetNet Solutions Inc.

Type of Action: Renewal, Amendment

Dates Issued: 2/5/08, 5/16/08

License No.: 202-281-32

Amendment Nos.: 13, 14

License Reviewers: AB, MMG

Comment:

License tie-down condition does not list all of the licensee's renewal application commitments.

File No.: 5

Licensee: Cardinal Health Nuclear Pharmacy Services

Type of Action: Renewal

Date Issued: 2/18/08

License No.: 202-204-32

Amendment No.: 53

License Reviewer: AB

Comments:

- a) License tie-down condition does not list all of the licensee's renewal application commitments.
- b) Item 9 on the license lists correspondence containing licensee's commitments (dated 1991), and this correspondence is not in the license file.

File No.: 6

Licensee: Consol of KY, Inc.

Type of Action: Termination

Date Issued: 6/2/08

License No.: 201-507-51

Amendment No.: 18

License Reviewer: MG

File No.: 7

Licensee: Ronan Engineering Company  
Type of Action: Amendments  
Dates Issued: 8/17/06, 8/21/06, 6/16/08

License No.: 201-260-95  
Amendment Nos.: 42, 60, 61  
License Reviewer: MG

Comments:

- a) The license's was last comprehensive renewal was issued February 1, 2002. Based on the program's protocol, this license should have been renewed within 5 years.
- b) The license does not have any of the sealed source registry certificate licensee commitments identified either by license or tie-down condition.

File No.: 8

Licensee: Murray State University  
Type of Action: Amendment  
Date Issued: 3/3/08

License No.: 203-018-83  
Amendment No.: 59  
License Reviewer: MK

File No.: 9

Licensee: Dart Polymer  
Type of Action: Amendment  
Date Issued: 8-29-96-Annual Fee Expiration Date

License No.: 201-586-56  
Amendment Nos.: 0-7  
License Reviewers: Various

Comment:

The license was issued in 1996 and has never been renewed in its entirety.

File No.: 10

Licensee: The Medical Center at Bowling Green.  
Type of Action: Amendments  
Dates Issued: 5/1/07, 4/9/08, 5/28/08

License No.: 202-124-26  
Amendment Nos.: 90, 91, 92,  
License Reviewer: BP

Comments:

- a) The license does not identify the sealed source model numbers authorized for large activity sources.
- b) Incorrect documentation on the license documents. Both amendments were identified as "Amended in its Entirety," which is essentially a "renewal;" however, neither amendment was the 5- or 7-year resubmittal.

File No.: 11

Licensee: University of Kentucky  
Type of Action: Amendments  
Dates Issued: 12/13/07, 6/6/08

License No.: 202-024-31  
Amendment Nos.: 56, 57  
License Reviewer: AB

Comments:

- a) The license does not identify the sealed source model numbers authorized for large activity sources.
- b) Deficiency in the facility diagram was not addressed in a deficiency letter, but additional information was gathered and documented during the pre-licensing visit which addressed the deficiency in the submitted material reviewed. A shield plan survey diagram dated May 23, 2008, is in the license file.

File No.: 12

Licensee: Cardiovascular Specialists  
Types of Action: Renewal, Amendments  
Dates Issued: 2/16/06, 9/29/06, 7/5/07, 3/10/08

License No.: 202-162-24  
Amendment Nos.: 47, 49, 50, 51  
License Reviewer: AB

File No.: 13

Licensee: JANX  
Types of Action: New, Amendment  
Dates Issued: 12/12/06, 6/11/08

License No.: 201-700-05  
Amendment Nos.: 0, 2  
License Reviewers: CP, SB

Comment:

The licensee's response to the deficiency letter contained sensitive information and was not appropriately marked.

File No.: 14

Licensee: Associated Veterinary  
Type of Action: Termination  
Date Issued: 6/20/08

License No.: 201-696-33  
Amendment No.: 2  
License Reviewer: MG

File No.: 15

Licensee: Derby City Engineering and Inspection  
Type of Action: Amendments  
Dates Issued: 12/3/04, 3/21/06, 4/26/07, 8/8/07

License No.: 201-523-05  
Amendment Nos.: 42, 44, 46, 47  
License Reviewers: SB, RH, RH, MG

Comment:

License does not limit the maximum number of sources. The licensee is authorized to possess an unlimited number of devices.

File No.: 16

Licensee: Harlan Appalachian Regional Healthcare  
Type of Action: Renewal  
Date Issued: 6/16/08

License No.: 202-018-24  
Amendment No.: 51  
License Reviewer: RH

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File No.: 17  
Licensee: EEC-Maxey Flats Project  
Type of Action: Amendments, Renewal  
Dates Issued: 3/1/05, 10/21/05, 11/23/05, 6/16/08

License No.: 206-002-03  
Amendment Nos.: Various  
License Reviewer: MM

## APPENDIX E

### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Equitable Production Co.

Date of Incident: 2/1/05

Investigation Date: 2/18/05

License No.: 201-027-56

NMED Log No.: 050103

Type of Incident: Abandoned Source

Type of Investigation: Telephone

File No.: 2

Licensee: Asher, Inc.

Date of Incident: 5/13/05

Investigation Date: 5/14/05

License No.: 201-565-51

NMED Log No.: 050332

Type of Incident: Lost Gauge

Type of Investigation: Site Visit

File No.: 3

Licensee: Cardinal Health

Date of Incident: 6/7/05

Investigation Date: 6/21/05

License No.: 202-204-32

NMED Log No.: 060195

Type of Incident: Overexposure

Type of Investigation: Telephone

File No.: 4

Licensee: Cardinal Health

Date of Incident: 10/31/05

Investigation Date: 10/31/05

License No.: 202-204-32

NMED Log No.: Not Reportable

Type of Incident: Transportation Accident

Type of Investigation: Telephone/Data Review

File No.: 5

Licensee: National Standard Co.

Date of Incident: 12/14/05

Investigation Dates: 12/14-20/05

License No.: 401-637-00

NMED Log No.: Not Reportable

Type of Incident: Lost Material

Type of Investigation: Telephone

File No.: 6

Licensee: University of Kentucky

Date of Incident: 4/4/06

Investigation Date: 6/12/06

License No.: 202-049-22

NMED Log No.: 060372

Type of Incident: Equipment Failure

Type of Investigation: Telephone/Site Visit

File No.: 7

Licensee: Pikeville Medical Center

Date of Incident: 9/22/06

Investigation Date: 9/22/06

License No.: 202-053-26

NMED Log No.: 060603

Type of Incident: Medical Event

Type of Investigation: Telephone

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File No.: 8

Licensee: Fuller, Mossbarger, Scott  
and May Engineering, Inc.

Date of Incident: 7/12/07

Investigation Dates: 7/12/07, 9/19/07

License No.: 201-142-51

NMED Log No.: 070435

Type of Incident: Stolen Gauge

Type of Investigation: Telephone/Site Visit

File No.: 9

Licensee: Rogers Group, Inc.

Date of Incident: 5/22/07

Investigation Dates: 5/22/07, 10/4/07

License No.: 201-412-51

NMED Log No.: 070319

Type of Incident: Lost Gauge

Type of Investigation: Telephone/Site Visit

File No.: 10

Licensee: Weatherford International, Inc.

Date of Incident: 7/27/07

Investigation Date: 7/27/07

License No.: 201-094-40

NMED Log No.: 070510

Type of Incident: Overexposure

Type of Investigation: Telephone

File No.: 11

Licensee: Owensboro Medical Health System

Date of Incident: 1/11/07

Investigation Date: 1/11/08

License No.: 202-161-26

NMED Log No.: 080041

Type of Incident: Medical Event

Type of Investigation: Telephone/Site Visit

File No.: 12

Licensee: International Specialty Products, Inc.

Date of Incident: 7/27/08

Investigation Date: 7/27/08

License No.: GL-401-693-10

NMED Log No.: Not Reportable

Type of Incident: Damaged Gauge

Type of Investigation: Telephone

## APPENDIX F

### SEALED SOURCE & DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Registry No.: KY-576-D-101-B

Applicant Name: Ronan Engineering Company

Date Issued: 8/21/06

SS&D Type: (D) Gamma Gauge

Type of Action: Amendment

Reviewers: MG, MK

Comments:

- a) The registry sheet was marked as an amendment rather than as an "Amendment in its Entirety," as specified in NUREG 1556, Volume 3, Revision 1.
- b) The principal use code was listed as "Gamma Gauge" instead of "(D) Gamma Gauge."

File No.: 2

Registry No.: KY-576-D-115-S

Applicant Name: Ronan Engineering Company

Date Issued: 9/25/07

SS&D Type: (D) Gamma Gauge

Type of Action: Amendment

Reviewers: MG, MK

Comments:

- a) The registry sheet was marked as an amendment rather than as an "Amendment in its Entirety," as specified in NUREG 1556, Volume 3, Revision 1.
- b) The principal use code was listed as "Gamma Gauge" instead of "(D) Gamma Gauge."

File No.: 3

Registry No.: KY-8195-S-801

Applicant Name: New England Nuclear

Date Issued: 2/25/08

SS&D Type: (G) Portable Gauge

Type of Action: Inactivation

Reviewers: MG, MK

File No.: 4

Registry No.: KY-512-D-809-S

Applicant Name: Ohmart/Vega Corporation

Date Issued: 12/28/07

SS&D Type: (D) Gamma Gauge

Type of Action: Inactivation

Reviewers: MG, MK

ATTACHMENT

October 6, 2008, Letter from William D. Hacker  
Kentucky's Response to Draft IMPEP Report

ADAMS Accession Number: ML082830013





**CABINET FOR HEALTH AND FAMILY SERVICES**  
**Department for Public Health**

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**Janie Miller**  
Secretary

October 6, 2008

KATHLEEN N SCHNEIDER  
SENIOR PROJECT MANAGER  
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON DC 20555-001

Re: Kentucky Radiation Health Branch Comments in Response to Nuclear Regulatory Commission (NRC)  
2008 Integrated Materials Performance Evaluation Program (IMPEP) Draft Response

Dear Ms. Schneider:

In response to your letter dated August 28, 2008, please find attached the Kentucky Radiation Health Branch's response to the Agreement State review conducted in Kentucky by NRC July 28, 2008 thru August 1, 2008. Per your request, Matthew McKinley, Radioactive Materials Supervisor is also submitting an electronic copy of the comments for your convenience.

If there are any concerns or if clarification is needed, please feel free to contact Matthew McKinley or Dewey Crawford at 502/564-3700.

Sincerely,

A handwritten signature in black ink, appearing to read "William D. Hacker".

William D. Hacker, M.D., FAAP, CPE, Commissioner  
Department for Public Health

## Kentucky Radiation Health Branch Comments on 2008 KY Draft IMPEP Report and Letter

### Section 1.0, 5<sup>th</sup> paragraph (not counting the pending MRB paragraph)

"...field accompaniments of six inspectors..." should be "...field accompaniments of eight inspectors..."

### Section 3.2, 4<sup>th</sup> paragraph

There was no misunderstanding regarding the increased controls implementation date imposed on our licensees. It was always fully understood that IC licensees were expected to be fully compliant with IC requirements as of the implementation date. This is evident based on the fact no new license was issued after the original implementation date without a pre-licensing inspection and verification of full IC compliance. Since all inspections were to be completed within three years of the implementation date, we interpreted that full compliance must be *verified* within three years of the implementation date. Although we did not submit, nor can I recall ever being asked for, a written inspection timeline, we imposed upon ourselves a one year period in which all licensees would be initially inspected. If a licensee was found to be non-compliant, deficiencies were noted and discussed and a next inspection due date of six months later was set. The idea was to work with our licensees as we both became more familiar with these new requirements. It seems that our weakness in this area was not a misunderstanding or misinterpretation, but rather a failure to successfully integrate IC inspections into our existing data management system. Had we succeeded in that endeavor, all of our "site visits" would have counted as full inspections and the sporadic delays in dispatching inspection findings would have been on par with the health and safety inspection reporting.

### Section 3.2, 7<sup>th</sup> paragraph 2<sup>nd</sup> sentence through end of paragraph

Consider changing to the following language:

The weakness appears to be the result of section Staff regarding the on-site visits in which deficiencies were identified and documented as inspections, when on 24 of 36 occasions, NRC inspection documentation criteria were not fully met. Given that the remaining outstanding Increased Controls inspections were subsequently completed coupled with the performance of the Section regarding health and safety inspections, a finding of satisfactory, but needs improvement, is justified

### Section 4.1.2 10<sup>th</sup> bullet "Requirements for Certain Generally Licensed..."

In the "Status" paragraph, 2<sup>nd</sup> line, the word "draft" should be "drafted"

### Section 4.1.2 13<sup>th</sup> bullet "Financial Assurance for Materials Licensees"

Insert a line space prior to the "Status" paragraph.

Natural Resources and Environmental Protection Cabinet (NREPC) has been changed to Energy and Environment Cabinet (EEC). References to NREPC appear in:

Section 4.3, 3<sup>rd</sup> paragraph

Section 4.3.3, 1<sup>st</sup> paragraph

Section 4.3.4, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs

### Appendix D "License Casework Reviews", File #10, Comment b)

"which is a essentially" should read "which is essentially"