September 28, 2012

Steve Davis, M.D.
Commissioner
Department for Public Health
275 E. Main Street
Frankfort, KY 40601

Dear Dr. Davis:

On September 6, 2012, 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 program.

Section 5.0, page 16 of the enclosed final report contains a summary of the IMPEP team's findings and an MRB recommendation. We request your evaluation and response to the MRB's recommendation regarding oversight of the inspection program within 30 days from receipt of this letter. Based on the results of the current IMPEP review, the next full review of the Kentucky Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for June 2014. In addition, the MRB directed the period of monitoring continue.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also 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,

/RA/

Michael F. Weber
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: Matthew W. McKinley, Administrator
Radiation Health Program

Jennifer Opila, Colorado
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE KENTUCKY AGREEMENT STATE PROGRAM

JUNE 11-15, 2012

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Kentucky Agreement State Program. The review was conducted during the period of June 11-15, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas.

Based on the results of this review and in accordance with the criteria in the NRC Management Directive 5.6, “Integrated Materials Performance Evaluation Program (IMPEP),” the review team recommended, and the Management Review Board (MRB) agreed, that the Kentucky Agreement State Program's performance be found unsatisfactory for the performance indicator Status of Materials Inspection Program, satisfactory, but needs improvement for the performance indicator Compatibility Requirements, and satisfactory for the remaining five performance indicators reviewed. The review team did not make any specific recommendations regarding program performance by the Commonwealth; however, the MRB directed that one recommendation be made regarding the oversight of the inspection program. The review team recommended, and the MRB agreed, that the Kentucky Agreement State Program remain on Monitoring to provide continued assurance that the program maintains sustained performance in the area of timely inspections and promulgation of the required regulations.

The review team recommended, and the MRB agreed, that the six recommendations from the 2008 IMPEP review, regarding the inspection and licensing programs, be closed. These recommendations are based on the team's review of the specific changes to licensing and inspection checklists, observations made during the inspection accompaniments, and documentation in the respective licensing and inspection files.

Accordingly, the review team recommended, and the MRB agreed, that the Kentucky Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program. The review team recommended that the next IMPEP review take place in approximately four years and two periodic meetings be conducted, with the first meeting to be held in approximately 18 months. The MRB agreed that the next IMPEP review take place in approximately four years, but directed that just one periodic meeting be held in approximately two years.

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 June 11-15, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas. 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 the 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 August 1, 2008, through June 15, 2012, were discussed with Kentucky managers and the acting Commissioner for the Department of Public Health on the last day of the review.

A draft of this report was provided to Kentucky for factual comment on July 13, 2012. The Commonwealth responded by electronic mail dated August 7, 2012. A copy of the Commonwealth's response is included as an Attachment to this report. The Management Review Board (MRB) met on September 6, 2012, 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 the NRC's program.

The Kentucky Agreement State Program is administered by the Radiation Health Branch (Branch) which is located within the Department of Public Health (Department). The Department is part of the Cabinet for Health and Family Services (Cabinet). The Branch is composed of three sections which includes the Radioactive Materials Section (Section), the Radiation Producing Machines Section, and the Radiation/Environmental Monitoring Section. The Radioactive Materials Section implements the elements of the Agreement State Program. Organization charts for the Branch and Cabinet are included as Appendix B.

At the time of the review, the Kentucky Agreement State Program regulated 423 specific licenses authorizing possession and use of radioactive 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 14, 2012. The Branch provided its initial response to the questionnaire on May 30, 2012. A copy of the questionnaire response may be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML12152A407. A revision to the initial response was submitted on August 20, 2012. A copy of the revised questionnaire response may be found in ADAMS using the Accession Number ML12233A222.

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

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

The Commonwealth's actions in response to recommendations made during the previous review are presented in Section 2.0. Results of the team's review of the common performance indicators are presented in Section 3.0. Results of the team's review of the applicable non-common performance indicators are presented in Section 4.0. A summary of the review team's findings are presented in Section 5.0.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on August 1, 2008, the review team made six recommendations regarding the Kentucky Agreement State Program's performance. The status of each recommendation is as follows:

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 meeting with the licensee. (Section 3.3)"

   Status: The Branch revised its inspection procedures to address this recommendation and has trained the staff on the revised procedures. The Branch stated in its questionnaire response, that in order to close any violation, the licensee must submit both, documentation to close the violation and written commitment(s) to implement corrective measures to prevent reoccurrence. The Branch also indicated that all items of non-compliance from the previous inspection are discussed with the licensee and the status verified and documented in subsequent inspection reports. Based on the inspection reports reviewed, the review team determined that the staff follows-up on the licensee's corrective actions and evaluates the preventive measures put in place by the licensee, as evidenced by the documentation in the inspection report. The review team finds that the Branch has adequately addressed the issue. This recommendation is closed.

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)"

   Status: The Branch revised its inspection procedures to address this recommendation and has trained the staff on the revised procedures. The Branch stated that the staff was responsible for discussing and reviewing previous inspection findings and verifying corrective actions were implemented in response to those violations. In addition, the staff discussed that they communicated any potential or alleged violation with the licensee during the exit briefing. Based on the inspection reports reviewed and as observed through the inspection accompaniments performed, the review team determined that items of non-compliance identified during the current inspection were documented and discussed with the licensee during the exit briefing. This recommendation is closed.

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)”

   Status: The Branch revised its inspection procedures to address this recommendation and trained the staff on the revised procedures and the need to use the Branch's equipment when conducting radiation surveys/measurements at licensee facilities. During the accompaniments, the review team observed the staff using the Branch's instruments during the performance of the inspections. This recommendation is closed.

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)”

   Status: The review team observed that a new database had been developed, which tracked and identified licensees that met the criteria for an amendment in entirety. Procedure Title 200, Section 206, "Entireties" provides the amendment in entirety selection criteria, which is five or seven years from the date the license is granted. The Branch typically sends ten requests per quarter to identified licensees. The number of requests may vary depending on the licensing action workload and other actions, such as adding possession limits to the licenses. During 2012, the Branch had received 32 requests for "amendment in entirety" and had completed 17 of those requests. At the time of the review, the Branch had not requested any amendments in entireties, due to adding possession limits to the licenses. The Branch anticipated initiating the process again, once the possession limits were completed. The review team determined that the Branch had a reliable mechanism to identify licenses that met the criteria and had a procedure to perform the amendments in entirety. This recommendation is closed.

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)”

   Status: The review team confirmed that the Branch developed a new procedure to implement the requirements of FSME 07-026. The procedure, Title 200, Section 212, "Prelicensing Guidance To Ensure Radioactive Materials Used As Intended" was provided to the staff for review. In addition, staff meetings were conducted to discuss the pre-licensing requirements. The Branch implemented a checklist which contained the essential elements of the guidance and the review team observed the checklist was being used to evaluate new applicants for a radioactive material license. This recommendation is closed.

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 of the SS&D manufacturer’s program. (Section 4.2.2)”

Status: The Branch revised the manufacturing and distribution inspection forms, to include verification that the licensee implements the manufacturers' approved quality assurance and quality control programs. Furthermore, the license for the only affected M&D licensee, Ronan Engineering, was amended to list the SSDR numbers of all approved devices currently in production, as a license condition. Other license conditions were modified to require tracking of all reportable events involving those approved devices. The Branch has also scheduled quarterly meetings with the licensee to review all events reported in the Nuclear Material Events Database (NMED) involving its devices. The reports generated for the Ronan Engineering inspections documented that the quality assurance and quality control programs were verified during the inspection. 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 Branch's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Branch's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Branch is located in the Department, which is located in the Cabinet. The Section, which is within the Branch, is responsible for the materials inspection and licensing activities of the Agreement State program.

During most of the review period, the Branch was composed of one manager, one supervisor and eight staff positions. Between December 2011 and March 2012, the Branch lost three staff members due to retirement or leaving the program. The Branch lost one of those staff positions as part of the Commonwealth's reduction in force, which brought the total available staff positions to seven. At the time of the review, the two remaining staff positions had not been filled. At the time of the review, the Branch was able to solicit interest for the two vacant positions and expected the two individuals to join the program. In addition, one other staff member is on deployment with the military and is not expected to return until sometime in 2013.

Therefore, at the time of the review, there were a total of four staff members, one supervisor, and one manager, totaling approximately 5.2 full-time equivalents (FTE). The review team recognized that the supervisory position continues to perform some licensing, emergency and incident response activities. The deployed position can not be back-filled and therefore, the one-FTE is not captured in the total above. The Branch has been able to fill vacant positions in a timely manner during the review period. While one position has been reduced during the

review period, the review team determined that staffing levels were adequate for the size and scope of the Agreement State program.

The Branch has a newly revised documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members are assigned increasingly complex duties as they progress through the qualification process. 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. Qualification is established through a combination of education and experience through formal classroom, in-house, and on-the-job training. The Section considers both attendance at the NRC-sponsored training courses and alternate resources for training as a means to meet the education component of the training program. The review team observed that all current staff members have met the qualification requirements in at least one modality. The review team concluded that the Branch's training program is adequate to carry out its regulatory duties and noted that Kentucky's management is supportive of the training program.

The Commonwealth does not currently have a radiation advisory board. The Branch is in discussions with upper Cabinet level administrators regarding the formation of a Medical Advisory Board (Board) composed of program administration staff members and professionals from the private sector. This Board would encompass both radioactive materials and radiation producing machines. Several current medical radiation safety officers, authorized medical physicists, and physician authorized users have been approached about possibly serving on this Board. The individuals contacted have responded favorably to the request to serve on the Board. Preliminary discussions have started on how to establish the Board, appoint its members, and develop its mission and by-laws. The Commonwealth anticipates having the Board established by the end of December 2012.

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, be found 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 management and staff.

The review team verified that Kentucky's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar types of licenses listed in IMC 2800, "Materials Inspection Program." Prior to January 2012, some of Kentucky's inspection frequencies were more frequent than the similar license types as listed in IMC 2800. However, as of January 1, 2012, Kentucky chose to inspect all licenses at the same frequency as those

listed in IMC 2800 to make better use of available resources while still providing appropriate licensee oversight.

During the review period, the Branch created a new spreadsheet for tracking inspections, resulting in two inspection tracking spreadsheets which were not integrated. The Branch was aware of the monthly and quarterly inspections that were due; however, the Branch did not realize the percentage of overall inspections that were conducted overdue nor did the Branch perform an assessment to ensure that the licensees with the highest safety significance were receiving priority attention. The review team calculated the Branch conducted 48 high priority (Priority 1, 2, and 3) inspections overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800, during the review period. The review team found that the Branch had diverted resources in 2009 to support an onsite presence and perform inspections at a large, decommissioning/remediation activity in downtown Louisville. The Branch subsequently performed the backlog inspections and continued to perform the rolling backlog of inspections during the review period. During the period, the Branch conducted two campaigns to eliminate or minimize the number of overdue inspections. Although a large number of inspections were overdue during this period, the Branch made considerable progress in reducing the number of overdue inspections by the close of the review period. At the time of the review, two Priority 1, 2, and 3 inspections were currently overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800.

The review team determined that the Branch performed 34 initial inspections during the review period, in which 8 were conducted overdue based on the 12 month requirement in IMC 2800. Overall, the review team calculated that the Branch performed 41 percent of its Priority 1, 2, and 3 and initial inspections overdue during the review period. The review team found that the Branch had expended considerable effort in completing overdue inspections since 2004, and had achieved no overdue inspections at the time of each IMPEP review. (Note: The 2008 review team found that during the 2004 IMPEP review, the number of high priority inspections reported was incorrect due to a miscalculation. It should have been reported as exceeding the 25 percent metric, not the 9.6 percent stated in the report.)

The reasons contributing to the overdue inspections since 2004 included a total staff turnover and minimal staffing levels during 2004 and 2008, and management decisions to address emergent activities during the current review period. The fact that there were two spreadsheets also contributed to management not fully realizing the high percentage of overdue inspections. The Branch has a new spreadsheet to track and assign inspections to ensure inspections are completed as expected.

The review team evaluated the timeliness of issuing 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. A sampling of 30 inspection reports indicated that 4 of the inspection findings were communicated to the respective licensee beyond the Branch’s goal of 30 days after the inspection. Those letters that were issued greater than the 30 day issuance goal, ranged from a few days to a few months past the goal date. Three of the four letters that were issued late had violations associated with the inspection reports, and the Section Supervisor was aware of the delays.

During the review period, the Branch granted 211 reciprocity permits, in which 42 were candidate licensees 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 or exceeded the criteria of inspecting 20 percent of candidate licensees operating under reciprocity in two of the four years covered by the review period and did not meet the 20 percent inspection criteria in the other two years.

Based on the criteria in Management Directive 5.6, the review team recommends a finding of unsatisfactory because of the high percentage of inspections that the Branch performed overdue during the review period and because the Branch did not perform an assessment or develop a plan to address the potential health and safety impacts from significantly reducing its regulatory presence in the field. The MRB directed that a recommendation be made for the Branch to perform a self-assessment to determine the effectiveness of its oversight of the inspection program. The results of this self-assessment would be discussed at the next periodic meeting.

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, be found unsatisfactory.

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 31 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by six Branch inspectors and covered inspections of various license types, including: medical broad scope, medical institutions-imaging/therapy (HDR, permanent/temporary brachytherapy), medical-diagnostic, portable gauges, industrial radiography, gamma knife, well logging, nuclear pharmacy, mobile nuclear medicine, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team confirmed that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. Documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Branch are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the Section Supervisor or the Branch Manager.

Supervisory accompaniments of Branch inspectors were conducted in the review period. Some inspectors did not have supervisory accompaniments in 2011. In addition, the documentation for inspector accompaniments in 2009 and 2010 could not be located. However, at least four inspectors were accompanied during this two-year period as determined through other methods of documentation including inspection reports, staff interviews and notes to file.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports. Inspection findings were sent to the licensees by a letter summarizing the results of the inspection. The Branch issues either a letter indicating a clear inspection or a Notice of Violation (NOV). When the Branch issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 30 days. All findings are reviewed by the Section Supervisor or the Branch Manager.

The review team noted that the Branch has an adequate supply of survey instruments to support their inspection program. Appropriate, calibrated survey instrumentation was observed to be available. Instruments are calibrated at least annually, or as needed.

The review team accompanied four of the Branch's radioactive materials inspectors during the weeks of April 23 and June 7, 2012. The inspectors were accompanied during health and safety inspections of nuclear medicine, radiography, medical therapy, including a security inspection at a gamma stereotactic radiosurgery facility. The accompaniments are identified in Appendix C.

During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance based inspections. The inspectors were trained, well-prepared for the inspection, 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 inspections were adequate to assess radiological health and safety and Increased Controls at the licensed facilities.

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, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 27 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, 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

3 new licenses, 1 renewal in entirety, 1 decommissioning or termination action, and 22 amendments (including one transfer of control). Files reviewed represented a cross-section of license types, including: broadscope, medical diagnostic and therapy (including, high dose rate remote afterloader and unsealed radioiodine therapy), mobile nuclear medicine, industrial radiography, well logging, waste disposal service, research and development, nuclear pharmacy, gauges and manufacturers. The casework sample represented work from ten license reviewers. A listing of the licensing casework evaluated is provided in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions and were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use the Branch's licensing guides and/or NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

All licensing actions undergo a peer and management review by the Section Supervisor. The Branch Manager subsequently signs the license. The license reviewers and Section Supervisor do not have signatory authority for licensing actions. Licenses are issued for a one-year period based on the collection of an annual fee. The Commonwealth's regulations require, and the Branch's licensing guidance documents note, that an amendment in entirety must be performed every five to seven years. However, due to staff turnover and license backlog issues, requests for amendment in entirety have been temporarily suspended.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Branch licensing procedures and NUREG-1556 guidance documents, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

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 initial licenses that required financial assurance. The review team also noted that the Branch places a license condition on all licenses, which restricts the licensee to possess radioactive material in amounts less than the amount required for financial assurance or the licensee is required to provide financial assurance. The review team identified two cases in which the Branch did not address financial assurance requirements properly. One involved a licensing action to increase the maximum possession of radioactive material above limits that would require the licensee to obtain financial assurance for decommissioning; however, this was not addressed as part of the licensing action. The second case was noted during a review of one cyclotron license, which also indicated that financial assurance was not addressed as a component of the licensing action. The review team discussed these observations with the Branch. The Branch immediately took the appropriate steps to ensure compliance with the financial assurance requirements which included implementing the use of a financial assurance spreadsheet calculator and updating the checklists to include a review of financial assurance as part of the license amendment process. In addition, the Branch initiated an entire review of

licenses to verify financial assurance was properly addressed. On September 10, 2012, the review team was notified that the Branch had completed its review and identified one other license that required financial assurance and it was being addressed.

The Branch performs pre-licensing checks of all new applicants. The Branch's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Branch's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the Commonwealth uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, 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 review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Branch requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Branch's practice for the control of sensitive information. The review team noted that the Branch controls access to all of its licensing and inspection files. Files that contained sensitive information are conspicuously marked and were further secured in locked file cabinets.

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, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Branch's actions in responding to radioactive material incidents, 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 nine radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E.

The review team examined the Branch's allegation and incident processes and procedures, including Section 412, "Responding to Allegations/Complaints" and Section 413, "Responding to Incidents." These written procedures described the criteria for responding to incident and allegations, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Section Supervisor determines the appropriate level of initial response. The review team determined that the basis for performing an onsite investigation was commensurate with the potential health and safety impacts of the incident. The review team observed that procedure Section 413 did not contain any response criteria for a medical event. However, the review team determined that the Branch responded to medical events as expected. The Branch agreed to incorporate the medical response criteria that it utilizes into written procedures.

The review team selected nine incidents for review, including the following categories: lost radioactive material, potential overexposure, medical event, and damaged portable gauge equipment. The review team determined that the Branch's response to incidents reflected the response criteria in its written procedures and guidance from the Section Supervisor. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 “Reporting Material Events,” then the Commonwealth notified the NRC Headquarters Operations Center and entered the information into NMED in a prompt manner.

The review team identified 28 radioactive material incidents in NMED for Kentucky during the review period of which 22 were reported in accordance with SA-300. Six non-reportable incidents in NMED for Kentucky were reviewed for reportability and found to be correctly categorized as non-reportable by the Branch. For the radioactive material incidents evaluated, the Branch dispatched inspectors for on-site investigations in three of the nine cases reviewed. The review team determined that the Branch's responses to incidents were thorough and complete. While the actions taken in response to incidents were documented and completed in NMED, the review team identified that the Branch did not always perform follow-up reviews of the incident during the subsequent inspection. A follow-up review would verify that the corrective actions were adequate and or the incident was sufficiently closed. In some instances, the cases reviewed indicated that the inspector was not aware that an incident had occurred during the inspection review period. The Branch immediately modified its checklist to ensure that a copy of the incident tracking sheet was included in the license folder, so that it would be readily apparent to the inspector, and to ensure that appropriate follow-up would be performed during a subsequent inspection.

The Branch did not receive any allegations during the review period. Therefore, the review team was unable to review the implementation of this aspect of the program. The Branch indicated that by procedure, the Commonwealth will notify concerned individuals of the conclusion of its investigation and that the Branch protects the identity of concerned individuals within its regulations.

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

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 (SS&D), (3) Low-Level Radioactive Waste (LLRW) Disposal Program, and (4) Uranium Recovery Program. The Agreement State program has been performing routine inspections at the former LLRW facility, Maxey Flats. The facility was closed in 1977 and an interim cap was put into place in 2003. Therefore, the review team did not review this indicator, although the status of the facility is briefly discussed in the report. In addition, the NRC’s Agreement with Kentucky does not relinquish regulatory authority for a uranium recovery program. Therefore, only the first two non-common performance indicators applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Kentucky became an Agreement State on March 26, 1962. The current effective statutory authority is contained in the Kentucky Revised Statutes 13B.170, 194A.050, 211.090, 211.842 to 852, 211.859, 211.990(4), and 211.861 to 869. The Branch is designated as the Commonwealth's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Kentucky regulations for "Control of Radiation" are located in 902 Kentucky Administrative Regulations (KAR) Chapter 100 "Regulations for Radioactive Materials," and apply to all ionizing radiation. Kentucky requires a license for the receipt, possession, use, ownership, or transfer of all radioactive material, including byproduct, source, certain quantities of special nuclear material, accelerator-produced radionuclides, and naturally-occurring materials, such as radium.

The review team examined the Commonwealth's administrative rulemaking process and found that the process takes approximately 19 months from the development stage to the final approval. The public, the NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized.

The review team noted that the Commonwealth's rules and regulations are not subject to sunset laws. The Commonwealth has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team evaluated Kentucky'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.

During the review period, Kentucky submitted 14 final regulation amendments and 1 legally binding license condition to the NRC for a compatibility review. Fourteen of the amendments were overdue for Agreement State adoption at the time of submission.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after the effective date of NRC's regulations. The review team observed that the Commonwealth had made considerable progress in the promulgation of regulations since the last IMPEP review. At that time, the Commonwealth had 16 amendments, which ranged from one to ten years overdue. At the time of this review, the following five amendments were overdue. The Branch is currently drafting proposed regulations for these five amendments and plans to submit them to NRC for review.

- "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 adoption by February 16, 2004.

- "Medical Use of Byproduct Material –Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that was due for Agreement State adoption by October 29, 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 was due for Agreement State adoption by December 17, 2010.

- "Requirements for Expanded Definition of Byproduct Material,"10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150 amendment (72 FR 55864), that was due for Agreement State adoption by November 30, 2010.

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

The review team identified the following NRC amendments that the Commonwealth will need to address in the future.

- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), due for Agreement State adoption by September 28, 2012.

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendments (76 FR 35512), due for Agreement State adoption by December 17, 2015.

- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendments (76 FR 56951), due for Agreement State adoption by November 14, 2014.

- "Change of Compatibility of 10 CFR 31.5 and 31.6 in the Withdrawal of Proposed Rule and Closure of Petition For Rulemaking: Organization of Agreement States and Florida Department of Health, Bureau of Radiation Control," 10 CFR Part 31 amendment (77 FR 3640), due for Agreement State adoption by January 25, 2015.

- "Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste," 10 CFR Part 71 amendment (77 FR 34194), due for Agreement State adoption by August 10, 2015.

- "Technical Corrections," 10 CFR Parts 30, 34, 40, and 71 amendments (77 FR 39899), due for Agreement State adoption by August 6, 2015.

- "Requirements for Distribution of Byproduct Material," 10 CFR Parts 30, 31, 32, 40, and 70 amendments (77 FR 43666), due for Agreement State adoption by October 23, 2015.

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, be found 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 Sealed Source and Device (SS&D) Evaluation Program: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and 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 issued one amendment to an existing registration during the review period. There were no inactivations or new evaluations performed 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 had three reviewers who were qualified to perform safety evaluations of SS&D applications during the review period. However, one SS&D reviewer retired in March 2012, but a new reviewer is in the process of becoming qualified. All reviewers have degrees in a physical science or engineering and have attended the NRC's SS&D Workshop or the Branch's contracted training course that was conducted in July 2007. 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 Commonwealth currently has one device manufacturer who has eleven active SS&D registrations. Registrations clearly summarize the product evaluations and 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 evaluation was thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the product during use and under accident conditions.

The review team evaluated the one amendment action issued during the review period. The casework reviewed represented the efforts of two of the SS&D reviewers. An amendment was also submitted for a second registry; however, the Branch indicated that it was not approved due to health and safety concerns not being adequately addressed by the manufacturer. Since this second action was not completed, it was not included in the casework evaluated. A listing of the one SS&D casework examined may 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 communication via e-mail with a licensee and the use of the evaluation checklist as recommended in NUREG 1556 Vol. 3, Rev. 1.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED, the review team examined 26 incidents involving SS&D registered products during the review period. The review team examined all events that occurred in Kentucky that involved equipment or source failures within the period, as well as any events that occurred nationally involving devices registered by the Commonwealth. The review team determined that the Branch analyzed the events, reviewed the issues, and followed up on the incidents. None of the events involving sources/devices manufactured or distributed by a licensee with a SS&D registered in Kentucky were related to manufacturing or design of the product.

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, be found satisfactory.

4.3 Low-Level Radioactive Waste Disposal Program

The LLRW program consists of oversight of one facility, the Maxey Flats site, which is located on approximately 800 acres 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 facility used trenches as the disposal method. The trenches were located in a fenced portion of the site. Once the license was terminated, the site was transferred to the Commonwealth of Kentucky.

A temporary cover was placed over approximately 30 acres of the trenched area for stabilization. Maintenance activities for surface water controls and environmental monitoring was initiated. However, water continued to collect in the trenches and leach radioactive material into the surrounding environment. The site was listed on the National Priorities List in 1986, and a Record of Decision (ROD) was issued in September 1991, by the Environmental Protection Agency (EPA) under its Comprehensive Environmental Response, Compensation, and Liability Act authority. The ROD selected a remedy of natural stabilization, which also included installing and monitoring a landfill cap made of a synthetic liner, replacing the landfill cap after 20 years, and installing a final landfill cap after 35 to 100 years. The final cap would allow for the natural stabilization of wastes in the trenches. Construction of the interim cap was completed in 2003, and the site entered the "interim maintenance period" of operation. The plan to replace the cap after 20 years would allow the trenches to stabilize and allow further decay of the shorter half-life radionuclides. Although natural stabilization was estimated to require 35 to 100 years, the EPA is evaluating whether to proceed to the Final Closure Period, which would require a final cap. If the Commonwealth and EPA agree to proceed to the final closure, then there would be

an increase in support activities by the Branch. Once the Final Closure Period is complete, then the site would enter the Custodial Maintenance Period, in perpetuity.

The review team did not review this indicator and therefore, the performance indicator is not incorporated into the overall assessment of the Kentucky Agreement State program.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Kentucky's performance was found satisfactory for five of the seven performance indicators reviewed, satisfactory, but needs improvement for the performance indicator Compatibility Requirements, and unsatisfactory for the performance indicator Status of Materials Inspection Program. The review team did not make any recommendations regarding program performance by the Commonwealth and determined that the six recommendations from the 2008 IMPEP review should be closed. The MRB directed that a recommendation be made under Section 3.2, Status of Materials Inspection Program, and as indicated below. Accordingly, the review team recommended, and the MRB agreed that the Kentucky Agreement State Program be found adequate to protect public health and safety, but needs improvement and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended that the next full IMPEP review take place in approximately four years and two periodic meetings be conducted with the first meeting to be held in approximately 18 months. The MRB agreed that the next full IMPEP review take place in four years, but directed that just one periodic meeting be held in two years. The review team also recommended, and the MRB agreed, that the period of monitoring will continue in order to assess the status of the inspection program during the quarterly conference calls.

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

1. The MRB recommends that the Branch perform a self-assessment to determine the effectiveness of its oversight of the inspection program and that the results of this self-assessment be reviewed as part of the periodic meeting.

LIST OF APPENDICES

APPENDIX A

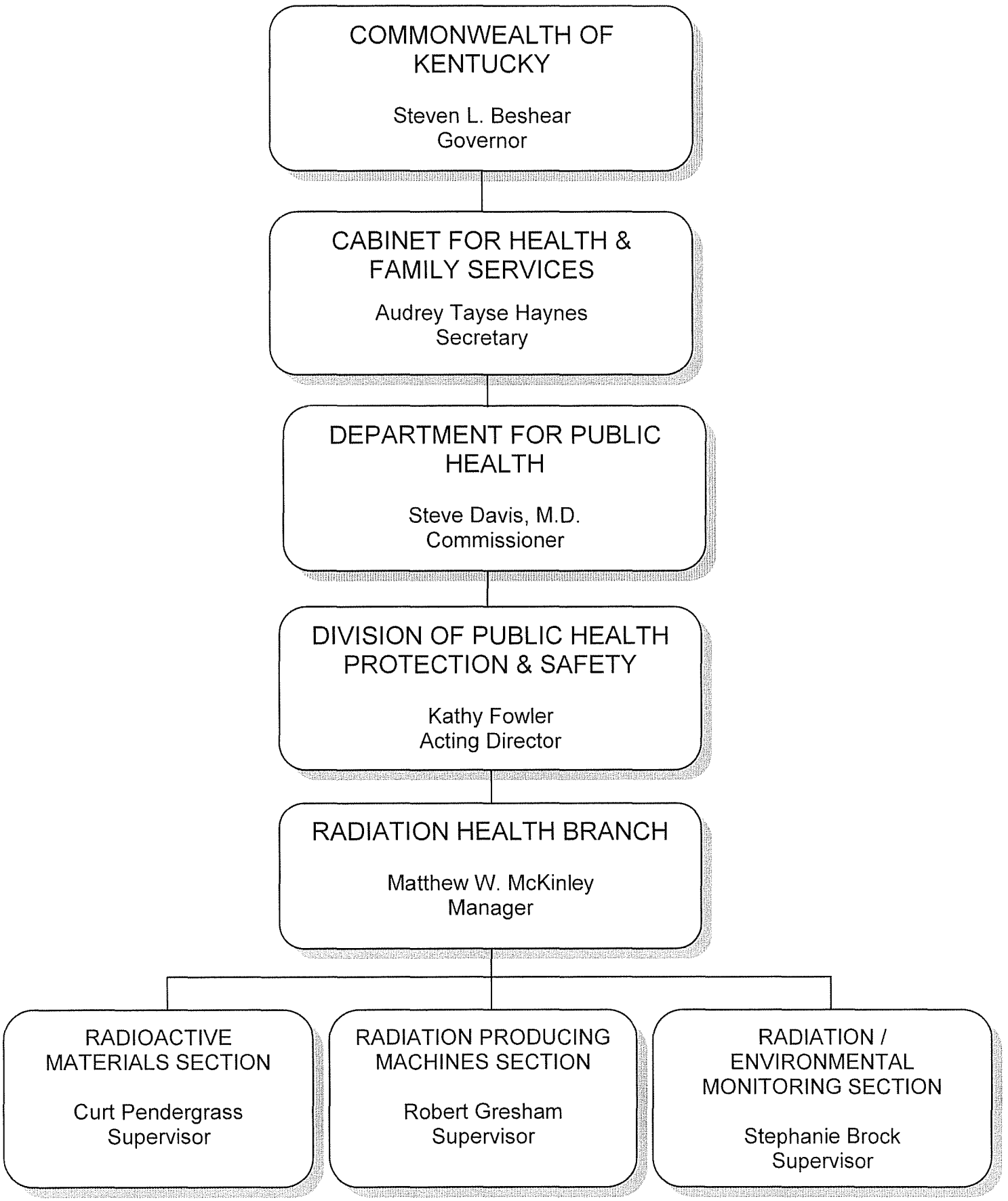
IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Rachel S. Browder, Region IV	Team Leader Technical Quality of Incidents and Allegations
Monica L. Orendi, Region I	Technical Staffing and Training Status of Materials Inspection Program Compatibility Requirements
Joseph L. Nick, Region I	Technical Quality of Inspections
Lymari Sepulveda, FSME	Sealed Source and Device Evaluation Program
James Harris, State of Kansas	Technical Quality of Licensing Actions
Randy Erickson, Region IV	Inspection Accompaniments
Michelle Beardsley, FSME	Inspection Accompaniments

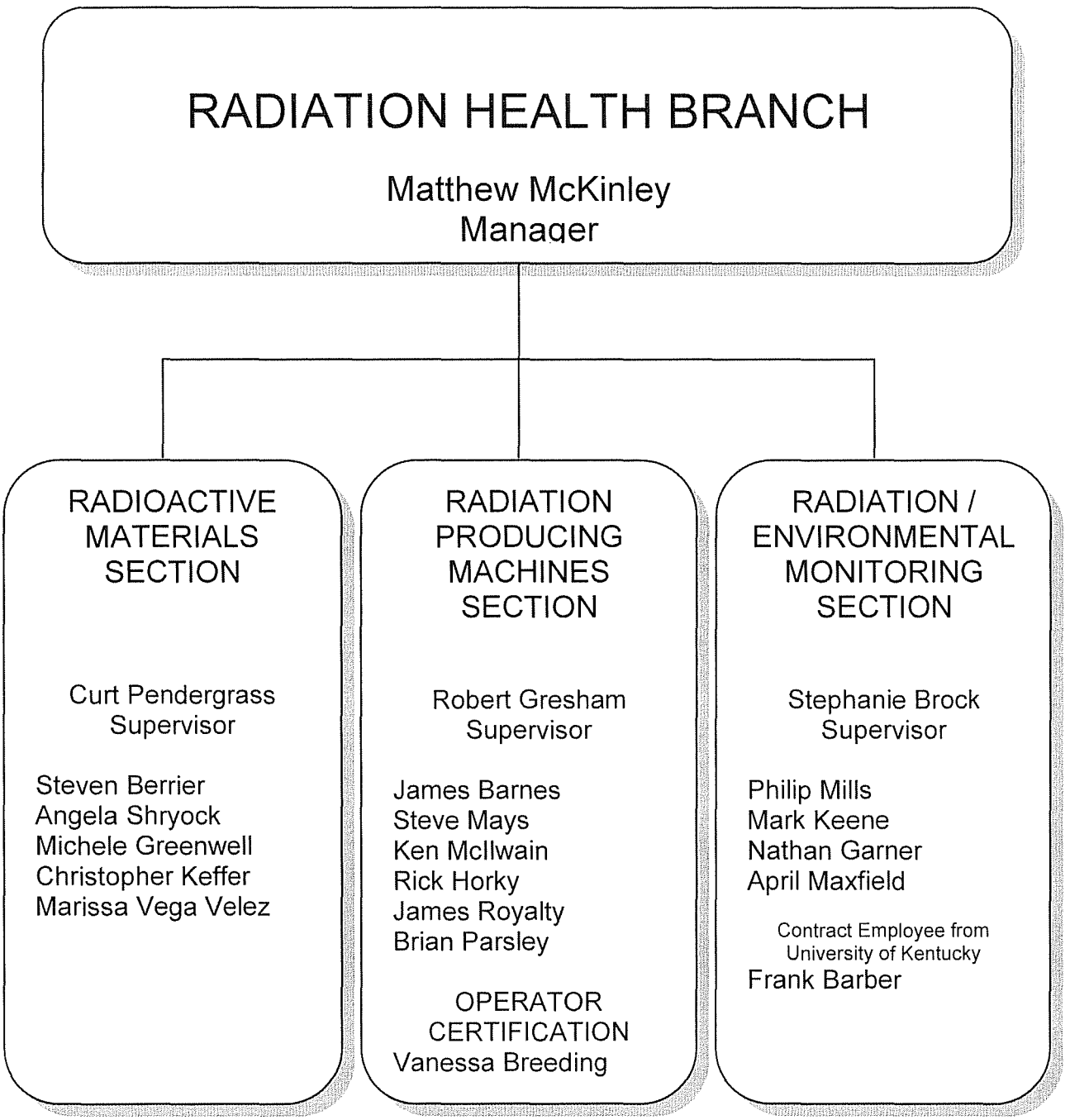
APPENDIX B

KENTUCKY ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML12194A751


COMMONWEALTH OF KENTUCKY
Steven L. Beshear
Governor
CABINET FOR HEALTH & FAMILY SERVICES
Audrey Tayse Haynes
Secretary
DEPARTMENT FOR PUBLIC HEALTH
Steve Davis, M.D.
Commissioner
DIVISION OF PUBLIC HEALTH PROTECTION & SAFETY
Kathy Fowler
Acting Director
RADIATION HEALTH BRANCH
Matthew W. McKinley
Manager
RADIOACTIVE MATERIALS SECTION
Curt Pendergrass
Supervisor
RADIATION PRODUCING MACHINES SECTION
Robert Gresham
Supervisor
RADIATION / ENVIRONMENTAL MONITORING SECTION
Stephanie Brock
Supervisor

(b) A chart showing positions of current radiation control program including management; and



APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Central Baptist Hospital — License No.: 202-004-26
Inspection Type: Routine Unannounced — Priority: 2
Inspection Date: 8/18/11 — Inspector: AS

File No.: 2
Licensee: Radiopharmacy of Paducah — License No.: 202-221-32
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 11/16/11 — Inspector: MMG

File No.: 3
Licensee: Alliance Imaging — License No.: 202-227-29
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 4/16/10 — Inspector: MMG

Comment: Inspection findings were dispatched to the licensee 90 days after the date of the inspection.

File No.: 4
Licensee: Norton Suburban Hospital — License No.: 202-099-26
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 12/20/11 and 1/26/12 — Inspector: MV

File No.: 5
Licensee: Hardin Memorial Hospital — License No.: 202-148-26
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 6/28/11 — Inspector: MMG

Comment: Inspection findings were dispatched to the licensee 172 days after the date of the inspection.

File No.: 6
Licensee: Cardinal Health Lexington — License No.: 202-204-32
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 8/19/11 — Inspector: AS

Comment: Previous inspection identified noncompliance and current inspection did not mention close out of the noncompliance issue.

File No.: 7
Licensee: Manalapan Mining Company License No.: 201-307-51
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/17/12 Inspector: CK

File No.: 8
Licensee: TPM, Inc. License No.: 201-654-51
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 4/19/12 Inspector: CK

File No.: 9
Licensee: Jewish Hospital License No.: 202-294-25
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/24/12 Inspector: MV

File No.: 10
Licensee: University of Kentucky License No.: 202-049-22
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/29/11 Inspector: AS

Comment: No documentation of a medical event that occurred in April 2009.

File No.: 11
Licensee: Hinkle Contracting Corp. License No.: 201-472-51
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 9/22/11 Inspector: MG

File No.: 12
Licensee: Murray Calloway County Hospital License No.: 202-120-26
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 11/16/11 Inspector: MMG

Comment: No documentation of a medical event that occurred in December 2008.

File No.: 13
Licensee: Our Lady of Bellefonte Hospital License No.: 202-144-26
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 11/30/10 Inspector: MMG

File No.: 14
Licensee: LE Gregg Associates License No.: 201-098-52
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 4/19/12 Inspector: CP

File No.: 15
Licensee: Huntingdon Testing & Technology, Inc. License No.: 201-551-05
Inspection Type: Special, Announced Priority: 1
Inspection Date: 12/29/11 Inspector: RJ

Comment: No documentation of an event that occurred in September 2011.

File No.: 16
Licensee: Mistras Services License No.: 201-736-05
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 11/18/11 Inspector: RJ

Comment: No documentation of an event that occurred in November 2011.

File No.: 17
Licensee: Medical Center at Bowling Green License No.: 202-124-26
Inspection Type: Special, Announced Priority: 3
Inspection Date: 11/29/11 Inspector: MGG

File No.: 18
Licensee: Mistras Group, Inc. License No.: 201-699-05
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 3/15/12 Inspector: MG

File No.: 19
Licensee: Professional Services Industries License No.: 209-137-05
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 8/18/10 Inspector: MG

File No.: 20
Licensee: Varian Medical Systems License No.: 209-119-90
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/30/11 Inspector: MG

File No.: 21
Licensee: Elekta License No.: 209-087-90
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/10/11 Inspector: AS

File No.: 22
Licensee: America Tower Scanning License No.: 209-372-60
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 9/22/10 Inspector: MG

File No.: 23
Licensee: Nucletron License No.: 209-016-60
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 6/3/10 Inspector: MG

Comment: No supervisory review signature on the inspection record.

File No.: 24
Licensee: Albany International License No.: 209-028-51
Inspection Type: Initial, Announced Priority: 5
Inspection Date: 2/11/09 Inspector: MG

File No.: 25
Licensee: Industrial Dynamics License No.: 209-204-60
Inspection Type: Initial, Announced Priority: 5
Inspection Date: 3/11/09 Inspector: CP

File No.: 26
Licensee: World Testing License No.: 209-061-05
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 2/26/09 Inspector: MG

File No.: 27
Licensee: Southern Well Services License No.: 201-170-40
Inspection Type: Routine, Unannounced Priority: 1
Inspection Dates: 11/21/11 Inspector: CK

File No.: 28
Licensee: Ace Clinique License No.: 202-376-24
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 10/22/09 Inspector: MGG

File No.: 29
Licensee: Danville Cardiovascular Consultants License No.: 202-257-24
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 9/2/11 Inspector: AS

Comment: Two violations noted during the inspection. Inspection findings were dispatched to the licensee approximately 60 days after the date of the inspection.

File No.: 30
Licensee: 21st Century Radiation Oncology License No.: 202-352-27
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 9/28/11 Inspector: AS

Comment: Seven violations noted during the inspection. Inspection findings were dispatched to the licensee approximately 45 days after the date of the inspection.

File No.: 31
Licensee: Enterprise Mining Company License No.: 201-280-51
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 4/30/10 Inspector: CK

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Saints Mary and Elizabeth Hospital License No.: 202-096-26
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/23/12 Inspector: MMG

Accompaniment No.: 2
Licensee: Jewish Hospital License No.: 202-294-25
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/24/12 Inspector: MV

Accompaniment No.: 3
Licensee: University of Kentucky License No.: 202-024-31
Inspection Type: Routine/Special, Unannounced Priority: 2
Inspection Date: 4/25/12 Inspector: AS

Accompaniment No.: 4
Licensee: Technical Welding Insp., Inc. License No.: 201-324-05
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 6/6/12 Inspector: CK

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APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Ronan Engineering Co. License No.: 201-260-95
Type of Action: Amendment Amendment No.: 65
Date Issued: 5/14/10 License Reviewer: MG

File No.: 2
Licensee: Medical Mall Imaging Center License No.: 202-416-29
Type of Action: New Amendment No.: N/A
Date Issued: 10/26/11 License Reviewer: MV

File No.: 3
Licensee: Bizzack Construction, LLC License No.: 201-765-51
Type of Action: New Amendment No.: N/A
Date Issued: 5/30/12 License Reviewer: CK

File No.: 4
Licensee: GEM Engineering License No.: 201-642-51
Type of Action: Amendment Amendment No.: 21
Date Issued: 3/5/09 License Reviewer: CP

File No.: 5
Licensee: GEM Engineering License No.: 201-642-51
Type of Action: Amendment Amendment No.: 24
Date Issued: 5/12/11 License Reviewer: CK

File No.: 6
Licensee: GEM Engineering License No.: 201-642-51
Type of Action: Amendment Amendment No.: 25
Date Issued: 4/3/12 License Reviewer: MG

File No.: 7
Licensee: Lake Cumberland Regional Hospital License No.: 202-123-26
Type of Action: Amendment Amendment No.: 86
Date Issued: 4/16/12 License Reviewer: AS

File No.: 8
Licensee: Cardinal Health Louisville License No.: 202-206-32
Type of Action: Amendment Amendment No.: 51
Date Issued: 4/22/09 License Reviewer: BP

File No.: 9
Licensee: Cardinal Health Louisville
Type of Action: Amendment
Date Issued: 8/30/10
License No.: 202-206-32
Amendment No.: 57
License Reviewer: AS

File No.: 10
Licensee: Cardinal Health Louisville
Type of Action: Amendment
Date Issued: 1/17/12
License No.: 202-206-32
Amendment No.: 61
License Reviewer: CP

File No.: 11
Licensee: Superior Well Service
Type of Action: Amendment
Date Issued: 11/17/11
License No.: 201-714-40
Amendment No.: 12
License Reviewer: RJ

File No.: 12
Licensee: AMEC Environment & Infrastructure
Type of Action: Transfer Control
Date Issued: 3/29/12
License No.: 201-257-51
Amendment No.: 65
License Reviewer: CP

File No.: 13
Licensee: Morehead State University
Type of Action: Amendment
Date Issued: 9/2/09
License No.: 203-022-83
Amendment No.: 60
License Reviewer: MG

File No.: 14
Licensee: Morehead State University
Type of Action: Amendment
Date Issued: 8/27/08
License No.: 203-022-83
Amendment No.: 58
License Reviewer: SB

File No.: 15
Licensee: Morehead State University
Type of Action: Amendment
Date Issued: 4/3/12
License No.: 203-022-83
Amendment No.: 63
License Reviewer: MG

File No.: 16
Licensee: Trieco, LLC
Type of Action: Amendment
Date Issued: 7/9/10
License No.: 201-717-90
Amendment No.: 3
License Reviewer: CK

File No.: 17
Licensee: Pharmacology Toxicology Research Lab
Type of Action: Termination
Date Issued: 2/1/12
License No.: 201-332-04
Amendment No.: 30
License Reviewer: CP

File No.: 18
Licensee: Northern Shared Medical
Type of Action: Amendment
Date Issued: 3/16/12
License No.: 202-368-29
Amendment No.: 7
License Reviewer: MV

File No.: 19
Licensee: Radiopharmacy of Paducha
Type of Action: Amendment
Date Issued: 1/4/12
License No.: 202-221-32
Amendment No.: 37
License Reviewer: RP

File No.: 20
Licensee: Oncology Hematology Care
Type of Action: Amendment
Date Issued: 12/11/08
License No.: 202-336-27
Amendment No.: 12
License Reviewer: AS

File No.: 21
Licensee: Oncology Hematology Care
Type of Action: Amendment
Date Issued: 3/20/09
License No.: 202-336-27
Amendment No.: 13
License Reviewer: BP

File No.: 22
Licensee: University Louisville
Type of Action: Amendment
Date Issued: 10/26/11
License No.: 202-029-22
Amendment No.: 89
License Reviewer: MV

File No.: 23
Licensee: Bourbon Community Hospital
Type of Action: Entirety Renewal
Date Issued: 8/14/08
License No.: 202-186-24
Amendment No.: 34
License Reviewer: MMG

File No.: 24
Licensee: K.D. Analytical Consultants
Type of Action: New
Date Issued: 5/30/12
License No.: 201-763-60
Amendment No.: N/A
License Reviewer: CK

File No.: 25
Licensee: Stupp Bridge Co.
Type of Action: Amendment
Date Issued: 3/17/09
License No.: 201-674-5
Amendment No.: 19
License Reviewer: SB

File No.: 26
Licensee: Chemical Solutions
Type of Action: Amendment
Date Issued: 4/6/12
License No.: 201-735-4
Amendment No.: 1
License Reviewer: CK

File No.: 27
Licensee: Applied Technical Services
License No.: 201-754-5
Type of Action: Amendment
Amendment No.: 1
Date Issued: 9/22/11
License Reviewer: CK

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Mistras Group Inc. License No.: 201-699-05
Date of Incident: 3/31/12 NMED No.: 120280
Inspection Date: 5/8/12 Type of Incident: Possible Overexposure
Type of Investigation: N/A

Comment: An inspection was conducted on May 8, 2012; however, there was no follow-up documented regarding the possible overexposure.

File No.: 2
Licensee: Medical Center of Bowling Green License No.: 202-124-26
Date of Incident: 11/16/11 NMED No.:110625
Investigation Date: 11/23/11 Type of Incident: Medical event
Type of Investigation: Site

File No.: 3
Licensee: Mistras Services License No.: 201-736-05
Date of Incident: 11/13/11 NMED No.:110600
Inspection Date: 11/18/11 Type of Incident: Radiography, source disconnect
Type of Investigation: N/A

Comment: The inspection conducted on November 18, 2011, was a security inspection only; no follow-up was documented regarding the source disconnect.

File No.: 4
Licensee: Huntington Testing & Technology, Inc. License No.: 201-551-05
Date of Incident: 9/11/11 NMED No.:110598
Investigation Date: N/A Type of Incident: Radiography, breached boundary
Type of Investigation: N/A

File No.: 5
Licensee: L.E. Gregg Associates License No.: 201-098-52
Date of Incident: 8/25/11 NMED No.:110444
Investigation Date: 8/27/11 Type of Incident: PG
Type of Investigation: Site

File No.: 6
Licensee: Our Lady of Bellefonte Hospital
Date of Incident: 7/15/11
Investigation Date: N/A
License No.: 202-144-26
NMED No.:110426
Type of Incident: Medical event
Type of Investigation: N/A

File No.: 7
Licensee: Jewish Hospital
Date of Incident: 12/15/09
Investigation Date: N/A
License No.: 202-115-22
NMED No.:110037
Type of Incident: Lost source
Type of Investigation: N/A

File No.: 8
Licensee: Hinkle Contracting Corp.
Date of Incident: 5/25/10
Investigation Date: 5/25/10
License No.: 201-472-51
NMED No.:110288
Type of Incident: Damaged PG
Type of Investigation: Site

File No.: 9
Licensee: University of Kentucky
Date of Incident: 2/23/10
Investigation Date: N/A
License No.: 202-024-31
NMED No.:100079
Type of Incident: Medical event
Type of Investigation: N/A

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: KY-576-D-101-B
Applicant Name: Ronan Engineering Company
Date Issued: 10/08/08

SS&D Type: (D) Gamma Gauge
Type of Action: Amendment
Reviewers: MG, MK

ATTACHMENT

August 7, 2012 email from Matthew McKinley
Kentucky's Response to the Draft Report
ADAMS Accession No.: ML12220A281

From: Browder, Rachel
To: McKinley, Matthew W (CHS-PH)
Subject: RE: KY Draft IMPEP Report
Date: Tuesday, August 07, 2012 11:09:00 AM

Matt,
Thank you. This email is sufficient for your response to the report.
Rachel

-----Original Message-----
From: McKinley, Matthew W (CHS-PH) [mailto:MatthewW.McKinley@ky.gov]
Sent: Tuesday, August 07, 2012 9:09 AM
To: Browder, Rachel
Subject: KY Draft IMPEP Report

I am happy with the completeness and accuracy of this report. I have no comments to submit. Let me know if you need a more formal response.