October 5, 2004

MEMORANDUM TO: Martin J. Virgilio, Deputy Executive Director
for Materials, Research and State Programs

Paul H. Lohaus, Director
Office of State and Tribal Programs

Thomas H. Essig , Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety, NMSS

Karen D. Cyr, General Counsel

FROM: Josephine M. Piccone, Deputy Director ***/RA/***
Office of State and Tribal Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE KENTUCKY RADIATION CONTROL PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Attachment 1) documenting the IMPEP review of the Kentucky Radiation Control Program. The review of the Kentucky program was conducted by an interoffice team during the period of July 19-23, 2004. The team issued a draft report to Kentucky on August 25, 2004 for factual comment. Kentucky responded with no questions, corrections, or challenges by letter dated September 24, 2004 from William D. Hacker, M.D., Acting Commissioner (Attachment to the proposed final report).

The review team found Kentucky's performance to be satisfactory for five performance indicators, and satisfactory, but needs improvement, for the performance indicators, Technical Quality of Incident and Allegation Activities, Compatibility Requirements, and Sealed Source and Device Evaluation Program. Accordingly, the review team recommends that the Kentucky Agreement State program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next IMPEP review be conducted in approximately four years.

The MRB meeting to consider the Kentucky report is scheduled for **Tuesday, October 12, 2004, from 2:00 p.m. to 4:00 p.m., in One White Flint North, Room O-7-B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is attached (Attachment 2).

If you have any questions prior to the meeting, please contact me at 301-415-2325 or Duncan White at 610-337-5042.

Attachments:
As stated

cc: See next page.

cc: William D. Hacker, M.D.
Acting Commissioner
Department for Public Health
Cabinet for Health and Family Services

Clyde Bolton, Director
Division of Public Health Protection and Safety

Robert L. Johnson, Manager
Radiation Health and Toxic Agents Branch

Alice Rogers, TX
OAS Liaison to the MRB

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF KENTUCKY AGREEMENT STATE PROGRAM

July 19-23, 2004

PROPOSED FINAL REPORT

U.S. Nuclear Regulatory Commission

ATTACHMENT 1

1.0 INTRODUCTION

This report presents the results of the review of the Kentucky Agreement State program. The review was conducted during the period July 19-23, 2004, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement States of Ohio and Texas. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of July 22, 2000 to July 23, 2004, were discussed with Kentucky management on July 23, 2004.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The Kentucky Agreement State program is administered by the Radiation Health and Toxic Agents Branch (the Branch). The Radioactive Materials Section (the Section) along with Radiation Producing Machines and Radiation/Environmental Monitoring Sections comprise the Branch. The Branch is part of the Division of Public Health Protection and Safety within the Department for Public Health (the Department). The Department is part of the Cabinet for Health and Family Services (the Cabinet). The Branch Manager reports to the Division Director who in turn reports to the Commissioner of the Department. Organization charts are included in Appendix B. At the time of the review, the Kentucky Agreement State program regulated approximately 430 specific licenses authorizing Agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Kentucky.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Branch on April 27, 2004. The Branch provided a response to the questionnaire on July 9, 2004. A copy of the questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML042110358.

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

Section 2 below discusses the Commonwealth's actions in response to recommendations made following the previous IMPEP review and the review team's conclusion regarding close out of the recommendations. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings.

Recommendations made by the review team are comments that relate directly to performance by the Commonwealth. A response is requested from the Commonwealth to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

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

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

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

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

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

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

   Current Status: The Branch has revised their training program to include supervisory sign off, but the documentation of the current staff's training and experience was found to be incomplete. This matter is further discussed in Section 3.1, Technical Staffing and Training and the team has made a new recommendation. This recommendation is closed.

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

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

Product Evaluation, and the review team has made a new recommendation. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Branch's questionnaire response relative to this indicator, interviewed Branch management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

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

At the time of the review, there were five technical staff members with various degrees of involvement in the radioactive materials program. The review team determined that a total of 3.25 full time equivalents (FTE) is dedicated to the materials licensing and inspection programs, and 0.3 FTE to emergency response, reciprocity, and transportation.

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

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

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

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

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

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

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

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

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

The review team considered a finding of satisfactory, but needs improvement for this indicator based on the complete turnover of staff and the number of identified weaknesses. However, the review team notes that the Branch identified a number of needed improvements, developed and in some cases implemented action plans to correct specific performance issues. In addition, the Branch continued to perform the core inspection and licensing functions and has recently received authorization to fill one vacant position and to add two new positions. The review team concluded that the Branch has an adequate plan to sufficiently staff the Section and make the necessary improvements to the program. Based on the IMPEP evaluation criteria, the review team recommends 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 in reviewing the status of the material inspection program: inspection frequency, overdue inspections, initial inspections of new licensees, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The review team's evaluation is based on the Branch's questionnaire response relative to this indicator, data gathered independently from the Branch's licensing and inspection data tracking system, the examination of complete licensing and inspection casework, and interviews with management and staff.

The team's review of the Branch's inspection priorities verified that inspection frequencies for various types of Kentucky material licenses are generally the same as those listed in NRC Manual Chapter (MC) 2800. However, there are some categories of licenses that were assigned inspection priority codes that prescribe a more frequent inspection schedule than those currently prescribed in MC 2800. These reduced inspection intervals are assigned to activities the Branch has determined to be of higher risk, or for licensees who have demonstrated poor performance.
In their response to the questionnaire, the Branch indicated that there were 10 core licenses

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

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

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

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

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

3.3 Technical Quality of Inspections

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

Based on the casework file reviews, the review team found that routine inspections covered all

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

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

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

Members of the review team accompanied four Kentucky inspectors from June 1 to 4, 2004, and observed their activities during inspections of an industrial radiography facility, a small medical facility licensed for diagnostic nuclear medicine and radiopharmaceutical therapy, a broad scope medical facility, and a Type A Broad Scope academic licensee which are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their review of each of the licensee's radiation safety programs. The inspections were adequate to assess radiological health and safety at each of the licensed facilities.

The Branch has an adequate number and selection of survey instruments to support the inspection program. Each inspector is assigned a calibrated dual function (GM and micro-R) survey meter that is carried with them at all times to facilitate a rapid response in emergency situations. The meters are calibrated by the manufacturer or a properly licensed facility. The Branch Manager indicated that the Branch has plans to set up a calibration facility to calibrate their meters. The task of ensuring the survey meters are calibrated has been assigned to a senior member of the inspection staff. The Branch also oversees a Radiation/Environmental Monitoring Section which maintains a well equipped and adequately staffed analytical

laboratory. Members of the review team toured the facility. The laboratory has broad analytical capability including liquid scintillation counters, gas proportional counters, intrinsic germanium detectors, multichannel analyzers, alpha spectroscopy, and radiochemistry. The laboratory is capable of analyzing a broad range of environmental media.

Based on the IMPEP evaluation criteria, the review team recommends 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 interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 16 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period. The cross-section sampling focused on the new licenses, amendments, renewals, and licenses terminated during the review period. The sampling included the following types: medical broad scope, general license distribution, manufacturing and distribution, medical (institution and private practice), research and development, nuclear pharmacy, industrial radiography, self-shielded irradiator, laboratory analysis and source material. Licensing actions reviewed included three new, seven renewals, five amendments and one termination file. A listing of the casework licenses evaluated with case specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. The review team confirmed that there were no exemptions issued as indicated on the Branch's questionnaire response.

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

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

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

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

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

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

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

completely documented in only three cases.

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

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

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

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

The review team recognizes that the Section has identified the need to document responses to incidents and allegations through their self assessment and included this item in their corrective action plan. Documentation of the Section's responses will also facilitate the follow up to the incident or review of licensee corrective actions during the next inspection. The review team recommends that the Branch document incident and allegation responses in accordance with their procedures and provide training on the procedures to all technical staff.

Although the Branch makes an effort to protect the identity of an alleger, the team noted that Kentucky law requires that all public documents be made available for inspection and copying unless specifically exempted from disclosure under Kentucky's Open Records Act. The Branch procedure, "Availability of Files to the Public," Section 414, Title 400, of the Branch Administrative Manual provides guidance to the staff on handling public documents. Legal council is available in the Department to assist the staff in deciding whether or not to release information.

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky's

performance with respect to the indicator, Technical Response to Incident and Allegation Activities, be found satisfactory, but needs improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Compatibility Requirements

4.1.1 Legislation

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

4.1.2 Program Elements Required for Compatibility

The Kentucky Regulations for Control of Radiation, found in 902 Kentucky Administrative Regulations (KAR) Chapter 100, Regulations for Radioactive Materials, apply to all ionizing radiation, whether emitted from radionuclides or machine sources. Kentucky requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the Commonwealth's administrative rulemaking process and found that the process takes approximately 12 months after the Branch submits the drafted amendment for Cabinet review. The public and other interested parties are provided an opportunity to comment on proposed rules. The NRC is provided with proposed rules for comments during the promulgation process. The Commonwealth can adopt other agency's regulations by reference and has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. The regulations are not subject to sunset provisions.

The review team evaluated the Branch's response to the questionnaire, reviewed the status of regulations required to be adopted by the Commonwealth under the Commission's adequacy and compatibility policy and verified the adoption of regulations with data obtained from the

Office of State and Tribal Programs' State Regulation Status Data Sheet. Since the previous IMPEP review, the Branch adopted six amendments that became effective in March 2001, February 2002, and June 2004.

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

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998.

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

- "Energy Compensation Sources for Well Logging and other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.

- "New Dosimetry Technology," 10 CFR Parts 34, 36 and 39 amendments (65 FR 63749) that became effective January 8, 2001.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. The Branch has amended the appropriate licenses with license conditions compatible with the requirements in 10 CFR 32.52 (a) and (b). The Branch has not adopted the remainder of the amendment.

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

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002.

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40 and 70 amendments (68 FR 57327) that became effective on December 3, 2003.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that becomes effective October 1, 2004.

The team discussed the status of overdue NRC amendments with the Branch Manager and Section Supervisor. As discussed in Section 3.1, the Branch self audit identified the need to adopt overdue NRC amendments. The Branch's action plan specifies schedules for the

adoption of overdue NRC amendments during 2005. In addition, the Branch also recognized the need to update their various policy and procedure manuals to reflect changes in the regulations. These planned revisions are also reflected in the Branch's action plan with planned completion in late 2005. Since the Branch has already developed an action plan to adopt the overdue NRC amendments, the review team determined that a specific recommendation was not needed.

Based on IMPEP evaluation criteria, the review team recommends that Kentucky's performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

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

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

In assessing the Branch's SS&D evaluation program, the review team examined information provided by the Branch in response to the IMPEP questionnaire on this indicator. A review of two amended SS&D registration evaluations and supporting documents covering the review period was conducted. The review team interviewed the Section Supervisor and Branch Manager and assessed the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

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

In April 2001, one concurrence reviewer attended the NRC/State SS&D Workshop and received management approval for performing SS&D reviews. This reviewer is presently the only reviewer with management approval to perform SS&D reviews. A second reviewer attended the SS&D workshop in September 2003, but does not have documented management approval to perform SS&D reviews, yet signed as a concurrence reviewer for one of the amended registration certificates in May 2002. This reviewer stated that verbal approval to be a qualified reviewer was given by the former Branch Manager in 2002 prior to signing as a concurrence reviewer. A third staff member also attended the September 2003 workshop, but has not attained management approval for performing SS&D reviews.

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

4.2.2 Technical Quality of the Product Evaluation

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

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

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

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

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

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

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

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

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

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

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

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

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

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

4.3.1 Technical Staffing and Training

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

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

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

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

4.3.3 Technical Quality of Inspections

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

As discussed in Section 3.3, the review team visited the Radiation/Environmental Monitoring Section laboratory and found the facility equipped to support monitoring activities at the site. Periodic site visits are made by the laboratory technical staff on at least a monthly basis and

also during major rainfall for environmental sampling and monitoring purposes. Sampling includes surface water from creeks and storm water runoff from the site. Results of environmental monitoring are maintained at the laboratory. The Branch maintains an adequate variety of calibrated radiation survey instruments as discussed in Section 3.3. Survey instruments are also available at the laboratory.

4.3.4 Technical Quality of Licensing Actions

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

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

4.3.5 Technical Quality of Incident and Allegation Activities

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

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

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Kentucky's performance to be satisfactory for five performance indicators and satisfactory, but needs improvement, for three performance indicators. Accordingly, the review team recommends finding the Kentucky Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. The team considered a finding of adequate, but needs improvement, but noted that the Branch identified a number of needed improvements, developed and in some cases implemented action plans to correct specific performance issues and has been approved to expand the Section's staff. Based on the results of the current IMPEP review, the review team recommends that the next full review should be in approximately four years.

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

RECOMMENDATIONS:

1. The review team recommends that the Branch upgrade their database so that all relevant licensee data are incorporated and maintained to ensure that inspections can be scheduled and performed in accordance with the requirements of MC 2800. (Section 3.2)

2. The review team recommends that the Branch identify those licensees who require financial assurance and take appropriate action to have them comply with the Commonwealth's decommissioning and financial assurance requirements. (Section 3.4)

3. The review team recommends that the Branch document incident and allegation responses in accordance with its procedures and provide training on their procedures to all technical staff. (Section 3.5)

4. The review team recommends that the Branch establish, implement and document a training program for SS&D reviewers. (Section 4.2.1)

5. The review team recommends that the registration certificate evaluation criteria and document format be consistent with NUREG 1556, Volume 3. (Section 4.2.2)

6. The review team recommends that the Branch review and determine the status of SS&D registrations issued to non-Kentucky manufacturers and take appropriate action to either update or inactivate the registration certificates. (Section 4.2.2)

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

LIST OF APPENDICES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

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

APPENDIX B
KENTUCKY ORGANIZATION CHARTS

ADAMS: ML042170062

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: University of Louisville — License No.: 202-029-22
Location: Louisville, KY — Inspection Type: Routine, Announced
License Type: Broad Scope Medical, HDR — Priority: 1
Inspection Date: 06/03/04 — Inspectors: MM/RG/RH

File No.: 2
Licensee: University of Louisville — License No.: 203-034-71
Location: Louisville, KY — Inspection Type: Routine, Announced
License Type: Broad Scope Academic — Priority: 1
Inspection Date: 06/03/04 — Inspectors: MM/RG/RH

File No.: 3
Licensee: Louisville Radiation Oncology — License No.: 202-231-27
Location: Louisville, KY — Inspection Type: Routine, Unannounced
License Type: Brachytherapy - HDR — Priority: 1
Inspection Date: 06/13/03 — Inspectors: JJ/RG

File No.: 4
Licensee: Stupp Bridge Company — License No.: 201-674-05
Location: Bowling Green, KY — Inspection Type: Routine, Unannounced
License Type: Industrial Radiography — Priority: 1
Inspection Date: 06/19/03 — Inspector: SB

File No.: 5
Licensee: Jewish Hospital — License No.: 202-115-22
Location: Louisville, KY — Inspection Type: Routine, Announced
License Type: Broad Scope Medical — Priority: 1
Inspection Date: 8/14-15/01 — Inspector: EL

File No.: 6
Licensee: Cardinal Health — License No.: 202-206-32
Location: Louisville, KY — Inspection Type: Routine, Unannounced
License Type: Radiopharmacy — Priority: 1
Inspection Date: 09/11/00 — Inspector: VJ

File No.: 7
Licensee: University of Kentucky — License No.: 202-049-22
Location: Lexington, KY — Inspection Type: Routine, Announced
License Type: Broad Scope Medical - IVB - HDR — Priority: 1
Inspection Date: 05/24/04 — Inspector: RH

File No.: 8
Licensee: Radiopharmacy of Paducah, Inc. License No.: 202-221-32
Location: Paducah, KY Inspection Type: Routine, Unannounced
License Type: Radiopharmacy Priority: 1
Inspection Date: 10/21/02 Inspector: JJ

File No.: 9
Licensee: University of Kentucky License No.: 202-024-31
Location: Lexington, KY Inspection Type: Routine, Announced
License Type: Gamma Knife Priority: 1
Inspection Date: 05/24/04 Inspector: RH

File No.: 10
Licensee: Central Kentucky Blood Center License No.: 202-243-96
Location: Lexington, KY Inspection Type: Routine, Unannounced
License Type: Blood Irradiator Priority: 3
Inspection Date: 01/30/01 Inspector: JJ

File No.: 11
Licensee: Gilco Nuclear Surveys License No.: 201-214-40
Location: Glasgow, KY Inspection Type: Routine, Unannounced
License Type: Well Logging Priority: 3
Inspection Date: 01/25/02 Inspector: EL

Comment:
The licensee failed to respond to the notice of violation (NOV) dated 02/07/02 and there was no follow up by the Branch

File No.: 12
Licensee: American Red Cross Blood Services License No.: 202-216-96
Location: Louisville, KY Inspection Type: Routine, Unannounced
License Type: Self Shielded Irradiator Priority: 3
Inspection Date: 06/13/03 Inspector: JJ

File No.: 13
Licensee: Marshall Miller & Associates License No.: 201-430-40
Location: Lexington, KY Inspection Type: Routine, Unannounced
License Type: Well Logging & Portable Gauges Priority: 3
Inspection Date: 10/03/02 Inspector: SB

File No.: 14
Licensee: Allegheny Wireline Services License No.: 201-094-40
Location: London, KY Inspection Type: Routine, Unannounced
License Type: Well Logging Priority: 3
Inspection Date: 07/17/02 Inspector: SB

File No.: 15
Licensee: Southern Well Services License No.: 201-170-40
Location: Henderson, KY Inspection Type: Routine, Unannounced
License Type: Well Logging Priority: 3
Inspection Date: 10/21/02 Inspector: JJ

Comment:
The licensee did not respond to the second deficiency letter and there was no Branch follow up.

File No.: 16
Licensee: Georgetown Community Hospital License No.: 202-220-26
Location: Georgetown, KY Inspection Type: Routine, Unannounced
License Type: Medical Institution - Written Directive Required Priority: 3
Inspection Date: 09/13/02 Inspector: RJ

File No.: 17
Licensee: Western Baptist Hospital License No.: 202-142-26
Location: Paducah, KY Inspection Type: Routine, Unannounced
License Type: Medical License - Written Directive Required Priority: 3
Inspection Date: 11/21/01 Inspector: EL

File No.: 18
Licensee: Northern Kentucky Heart PSC License No.: 202-220-26
Location: Crestview Hills, KY Inspection Type: Routine, Unannounced
License Type: Nuclear Cardiology Priority: 5
Inspection Date: 05/12/04 Inspector: RH

File No.: 19
Licensee: Patriot Engineering and Environmental License No.: 201-643-52
Location: Indianapolis, IN Inspection Type: Routine, Unannounced
License Type: Portable Gauge - Temporary Jobsite Priority: 5
Inspection Date: 04/28/04 Inspector: SB

File No.: 20
Licensee: H.G. Mays Corp. License No.: 201-471-51
Location: Frankfort, KY Inspection Type: Routine, Unannounced
License Type: Portable Gauge - Temporary Jobsite Priority: 5
Inspection Date: 08/06/03 Inspector: SB

File No.: 21
Licensee: Scotty's Contracting Inc. License No.: 201-254-52
Location: Bowling Green, KY Inspection Type: Routine, Unannounced
License Type: Portable Gauge - Temporary Jobsite Priority: 5
Inspection Date: 08/05/03 Inspector: SB

File No.: 22
Licensee: IveyCooper Services, LLC Tennessee License No.: R-33145-G11
Location: Chattanooga, TN Inspection Type: Reciprocity, Unannounced
License Type: Industrial Radiography - Temporary Jobsite Priority: 1
Inspection Date: 04/15/04 Inspector: RJ

File No.: 23
Licensee: Elekta Instruments, Inc. Georgia License No.: GA 1153-1
Location: Norcross, GA Inspection Type: Reciprocity, Announced
License Type: Service Provider - Temporary Jobsite Priority: 3
Inspection Date: 05/21/03 Inspectors: JJ/ RG

File No.: 24
Licensee: Voith Fabrics Shreveport, Inc. NRC License No.: 17-26958-01
Location: Shreveport, LA Inspection Type: Reciprocity, Unannounced
License Type: Portable Gauges - Temporary Jobsite Priority: 5
Inspection Date: 05/06/03 Inspector: JJ

File No.: 25
Licensee: Huntington Testing & Technology, Inc. License No.: 201-551-05
Location: Louisville, KY Inspection Type: Reactive, Announced
License Type: Industrial Radiography Priority: 1
Inspection Date: 01/28/04 Inspector: SB

File No.: 26
Licensee: Cook and Sons Mining, Inc. License No.: 201-268-51
Location: Louisville, KY Inspection Type: Reactive, Announced
License Type: Portable & Fixed Gauges Priority: 5
Inspection Date: 08/26/03 Inspector: SB

File No.: 27
Licensee: Wood Hudson Cancer Research Laboratory, Inc. License No.: 201-641-85
Location: Newport, Ky Inspection Type: Routine, Unannounced
License Type: Laboratory Priority: 5
Inspection Date: 05/06/03 Inspector: RJ

File No. 28
Licensee: NREPC - Maxey Flats Project
License No. 206-002-03
Location: Fleming County, KY
Inspection Type: Routine, Announced
License Type: Closed LLRW Disposal Site
Priority: 2
Inspection Date: 01/15/04
Inspectors: SB/MM/RG/RH

Comment:
Inspection report issued to licensee nearly six months after completion of inspection.

INSPECTOR ACCOMPANIMENTS

The following inspection accompaniments were performed as part of the IMPEP review:

Accompaniment No.: 1
Licensee: University of Louisville
License No.: 202-029-22
Location: Louisville, KY
Inspection Type: Routine, Announced
License Type: Broad Scope Medical
Priority: 2
Inspection Date: 06/03/04
Inspectors: MM/RG/RH

Accompaniment No.: 2
Licensee: University of Louisville
License No.: 203-034-71
Location: Louisville, KY
Inspection Type: Routine, Announced
License Type: Type A Broad Scope Academic
Priority: 3
Inspection Date: 06/03/04
Inspectors: MM/RG/RH

Accompaniment No.: 3
Licensee: Derby City Engineering & Inspection, Inc.
License No.: 201-523-05
Location: Louisville, KY
Inspection Type: Routine, Unannounced
License Type: Industrial Radiography
Priority: 1
Inspection Date: 7/02/04
Inspectors: SB/MM

Accompaniment No.: 4
Licensee: Norton Southwest Hospital
License No.: 202-133-25
Location: Louisville, KY
Inspection Type: Routine, Unannounced
License Type: Medical Institution - WD Required
Priority: 3
Inspection Date: 7/01/04
Inspector: RH

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Cardinal Health — License No.: 202-206-32
Location: Louisville, KY — Amendment No.: 24
License Type: Nuclear Pharmacy — Type of Action: Renewal
Date Issued: 11/06/00 — License Reviewers: JJ/VJ

Comment:
License file contained personal information (social security numbers and dates of birth).

File No.: 2
Licensee: H&H X-Ray Services, Inc. — License No.: 201-342-05
Location: Paintsville, KY — Amendment No.: 28
License Type: Industrial Radiography — Type of Action: Renewal
Date Issued: 07/10/02 — License Reviewer: SB

File No.: 3
Licensee: Western Baptist Hospital — License No.: 202-142-26
Location: Paducah, KY — Amendment No.: 71
License Type: Medical Institution - WD required, HDR — Type of Action: Amendment
Date Issued: 09/05/03 — License Reviewer: RH

File No.: 4
Licensee: Georgetown Community Hospital — License No.: 202-220-26
Location: Georgetown, KY — Amendment No.: 21
License Type: Medical Institution - WD required — Type of Action: Amendment
Date Issued: 04/08/04 — License Reviewer: RH

File No.: 5
Licensee: Northern Kentucky Heart, PSC — License No.: 202-308-24
Location: Crestview Hill, KY — Amendment No.: NA
License Type: Medical Private Practice - no WD required — Type of Action: New
Date Issued: 11/13/03 — License Reviewer: RJ

File No.: 6
Licensee: University of Kentucky — License No.: 201-266-96
Location: Lexington, KY — Amendment No.: 31
License Type: Self Shielded Irradiator — Type of Action: Renewal
Date Issued: 08/09/01 — License Reviewer: VJ

File No.: 7
Licensee: Hayes Testing Laboratory, Inc. License No.: 201-168-05
Location: Louisville, KY Amendment No.: 57
License Type: Industrial Radiography Type of Action: Renewal
Date Issued: 03/13/03 License Reviewer: SB

Comments:
a) License did not include condition for restricting possession limit to avoid the need for financial assurance.
b) Radiation safety manual included 20 year old contact information for various regulatory agencies.

File No.: 8
Licensee: SUD-Chemie License No.: 204-006-92
Location: Louisville, KY Amendment No.: 49
License Type: Source Material Type of Action: Amendment
Date Issued: 04/11/03 License Reviewer: JJ

Comment:
Licensee's possession limits required financial assurance for decommissioning; none was submitted.

File No.: 9
Licensee: Ronan Engineering Co. License No.: 201-260-95
Location: Florence, KY Amendment No.: 51
License Type: Manufacturing Type of Action: Renewal
Date Issued: 02/01/02 License Reviewer: EL

Comment:
No requirement for licensee to report equipment problems to the Commonwealth.

File No.: 10
Licensee: Ronan Engineering, Co. License No.: 201-267-95
Location: Florence , KY Amendment No.: 32
License Type: General License Distribution Type of Action: Renewal
Date Issued: 02/01/02 License Reviewer: EL

File No.: 11
Licensee: United States Enrichment Corporation License No.: 201-661-85
Location: Puducah, KY Amendment No.: NA
License Type: Laboratory Analysis Type of Action: New
Date Issued: 12/05/03 License Reviewers: EL/RJ

Comments:
a) Licensee not listed in Commonwealth's database.
b) Licensee's possession limits required financial assurance for decommissioning; none was submitted.
c) License issued 26 months after application was submitted in order to resolve Federal/State jurisdictional issues.

File No.: 12
Licensee: Cardinal Health License No.: 202-249-32
Location: Lexington, KY Amendment No.: 21
License Type: Nuclear Pharmacy Type of Action: Termination
Date Issued: 07/22/03 License Reviewers: JJ/RG

File No.: 13
Licensee: Chem Pharma International LLC License No.: 201-671-04
Location: Richmond, KY Amendment No.: NA
License Type: Research and Development Type of Action: New
Date Issued: 01/10/03 License Reviewer: RJ

File No.: 14
Licensee: University of Louisville License No.: 202–029-22
Location: Louisville, KY Amendment No.: 71
License Type: Medical Broad Scope Type of Action: Amendment
Date Issued: 04/28/04 License Reviewer: RG

Comment:
Licensee's possession limits required financial assurance for decommissioning; none was submitted.

File No.: 15
Licensee: Columbia Greenview Regional Hospital License No.: 202-098-26
Location: Bowling Green, KY Amendment No.: 65
License Type: Medical Institution - WD required Type of Action: Amendment
Date Issued: 05/07/04 License Reviewer: MM

File No.: 16
Licensee: Twins Lakes Regional Medical Center
Location: Leitchfield, KY
License Type: Medical Institution - no WD required
Date Issued: 07/21/04
License No.: 202-194-24
Amendment No.: 26
Type of Action: Renewal
License Reviewer: MM

File No.: 17
Licensee: NREPC - Maxey Flats Project
Location: Fleming County, KY
License Type: Closed LLRW Disposal Site
Date Issued: 08/29/03
License No.: 206-002-003
Amendment No.: 53
Type of Action: Renewal
License Reviewer: JJ

Comment:
Licensee took three years to submit renewal application.

File No.: 18
Licensee: NREPC - Maxey Flats Project
Location: Fleming County, KY
License Type: Closed LLRW Disposal Site
Date Issued: various
License No.: 206-002-03
Amendment Nos.:48-52, 55
Type of Actions: Amendment
License Reviewer: VJ/RJ/SB

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: H. C. Nutting Company — Ohio License No.: 312103100
Site of Incident: Park Hills, KY — Incident Log No.: NMED-020123
Date of Incident: 01/17/02 — Type of Incident: Stolen Source
Investigation Date: 1/17/02 — Type of Investigation: Phone

File No.: 2
Licensee: University of Kentucky — License No.: 203-021-72
Site of Incident: Lexington, KY — Incident Log No.: NMED-030645
Date of Incident: 06/18/03 — Type of Incident: Lost or Stolen Material
Investigation Date: Not Documented — Type of Investigation: Not Documented

Comments:
a) Date and type of investigation not documented in file.
b) File contains a memo from the licensee responding to a request from the Branch. No copy or documentation of the request is in the file.

File No.: 3
Licensee: Lexington Clinic — License No.: 202-061-26
Site of Incident: Lexington, KY — Incident Log No.: NMED-030987
Date of Incident: 11/24/03 — Type of Incident: Misadministration
Investigation Date: Not Documented — Type of Investigation: Not Documented

Comment:
Branch's investigation is still open.

File No.: 4
Licensee: Huntington Testing & Technology — License No.: 201-551-05
Site of Incident: Ghent, KY — Incident Log No.: NMED-021063
Date of Incident: 10/18/02 — Type of Incident: Overexposure
Investigation Date: Not Documented — Type of Investigation: On-site

Comment:
No copy of correspondence from Branch to licensee.

File No.: 5
Licensee: Jefferson County Health Department License No.: 201-172-58
Site of Incident: Louisville, KY Incident Log No.: NMED-000763
Date of Incident: 09/01/00 Type of Incident: Lost or Stolen Material
Investigation Date: Not Documented Type of Investigation: Not Documented

Comments:
a) No incident file or documentation of incident in license file.
b) No follow up during February 2004 inspection.
c) NMED record is incomplete and open.

File No.: 6
Licensee: Fuller, Mossbarger, Scott & May Engineers INC License No.: 201-142-51
Site of Incident: Lexington, KY Incident Log No.: NMED-000682
Date of Incident: 09/11/00 Type of Incident: Lost or Stolen Material
Investigation Date: Not Documented Type of Investigation: Not Documented

Comments:
a) No incident file or documentation of incident in license file.
b) No follow up during February 2004 inspection.
c) NMED record is incomplete and open.

File No.: 7
Licensee: The Medical Center at Bowling Green License No.: 202-124-26
Site of Incident: Bowling Green, KY Incident Log No.: NMED-010202
Date of Incident: 11/29/00 Type of Incident: Leaking source
Investigation Date: Not Documented Type of Investigation: Not Documented

Comments:
a) No incident file.
b) Documentation of incident in license file is incomplete.
c) No follow up during November 2003 inspection.
d) NMED record is complete, but was not closed.

File No.: 8
Licensee: The Medical Center at Bowling Green License No.: 202-124-26
Site of Incident: Bowling Green, KY Incident Log No.: NMED-040051
Date of Incident: 01/19/04 Type of Incident: Medical Event
Investigation Date: Not Documented Type of Investigation: Not Documented

Comment:
No incident file or documentation of incident in license file.

File No.: 9
Licensee: Mountain Enterprises
License No.: 201-447-51
Site of Incident: Ashland, KY
Incident Log No.: NMED-030703
Date of Incident: 08/27/03
Type of Incident: Lost or Stolen Material
Investigation Date: 08/27/03
Type of Investigation: On-site

Comments:
a) No incident file.
b) No documentation of incident in license file, other than a copy of NOV dated 09/10/03.

File No.: 10
Licensee: Hays Testing Laboratories, Inc
License No.: 201-168-05
Site of Incident: Louisville, KY
Incident Log No.: NMED-030355
Date of Incident: 03/28/03
Type of Incident: Equipment Failure
Investigation Date: Not Documented
Type of Investigation: Not Documented

Comments:
a) No incident file.
b) No documentation of investigation by Branch, but NMED record indicates an investigation was conducted.

The following incidents involved devices covered by SS&D registry sheets issued by the Commonwealth.

File No.: 11
Licensee: Transalta Centralia Mining, Inc.
License Number: WA-WN-I0241-1
Site of Incident: Centralia, WA
Incident Log No.: NMED-000697
Date of Incident: 09/13/00
Type of Incident: Mechanical Failure
Investigation Date: None
Type of Investigation: None

Comments:
a) No incident file.
b) No documentation of investigation by Branch.

File No.: 12
Licensee: TN Technologies, Inc.
License Number: TX-L03524
Site of Incident: Round Rock, TX
Incident Log No.: NMED-000708
Date of Incident: 07/07/00
Type of Incident: Leaking sources
Investigation Date: None
Type of Investigation: None

Comments:
a) No incident file.
b) No documentation of investigation by Branch.

File No.: 13
Licensee: Transalta Centralia Mining, Inc. License Number: WA-WN-I0241-1
Site of Incident: Centralia, WA Incident Log No.: NMED-000788
Date of Incident: 10/05/00 Type of Incident: Device Failure
Investigation Date: None Type of Investigation: None

Comments:
a) No incident file.
b) No documentation of investigation by Branch.

File No.: 14
Licensee: Transalta Centralia Mining, Co. License Number: WA-WN-I0241-1
Site of Incident: Centralia, WA Incident Log No.: NMED-000919
Date of Incident: 11/21/00 Type of Incident: Device Failure
Investigation Date: None Type of Investigation: None

Comment:
a) No incident file.
b) No documentation of investigation by Branch.

File No.: 15
Licensee: Transalta Centralia Mining, Co. License Number: WA-WN-I0241-1
Site of Incident: Centralia, WA Incident Log No.: NMED-020170
Date of Incident: 02/06/02 Type of Incident: Device Failure
Investigation Date: None Type of Investigation: None

Comments:
a) No incident file.
b) No documentation of investigation by Branch.

File No.: 16
Licensee: Albemarle Corporation License Number: AR-717
Site of Incident: Magnolia, AR Incident Log No.: NMED-020582
Date of Incident: 06/06/02 Type of Incident: Device Failure
Investigation Date: None Type of Investigation: None

Comments:
a) No incident file.
b) No documentation of investigation by Branch.

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

File No.: 1
Registry No. KY-0576-D-101-B — SS&D Type: Gamma Gauge
Manufacturer: Ronan Engineering Company — Model: SA-1
Date Issued: 06/03/02 — Type of Action: Amendment

Comments:

a) No documentation of latest review or checklist in file.
b) Condition of normal use (temperature) exceeded ANSI device classification and prototype testing. Approval based on material of construction and not operational testing of moving parts.
c) In the registry sheet and application, labeling was identified in terms of NRC regulations and not Kentucky regulations.
d) Corrosion control of non stainless steel was not addressed, especially when used in corrosive environments. The only limitation for corrosive atmosphere was for limits of stainless steel under conditions of use.
e) No justification was presented as required by Commonwealth regulation 902 KAR 100:058 Section 4, (3)(a) for the manufacturer's request and subsequent approval for a three-year shutter test.
f) The "Diagrams" section of registry sheet needs to itemize the list of attachments instead of just stating "See Attachments," especially since a non standard numbering format was used.
g) Numbering format of the attachments was not in accordance with the NUREG 1556, Volume 3, guidance format. For example, attachment pages were numbered as Attachment 1 Figure A, Attachment 4 Figure B.
h) Sealed source models listed on the cover page of the registry sheet included inactive sealed source registration (e.g., Gamma Industries model VDHP) or were not specifically listed as a registered source model (e.g., 3M model 4F6ST)
I) There is insufficient information regarding the shutter mechanism which serves as the on-off mechanism for the device. Particularly, there is insufficient information (1) on how the shutter is attached to the shaft and handle; and (2) is there sufficient strength (i.e., what torque is applied) when a shutter actuator is added.
j) Copy of the QA program not in file.

File No.: 2
Registry No. KY-0576-D-113-B SS&D Type: Gamma Gauge
Manufacturer: Ronan Engineering Company Model: RLL-1
Dates Issued: 04/19/01 and 05/30/02 Type of Actions: Amendments

Comments:

a) Concurrence review for May 2002 amendment done by an individual that did not meet SS&D reviewer qualification.
b) No documentation of latest review or checklist in file.
c) Kentucky regulations (902 KAR 100: 050 Section 3 (3)(C)2.b) that require a device be leaked tested if it contains more than 100 microcuries was not followed. No leak test was required for this device since each individual sealed source contained approximately 90 microcuries; however, the entire device contains up to 900 microcuries of total activity (10 sources).
d) In the registry sheet and application, labeling was identified in terms of NRC regulations and not Kentucky regulations.
e) The “Diagrams” section of registry sheet needs to itemize the list of attachments instead of just stating “See Attachments” especially since a non standard numbering format was used.
f) Numbering format of the attachments was not in accordance with the NUREG 1556, Volume 3, guidance format.
g) Labels do not indicate if a single or multiple sources are used in a device.
h) Labels reference NRC rules for leak test and shutter test requirements instead of Kentucky rules.
l) Upper temperature limit for conditions of use not tested but was justified on material change temperature for stainless steel at 455/F. This does not address strength changes of material at that temperature.
j) Copy of QA program not in file.

ATTACHMENT

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

ADAMS: ML042780161

Agenda for Management Review Board Meeting
October 12, 2004, 2:00 p.m. - 4:00 p.m., O-7-B4

1. MRB Chair convenes meeting. Introduction of MRB members, review team members, Kentucky representatives, and other representatives participating through telephone bridge or video conferencing.

2. Consideration of the Kentucky IMPEP Report.

   A. Presentation of Findings Regarding Kentucky Program and Discussion.

      - Technical Staffing and Training
      - Status of Materials Inspection Program
      - Technical Quality of Inspections
      - Technical Quality of Licensing Actions
      - Technical Quality of Incident and Allegation Activities
      - Compatibility Requirements
      - Sealed Source and Device Evaluation Program
      - Low-level Waste Radioactive Waste Disposal Program

   B. MRB Consultation/Comments on Issuance of Report.

      - Adequacy and Compatibility Rating
      - Recommendation for Next IMPEP Review

   C. Comments

3. Status of IMPEP Reviews and Heightened Oversight/Monitoring Activities

4. Establishment of Precedents/Lessons Learned

5. Adjournment

Invitees:

Martin Virgilio, EDO	Duncan White, RI
Paul Lohaus, STP	Sheri Minnick, RI
Thomas Essig, NMSS	Richard Blanton, STP
Karen Cyr, OGC	Randy Erickson, RIV
Alice Rogers, OAS Liaison	Muhammadali Abbaszadeh, TX
Robert Johnson, KY	Karl Von Ahn, OH
John Zabko, STP	Kathleen Schneider, STP
Josephine Piccone, STP	Aaron McCraw, STP

ATTACHMENT 2