INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF KENTUCKY AGREEMENT STATE PROGRAM

April 15-19, 1996

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Kentucky radiation control program. The review was conducted during the period April 15-19, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Alabama. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period May 13, 1994, to April 19, 1996, were discussed with Kentucky management on April 18 and 19, 1996.

A draft of this report was issued to Kentucky for factual comment on June 13, 1996. The Commonwealth of Kentucky responded in a letter dated June 21, 1996 (Attachment 1), and the comments were incorporated into the proposed final report. The Management Review Board (MRB) met on July 17, 1996, to consider the proposed final report. The MRB concurred in the teams's overall recommendations and found that the Kentucky radiation control program was adequate to protect public health and safety and was compatible with the NRC's regulatory program.

The Cabinet for Health Services (CHS), which recently replaced the Cabinet for Human Resources, is the radiation control agency within the Commonwealth of Kentucky. The Secretary is appointed by and reports to the Governor. Within CHS, the Kentucky radiation control program is administered by the Radiation Control Branch (RCB) under the direction of the Department of Health Services through the Division of Environmental Health and Community Safety (DEHCS). The Department of Health Services will become the Department of Public Health in the near future. The RCB organization chart is included as Appendix B. The Kentucky program regulated 403 specific licensees, including the specific license for the Maxey Flats radioactive waste disposal site, at the time of the review. 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 indicators was sent to the RCB on February 14, 1996. Kentucky provided its response to the questionnaire on March 26, 1996. A copy of that response is included as Appendix C to this report.

The review team's general approach for conduct of this review consisted of: (1) examination of Kentucky's response to the questionnaire, (2) review of applicable Kentucky statutes and regulations, (3) analysis of quantitative information from the RCB licensing and inspection data base, (4) technical review of selected files, (5) field accompaniments of one Kentucky inspector, and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and non-common indicator and made a preliminary assessment of RCB's

performance. As noted above, that preliminary assessment was discussed with program management before the team's departure.

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

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on May 13, 1994, and the results were transmitted to Masten Childers II, Secretary, Cabinet for Human Resources, on January 27, 1995.

The May 1994 review findings resulted in recommendations in six program indicators: Status and Compatibility of Regulations, Adequacy of Product Evaluations, Staffing Level, Staff Continuity, Budget, and Licensing Procedures. The Commonwealth's corrective actions in response to the recommendations were evaluated during a review visit which concluded on April 18, 1995, and with one exception, all comments and recommendations were satisfactorily resolved and closed at that time. Results of the review visit were transmitted to the present Secretary, Cabinet for Health Services, John H. Morse, on March 15, 1996.

The April 1995 review visit findings resulted in recommendations in one indicator. We recommended the RCB take the following steps to improve the sealed source and device (SS&D) evaluation program: (a) obtain engineering technical expertise for SS&D reviews, such as through contractual agreements or through State agencies or universities, that could be called upon as needed for resolution of specific engineering issues that may be encountered during SS&D reviews; (b) develop an action plan for the review of all device sheets to assure that the files contain all current background information and drawings applicable to the device safety review; (c) establish documentation in the files which show that the generally licensed (GL) devices will meet the dose requirements; and (d) amend the Commonwealth's regulations to adopt requirements equivalent to those in 10 CFR 30.32(g) and 32.210(c), or amend the SS&D licenses with conditions that specifically tie the respective devices, drawings, and background information to the license.

The current status of the above SS&D evaluation program is as follows:

(a) The RCB Manager explained that if engineering expertise beyond the Commonwealth's capability was needed, that he had an informal arrangement with the School of Chemical Engineering, University of Kentucky, to assist the program with engineering evaluations of sealed sources and/or devices evaluations as needed. The RCB Manager also related that after receiving the SS&D Workshop training in 1995, he was confident that the Kentucky could perform the reviews in accordance with the NRC guidance received at the workshop. The review team feels that this action is sufficient and considers the issue closed.

(b) The Commonwealth developed an action plan for the reassessment of all previously issued device sheets by reviewing one device sheet every month. Although RCB evaluated new devices during the period, workload demands prevented the reassessment of the previously approved devices. The RCB has not been able to maintain this schedule; workload demands prevented the reassessment of the previously approved devices. RCB did review and register one new device and another device was reviewed; RCB is awaiting a response from the applicant. In Section 4.2 of this report, the team recommends that the work continue on the review of previous device sheets that remain under Kentucky jurisdiction, as planned. This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(c) One element of the Commonwealth's action plan called for documentation to be added to the files showing that the generally licensed (GL) devices meet the current dose requirements. This task was to have been completed at the time the old device sheets were reevaluated. However, since none of the previously issued device sheets were reviewed, the GL dose documentation has not been added to the files. In Section 4.2, the team also recommends that work on this portion of the action plan be continued to completion. (It should be noted that Ohmart Corporation notified Kentucky that the Kentucky facility would be closed prior to June 1996 and regulatory jurisdiction for these products will be transferred to the NRC.) This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(d) The Commonwealth amended the licenses of Ohmart (License Number 201-491-95) and Ronan (License Number 202-260-95) by incorporating the equivalent requirements of 10 CFR Part 32.210(c) into the license through the use of a binding commitment from the licensee and as incorporated into the license by license condition. The RCB manager verbally committed during the exit meetings to adopting the equivalent provisions of 10 CFR Parts 30.32(g) and 32.210(c) as regulations during the next regulation revision scheduled for FY 97. The license conditions were verified during the casework review, and the review team considers this issue 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 include: (1) Status of Materials Inspection Program; (2) Technical Staffing and Training, (3) Technical Quality of Licensing Actions, (4) Technical Quality of Inspections, and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: (1) inspection frequency, (2) overdue inspections, (3) initial inspection of new licenses, and (4) timely dispatch of inspection findings to licensees. This evaluation is based on the Kentucky's questionnaire responses regarding this indicator, data gathered independently from the Commonwealth's licensing and inspection data tracking system, the examination of licensing and inspection casework files, and interviews with managers and staff.

The team's review of the Commonwealth's inspection priorities verified that the Commonwealth's inspection frequencies for various types or groups of licenses are at least as frequent as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter 2800 (IMC 2800). In reviewing the Commonwealth's priority schedule, the review team noted that the Commonwealth requires more frequent inspections in some license categories as follows: Portable gauges are scheduled to be inspected on a four year frequency vs. NRC's five year frequency, and medical private practice licenses not required to have a quality management (QM) program have a four year frequency schedule vs. NRC's frequency of five years.

The inspection frequencies of licenses selected for inspection file review were compared with the frequencies listed in the Commonwealth's data system and verified to be consistent with the Commonwealth's system and as frequent as similar license types under the IMC 2800 system.

In their response to the questionnaire, Kentucky indicated that as of April 19, 1995, only two licenses identified as core inspections in IMC 2401 or IMC 2800, as appropriate, were overdue by more than 25 percent of the NRC's frequency. This number is well within the 10 percent criterion for overdue inspections of Management Directive 5.6. In fact, one of the overdue inspections had been inspected by the time of the review. The other overdue inspection was for the Maxey Flats Low-Level Waste Project and is discussed in Section 4.3.2 of this report.

With respect to initial inspections of new licensees, the team reviewed the inspection tracking data system and verified that the initial inspections had been entered into the tracking system. Discussions with staff members were conducted to determine how initial inspections are assigned and how data are entered into the system. The administrative staff sends the data generated by the technical staff to a contractor to update the data base. This is done on a monthly basis and then a quality check is performed by supervision based upon a computer printout provided by the contractor and used for inspection planning. All initial inspections were completed within 6 months of issuance.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Out of the files examined, all of the inspection correspondence had been sent to the licensee within 30 days after completion of the inspection.

Kentucky reported in their response to the questionnaire that 80 different licensees had submitted requests for reciprocity during the review period, of which 18 were from licensees with inspection intervals of 3 years or less. The Commonwealth reported that one of these was inspected and five other licenses having longer inspection frequencies were inspected.

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

3.2 Technical Staffing and Training

In reviewing this indicator, the review team considered the radioactive materials program staffing level, the technical qualifications of the staff, staff training, and staff turnover. To evaluate these issues, the review team examined the Commonwealth's questionnaire responses regarding this indicator, interviewed RCB management and staff, and considered any possible backlogs in licensing or compliance actions. Technical staffing and training for the low-level radioactive waste disposal program are addressed in Section 4.3.3.

At the time of the review, Kentucky's radiation control program was staffed by the Radioactive Materials Section (RMS) Supervisor and three other health physicists under the supervision of the Radiation Control Branch Manager. The RCB Manager is also indirectly responsible for all radiation safety matters administered by other DEHCS branches, such as machine radiation and laboratory services. The review team found that the current staffing level is adequate to administer the basic regulatory program, as evidenced by the lack of backlogs in licensing and inspections. However, according to program management and team observation, complex licensing and compliance cases, complicated investigations, specialized training needs, and frequent revisions to regulations often require use of overtime and delayed personal and annual leave by the supervisors and other technical staff.

The licensing and inspection functions of the program are integrated; therefore, all health physicists perform duties in licensing, inspection, and event response. Because of the need for continuity and specialized training, however, SS&D evaluations are assigned to one of two trained individuals. Balance between the licensing and inspection functions is achieved by basing staff assignments on program needs. Personnel information provided by the RCB showed that there had been no staff turnover and no vacancies in the radioactive materials program during the review period.

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

According to the information provided in the questionnaire and the RCB training procedures, all newly hired health physicists are required to attend the NRC core training courses outlined in the now suspended May 28, 1992, Policy Statement (57 FR 224950), as well as the five-week health physics course. The records show that all radioactive materials staff members have taken the five-week health physics course and the four NRC core courses. Most other NRC courses applicable to the materials program have also been taken by all professional staff.

Two individuals have not taken the Health Physics Engineering and Safety Aspects of Well Logging courses, but management explained they expect to schedule them soon.

Program management also explained their in-house and on-job training processes in their response and during interviews. Briefly, new staff are assigned increasingly complex licensing duties under the direction of senior staff and accompany experienced inspectors during increasingly complicated inspections. New staff are assigned independent inspections after demonstrating competence during accompaniment evaluations by the RMS Supervisor. In addition, the supervisor evaluates the level of radiation protection knowledge by use of written and oral examinations during the training period. The written examinations and training accompaniment evaluations were reviewed by the team and found to be excellent. The use of written examinations is a strength in the Kentucky program. The team noted that program management exhibited a strong commitment to training during the review.

As discussed above, the staff has used overtime and delayed personal and annual leave to avoid licensing and inspection backlogs. In order to free technical staff from excessive administrative and record keeping duties, the RCB is in the process of building an in-house local area network (LAN) with a licensing and inspection data base. Program management explained that they feel that their technical staff could operate more efficiently by having access to a system to collectively store, retrieve, manipulate, and transmit data and information. The review team agrees that, once installed and operating, a LAN system should enable staff to devote more of their efforts to the technical aspects of their responsibilities, thus enhancing the overall quality of the regulatory 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.

3.3 Technical Quality of Licensing Actions

The review team examined casework and interviewed the reviewers for 25 specific licenses. Licensing actions were reviewed for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authorities. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. The files were checked for retention of necessary documents and supporting data.

Kentucky policy requires each licensee to review its program at five-year intervals and submit a complete program for review by the staff as part of the license renewal. The RCB renews each license annually, and amends licenses as needed. The staff makes extensive use of checklists and standard review plans.

The cases were selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The cross-section sampling included two of Kentucky's major licenses and included the following types: medical broad scope (with a HDR afterloader), academic broad scope, nuclear pharmacy, research and development, mobile nuclear medicine, nuclear medicine, teletherapy, portable and fixed gauges, and industrial fixed radiography. Licensing actions included 6 new licenses, 3 five-year interval renewals, 10 amendments, and 6 terminations. A list of these licenses with case-specific comments can be found in Appendix D.

The review team found that, overall, the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. Special license tie-down conditions were almost always stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications. The Commonwealth's licensing guides and license policy procedures were revised and updated during the review period, and reviewers were observed to have good research skills in using these and other licensing documents. With few exceptions, reviewers appropriately used the new licensing guides and accompanying check sheets.

Normal peer review is accomplished as the RMS Supervisor reviews all new or renewed licenses and amendments prior to issuance. All licensing actions are signed by the RCB Manager. Complex reviews are performed by the RMS Supervisor and reviewed by the RCB Manager.

Just prior to the review, the RMS Supervisor had identified the need for revising and improving the procedures for terminating licenses. Although the Supervisor was using the guidance recently issued by the Office of Nuclear Material Safety and Safeguards (NMSS) to develop new procedures to ensure proper closeout of terminated licenses, the terminated files still showed some missing documentation as to the ultimate disposition of the radioactive material. The review team found the work to be progressing satisfactorily.

Kentucky's other licensing guides and license conditions were adopted directly from the NRC’s. No potentially significant health and safety issue were identified.

Based on the IMPEP evaluation criteria, the review team recommends that performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.4 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and the data base information for 20 materials inspections conducted during the review period. The casework included all of the Commonwealth's materials inspectors and covered a sampling of the higher priority categories of license types as follows: two institutional medical for diagnostic, four institutional medical with brachytherapy and isotope therapy, one institutional medical with an HDR unit, one teletherapy, two nuclear pharmacies, one broad medical, one veterinary, one industrial radiography, one distribution, and three portable gauges. Appendix E provides a list of the inspection cases reviewed in depth with case-specific comments.

The inspection procedures and techniques utilized by Kentucky were reviewed and determined to be consistent with the inspection guidance provided in IMC 2800. All inspections are conducted on an unannounced basis except those instances where notification is necessary because of the geographical location or to obtain a meeting with specific licensee management or individuals.

The inspection report forms were reviewed and found to be consistent with the types of information and data collected under IMC 2800 and 87100 documents. The Commonwealth uses separate supplements to the inspection report form for various classes of license types, such as medical, brachytherapy, pharmaceutical therapy, teletherapy, portable gauges, fixed gauges, field radiography, fixed-facility radiography, well logging, and laboratory type inspections. The reports were reviewed to determine if the reports adequately documented the scope of the licensed program, licensee organization, personnel protection, posting and labeling, control of materials, equipment, use of materials, transfer, and disposal. The reports were also checked to determine if the reports adequately documented operations observed, interview of workers, independent measurements, status of previous noncompliance items, substantiation of all items of noncompliance, and the substance of discussions during exit interviews with management.

For the most part, the review team found that the inspection reports contained only minor discrepancies when compared to Commonwealth internal guidance or standard practice. Two reports needed additional information to fully document the details of the independent measurements and associated results developed during the respective inspections. One report needed additional information to describe the circumstances and details under which a licensee survey meter was determined to be inoperable.

The Section Supervisor reviews and initials all inspection reports and signs all routine enforcement correspondence which enhances the quality of the correspondence to the licensee. Kentucky uses a manual logging system to track inspections performed, status of reports, letters to licensees, responses from licensees, and acknowledgment letters. Inspection data are also placed on computer change forms and sent to a contractor for updating the inspection and licensing data base. No discrepancies were found in the manual system. The desirability, convenience, flexibility, and efficiency of maintaining the data base on the Commonwealth's computers was discussed with the RMS Supervisor.

The files were found to be well organized, orderly, and easily accessed for information. The files were also found to be complete with all license and enforcement documents and correspondence. The enforcement letters and correspondence were determined to be written in appropriate regulatory language and timely in all cases.

The Commonwealth bases their enforcement program primarily upon onsite inspections, informal enforcement conferences and increased inspection frequencies as a means to obtain compliance. When the licensee responds to the notice of violation (NOV), the response is given to the inspector to evaluate the licensee's response, and to draft a reply for the supervisor's review or signature. The use of informal enforcement conferences (verbally requested meeting with licensee to discuss inspection findings and potential enforcement actions) has been an effective tool for the Commonwealth. These conferences are followed by

another unannounced inspection to confirm and evaluate the licensee's corrective actions. The review team concluded that the enforcement policies were effective, and this supervisory review enhanced the quality of the inspection and enforcement documents. Kentucky does not have civil penalty authority. The review team suggests that Kentucky consider obtaining necessary statutory authority to apply civil penalties as an additional enforcement option to supplement their enforcement efforts. The inspectors are also cross trained as license reviewers, which also strengthens the continuity of the regulatory program.

One inspector accompaniment was performed by a review team member during the visit on August 16, 1995. This accompaniment is identified in Appendix E. All of the other inspectors have been accompanied during previous reviews. On the accompaniment, the Commonwealth inspector demonstrated appropriate inspection techniques and knowledge of the regulations. The inspector was well prepared and thorough in the review of the licensees' radiation safety program. Overall, the technical performance of the inspector was satisfactory, and the inspection was adequate to assess radiological health and safety at the licensed facility.

In response to the questionnaire, Kentucky reported that no supervisory inspector accompaniments were performed during 1994; however, three inspectors were accompanied by the RMS Supervisor during 1995. Kentucky further reported that supervisory accompaniments are required for junior staff before they are allowed to perform independent inspections. Kentucky has a policy of annual supervisory accompaniments of all inspectors. The review team considered the high demands placed on supervisory staff during this review period because of the efforts necessary to update regulations, the need to evaluate new devices, issue and amend SS&D registrations and the efforts needed to prevent the development of licensing and inspection backlogs. However, supervisory accompaniments provide management with important insight into the quality of the inspection program. The review team recommends that the Commonwealth maintain its policy of annual supervisory accompaniments of all inspectors.

It was noted that Kentucky has a variety of portable instruments for routine confirmatory surveys and use during incidents and emergency conditions. The instruments were a good mix of low range GM tubes and pancake probes, micro R meters, high range instruments, instrumentation with calibration standards for alpha detection, a neutron rem ball, and a portable multichannel analyzer. Air monitoring equipment is also available. The portable instrument used during the inspector accompaniment was observed to be operational and calibrated. The portable instruments maintained in the office were also observed to be calibrated. Program staff explained that instruments are calibrated at least on an annual basis, and staggered so as to always have instruments calibrated within the calendar quarter for use during industrial radiography inspections.

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.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Commonwealth's actions in responding to incidents and allegations, the review team examined the Commonwealth's response to the questionnaire

regarding this indicator, reviewed the incidents reported for Kentucky in the "Nuclear Material Events Database" (NMED) against those contained in the Kentucky files and reviewed the casework of 15 reportable incidents and 6 allegations identified as involving byproduct material. In addition, the review team interviewed the RCB Manager, the RMS Supervisor, and the health physicists assigned to incident response.

Responsibility for initial response and follow up actions to radioactive materials incidents and allegations rests with the RCB. Written procedures require that notifications of incidents be referred to the RMS Supervisor, who will determine the extent of the investigation and/or response. Complex events or those with potential for impacting public safety or likely to involve media attention are referred to the RCB Manager. Review of the files indicated that this approach provided effective response actions and did not delay the response time.

All incident files of reportable incidents involving byproduct material that occurred during the review period were reviewed. The information in NMED agreed with the information in the Kentucky files. These included three misadministrations, three loss of control of material, three damaged devices, two leaking sources, one possible overexposure, one equipment failure, one contamination event, and one byproduct sealed source found in scrap. A list of the incident response case work with comments is included as Appendix F.

For the most part, the correct procedures were followed. In most instances actions were appropriate and timely. The level of effort was typically commensurate with the hazard to the public. Suitable enforcement actions were taken, and almost all items were followed to resolution. There were, however, instances in which improvement was needed.

- In 2 of 15 cases, the incident report did not document supervisory oversight.

- In four cases, the report did not document that the incident was closed. In two others, the report did not indicate that the incident was not closed nor did it contain an indication of the reason why it was not closed.

- In one case, the licensee was not cited for loss of control of the radioactive source or for failure to provide timely notification.

- After the Owens Illinois Labels incident, the Commonwealth waited 43 days before making an onsite response to a possible leaking source at a general licensee. The Commonwealth indicated that the delay was due to the reorganization of the program and lack of immediate availability of staff to respond to the incident. Without having good reason to believe the general licensee was capable of managing a leaking source, the Commonwealth should have responded sooner to this potentially serious problem. Furthermore, the issue of the license authorization for and approval of procedures utilized by the individual who apparently made an improper leak test at this facility was not adequately resolved.

- On 11 occasions during the review period the Commonwealth responded to incidents of unidentified unlicensed radioactivity, presuming the source to be naturally occurring and accelerator-produced radioactive material (NARM). The review team believes that

identification of the radioactive isotope involved could lead to a better resolution of these incidents because the source may not always be NARM. The review team recommends that the Commonwealth determine the specific isotope in all incidents rather than assuming the source to be NARM.

In spite of the number of incidents involving NARM radioactive material in Kentucky, especially an increasing number of incidents involving NARM radioactivity in scrap metal, Kentucky has been able to maintain its program for Atomic Energy Act material. In 1995, Kentucky issued 13 Department of Transportation (DOT) exemptions for the return of shipments that were turned away from Kentucky scrap mills due to NARM radioactivity in the scrap. Also, in 1995, four DOT exemptions were issued by other states for return to Kentucky of scrap containing NARM radioactivity. Seventeen potential incidents in 1995 due to NARM radioactivity in scrap metal amounted to approximately twice the number that occurred in 1994.

The response to six of the seven allegations received by the Commonwealth during the review period that involved byproduct radioactive materials were examined in detail. Allegations were responded to promptly with appropriate investigations and follow up actions. Proper procedures were used for the control of information, and the results of the investigation were promptly related to the alleger. No significant problems were observed.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Operations. Because Kentucky has no agreement to regulate uranium recovery operations, only the first three performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

Along with their response to the questionnaire, Kentucky provided the review team with copies of legislation that affects the radiation control program. Kentucky Revised Statutes (KRS) Title XVIII, Chapter 211, names the Cabinet for Human Resources as the radiation control agency of the Commonwealth of Kentucky. (At the time of the review, the Governor was in the process of changing the title of the Cabinet of Human Resources to the Cabinet for Health Services, and it is so designated on the organization charts for this report.) Chapter 211 also authorizes the Cabinet to regulate the registration and licensing of the possession or use of any sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste and to fix fees and charges.

4.1.2 Status and Compatibility of Regulations

All regulations that are required for compatibility that were identified as due or overdue for adoption at the time of the 1994 routine review had been adopted at the time of the April 1994 review visit and had received final NRC review and approval as of August 18, 1995. The Commonwealth regulations were acknowledged to be compatible in correspondence dated March 15, 1996, from Richard L. Bangart, Director, Office of State Programs, to John H. Morse, Secretary, Cabinet for Human Resources.

The Commonwealth regulates a low-level radioactive waste disposal facility licensed prior to NRC's 10 CFR Part 61. This is the only licensed low-level waste disposal facility in Kentucky and is not an operating facility. The Commonwealth requires the licensee to carry out a comprehensive quality assurance program for the licensed activities presently through license tiedown condition. Previously, the Commonwealth had promulgated a rule equivalent to NRC's 10 CFR Part 61. The Commonwealth, however, does not expect to be designated as a host State for a new low-level radioactive waste disposal facility. If Kentucky, in the future, becomes aware of the need to regulate a new low-level radioactive waste disposal facility, the Commonwealth would be expected to put in place all regulations necessary for compatibility. In the interim, however, given the legally binding license condition requirement to conduct a comprehensive quality assurance program, the review team concluded Kentucky does not need to adopt any change to their Part 61 equivalent regulations to maintain compatibility. Therefore, Kentucky will not adopt the following amendment to their regulations equivalent to the following NRC rules:

- "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 amendments that became effective on July 22, 1993.

With the following exceptions, Kentucky has adopted all compatibility regulations which will become due through June 1998:

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994, is under review and is expected to become effective by the due date of August 15, 1997.

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995, is under review and is expected to become effective by the due date of January 1, 1998.

Kentucky has the following rules under consideration, but has no estimated date for the adoption:

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.

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

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

During this review period, the only two regulations that were required for compatibility which were not adopted within the three-year time frame became effective within six months after the due date. Kentucky strives to meet the three-year compatibility requirement, and has enacted emergency regulations to implement rules sooner if requested to do so by the NRC. The quality management rule (QM), which was enacted as an emergency regulation in January 1994, was one recent example of Kentucky's willingness to cooperate with the NRC.

The review team examined the procedures used in the Kentucky's promulgation process and found the public is offered several opportunities to comment on proposed regulations throughout the process. According to program management, the NRC is provided with drafts of the proposed regulations for comment during the process and any changes suggested by the NRC are incorporated into the final rules.

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

4.2 Sealed Source and Device Evaluation Program

In evaluating the Commonwealth's SS&D evaluation program, the review team studied the information provided by the questionnaire, reviewed the casework and background information of all certificates of registration issued since the May 13, 1994, review, reviewed new procedures and guidance, and interviewed RCB staff and managers responsible for SS&D evaluations.

At the time of the 1994 review, Kentucky had two major device manufacturers, Ohmart Corporation and Ronan Engineering Company. On March 28, 1996, Ohmart Corporation notified Kentucky that the Kentucky facility would be closed prior to June 1996. Ohmart also stated that all sources had been moved, provided a survey protocol to the Commonwealth, and stated that the final survey was planned for the week of April 29, 1996. Kentucky has scheduled an inspection of the Ohmart facility during the time Ohmart's final survey will be performed. Only one Ohmart device was registered by Kentucky since the 1994 review. Ronan is currently the only device manufacturer in Kentucky and has nine registered devices.

4.2.1 Technical Quality of the Product Evaluation Program

The April 1995 review visit resulted in recommendations for improvement in the Commonwealth's SS&D evaluation program. In response, Kentucky developed an action plan calling for the reassessment of all previously issued device sheets to assure that the files contain all current background information and drawings applicable to the device safety review, including documentation that generally licensed (GL) devices meet the current dose requirements. Although the Commonwealth evaluated new devices during the period, workload demands prevented the reassessment of the previously approved devices. The review team recommends that the RCB continue with their plan to reassess all previously issued SS&D

sheets, under their regulatory jurisdiction to assure that the files contain all current background information and drawings applicable to the device safety review and to verify and document that GL devices meet the current dose requirements.

As noted in the questionnaire, since the previous review, Kentucky has completed one device evaluation and registration for Ohmart (KY-512-D-112-S) and one device evaluation for Ronan.

Following Kentucky's initial evaluation of the Ronan device, the application package, including the Commonwealth's review and proposed deficiency letter, was sent to the NRC Office of State Programs as a technical assistance request (TAR). This TAR was referred to the NRC Division of Industrial and Medical Nuclear Safety (IMNS) on April 12, 1995, and a response from IMNS was provided to Kentucky on May 17, 1995. The comments from IMNS and Kentucky have been provided to Ronan and a response is pending. During the Commonwealth's evaluation of the application, the Commonwealth utilized the guidance obtained during the SS&D Workshop sponsored by NRC in September 1995. Documents in the file confirm that the Commonwealth followed the NRC guidance during their evaluation of the Ronan device. Also, the RCB notified Ronan on March 15, 1995, that Condition 19 of Ronan's license would require the devices to be manufactured in accordance with their quality control program and provided Ronan a copy of the NRC Regulatory Guide 6.9. Ronan provided a Quality Control Manual dated September 28, 1995, to Kentucky. The review of this manual is still pending and the completed registration of the device cannot be completed until the additional information is received from Ronan.

The Ohmart device evaluation was completed and the registration KY-512-D-112-S was issued on January 19, 1996. A review of the file confirms that the Commonwealth utilized the information obtained during the SS&D Workshop and followed the recommended guidance. The registration file contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant.

4.2.2 Technical Staffing and Training

Kentucky has two persons that have the experience and training needed to perform SS&D reviews. Both the RCB Manager and the RMS Supervisor attended the September 1995 SS&D Workshop for training on device reviews and registrations. During interviews, the RCB Manager stated that based upon the Commonwealth's successful review of the Ronan device, which was subsequently reviewed by IMNS under a TAR, and the training received at the workshop, he was confident that Kentucky could perform the needed device reviews. The RCB Manager said that if engineering expertise beyond the Commonwealth's capability was needed, that he had an informal arrangement with the School of Chemical Engineering, University of Kentucky, to assist the program with engineering evaluations of sealed sources and/or devices evaluations as needed. The RCB Manager also stated that he had plans to train additional backup personnel for SS&D reviews, and when this occurs, he would consider sending a person to train at NRC if the option is still available.

The RCB Manager has a Ph.D. in Biochemistry and has teaching experience. He managed the Radiochemistry Laboratory for the Commonwealth for several years. He is also the Commonwealth's consultant on all radiation matters. The RMS Supervisor conducted the

current device evaluations. She is an experienced health physicist who has served several years as supervisor of the materials section and is responsible for evaluating all major or complex license applications. Based upon the previous device reviews performed by the Commonwealth and interviews with the staff, the review team believes that the Commonwealth's SS&D reviewers are qualified to understand and interpret appropriate prototype tests which ensure the integrity of the products under normal, and likely accidental conditions of use; understand and interpret test results; read and understand blueprints and drawings; understand how the devices work and how the safety features operate; understand and apply the appropriate regulations; understand the conditions of use; and understand external dose rates, source activities and nuclide chemical form.

Based upon the additional technical training received by the device reviewers during the SS&D workshop, the experience in performing complete device reviews since the previous review, a reduction in the projected device workload (Ohmart moving to Ohio), and our interviews with the device reviewers, the review team found that the Kentucky staff has adequate qualifications and training for the current and anticipated device reviews.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team determined that there were no incidents or defects regarding SS&Ds as determined from the evaluation of the incident files and responses to the questionnaire from Kentucky.

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

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

Kentucky has no separate low-level radioactive waste (LLRW) disposal program. The Commonwealth and RCB treat the closed radioactive waste burial site at Maxey Flats in the same manner as any other complex specific licensee with all program requirements incorporated as license conditions. The statutes and regulations, including Kentucky's equivalent to 10 CFR 61, apply to the site license.

4.3.1 Introduction

In 1962, the Commonwealth of Kentucky became an Agreement State, and that same year, the Kentucky General Assembly also passed legislation to enable the Commonwealth to purchase lands for the disposal of radioactive waste, to be owned and controlled in perpetuity by the Commonwealth. The Agreement vested in the Commonwealth the authority to license the disposal of LLRW. Also in 1962, a commercial enterprise, Nuclear Engineering Company (NECO)[1], purchased 280 acres of land in Fleming County in an area known as Maxey Flats. NECO submitted an application to the Commonwealth and was issued a license to dispose of

[1]Now U S Ecology

radioactive waste at the Maxey Flats Disposal Site (MFDS) in January 1963. A condition of the license was that title to the land be given to the Commonwealth and leased back to NECO for 25 years with conditions in the lease providing for a perpetual care fund. From May 1963 through December 1977, NECO disposed of 4,750,000 cubic feet of LLRW at the site.

In 1977, due to water management problems, the Commonwealth ordered NECO to cease receipt and burial of radioactive waste. Throughout the years since disposal activities ceased in 1977, various stabilization and maintenance activities have been conducted in an effort to control excessive water accumulation. On October 7, 1991, Kentucky was notified by the U.S, Environmental Protection Agency (EPA) that the site has been approved for remedial action under the Comprehensive Environmental Response, Compensation and Liability Act (Superfund).

In a 1978 financial agreement with NECO, Kentucky purchased NECO's license rights and other assets and assumed responsibility for site-related liabilities, thus making the Commonwealth both licensee and regulator, a situation that remains today. Responsibility for the MFDS operations rests within the Natural Resources and Environmental Protection Cabinet (NREPC) while regulatory responsibility for the project's radiation safety program rests with CHS. The review team concluded that this separation of operational and regulatory functions is adequate to avoid conflicts of interest.

The license is still active and authorizes care, maintenance, stabilization and remedial operations as well as onsite and offsite environmental monitoring. The closure plan and consent decree statement of work developed jointly by the Commonwealth, the EPA, and the Potentially Responsible Parties (PRP) were added to the license as Amendment 36 issued October 12, 1995. The site is now on standby awaiting a Federal court order for the use of Superfund monies. The approval is expected to occur some time in 1996.

Meanwhile, maintenance continues, including the placement of a new 10 year plastic cover over the trenches to further inhibit infiltration of water. Environmental monitoring continues on a monthly or more frequent basis by both CHS and NREPC. The sampling includes air, water, soil, vegetation, and direct radiation. Annual monitoring reports are published by the Commonwealth. The latest report concluded that there is no significant off-site migration of radioactive contaminants under present conditions. When the Superfund remediation project begins, it will operate in compliance with the license. CHS will continue to conduct inspections to ensure that the contractor meets the standards set in Kentucky equivalent regulations to 10 CFR Parts 19, 20, 30, 61, and other applicable Kentucky regulations.

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

The Commonwealth's frequency of inspection for the MFDS is one year, the same as in IMC 2800 and IMC 2401. However, by a note to file, the inspection frequency has temporarily been extended to two years. This decision was based on the lack of activity at the site and the fact that the few previous items of non-compliance were administrative in nature and had been corrected. However, the last full inspection was conducted in April 1993, making the inspection overdue at the time of the review. The Commonwealth has committed to conducting an inspection of this license within 30 days of the IMPEP review.

As noted previously, the site is awaiting Superfund remedial work, and there has been very little work going on at the site except for radiation monitoring. Also, monthly site visits are being conducted by the Radiation Environmental Laboratory staff and the RCB Manager. This monthly environmental monitoring protects the worker, as well as the public, from the radioactive material located at MFDS and can be considered partial inspections. The team agrees with the decision to defer the inspection interval to two years. However, the team agrees that the Commonwealth should conduct the routine inspection at the earliest possible time.

In addition, CWS radiation laboratory staff is on-site at least monthly, and the RCB Manager visits the site frequently. When the activities increase under Superfund clean-up, the Commonwealth intends to resume inspections on an annual basis. Review of the files showed that past inspections had been conducted as scheduled and the results transmitted to NREPC within 30 days. All previous inspection reports are on file, but were not reviewed by the team because they were not performed during the review period.

4.3.3 Technical Staffing and Training

The RCB Manager and RMS Supervisor, whose training and experience are discussed in Section 3.2, also serve as the LLRW site reviewers and inspectors. They have many years' experience regulating the MFDS project. The review team believes they are both fully qualified for their responsibilities.

In addition, the CHS Radiation and Environmental Monitoring Laboratory (REML) provides approximately 3.5 FTEs dedicated to MFDS environmental monitoring. Although not directly part of the RMS, this lab is also directed by the RCB Manager. The REML technical staff are all professional chemists who have been trained in radiochemistry, environmental sampling, and analysis and evaluation. The review team examined the training records and educational background of the five laboratory staff members, and found that the qualifications of the technical staff are commensurate with expertise identified as necessary to regulate a low-level radioactive waste disposal facility. Management has developed and implemented a training program for staff. Staff trends that could have an adverse impact on the quality of the program are tracked, analyzed and addressed.

4.3.4 Technical Quality of Licensing Actions

The MFDS license was renewed in its entirety during the review period. In examining the license and background information in the file, the review team found that the license:

- meets standard licensing practices (activity, location, RSO, regulations, tie-downs, etc.);
- ties the license to Kentucky regulations, including the equivalent Part 61;
- limits activity to remedial and monitoring activities;
- precludes receipt or disposal of waste;

- limits possession to existing material and addresses possible form changes due to remediation efforts; and

- requires qualified personnel to be designated in writing before working on site.

The tiedown condition properly cites the renewal application; the radiological protection program revised to meet the new Part 20; radiological procedures, Superfund consent decree Statement of Work; and procurement, receipt, possession and use of laboratory standard sources for onsite use. The license file was complete with all background documents.

Applicable guidance documents such as the NUREGs that support 10 CFR 61 are available and used as needed. Review of certain technical and administrative aspects of the MFDS license and background materials indicated to the team that the review was generally thorough, complete, consistent, and of acceptable technical quality. Health and safety issues, as well as environmental issues, are properly addressed. No potentially significant health and safety issues can be linked to licensing practices.

4.3.5 Technical Quality of Inspections

Inspection and enforcement is handled in the same manner as any Commonwealth licensee. In addition to the laboratory equipment, the RCB possesses a good mix of calibrated instrumentation used at the site, including micro R meters.
The review team examined the environmental monitoring log, and from checking a random sampling of approximately ten of the reports concluded the Commonwealth is gathering sufficient data necessary to evaluate the status of the possible contaminant migration.

Although no full, routine inspection occurred in the review period, past inspection reports show that past inspections adequately covered the scope, completeness, and technical accuracy necessary to determine compliance with regulations, license conditions, and available guidance.

4.3.6 Response to Incidents and Allegations

There were no incidents or allegations pertaining to the Commonwealth’s low-level radioactive waste program activities during the review period. The Commonwealth explained to the review team that incidents and allegations relating to the MFDS would be handled in the same manner as those pertaining to any materials licensee.

Based on the IMPEP evaluation criteria for the above five performance areas, 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 the Commonwealth's performance with respect to each of the performance indicators to be satisfactory. The MRB concurred in the team's individual and overall recommendations and found that the Kentucky program was adequate to protect public health and safety and was compatible with NRC's regulatory program.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for action by the Commonwealth.

1. The review team suggests that the Commonwealth consider obtaining necessary statutory authority to apply civil penalties as an additional enforcement option to supplement their enforcement efforts. (Section 3.4)

2. The review team recommends that the Commonwealth maintain its policy of annual supervisory accompaniments of all inspectors. (Section 3.4)

3. The review team recommends that the Commonwealth determine the specific isotope in all incidents rather than assuming the source to be NARM. (Section 3.5)

4. The review team recommends that the RCB continue with their plan to reassess all previously issued SS&D sheets, under their regulatory jurisdiction to assure that the files contain all current background information and drawings applicable to the device safety review and to verify and document that GL devices meet the current dose requirements. This is a recommendation from the 1995 review visit. (Section 4.2)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Jack Hornor, RIV, WCFO	Team Leader Technical Staffing and Training Legislation and Regulations Low Level Radioactive Waste Program
Richard Woodruff, RII	Status of Materials Inspection Program Technical Quality of Inspections Sealed Source and Device Evaluation Program
David Collins, RII	Technical Quality of Licensing Actions
James McNees, Alabama	Response to Incidents and Allegations

APPENDIX B

KENTUCKY RADIATION CONTROL PROGRAM
ORGANIZATION CHART

APPENDIX C

Approved by OMB[2]
No. 3150-0183
Expires 4/30/98

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

Name of State: KENTUCKY
Reporting Period: May 13, 1994, to April 19, 1996.

A. COMMON PERFORMANCE INDICATORS

I. Status of Materials Inspection Program

1. Please prepare a table identifying the licenses with inspections that are overdue by more than 25% of the scheduled frequency set out in NRC Inspection Manual Chapter 2800 (issued 4/17/95). The list should include initial inspections that are overdue.

Licensee Name	Insp. Frequency (Years)	Due Date	Months O/D
Maxey Flats	1	4-26-95	8
Jewish Hospital	1	11-28-95	4

2. Do you currently have an action plan for completing overdue inspections? If so, please describe the plan or provide a written copy with your response to this questionnaire.

Jewish Hospital has been scheduled for inspection by April 10, 1996. Maxey Flats will be scheduled within thirty (30) days after the NRC review if not inspected prior

---

Estimated burden per response to comply with this voluntary collection request: 60 hours. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0052), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

to the review. However, at least monthly visits are made by the Radiation Environmental Laboratory staff and the Branch Manager of RCB for collecting samples and providing training. Any health and radiation problems would be noted during these visits. Site is awaiting remediation under Superfund and very little activity is occurring at this time except for sampling.

3. Please identify individual licensees or groups of licensees the State/Region is inspecting less frequently than called for in NRC Inspection Manual Chapter 2800 (issued 4/17/95) and state the reason for the change.

   No licensees or groups of licensees are inspected less frequently than called for in the NRC Inspection Manual Chapter 2800. Some licensees, such as Medical private Practice (no QMP required) and Portable Gauge licensees, are inspected more frequently than specified in the manual.

4. How many licensees filed reciprocity notices in the reporting period?

   Approximately 80 different licensees requested reciprocity during the reporting period with a total of approximately 600 entries into the state.

   a. Of these, how many were industrial radiography, well-logging or other users with inspection frequencies of three years or less?

      18

   b. For those identified in 4a, how many reciprocity inspections were conducted?

      One, however, approximately 5 other reciprocity inspections were performed. Inspection requirements have been changed to require each inspector to perform at least four (4) reciprocity inspections per year. This procedure will assure that more inspections will be conducted of these licensees.

5. Other than reciprocity licensees, how many field inspections of radiographers were performed?

   One

6. For NRC Regions, did you establish numerical goals for the number of inspections to be performed during this review period? If so, please describe your goals, the number of inspections actually performed, and the reasons for any differences between the goals and the actual number of inspections performed.

N/A

II. Technical Staffing and Training

7. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLRW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

NAME	POSITION	AREA OF EFFORT	FTE
John Volpe	Branch Manager	Administration	.20
Vicki Jeffs	Supervisor	Administration	.90
		Licensing/inspecting	.10
Mike Cleaver	Inspector	Inspecting/licensing	1.00
Mike Wilcoxson	Inspector	Inspecting/licensing	1.00
Sue Osborne	Inspector	Inspecting/inspecting	1.00

(The above individuals also have emergency response responsibilities as required.)

The following individuals are in the Environmental Monitoring Section:

Mary Todd	Supervisor	Laboratory	1.00
Harry Skinner	Senior Chemist	Laboratory	1.00
Phillip Mills	Senior Chemist	Laboratory	1.00
Todd Adams	Senior Chemist	Laboratory	1.00
Steve Hampson	Hydrologist	Laboratory	1.00
Becky Wilson	Lab Technician	Laboratory	1.00
Jonathan Doyle	Chemist	Laboratory	1.00

8. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

Steve Hampson - M.S., Hydrologist, 5 years experience

Jonathan Doyle - B.S., Chemistry, 9 months experience
Becky Wilson - no degree, 12 years experience

9. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapters 1245 and 1246; for Agreement States, please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

All inspectors/license reviewers are required to attend, as a minimum, the NRC Core Courses (licensing, inspecting, nuclear medicine, 5-week health physics course, and industrial radiography). Other NRC courses are required as openings are available and NRC approval for attending is received. All current staff members have also attended the transportation course. Staff members also receive on-the-job training in all areas of the Radioactive Materials Program. Knowledge of areas is determined by written and oral tests. Junior staff members are accompanied by senior staff members until the senior member determines the junior member is proficient in inspecting a category of licensee. Prior to approving the junior member to conduct independent inspections, the Section Supervisor accompanies the individual on an inspection of that license category.

All licensing actions and inspection reports are reviewed by the section supervisor prior to issuance.

Training courses needed for staff are as follows:

Mike Wilcoxson - Health Physics Engineering
Safety Aspects of Well Logging

Sue Osborne - Health Physics Engineering
Safety Aspects of Well Logging

10. Please identify the technical staff who left the RCP/Regional DNMS program during this period.

Gretchen Maxson
Keith Ewing

Both of these individuals worked in the laboratory.

II. <u>Technical Quality of Licensing Actions</u>

11. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, terminated or renewed in this period.

LICENSEE	LICENSE NO.	ACTION
Maxey Flats	201-006-03	Renewal
Advanced Chemtech (Manufacturer of RIA Kits for research)	201-543-93	Issuance
Cardiovascular Cons. (Mobile Nuc. Med.)	202-228-29	Issuance

12. Please identify any new or amended licenses added or removed from the list of licensees requiring emergency plans?

N/A. No licenses were added or removed.

13. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

United Catalysts (KRML No. 204-006-92) has been given a variance on disposal of insoluble material into the sewer system until installation of their evaporator system. Upon installation of the new system they should be in compliance.

14. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

Licensing guides, licensing checklists, standard review plans, and inspection forms were revised for portable and fixed gauges. Licensing guide was revised for HDRs. Plans are underway for revising other licensing category documents.

Standard license conditions were revised to reflect revised 902 KAR 100:019, Standards for protection against radiation.

15. For NRC Regions, identify by licensee name, license number and type, any renewal applications that have been pending for one year or more.

N/A

IV. Technical Quality of Inspections

16. What, if any, changes were made to your written inspection procedures during the reporting period?

Inspection procedures were revised to include new requirements of the revised regulations, 902 KAR l00:019, Standards for protection against radiation and 902 KAR 100:100, Industrial Radiography.

Also procedures were written to allow an increase in the inspection frequency of a licensee based on inspection results of the current inspection and past compliance history. Procedure also allows a decreased inspection frequency based on poor performance and past compliance history.

Staff members of the Radioactive Materials Program were also provided revisions to inspection procedures to be implemented as the result of the comments provided during the last NRC review. These revisions were provided as a written procedure dated August 3, 1994.

17. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Supervisor	Inspector	License Cat.	Date
Vicki D. Jeffs	Mike Wilcoxson	Medical	3/22/95
Vicki D. Jeffs	Mike Cleaver	Medical	7/21/95
Vicki D. Jeffs	Sue Osborne	Medical	6/14/95

18. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. If supervisory accompaniments were documented, please provide copies of the documentation for each accompaniment.

Documentation of accompaniments are maintained by the section supervisor. Annual accompaniments are performed by the section supervisor for individuals in the Radioactive Materials Program.

19. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time?

Instruments are maintained calibrated at the same frequency required by the licensee being inspected. Currently calibrations are performed by K&S Associates in Nashville, TN, except for Ludlum instruments which are calibrated by Ludlum.

New instruments obtained since the last review include:

alarming rate meters
Ludlum Model 4 (alpha meter)
Ludlum Model 14C (GM Total of 5 purchased)
Ludlum Model 77-3 (GM stretch probe)

Ludlum Model 2350 (data logger-scaler)
Bicron Analyst with pipe monitor
Bicron Analyst with pancake probe
Canberra Portable MCA high purity Germanium detector

V. Responses to Incidents and Allegations

20. Please provide a list of the most significant incidents (i.e., medical misadministration, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc.) that occurred in the Region/State during the review period. For Agreement States, information included in previous submittals to NRC need not be repeated. The list should be in the following format:

LICENSEE NAME LICENSE # DATE OF INCIDENT/REPORT TYPE OF INCIDENT

All incidents have been reported to NRC Headquarters as required.

21. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified?

Two incidents of leaking sources occurred. In the case of the leaking promethium-147 the manufacturer of the device was notified. This incident appeared to be caused by an improper wipe method and the company performing the wipe was notified by the device manufacturer of the proper wipe test method.

The leaking cesium-137 source was a brachytherapy source. Our licensees have been informed on numerous previous occasions, via informational notices, of the importance of leak testing sources at required frequencies which is how this was discovered. Additional notices were not sent to our licensees as the result of this one incident. The review of the source would have been performed by NRC. Office of State Programs was notified immediately by fax when we learned of the problem.

We are presently attempting to determine if an incident is the result of equipment failure. In this case, a gauge's mounting bolts failed as the result of vibration and exposure to the weather according to the manufacturer. We are trying to determine if the bolts were reviewed as part of the device review performed by NRC.

a. For States, was timely notification made to the Office of State Programs? For Regions, was an appropriate and timely PN generated?

Timely notification of all incidents were made to NRC in all cases. One delay in the reporting of a leaking source to NRC occurred due to awaiting wipe results taking by RCB to confirm the absence of area contamination.

22. For incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

Assessment ongoing. See answer to Question 21.

23. In the period covered by this review, were there any cases involving possible wrongdoing that were reviewed or are presently undergoing review? If so, please describe the circumstances for each case.

See answer to Question 24 a. below.

24. Identify any changes to your procedures for handling allegations that occurred during the period of this review.

No specific changes have been made.

a. For Agreement States, please identify any allegations referred to your program by the NRC that have not been closed.

An allegation against Western Kentucky University, KRML No. 203-017-83 was investigated and the case considered closed by the Kentucky RCB; however, it appears this case may have to be reopened if additional information is provided by the alleger.

VI. General

25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

The following provides the action taken as the result of the comment or recommendation made as the result of the last review:

1. Status and compatibility of regulations. All regulations required to be adopted have now been adopted.

2. Adequacy of product evaluations. Additional training was received by staff members responsible for the review of sealed sources and devices. Two

new devices have been reviewed since the last NRC review. One of these reviews was sent to NMSS for concurrence prior to sending the request for additional information to the manufacturer. NMSS did not indicate any problems with the review. One gauge manufacturer is in the process of moving out of the state. The reviews of the devices of the other manufacturer will continue once they respond to the review performed on their new device.

3. Staffing level. No additional staff has been added; however, certain office procedures have been or are the process of being streamlined to allow for more efficient use of current staff. Staff members of the Radioactive Materials Section have just received their own individual personal computers. This will assist in our attempt to streamline office procedures.

4. Staff continuity. No progress has been made in upgrading staff salaries.

5. Budget. No changes have been made in this area.

6. Licensing procedures. This was in reference to a license condition that was not included on pharmacy licenses. This was corrected by June 1, 1994 and remains corrected.

It is noted, this office was last reviewed by the NRC April 25-29 and May 10-13, 1994. A report of that review was not received until a letter dated **January 27, 1995** was received by this office. A response dated **March 13, 1995** was sent to OSP describing our actions taken as the result of the comments and recommendations given in the January 27 letter. A visit by NRC was conducted August 15-17, 1995. As of this date, **March 22,** 1996 we **have not** received a letter indicating if our responsive actions were considered adequate. We also have not received a report of the visit that was conducted.

26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems or difficulties which occurred during this review period.

Strengths:

1. Quality staff with extensive experience has allowed the RCP to protect public health and safety in the continued use of radioactive material for the benefit of the citizens of the Commonwealth.

2. Equipment improvements are continuing and adding the ability of staff to conduct their responsibilities in an efficient and cost-effective manner. For example, updates in equipment for emergency response and in obtaining personal computers for radioactive material staff.

Weaknesses:

1. Salary for present staff remains extremely low as compared to other Agreement States in the southeast region.

2. Laboratory staff lacks experience and has difficulty in addressing radiochemical problems.

3. Licensing fees for radioactive material licensees need to be increased to ensure sufficient funding.

4. Division lacks stability and needs more positive leadership for the programs. The last division director was unable to communicate with staff which led to a lack of direction.

B. NON-COMMON PERFORMANCE INDICATORS

I. Regulations and Legal Authority

27. Please list all currently effective legislation that affects the radiation control program (RCP).

Kentucky Revised Statutes (KRS)194.050, 211.090, 211.842 to 211.852, 211.990(4)
Kentucky Administrative Regulations 902 KAR 100

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

No

29. Please complete the enclosed table based on NRC chronology of amendments. Identify those that have not been adopted by the State, explain why they were not adopted, and discuss any actions being taken to adopt them.

See table.

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

N/A

II. Sealed Source and Device Program

31. Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the review period. The table heading should be:

SS&D Registry Number	Manufacturer, Distributor or Custom User	Type of Device or Source
KY-512-D-112-S	Ohmart	Source Holder

32. What guides, standards and procedures are used to evaluate registry applications?

NRC Regulatory Guides 10.10 and 10.11, ANSI and ISO Standards are used. Information received during the Sealed Source & Device Workshop is also used.

33. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Responses to Incidents and Allegations - A.V.20-23

Sealed source and device reviews are conducted by Vicki Jeffs, Supervisor, Radioactive Materials Section and John Volpe, Ph.D., Branch Manager.

No registrations were revised since the last review. A new registration was issued as noted above.

No variances were granted for any registration.

The only possible incident that could be considered an equipment failure is being reviewed at the present time. See answer to Question 21 above.

III. Low-Level Waste Program

34. Please include information on the following questions in Section A, as they apply to the Low-level Waste Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6
Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Technical Quality of Inspections - A.IV.16-19
Responses to Incidents and Allegations - A.V.20-23

N/A

IV. Uranium Mill Program

35. Please include information on the following questions in Section A, as they apply to the Uranium Mill Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6
Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Technical Quality of Inspections - A.IV.16-19
Responses to Incidents and Allegations - A.V.20-23

N/A

TABLE FOR QUESTION 29.

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Any amendment due prior to 1991. Identify each regulation (refer to the Chronology of Amendments)	N/A			
Decommissioning; Parts 30, 40, 70	7/27/91	4/21/93		
Emergency Planning; Parts 30, 40, 70	4/7/93	4/11/94		
Standards for Protection Against Radiation; Part 20	1/1/94	4/11/94		
Safety Requirements for Radiographic Equipment; Part 34	1/10/94	4/11/94		
Notification of Incidents; Parts 20, 30, 31, 34, 39, 40, 70	10/15/94	4/19/95		
Quality Management Program and Misadministrations; Part 35	1/27/95	4/11/95		
Licensing and Radiation Safety Requirements for Irradiators; Part 36	7/1/96	N/A	Not required. KY does not have any irradiator licensees	
Definition of Land Disposal and Waste Site QA Program; Part 61	7/22/96		Under review	
Decommissioning Recordkeeping: Documentation Additions; Parts 30, 40, 70	10/25/96	4/19/95		
Self-Guarantee as an Additional Financial Mechanism; Parts 30, 40, 70	1/28/97	4/19/95		

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Uranium Mill Tailings: Conforming to EPA Standards; Part 40	7/1/97		Not required. KY has no uranium mill tailings sites	
Timeliness in Decommissioning Parts 30, 40, 70	8/15/97		Under review	
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use; Parts 30, 32, 35	1/1/98		Under review	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment	3/13/98	4/11/94		
Low-Level Waste Shipment Manifest Information and Reporting	3/1/98	5/18/94		
Performance Requirements for Radiography Equipment	6/30/98	4/19/95		
Radiation Protection Requirements: Amended Definitions and Criteria	8/14/98		Under review	
Clarification of Decommissioning Funding Requirements	11/24/98		Under review	
10 CFR Part 71: Compatibility with the International Atomic Energy Agency	4/1/99		Under review	
Medical Administration of Radiation and Radioactive Materials.	10/20/98		Under review	

APPENDIX D
LICENSE FILE REVIEWS

File No.: 1
Licensee: University of Louisville License No.: 202-029-22
Location: Louisville KY Amendment No.: 34
License Type: Medical Broad Scope Type of Action: Amendment
Date Amendment Issued: 3/21/96 License Reviewer: SO

Comments:
a) HDR afterloader conditions are yet to be put into this license. This license has had HDR for some period, prior to NRC guidance on HDR specific conditions.
b) Sr-90 eye applicator added to license properly.

File No.: 2
Licensee: Narrows Branch Coal Company License No.: 201-532-56
Location: Hardy KY Amendment No.: 2
License Type: Fixed gauge Type of Action: Termination
Date Terminated: 8/16/95 License Reviewer: MC

Comments:
a) Out-of-state service licensee removed source: no indication RCB attempted to check on license status service licensee nor no reference to reciprocal recognition.
b) No follow up on status of the source prior to terminating license.

File No.: 3
Licensee: Tri-State Reg. Cancer Centere License No.: 202-190-31
Location: Ashland KY Amendment No.: 9
License Type: Teletherapy Type of Action: Termination
Date Terminated: 8/16/95 License Reviewer: MC

Comments:
a) No independent review of action taken by Commonwealth for this termination.
b) No receipt notice from recipient of materials.

File No.: 4
Licensee: Murray State University License No.: 205-005-83
Location: Murray KY Amendment No.: 21

License Type: Plutonium sealed sources Type of Action: Termination
Date Terminated: 1/18/96 License Reviewer: MC

Comments:
a) Sources transferred to another Murray State license, this amendment does not state so, nor is there an indication of what license supersedes this license.
b) Action was based on amendment of the superseding license, no amendment for possession issued for this license.

File No.: 5
Licensee: Southeastern KY Radiation License No.: 202-180-31
Location: Corbin KY Amendment No.: 9
License Type: Teletherapy Type of Action: Termination
Date Terminated: 9/13/95 License Reviewer SO

Comments:
a) No verification on file of arrival of source and shield uranium at destination.
b) No indication of leak test prior to shipment in file.
c) No current copy of recipient's license in file.
d) No record of close-out survey of facility.

File No.: 6
Licensee: Louisville Gas & Electric License No.: 201-076-05
Location: Louisville KY
License Type: Industrial Radiography Type of Action: Termination
Date Terminated: 7/6/95 License Reviewer: SO

Comments:
a) No leak test reports in file.
b) No verification of receipt of source by recipient.

File No.: 7
Licensee: Advanced Roof Technology, Inc. License No.: 201-475-51
Location: Louisville KY Amendment No.: 7
License Type: Portable Gauge Type of Action: Amendment
License Reviewer: SO

File No.: 8
Licensee: McCoy Elkhorn Coal Corp. License No.: 201-488-51
Location: Kimper KY Amendment No.: 7

License Type: Portable Gauges Type of Action: Amendment
License Reviewer: SO

Comment:
a) New amendment has newly recommended statement on federal exclusive jurisdiction and licensing agency outside state borders.

File No.: 9
Licensee: Rogers Group, Inc. License No.: 201-412-51
Location: Hopkinsville KY Amendment No.: 10
License Type: Portable Gauges Type of Action: Amendment
License Reviewer: SO

Comment:
a) Updated program to match NRC SRP for portable gauges.

File No.: 10
Licensee: Big Rivers Electric Corp. License No.: 201-208-56
Location: Henderson KY Amendment No.: 28
License Type: Fixed gauges Type of Action: Amendment
Date Amendment Issued: 2/9/96 License Reviewer: SO

Comment:
a) No standard license condition format for shutter checks.

File No.: 11
Licensee: Western KY Diagnostic License No.:202-236-25
Location: Bowling Green KY
License Type: Nuclear Medicine Type of Action: New
Date Amendment Issued: 3/5/96 License Reviewer: SO

Comment:
a) Tc-99m pentatate in regulations, not needed in license condition.

File No.: 12
Licensee: Kentucky River Medical Center License No.: 202-235-24
Location: Jackson KY
License Type: Nuclear Medicine Type of Action: New
Date License Issued: 12/11/95 License Reviewer: MC

File No.: 13

Licensee: Birmingham Engineering License No.: 201-574-51
Location: Birmingham AL
License Type: Portable gauges Type of Action: New
Date License Issued: 1/18/96 License Reviewer: MC

File No.: 14
Licensee: Law Engineering License No.: 201-257-51
Location: Louisville KY Amendment No.: ?
License Type: Portable gauges Type of Action: Amendment
Date Amendment Issued: 4/1/96 License Reviewer: MW

Comments:
a) Uses very old temporary job site authorization, warrants updating next amendment.

File No.: 15
Licensee: American Air Filter Intl. License No.: 201-034-04
Location: Louisville KY Amendment No.: 34
License Type: G/C Industrial Type of Action: Amendment
Date Amendment Issued: 12/15/95 License Reviewer: MW

File No.: 16
Licensee: East KY Power Corporation License No.: 201-161-51
Location: Winchester KY Amendment No.: 26
License Type: Fixed gauges Type of Action: Renewal
Date Amendment Issued: 12/21/95 License Reviewer: SO

Comments:
a) No requirement for shutter checks.
b) 5 year renewal not yet completed, appears comprehensive review.

File No.: 17
Licensee: Louisville Radiation Oncology Center License No.: Pending
Location: Louisville
License Type: High Dose Rate Type of Action: New
Date Issued: Pending

Comments:

a) Reviewer did not request information on calibrating instruments.
b) Should require survey meter when entering room.
c) One user's training old, other acceptable, no guidance/ request to update older training.
d) Checklist/paper review extensive.
e) No onsite/prelicensing visit intended.

File No.: 18
Licensee: Flynn Bros. Contracting License No.: 201-572-51
Location: Louisville KY
License Type: Portable gauges Type of Action: New
Date License Issued: 8/3/95 License Reviewer: MW

Comment:
a) License doses not authorize new location as requested in license application.

File No.: 19
Licensee: MCIC License No.: Pending
Location: Louisville KY
License Type: Mobile Nuclear Medicine Type of Action: New
Date License Issued: Pending License Reviewer: MC

Comments:
a) Discussion with advisory committee on policy good.
b) Authorized user/RSO review of staff at 6 month intervals, guidance indicates monthly.

File No.: 20
Licensee: St. Joseph Hospital License No.: 202-047-25
Location: Lexington KY Amendment No.: 59
License Type: Nuclear Medicine Type of Action: Renewal
Date Amendment Issued: 10/28/94 License Reviewer: VJ

File No.: 21
Licensee: Baptist Regional Med. Ctr. License No.: 202-113-25
Location: Corbin KY Amendment No.: 39
License Type: Nuclear Medicine Type of Action: Amendment
Date Amendment Issued: 1/18/96 License Reviewer: MC

Comment:
a) Experience of physician not well documented, not up to 500 hrs experience for imaging requirements.

File No.: 22
Licensee: Cardiovascular Associates License No.: 202-179-24
Location: Louisville KY Amendment No.: 19
License Type: Nuclear Medicine Type of Action: Amendment
Date Amendment Issued: 2/14/96 License Reviewer: MC

File No.: 23
Licensee: Logan Aluminum License No.: 201-419-57
Location: Russellville KY Amendment No.: 11
License Type: Fixed gauges Type of Action: Renewal
Date Amendment Issued: 12/22/95 License Reviewer: MC

Comments:
a) Issued quickly, licensee review required clarification to add information based on licensee review of issued license.
b) Good review, retained older specification information.

File No.: 24
Licensee: University of KY License No.: 202-049-22
Location: Lexington KY Amendment No.: 48
License Type: Broad Scope A Type of Action: Amendment
Date Amendment Issued: 3/29/96 License Reviewer: VJ

File No.: 25
Licensee: Syncor International Corp License No.: 202-219-32

Location: Louisville KY Amendment No.: 11
License Type: Nuclear Pharmacy Type of Action: Termination
Date Amendment Issued: 3/29/96 License Reviewer: VJ

Comments:
a) Disposal acceptable.
b) Surveys conducted by licensee and submitted to Commonwealth for review; State did not conduct confirmatory surveys.

APPENDIX E
INSPECTION FILE REVIEWS

File No.: 1
Licensee: Pattie A. Clay Hospital License No.: 202-234-25
Location: Richmond, Ky Inspection Type: Routine
License Type: Institutional Medical Priority: 3
Inspection Date: 05-02-95 Inspector(s) SCO

Comment:
a) This inspection has 20 items of non-compliance and an enforcement conference was held in the Radiation Control Program Office on 12-09-94. A follow-up inspection was performed on 5/2/95 which resulted in a clear inspection.

File No.: 2
Licensee: Haworth Meyer and Boleyn Inc. License No.: 201-133-52
Location: Frankfort, KY Inspection Type: Routine, unannounced
License Type: Portable gauge Priority: 4
Inspection Date: 10-20-94 Inspector: MWW

Comment:
a) The inspection identified six items on non-compliance and an informal enforcement conference was held on 12/9/94. Corrective actions were taken by licensee with quarterly reports being submitted to RCB, and the inspection frequency was increased to an 18 month frequency.
b) The current inspection was listed for January of 1996. Not done as scheduled but does not exceed the NRC inspection frequency or policy.

File No.: 3
Licensee: St. Luke Hospital West License No.: 202-003-25
Location: Florence, KY Inspection Type: Unannounced, Routine
License Type: Institutional Medical Priority: 3
Inspection Date: 3-25-96 Inspector: GMC

Comment:
a) No evidence of documentation of inspector's evaluation of QM rule at licensee's facility.

File No.: 4
Licensee: St. Luke Hospital, Inc. License No.: 202-163-25
Location: Ft. Thomas, KY Inspection Type: Unannounced, Routine
License Type: Institutional Medical with Therapy Priority: 3
Inspection Date: 3-27-96 Inspector: GMC

Comments:
a) A NOV was sent to the Licensee dated 4/10/96 with 3 items of noncompliance. A reply had not been received at time of review.
b) Noted that the inspection report called for information on recordable events; however, this block of information was not completed

File No.: 5
Licensee: Radiopharmacy, Inc. License No.: 202-221-32
Location: Paducah, KY Inspection Type: Routine, Unannounced
License Type: Radiopharmacy Priority 1
Inspection Date: 02-27-96 Inspector: GMC

Comment:
a) A NOV with one item of non-compliance was sent to the Licensee on 3-8-96, and a Licensee response was dated 3-8-96. Supervisor related that licensee letter just came in and was incorrectly dated. Acknowledgment letter from Commonwealth is being drafted.

File No.: 6
Licensee: Allegheny Wireline Services, Inc License No.: 201-094-40
Location: London, KY Inspection Type: Routine, announced
License Type: Well Logging Priority: 3
Inspection Date: 7-25-95 Inspector: GMC

File No. 7
Licensee: Syncor International Corp. License No.: 202-219-32
Location: Louisville, KY Inspection Type: Special, unannounced
License Type: Radiopharmacy Priority 1
Inspection Date: 8-29-95 Inspectors: VDJ & GMC

File No.: 8

Licensee: Southern Well Surveys, Inc. License No.: 201-170-40
Location: Henderson, KY Inspection Type: Routine, unannounced
License Type: Well Logging Priority: 3
Inspection Date: 3-27-96 Inspector: MWW

File No. 9
Licensee: Equine Services, PSC License No.: 201-542-33
Location: Simpsonville, KY Inspection Type: Initial, unannounced
License Type: Veterinary Medicine Priority: 5
Inspection Date: 2-8-96 Inspector: MWW

Comment:
a) A NOV was issued on 2-21-96 and the Licensee responded by letter dated
3-11-96. The response was unsatisfactory, and a second NOV was issued on 3-29-96. A Licensee response was received during the review. The Commonwealth acknowledgment letter is pending the evaluation of the Licensee's response.

File No.: 10
Licensee: Jan X-ray Services, Inc. License No.: 201-544-05
Location: Parma, MI Inspection Type: Routine, unannounced
License Type: Industrial Radiography Priority 1
Inspection Date: 5-24-95 Inspector: MWW

File No.: 11
Licensee: Owensboro Mercy Health Systems License No.: 202-161-25
Location: Owensboro, KY Inspection Type: Routine, unannounced
License Type: Institutional Medicine with HDR Priority 1
Inspection Date: 3-26-96 Inspector: MWW

Comment:
a) This was an inspection only of the HDR unit, because all other personnel associated with the diagnostic and pharmaceutical therapy programs were out on training. The NRC 2800/024, Appendix A form for HDR units was used as a report form, and included the QMP portion. A clear letter was issued on 4-5-96.

File No.: 12
Licensee: Humana Hospital License No.: 202-158-25
Location: Lexington, KY Inspection Type: Routine, unannounced
License Type: Institutional Medical Priority: 3
Inspection Date: 8-16-95 Inspector: SCO

Comments:
a) This facility is authorized for diagnostic medicine, brachytherapy, and pharmaceutical therapy. The NOV was dated 8-20-95 and the Licensee's response was dated 9-8-95. The Commonwealth acknowledgment letter was dated 9-20-95.
b) This was also an accompaniment by the IMPEP team member Woodruff.
c) Additional information was needed to document the specific circumstances regarding the inoperable survey meter.

File No. 13
Licensee: St. Claire Medical Center License No.: 202-116-25
Location: Morehead, KY Inspection Type: Routine, unannounced
License Type: Institutional Medicine Priority: 3
Inspection Date: 2-23-96 Inspector: SCO

Comments:
a) This facility is authorized for diagnostic, radiopharmaceutical therapy and brachytherapy procedures. An NOV was issued dated 2-29-96 with 6 citations. The licensee's response was dated 3-12-96, and the Commonwealth acknowledgment letter was dated 3-20-96.
b) Additional details are needed in the report to describe the specifics of the independent measurements that were conducted by the inspector.

File No. 14
Licensee: Baker Engineering Unlimited License No.: 201-405-51
Location: Frankfort, KY Inspection Type: Routine, unannounced
License Type: Portable Gauge Priority: 4
Inspection Date: 3-21-96 Inspector: SCO

Comment:
a) The Commonwealth's NOV was issued on 4-2-96, and the licensee's response was dated 4-9-96. The Commonwealth's acknowledgment letter is still pending.

File No.: 15
Licensee: Nally and Haydon Surfacing License No.: 201-473-51
Location: Bardstown, KY Inspection Type: Routine, unannounced
License Type: Portable Gauge Priority: 4
Inspection Date: 10-18-95 Inspector: SCO

File No.: 16
Licensee: Bio-Products International Corp. License No.: 201-549-93
Location: Lexington, KY Inspection Type: Initial, unannounced
License Type: Distribution Priority: 3
Inspection Date: 1-24-96 Inspectors: SCO and MWW

File No.: 17
Licensee: University of Kentucky License No.: 202-024-31
Location: Lexington, KY Inspection Type: Announced, Routine
License Type: Teletherapy Priority: 1
Inspection Date: 10/12-14/95 Inspectors: VDJ, MWW, SCO, & GMC

File No.: 18
Licensee: University of Kentucky License No.: 202-049-22
Location: Lexington, KY Inspection Type: Routine, announced
License Type: Broad Medical Priority: 1
Inspection Date: 1/23-25/96 Inspectors: VDJ, MWW, SCO, & GMC

File No.: 19
Licensee: Spring View Medical Center License No.: 202-201-25
Location: Lebanon, KY Inspection Type: Routine, unannounced
License Type: Institutional Medical Priority: 3
Inspection Date: 6-14-95 Inspectors: SCO, VDJ

Comment:
a) A NOV was issued on 6-21-95 with 6 citations and the Licensee's response was dated June 26, 1995. The Commonwealth's acknowledgment letter was dated 7-11-95. This inspection was a supervisory accompaniment and documented in the personnel file.

File No.: 20
Licensee: Suburban Medical Center License No.: 202-09925
Location: Louisville, KY Inspection Type: Routine, unannounced
License Type: Institutional Medical Priority: 3
Inspection Date: 3-22-95 Inspectors: MWW & VDJ

Comment:
a) This facility is authorized for diagnostic and brachytherapy procedures. The Commonwealth issued a clear letter dated 4-10-95. This also was a supervisory accompaniment by the inspector's supervisor.

APPENDIX F
INCIDENT FILE REVIEWS

File No. 1
Licensee: Lexington Clinic License No: 202-061-25
Site of Event: Lexington, Ky
Date of Event: 2/13/96 Type of Event: Misadministration
Investigation Date: 3/18/96 Investigation Type: Phone

Summary of Incident and Final Disposition: A 12.1 mCi dose was given instead of the 10.0 mCi dose prescribed. The technologist picked up the vial containing the 12.1 mCi dose by mistake.

Comments:
a) Commonwealth was notified on 3/6/96.
b) Reported to NRC on 4/4/96.

File No. 2
Licensee: AAF International License No.: 201-034-04
Site of Event: Louisville, Ky
Date of Event: 12/12/95 Type of Event: Loss of Control
Investigation Date: 12/12/95 Investigation Type: Onsite

Summary of Incident and Final Disposition: Following a fire, the licensee discovered that they possessed many sources that the new RSO did not know about. The old inventory was found and all sources were accounted for except a 250 mCi H-3 source.

Comment:
a) Commonwealth responded promptly to assist new RSO.

File No. 3
Licensee: Civil & Environmental Consultants
License No.: NRC 37-28465-1
Site of Event: Sulphur, Ky
Date of Event: 11/4/95 Type of Event: Damage to Equipment
Investigation Date: 11/6/95 Investigation Type: Phone

Summary of Incident and Final Disposition: A density gauge being operated under reciprocity by an NRC licensee was damaged by a dozer. The source was secured and leak tested and taken to NRC jurisdiction to await disposal. The Commonwealth assured

reciprocity rules had been followed and that damaged source had been removed from Commonwealth.

Comment:
a) NRC licensee removed damaged gauge from Commonwealth jurisdiction prior to notification of Commonwealth.

File No. 4
Licensee: Owens Illinois Labels License No.: 401-126-10 GL
Site of Event: Bradstown, Ky
Date of Event: Unknown Type of Event: Leaking Source
Investigation Date: 1/17/96 Investigation Type: Onsite

Summary of Incident and Final Disposition: Radioactivity in excess of leak test standards was detected on a swipe due to improper leak test which removed material from a plated source. Commonwealth visited site and made wipe tests in the vicinity of and on the device. No contamination was found. Device was returned to manufacturer for testing.

Comments:
a) Commonwealth was notified on 12/5/95 but did not respond Onsite until 43 days later on 1/17/96. A more prompt response is needed for a leaking source where the Commonwealth does not have confidence the licensee can manage the potential problem.
b) License authorization for improper wipe test procedure should have been pursued.
c) NRC notified by Commonwealth on 1/19/96.

File No. 5
Licensee: University of Louisville License No.: 202-055-31
Site of Event: Louisville, Ky
Date of Event: 5/18/95 Type of Event: Misadministration
Investigation Date: 7/10/95 Investigation Type: Onsite

Summary of Incident and Final Disposition: Patient received 600 Rads per day instead of 300 Rads per day prescribed. Thus weekly total exceeded weekly prescribed by more than 30 percent. Error caused by the dosimetrist misreading the prescription. Upon discovery, treatment plan was modified to compensate for error. Commonwealth conducted Onsite investigation to verify calculations.

Comment:
a) NRC notified by Commonwealth on August 24, 1995.

File No. 6
Licensee: University of Kentucky License No.: 202-49-22
Site of Event: College of Medicine, Lexington, Ky.
Date of Event: 1/11/95 Type of Event: Leaking Source
Investigation Date: 1/12/95 Investigation Type: Phone

Summary of Incident and Final Disposition: A 12 mCi Cs-137 brachytherapy source was discovered to be leaking. Source was isolated and held for disposal. Commonwealth relied upon University RSO to manage problem. No immediate Onsite visit needed.

Comments:
a) NRC was notified by Commonwealth on 1/12/95
b) Commonwealth followed up by reviewing status of leaking source at the next inspection.

File No. 7
Licensee: MQS License No.: 201-278-05
Site of Event: No specific site
Date of Event: June 1994 Type of Event: Possible Overexposure
Investigation Date: 8/10/94 Investigation Type: Correspondence

Summary of Incident and Final Disposition: Possible overexposure of a radiographer who worked 1 day in Kentucky and 3 days in Ohio during June of 1994. Film badge for June read 11 Rads. Commonwealth accepted licensee's explanation of why Film badge reading was not valid exposure. Daily dosimeter totals were assigned as exposure received.

Comments:
a) Incident referred to Kentucky by NRC Region III.
b) Resolution was not in incident file but in a license file that had been terminated.

File No. 8
Licensee: Kentucky Electric Steel License No.: 201-130-57
Site of Event: Ashland, Ky
Date of Event: 2/16/96 Type of Event: Damage to Equipment
Investigation Date: Unknown Investigation Type: Phone

Summary of Incident and Final Disposition: Molten metal spilled on 3 radioactive devices causing loss of shielding. Manufacturer's representative came and packaged the damaged devices for disposal. Commonwealth reviewed reports from licensee and manufacturer's representative.

Comments:
a) Supervisory Oversight not documented.
b) Report failed to indicate that the sources were being stored at licensee awaiting disposal.

File No. 9
Licensee: Kentucky Utilities Co. License No.: 201-148-56
Site of Event: Ghent, Ky
Date of Event: 2/4/96 Type of Event: Equipment Failure

Investigation Date: 2/5/96 Investigation Type: Phone

Summary of Incident and Final Disposition: A 50 mCi Cs-137 gauge fell from it's mounting due to bolt failure. Licensee closed shutter. Manufacturer's representative came and reinstalled device. Commonwealth reviewed reports from licensee and manufacturer.

Comments:
a) Supervisory oversight not documented.
b) Report fails to indicate that the Commonwealth has not resolved the issue of whether the mounting bolts are part of the safety evaluation.

File No. 10
Licensee: A K Steel Corporation License No.: 201-002-56
Site of Event: Ashland, Ky
Date of Event: 4/25/95 Type of Event: Loss of Control
Investigation Date: Unknown Investigation Type: Correspondence

Summary of Incident and Final Disposition: A contractor removed a fixed gauge from the licensee's site by mistake. Once recognized the device was returned to the licensee. Commonwealth was notified 6/5/95 and reviewed and filed the notification.

Comments:
a) Licensee was not cited for failure to notify Commonwealth within 30 days as required by regulations.
b) Licensee was not cited for loss of control.
c) No documentation of closure.

File No. 11
Licensee: Law Engineering License No.: 201-257-51
Site of Event: Richmond, Ky
Date of Event: 11/14/94 Type of Event: Damaged to Equipment
Investigation Date: 11/14/94 Investigation Type: Phone

Summary of Incident and Final Disposition: A nuclear density gauge was damaged when it was run over by a scraper. Device was severely damaged but source remained intact. Commonwealth

discussed matter via telephone with licensee RSO, who returned damaged device to manufacturer for disposal.

Comment:
a) No documentation of closure.

File No. 12
Licensee: University of Kentucky License No.: 202-49-22
Site of Event: College of Medicine, Lexington, Ky
Date of Event: 11/13/95 Type of Event: Misadministration
Investigation Date: 1/23/96 Investigation Type: Onsite

Summary of Incident and Final Disposition: A physician gave an initial written directive for a 3 mCi dose of I-131 to evaluate thyroid cancer. That directive was later changed to 2 mCi, however the technologist was unaware of the change. A dose of 3.47 mCi was administered. The Commonwealth was notified on 1/22/96 and conducted an Onsite investigation the next day as part of a routine inspection.

Comment:
a) Reported to NRC by Commonwealth on 2/22/96

File No. 13
Licensee: Non-Licensee
Site of Event: Mansback Metal, Ashland, Ky
Date of Event: 6/30/94 Type of Event: Lost RAM
Investigation Date: 7/1/94 Investigation Type: Onsite

Summary of Incident and Final Disposition: A 200 mCi Cs-137 capsule was found in shredded scrap at Mansback Metal. The Commonwealth assisted non licensee in controlling area, identifying the material, and obtaining disposal. Capsule was transferred to a waste broker.

Comments:
a) No documentation of closure.
b) Commonwealth responded quickly and efficiently to a significant problem.

File No. 14
Licensee: Alt & Witzig Engineering License No.: NRC License
Site of Event: Florence, Ky
Date of Event: 9/6/94 Type of Event: Lost RAM
Investigation Date: 9/7/94 Investigation Type: Phone

Summary of Incident and Final Disposition: Device containing a radioactive source was taken from a pickup truck left unattended and found the next day behind a portable toilet. Licensee was cited for lack of reciprocity and lack of control. Reciprocity was obtained and device returned to service.

Comment:
a) No documentation of closure

File No. 15
Licensee: University of Kentucky License No.: 202-49-22
Site of Event: Chemistry/Physics Building
Date of Event: 10/8/94 Type of Event: Contamination Event
Investigation Date: 10/12/94 Investigation Type: Onsite

Summary of Incident and Final Disposition: Approximately 0.3 mCi of Tritium was released into a laboratory room when an unmarked jar containing an old tritium target was opened. Three individuals received detectable but inconsequential uptakes. The Commonwealth conducted an onsite inspection October 12-14, 1994. The licensee cleaned the area and was cited by the Commonwealth for the lack of a container label.

Comment:
a) No documentation of closure.