May 25, 2012

Shari Meghreblian, Ph.D.
Deputy Commissioner
Tennessee Department of Environment
and Conservation
401 Church Street
1st Floor, L&C Annex
Nashville, TN 37243

Dear Dr. Meghreblian:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review held in Tennessee on April 23–27, 2012. I was the team leader for the review. The review team's preliminary findings were discussed with you and your staff on the last day of the review. The review team's proposed recommendations are that the Tennessee Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with the NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement States' and NRC Regional Offices' radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Two additional areas applicable to your program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the Tennessee MRB meeting for July 10, 2012, from 1:00 p.m. - 4:00 p.m. EDT. NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (630) 829-9661. Thank you for your cooperation.

Sincerely,

/RA L. Dimmick for/

Jim Lynch
State Agreements Officer
Division of Nuclear Materials Safety
NRC Region III

Enclosure:
As stated

cc w/ encl: Debra Shults, Director
Division of Radiological Health

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Division of Radiological Health

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE TENNESSEE AGREEMENT STATE PROGRAM

April 23–27, 2012

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Tennessee Agreement State Program. The review was conducted during the period of April 23–27, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission and the State of Arkansas.

Based on the results of this review, Tennessee's performance was found satisfactory for all seven performance indicators. The review team made one recommendation regarding program performance by the State to develop a process improvement to ensure that all future reportable radioactive material incidents are appropriately reported in accordance with SA-300, "Reporting Material Events." In addition, the review team determined that the recommendations from the 2008 IMPEP review regarding staffing and training, and the sealed source and device evaluation program, should be closed.

Accordingly, the review team recommends that the Tennessee Agreement State Program is adequate to protect public health and safety and is compatible with NRC's program. The review team recommends that the next IMPEP review take place in approximately four years.

1.0 INTRODUCTION

This report presents the results of the review of the Tennessee Agreement State Program. The review was conducted during the period of April 23–27, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arkansas. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 25, 2008, to April 27, 2012, were discussed with Tennessee managers on the last day of the review.

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

The Tennessee Agreement State Program is administered by the Division of Radiological Health (the Division). The Division is located in the Bureau of Environment, which is in the Department of Environment and Conservation (the Department). The Division Director reports to the Deputy Commissioner for Environment and Conservation, who in turn reports to the Commissioner of the Department. Organization charts for the Department and the Division are included as Appendix B.

At the time of the review, the Tennessee Agreement State Program regulated 576 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of Tennessee.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Division on January 5, 2012. The Division provided its response to the questionnaire on April 9, 2012. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML121010376.

The review team's general approach for conduct of this review consisted of (1) examination of the Division's response to the questionnaire, (2) review of applicable Tennessee statutes and regulations, (3) analysis of quantitative information from the Division's database, (4) technical review of selected regulatory actions, (5) field accompaniments of nine inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators and made a preliminary assessment of the Tennessee Agreement State Program's performance.

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

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the 2008 IMPEP review, which concluded on April 25, 2008, the review team made four recommendations regarding the Tennessee Agreement State Program's performance. The status of each recommendation is as follows:

1. The review team recommends that the State evaluate the Division's projected staffing level and take appropriate action to ensure the Division has adequate resources to achieve its primary objective of protecting the public health, safety and security.

   Status: The Division analyzed its staffing needs for the Central and regional office functions. The Program staffing level has remained stable during the review period and the Program is not experiencing any significant backlogs in licensing or inspection activities. Four positions (three technical and one clerical) were vacant at the time of this review, and, according to the Director, will likely be eliminated in future staffing cuts. Despite the potential cuts, the review team determined that staffing levels were adequate for the Agreement State program. This recommendation is closed.

2. The review team recommends that the State develop a method to document clearly that an inspector or license reviewer is qualified or approved to perform inspections or licensing actions of the different license types upon completion of specified training.

   Status: The Program maintains training records for each inspector and license reviewer to document qualification/approval for the different types of licenses after completion of training courses and supervisory accompaniments. The Central Office maintains records for staff member qualifications, including documentation of training courses and on-the-job training. This recommendation is closed.

3. The review team recommends that the State review the training policy to ensure that it meets current and future needs of staff and revise the policy, as appropriate, to include on-the-job training and security training.

   Status: The Program's current training policy includes on-the-job training and security training to address current and future needs of the staff. License reviewers and inspectors from each of the regional offices have attended the NRC security training course. This recommendation is closed.

4. The review team recommends that the State establish a means to ensure evaluations are conducted with thoroughness; consistency with ANSI standards and NUREG-1556, Volume 3, for all SS&D licensing actions.

   Status: In order to ensure thoroughness and consistency with ANSI standards and existing guidance, the Program's SS&D reviewers implemented a review checklist based on the checklist found in NUREG-1556, Volume 3, for SS&D licensing actions requiring a safety review. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. These indicators are (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

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

The Division is composed of the Office of the Director and four Sections: Inspection and Enforcement; Licensing/Registration/Policy; Technical Services; and Administrative Services. All Sections, other than Inspection and Enforcement, are located at the Central Office in Nashville. Inspection, enforcement and incident response activities are conducted primarily by four field offices located in Knoxville, Memphis, Chattanooga, and Nashville. Inspection and enforcement activities are coordinated by the Inspection and Enforcement Section Manager, located at the Knoxville Field Office. The former Division Director is currently employed as a part-time rehired annuitant.

At the time of the review, the Division had 49 individuals with various degrees of involvement in the radioactive materials program, totaling approximately 24 full-time equivalents (FTE). During the review period, nine staff members left the Division and nine staff members were hired. Four positions (three technical and one clerical) were vacant at the time of this review, and, according to the Director, will likely be eliminated in future staffing cuts. Despite the potential cuts, the review team determined that staffing levels were adequate for the Agreement State program.

The Division has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The plan is currently under revision to update training expectations, including security training. The State relies on the NRC-sponsored training courses for basic training, and supplements that training with on-the-job training. Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team shared the draft IMC 1248 "Qualification Programs for Federal and State Materials and Environmental Management Programs" with the State to help with employee qualifications. The review team concluded that the Division's training program is adequate to carry out its regulatory duties and noted that Tennessee management supports the Division training program.

Based on the IMPEP evaluation criteria, the review team recommends that Tennessee's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of Materials Inspection Program

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

The review team verified that Tennessee's inspection frequencies for all types of radioactive material licenses are at least as frequent as license types listed in IMC 2800, "Materials Inspection Program." The review team confirmed the Division is conducting Increased Controls inspections in conjunction with the routine health and safety inspections.

The Division conducted approximately 479 high priority (Priority 1, 2, and 3) inspections during the review period based on the inspection frequencies established in IMC 2800. Twelve of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800.

The Division performed approximately 74 initial inspections during the review period, 4 of which were conducted overdue. Two initial inspections were overdue at the time of the IMPEP review. As required by IMC 2800, initial inspections are to be conducted within 12 months of license issuance. These inspections were overdue because of a misinterpretation of the IMC 2800 requirements for initial inspections. When the Division contacts a licensee to schedule the initial inspection and is told that no radioactive material has been received, the Division defers the initial inspection. The Division follows up with the licensee annually in the same manner until the licensee indicates that radioactive material has been received. In the two overdue cases, the Division attempted to schedule the initial inspection but the licensees indicated no licensed activities were being conducted so the initial inspections were deferred and not performed within 12 months of license issuance. The Division committed to making a swift modification to its inspection procedures requiring that initial inspections be performed within the first 12 months regardless of whether licensed activities were being conducted. The Division also committed to train inspection staff accordingly. The two overdue initial inspections were scheduled during the IMPEP review. Overall, the review team calculated that the Division performed 2.9 percent of its inspections overdue during the review period.

The review team evaluated the Division's timeliness in providing inspection findings to licensees. The Division has a policy of issuing inspection findings to licensees within 30 days from the date of the inspection. All inspection reports are submitted for a supervisory review. Based on a sampling of 34 inspection reports, no inspection findings were communicated to the licensees beyond the Division's goal of 30 days after the inspection. Each field office tracks the 30-day metric for inspection report timeliness. Computer printouts generated by each office indicated that only a few inspection reports were issued beyond 30 days during the review period.

During the review period, the Division granted 149 reciprocity permits, 84 of which were candidate licensees based upon the criteria in IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." The review team

determined that the Division exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 24 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 20 Division inspectors and covered inspections of various license types, including: medical broad scope, academic broad scope, medical institutions, industrial radiography, veterinary use, gamma knife, nuclear pharmacy, service provider, nuclear laundry, well logging, research and development, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

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

The inspection procedures utilized by the Division are generally consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the Field Office Manager and/or Inspection and Enforcement Manager. Supervisory accompaniments were conducted annually for all inspectors.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. All inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Division issues to the licensee either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format, which details the results of the inspection. When the Division issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 15 days. All findings are reviewed and acknowledged by the inspector.

The review team noted that the Division has an adequate supply of survey instruments to support their inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, was observed to be available. The Division also has portable multi-channel analyzers located in offices across the State. Instruments are calibrated at least annually, or as needed, by K&S Associates or Ludlum with National Institute of Standards and Technology

traceable sources. The Division uses a spreadsheet to track each instrument, its current location, and next calibration date.

Accompaniments of 11 Division inspectors were conducted by three IMPEP team members during the weeks of February 20, March 12, April 2, and April 9, 2012. The inspectors were accompanied during health and safety inspections of industrial radiography, service provider, irradiator, medical therapy, medical diagnostic, and waste processor licenses. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and Increased Controls at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Tennessee's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 43 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 8 new licenses, 10 renewals, 4 termination actions, and 21 amendments. Files reviewed included a cross-section of license types, including: licenses of broad scope, medical diagnostic and therapy, gamma knife, industrial radiography, research and development, nuclear pharmacy, production of radionuclides using accelerators, veterinary use, fixed and portable gauges, manufacturers, self-shielded irradiators, decommissioning and decontamination services, and waste processors. The casework sample represented work from all four license reviewers. A listing of the licensing casework evaluated is provided in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were documented; however, two of the files reviewed were missing receipt information indicating final

disposition of the radioactive material. License reviewers use the Division's licensing guides and/or NUREG-1556 series guidance documents, policies, checklists, and standard license conditions to ensure consistency in licenses.

All license reviewers have signature authority and sign their own licensing actions. The next higher level supervisor to the license reviewer, (Program Manager, Director or Licensing Manager) performs a technical and supervisory review on all licensing actions before issuance to the licensee. Licenses are issued for a 10-year period under a timely renewal system.

The license reviewers followed standard procedures, guidance documents and checklists that are similar to those used by the NRC. During the review period, the Division revised in full the Medical License Application Guide and issued five updates to existing procedures. Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Division licensing procedures and/or NUREG-1556 guidance documents, the State's regulations, and good health physics practices.

The Division authorizes a number of unique licenses, identified as waste processors, who process radioactive wastes received from licensees throughout the entire country. In April 2010, the Division amended the licenses of the four waste processors who were authorized to dispose of materials with extremely low levels of contamination into Class I (Subtitle D) landfills, and required them to re-submit dose assessments for such disposal. The Division specified the minimum criteria for the assessment and established new licensing requirements for this activity. Evaluation of the re-submitted dose assessments were performed by the Division's Health Physics Consultant using accepted industry codes, data, and modeling to confirm the dose assessments.

The review team evaluated two waste processor licensing actions issued during this review period that required submission of Emergency Preparedness plans in accordance with State regulations. During the review period, waste processor licensing actions were reviewed by one license reviewer. A second reviewer on staff had done waste processor reviews in the past. The Division has started to train an additional reviewer to perform reviews of waste processor activities. During the 2008 IMPEP review, the review team discussed with Division managers the possibility of developing a guidance document or checklist for licensing the unique activities associated with waste processors in an effort to capture the expertise and experience of the Division that could be used for knowledge management within the Division or by other regulatory agencies. A list of standard license conditions for waste processors was available during the 2012 review, but no additional written guidance was developed.

The Division performed pre-licensing checks of all new license applicants evaluated by the review team. The Division's pre-licensing review methods incorporated the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. When applicable, new licensees received a pre-licensing site visit which included an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Division's licensing practices regarding the Increased Controls and Fingerprinting Orders, and the National Source Tracking System (NSTS). The review team

noted that the State used legally binding license conditions that met the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The State also used legally binding license conditions that met the criteria for implementing the requirements of the NSTS. The review team analyzed the Division's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Division required full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Division's procedure for the control of sensitive information. The Division procedure addressed the marking, control and handling of documents that contain sensitive information related to the Increased Controls. The review team noted that the Division licensing and inspection files were available to all workers, except that inspection files that contained sensitive information related to Increased Controls were further secured in locked file cabinets.

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

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Division's actions in responding to incidents and allegations, the review team examined the Division's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Tennessee in the Nuclear Material Events Database (NMED) against those contained in the Division's files, and evaluated the casework for 16 radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Division's response to 12 allegations involving radioactive materials, including 6 allegations referred to the State by the NRC during the review period.

The incidents selected for review included the following categories: lost/stolen radioactive material; medical event; equipment failures; leaking sources, contamination; and radioactive material release. The review team determined that the Division's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Division dispatched inspectors for on-site investigations in 12 of the cases reviewed and took suitable enforcement and follow-up actions.

Several months prior to this IMPEP review, Division managers identified that reporting of incidents was not being performed as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events." The reporting lapse was due to changing responsibilities amongst managers, and although all incidents were responded to in an effective manner, the reporting to the NRC Headquarters Operations Center and download of information into NMED, was overlooked.

In early 2012, the Division placed a manager in charge of incident reporting and they analyzed incidents which had occurred since 2008 to determine if any of the incidents were reportable.

They reported 2 of the incidents to the NRC Headquarters Operations Center and information for 38 incidents was sent to NMED. The Division also arranged for NRC's contractor for the NMED database, Idaho National Laboratory, to provide training to staff in June 2012. The training session will be supplemented with SA-300 training by the Region I State Agreements Officer.

The review team identified three additional incidents that occurred during the review period, which met the criteria for reporting to the NRC Headquarters Operations Center. The Division appropriately responded to these incidents. The Division reported these incidents to NRC on April 30, 2012, after the review. The review team recommends that the State develop a system to ensure that all future reportable radioactive material incidents are appropriately reported in accordance with SA-300, "Reporting Material Events."

In evaluating the effectiveness of the Division's response to allegations, the review team evaluated the completed casework for the 12 allegations. The review team concluded that the Division consistently took prompt and appropriate actions in response to concerns raised. The review team noted that the Division documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Division notified the concerned individuals of the conclusion of their investigations. The review team determined that the Division adequately protected the identity of concerned individuals within the limitations of the State's rules and policy related to alleger identity protection.

Based on the IMPEP evaluation criteria, the review team recommends that Tennessee's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. NRC's Agreement with Tennessee does not relinquish regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Tennessee became an Agreement State on September 1, 1965. The statutory authority for the radiation control program is found in Title 68, Chapter 202-101 through 202-709 of the Tennessee Code Annotated. The Division is designated as the State's radiation control agency in Title 68, Chapter 203-101 through 203-105.

The review team verified with Division staff that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

Tennessee's regulations for the control of radiation are found in the "Rules of the Department of Environment and Conservation," Chapters 1200-2-4 through 1200-2-12, and apply to all ionizing radiation from radioactive materials and radiation-producing machines. Tennessee requires a license for possession and use of all radioactive material including naturally occurring materials (such as radium) and accelerator-produced radionuclides.

The regulatory process provides opportunity for the public and other interested parties to comment on proposed rules. The review team verified that no changes have been made to Division procedures since the last review. Tennessee has procedures for amending four types of regulations: Rulemaking Hearing Rules, Proposed Rules (non-controversial filed without a public hearing), Emergency Rules, and Public Necessity Rules. The Division generally uses the Rulemaking Hearing and Proposed Rules procedures.

Under Rulemaking Hearing Rules procedures, proposed rules are reviewed internally by the Division, the Department's Office of the General Counsel (OGC), and by outside interested parties before a rulemaking hearing is established. The proposed rules are published in the Tennessee Administrative Register during the month prior to the public hearing. Comments are accepted at the hearing and during the comment period. Changes are made to the rules, as needed; reviewed by the OGC; signed by the Department's Commissioner; reviewed by the Attorney General's Office; filed with the Secretary of State; and become effective 90 days after filing.

Under Proposed Rules, rules considered non-controversial may be filed without a public hearing. Proposed rules are reviewed internally by the Division, the OGC, and by outside interested parties. The proposed rules are published in the Tennessee Administrative Register. A petition requesting a public hearing may be filed within 60 days from the first day of the month subsequent to the filing of the proposed rule. In the absence of a petition, the rule becomes effective after a waiting period of 150 days.

After a rule becomes effective, representatives of the Division and OGC are scheduled to appear before the Government Operations Committee of the legislature for the Committee's hearing and approval of the rules. Rules adopted during the year are subject to sunset on June 30 of the following calendar year, unless approved by the legislature.

The review team evaluated the Division's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status sheet that FSME maintains.

During the review period, Tennessee submitted 16 final regulation amendments, and 2 legally binding license conditions to the NRC for compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. Twelve of the 16 final amendments were overdue for State adoption at the time of submission. The NRC's compatibility review of the final amendments resulted in no comments.

The following 12 amendments were submitted overdue during this review period:

- "Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]," 10 CFR Parts 30 and 40 amendment (58 FR 39628) that was due for Agreement State adoption by October 25, 1996.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendment (60 FR 38235) that was due for Agreement State adoption by November 24, 1998.
- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendment (61 FR 24669) that was due for Agreement State adoption by June 17, 1999.
- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendment (62 FR 39057) that was due for Agreement State adoption by August 20, 2000.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249) that was due for Agreement State adoption by October 24, 2005.
- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendment (68 FR 57327) that was due for Agreement State adoption by December 3, 2006.
- "Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that was due for Agreement State adoption by October 1, 2007.
- "Medical Use of Byproduct Material—Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336: 71 FR 1926) that was due for Agreement State adoption by April 29, 2008.
- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005) that was due for Agreement State adoption by March 27, 2009.
- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473) that was due for Agreement State adoption by December 17, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864) that was due for Agreement State adoption by November 30, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043) that was due for Agreement State adoption by February 15, 2011.

The Division will need to address the following amendments in the future:

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512) that is due for Agreement State implementation by December 17, 2015.
- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 70, and 150 amendment (76 FR 56951) that is due for Agreement State implementation by November 14, 2014.
- "Changes of Compatibility of 10 CFR 31.5 and 31.6," 10 CFR Part 31 amendment (77 FR 3640) that is due for Agreement State Implementation by January 25, 2015.

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

4.2 Sealed Source and Device Evaluation Program

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

In assessing the Division's SS&D evaluation activities, the review team examined information provided in response to the IMPEP questionnaire for this indicator. The review team conducted a review of all new and amended SS&D registrations and supporting documents processed during the review period. The review team noted the staff's use of guidance documents and procedures, interviewed the staff involved in SS&D evaluations, and verified the use of regulations and license conditions. The review team also evaluated SS&D staff training records and certain reported incidents involving products authorized in Tennessee SS&D registrations.

4.2.1. Technical Staffing and Training

The Division has a documented qualification program for SS&D reviewers as a subsection of its overall Licensing Evaluator Qualification Procedures. The Division utilizes a structured in-house training program due to the infrequent SS&D application for a new registration or amendment requests. Currently, the SS&D Evaluation Program is fully staffed, and the Division does not plan in the near future to add any more reviewers. The SS&D reviewers perform device evaluations as secondary duties. The reviewers have extensive health physics experience for the performance of SS&D evaluations.

The Division currently has three qualified reviewers, and two others are working on becoming fully qualified reviewers. All five individuals have completed the NRC SS&D Workshop. According to the Division's response to the questionnaire, the Division expends approximately 0.13 FTE on SS&D evaluations. The review team concluded that the current SS&D staffing level is adequate for the needs of the Division.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Division processed 16 SS&D actions. Fourteen of the actions were amendments and two were new applications. There were no inactivations of SS&D registrations or emerging technology evaluations processed during the review period. The review team evaluated all 16 actions processed during the review period. The casework selected for review was representative of five qualified reviewers. A listing of the SS&D certificates evaluated by the review team, with case-specific comments, may be found in Appendix F.

The Division performed evaluations based on sound conservative assumptions to ensure public health and safety was adequately protected. Good health physics practices were implemented throughout the evaluations.

In assessing the Division's SS&D evaluation activities, the review team examined information contained in the questionnaire response and interviewed program staff and managers. The review team confirmed that the Division follows the recommended guidance from the NRC SS&D Workshop, NUREG-1556 guidance, applicable and pertinent American National Standards Institute (ANSI) standards and Military standards, ISO-9001 and Tennessee regulations, statutes, policies and procedures. The review team verified these documents were available and used appropriately in performing SS&D evaluations.

Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. The review team determined that product evaluations were complete and adequately addressed the integrity of the products during use and in the event of accidents.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED, the review team determined that there were no incidents involving SS&D registered products during the review period. The review team determined that there were no events that occurred in Tennessee, or nationally, involving sealed sources/devices registered by the Division.

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

4.3 Low-level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of Low-level Radioactive Waste (LLRW) as a separate category. Although the Tennessee Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which

will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Tennessee. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Tennessee's performance was found satisfactory for all performance indicators reviewed. The review team determined that the four recommendations from the 2008 IMPEP review should be closed (Section 2.0). Accordingly, the review team recommends that the Tennessee Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately four years.

Below is the review team's recommendation, as mentioned in the report, for evaluation and implementation by the State.

RECOMMENDATION

The review team recommends that the State develop a system to ensure that all future reportable radioactive material incidents are appropriately reported in accordance with SA-300, "Reporting Material Events." (Section 3.5)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Jim Lynch, Region III	Team Leader Technical Staffing and Training Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Lisa Dimmick, FSME	Team Leader in Training Status of Materials Inspection Program Compatibility Requirements
Donna Janda, Region I	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Betsy Ullrich, Region I	Technical Quality of Licensing Actions Inspector Accompaniments
Steve Mack, Arkansas	Technical Quality of Licensing Actions
Steve Poy, FSME	Sealed Source and Device Evaluation Program Technical Quality of Incident and Allegation Activities

APPENDIX B

TENNESSEE ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML121010523

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: University of Tennessee Knoxville — License No.: R-47005
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Dates: 12/1-4/09 — Inspectors: AH, SH, BF

File No.: 2
Licensee: Horizon Medical Center — License No.: R-22001
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 8/1/11 — Inspector: GK

File No.: 3
Licensee: Cardinal Health — License No.: R-79174
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 5/31/11 — Inspector: AG

File No.: 4
Licensee: Music City Nuclear Pharmacy — License No.: R-19245
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 4/1/09 — Inspectors: GK, RH

File No.: 5
Licensee: Mountain States Health Alliance — License No.: R-90005
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 10/26/11 — Inspectors: SD, NM

File No.: 6
Licensee: Erlanger Health System Radiation Oncology — License No.: R-33090
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 12/5/08 — Inspector: SS

File No.: 7
Licensee: Le Bonheur Children's Medical Center — License No.: R-79172
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 8/23/11 — Inspector: JP

File No.: 8
Licensee: Tennessee Equine Hospital — License No.: R-94039
Inspection Type: Initial, Announced — Priority: 3
Inspection Date: 2/25/10 — Inspector: TB

File No.: 9
Licensee: Vanderbilt University License No.: R-19021
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 5/10-12/11 Inspectors: GK, RH, PR, DB, JB

File No.: 10
Licensee: Vanderbilt University Medical Center License No.: R-19021
Inspection Type: Special, Unannounced Priority: 2
Inspection Date: 5/26/11 Inspector: GK

File No.: 11
Licensee: Fort Sanders Regional Gamma Knife Center License No.: R-47188
Inspection Type: Initial, Special, Announced Priority: 2
Inspection Date: 12/9/10 Inspector: RM

File No.: 12
Licensee: Fort Sanders Regional Gamma Knife Center License No.: R-47188
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/9/11 Inspector: RM

File No.: 13
Licensee: Duratek Services, Inc. License No.: R-73008
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 7/20-23/10 Inspectors: RM, JT

File No.: 14
Licensee: Studsvik Processing Facility, LLC License No.: R-86011
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 10/9-10/08 Inspectors: AH, JT, NM, BW

File No.: 15
Licensee: Cardinal Health 414, Inc. License No.: R-57025
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/31/11 Inspector: THG

File No.: 16
Licensee: UniTech Services Group, Inc. License No.: R-01086
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 9/2/09 Inspector: JM

File No.: 17
Licensee: NDC Infrared Engineering, Inc. License No.: CA-1451-19
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 2/15/12 Inspector: DS

File No.: 18
Licensee: Hopewell Designs License No.: GA-1434-1
Inspection Type: Special, Announced Priority: 5
Inspection Date: 11/14/11 Inspector: SH

File No.: 19
Licensee: Norris Well Services, Inc. License No.: KY-201-251-40
Inspection Type: Special, Announced Priority: 3
Inspection Date: 3/18/10 Inspectors: SB, RM

File No.: 20
Licensee: Acuren Inspections, Inc. License No.: R-01006
Inspection Type: Routine, Unannounced Priority: 1
Inspection Dates: 4/11-12/11 Inspector: SH

File No.: 21
Licensee: Bionomics License No.: R-73021
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 7/21-25/11 Inspectors: NM, JT

File No.: 22
Licensee: Ivey Cooper License No.: R-33145
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 2/24/11 Inspector: SB

File No.: 23
Licensee: Microbac – Tri Cities Division License No.: R-90051
Inspection Type: Initial, Announced Priority: 5
Inspection Date: 12/8/09 Inspector: JM

File No.: 24
Licensee: Team Industrial Services, Inc. License No.: R-79304
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 3/16/12 Inspector: GS

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: SE International License No.: R-51002
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 3/13/12 Inspector: RH

Accompaniment No.: 2
Licensee: Lincoln Medical Center License No.: R-52002
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/14/12 Inspector: JB

Comment: Inspector did not perform an effective exit meeting with licensee management.

Accompaniment No.: 3
Licensee: Dyersburg Regional Medical Center License No.: R-23002
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/15/12 Inspector: AG

Accompaniment No.: 4
Licensee: Team Industrial Services, Inc. License No.: R-74005
Inspection Type: Special, Unannounced Priority: 1
Inspection Date: 3/16/12 Inspector: GS

Accompaniment No.: 5
Licensee: AFCO NDE License No.: R-01092
Inspection Type: Special, Announced Priority: 1
Inspection Date: 2/23/12 Inspector: JM

Accompaniment No.: 6
Licensee: Canberra Industries, Inc. License No.: R-01013
Inspection Type: Initial, Special, Unannounced Priority: 2
Inspection Date: 2/22/12 Inspector: RM

Accompaniment No.: 7
Licensee: Chattanooga Imaging License No.: R-06017
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/10/12 Inspector: SS

Accompaniment No.: 8
Licensee: Eagle Testing License No.: R-33155
Inspection Type: Special, Unannounced Priority: 1
Inspection Date: 4/11/12 Inspector: CB

Accompaniment No.: 9
Licensee: IMPACT Services License No.: R-73024
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 4/2-6/12 Inspectors: SD, SH, DS

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APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Saint Thomas Hospital — License No.: R-19001
Type of Action: Renewal — Amendment No.: 155
Date Issued: 12/2/08 — License Reviewer: GB

File No.: 2
Licensee: Advanced Specialty Pharmacy — License No.: R-47202
Type of Action: New — Amendment No.: N/A
Date Issued: 11/24/08 — License Reviewer: SK

File No.: 3
Licensee: Applied Technical Services — License No.: R-51004
Type of Action: New — Amendment No.: N/A
Date Issued: 3/20/09 — License Reviewer: RP

File No.: 4
Licensee: Alstom Power — License No.: R-33001
Type of Action: Termination — Amendment No.: *N/A
Date Issued: 12/12/08 — License Reviewer: RP

Comment: Termination amendments are not issued, letter only.

File No.: 5
Licensee: MedActinium — License No.: R-01098
Type of Action: Termination — Amendment No.: N/A
Date Issued: 4/20/10 — License Reviewer: CA

Comment: The licensee indicated that radioactive material had been shipped off-site for disposal; however, no receipt information was available in the file.

File No.: 6
Licensee: Baptist Riverside — License No.: R-47014
Type of Action: Termination — Amendment No.: N/A
Date Issued: 3/24/09 — License Reviewer: GB

Comment: The licensee indicated that radioactive material (sources) had been shipped off-site for disposal; however, no receipt information was available in the file.

File No.: 7
Licensee: Tennessee Equine Hospital License No.: R-94039
Type of Action: New Amendment No.: N/A
Date Issued: 6/2/09 License Reviewer: RP

File No.: 8
Licensee: Mistras Group License No.: R-19001
Type of Action: New Amendment No.: N/A
Date Issued: 4/16/10 License Reviewer: RP

File No.: 9
Licensee: Fort Sanders Regional Gamma Knife Center License No.: R-47188
Type of Action: Renewal Amendment No.: 15
Date Issued: 10/29/10 License Reviewer: RP

File No.: 10
Licensee: Professional Service Industries, Inc. License No.: R-79242
Type of Action: Renewal Amendment No.: 12
Date Issued: 2/22/10 License Reviewer: SK

File No.: 11
Licensee: Maury Regional Hospital License No.: R-60018
Type of Action: Amendment Amendment No.: 20
Date Issued: 9/26/11 License Reviewer: CA

File No.: 12
Licensee: Maury Regional Hospital License No.: R-60018
Type of Action: Amendment Amendment No.: 21
Date Issued: 10/11/11 License Reviewer: GB

File No.: 13
Licensee: Erlanger Health System License No.: R-33099
Type of Action: Amendment Amendment No.: 52
Date Issued: 6/9/11 License Reviewer: SK

File No.: 14
Licensee: Stern Cardiovascular Foundation License No.: R-79263
Type of Action: Renewal Amendment No.: 18
Date Issued: 3/8/12 License Reviewer: GB

File No.: 15
Licensee: Professional Engineers, Inc. License No.: R-47170
Type of Action: Renewal Amendment No.: 6
Date Issued: 10/23/09 License Reviewer: GB

File No.: 16
Licensee: Centennial Heart, LLC License No.: R-19234
Type of Action: Amendment Amendment No.: 13
Date Issued: 1/14/09 License Reviewer: GB

File No.: 17
Licensee: World Testing, Inc. License No.: R-95009
Type of Action: Amendment Amendment No.: 46
Date Issued: 3/7/12 License Reviewer: GB

File No.: 18
Licensee: St. Jude Children's Research Hospital License No.: R-79056
Type of Action: Amendment Amendment No.: 121
Date Issued: 2/10/09 License Reviewer: SK

File No.: 19
Licensee: Cognate BioServices, Inc. License No.: R-79275
Type of Action: Amendment Amendment No.: 6
Date Issued: 2/25/11 License Reviewer: SK

File No.: 20
Licensee: IMPACT Services, Inc. License No.: R-73024
Type of Action: Amendment Amendment No.: 42
Date Issued: 5/20/11 License Reviewer: CA

File No.: 21
Licensee: IMPACT Services, Inc. License No.: R-73024
Type of Action: Amendment Amendment No.: 41
Date Issued: 3/4/11 License Reviewer: CA

File No.: 22
Licensee: IMPACT Services, Inc. License No.: R-73024
Type of Action: Amendment Amendment No.: 40
Date Issued: 3/4/11 License Reviewer: CA

File No.: 23
Licensee: Duratek Services, Inc. License No.: R-73016
Type of Action: Amendment Amendment No.: 96
Date Issued: 10/11/11 License Reviewer: CA

File No.: 24
Licensee: Duratek Services, Inc. License No.: R-73016
Type of Action: Amendment Amendment No.: 88
Date Issued: 5/15/08 License Reviewer: CA

File No.: 25
Licensee: Philotechnics, Ltd. License No.: R-01084
Type of Action: Amendment Amendment No.: 23
Date Issued: 2/17/12 License Reviewer: CA

File No.: 26
Licensee: Diversified Scientific Services, Inc. License No.: R-73014
Type of Action: Amendment Amendment No.: 96
Date Issued: 8/14/09 License Reviewer: CA

Comment: The Emergency Preparedness plan required by regulation was referenced by the licensee in the amendment but the plan was not in the current license file. The plan was found in a folder labeled “superseded” with other documents that were replaced during a renewal that preceded this review period.

File No.: 27
Licensee: ATG Catalytics, Inc. License No.: R-73020
Type of Action: Termination Amendment No.: N/A
Date Issued: 7/17/08 License Reviewer: CA

File No.: 28
Licensee: East Tennessee Materials and Energy Corporation License No.: R-01088
Type of Action: Renewal Amendment No.: 49
Date Issued: 9/18/09 License Reviewer: CA

File No.: 29
Licensee: East Tennessee Materials and Energy Corporation License No.: R-01088
Type of Action: Amendment Amendment No.: 53
Date Issued: 11/30/10 License Reviewer: CA

Comment: Unlabeled computer disc with potentially sensitive information in current license file.

File No.: 30
Licensee: University of Memphis License No.: R-79315
Type of Action: New Amendment No.: N/A
Date Issued: 4/1/11 License Reviewer: SK

File No.: 31
Licensee: University of Tennessee - Knoxville License No.: R-47005
Type of Action: Renewal Amendment No.: 80
Date Issued: 9/22/08 License Reviewer: RP

File No.: 32
Licensee: Ameriphysics License No.: R-47205
Type of Action: New Amendment No.: N/A
Date Issued: 3/4/09 License Reviewer: RP

File No.: 33
Licensee: Manufacturing Sciences Corporation License No.: S-01046
Type of Action: Renewal Amendment No.: 89
Date Issued: 2/1/11 License Reviewer: CA

File No.: 34
Licensee: Cardinal Health, LLC License No.: R-47211
Type of Action: New Amendment No.: N/A
Date Issued: 7/26/11 License Reviewer: SK

File No.: 35
Licensee: Aerojet Ordnance Tennessee License No.: S-90009
Type of Action: Amendment Amendment No.: 155
Date Issued: 12/15/11 License Reviewer: RP

File No.: 36
Licensee: Aerojet Ordnance Tennessee License No.: S-90009
Type of Action: Renewal Amendment No.: 154
Date Issued: 10/28/11 License Reviewer: RP

File No.: 37
Licensee: Midtown Animal, LLC License No.: R-79311
Type of Action: New Amendment No.: N/A
Date Issued: 6/11/09 License Reviewer: SK

File No.: 38
Licensee: MediPhysics, Inc. License No.: R-79249
Type of Action: Amendment Amendment No.: 39
Date Issued: 11/12/10 License Reviewer: RP

File No.: 39
Licensee: Teledyne Brown Engineering, Inc. License No.: R-47173
Type of Action: Amendment Amendment No.: 12
Date Issued: 8/19/10 License Reviewer: RP

File No.: 40
Licensee: Erlanger Medical Center License No.: R-33008
Type of Action: Amendment Amendment No.: 98
Date Issued: 8/2/11 License Reviewer: GB

File No.: 41
Licensee: Mid Continent Laboratories, Inc. License No.: R-79219
Type of Action: Renewal Amendment No.: 18
Date Issued: 9/24/09 License Reviewer: GB

File No.: 42
Licensee: Nucor Steel Memphis, Inc.
License No.: R-79303
Type of Action: Amendment
Amendment No.: 1
Date Issued: 2/24/09
License Reviewer: GB

File No.: 43
Licensee: American Red Cross Blood Services
License No.: R-19180
Type of Action: Amendment
Amendment No.: 16
Date Issued: 1/29/10
License Reviewer: CA

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Studsvik
Date of Incident: 1/23/09
Investigation Date: 1/23/09
License No.: R-79273
NMED No.: 120258
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

Comment: Incident not reported to the NRC Headquarters Operations Center. [Note: reported to NRC HOC on 4/30/12]

File No.: 2
Licensee: Impact Services, Inc.
Date of Incident: 5/11/09
Investigation Date: 5/11/09
License No.: R-73024
NMED No.: N/A
Type of Incident: RAM Release
Type of Investigation: Site

Comment: Incident not reported to NMED.

File No.: 3
Licensee: Saint Thomas Hospital
Date of Incident: 8/10/09
Investigation Date: 9/1/09
License No.: R-19190
NMED No.: 120151
Type of Incident: Contamination
Type of Investigation: Telephone

Comment: Incident reported late to NMED, in 2012.

File No.: 4
Licensee: Bionomics, Inc.
Date of Incident: 12/9/09
Investigation Date: 12/15/09
License No.: R-73021
NMED No.: 090878
Type of Incident: Contamination
Type of Investigation: Site

File No.: 5
Licensee: Cookeville Regional Medical Center
Date of Incident: 12/15/09
Investigation Date: 12/15/09
License No.: R-71026
NMED No.: 090885
Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 6
Licensee: Eastman Chemical Company
Date of Incident: 1/19/10
Investigation Date: 1/19/10
License No.: R-82007
NMED No.: 120152
Type of Incident: Equipment Failure
Type of Investigation: Site

Comment: Incident reported late to NMED, in 2012.

File No.: 7
Licensee: Professional Service Industries
Date of Incident: 3/5/10
Investigation Date: 3/17/10
License No.: R-19014
NMED No.: 120164
Type of Incident: Equipment Failure
Type of Investigation: Site

Comment: Incident reported late to NMED, in 2012.

File No.: 8
Licensee: AFCO NDE
Date of Incident: 3/15/10
Investigation Date: 3/19/10
License No.: R-01092
NMED No.: 120163
Type of Incident: Equipment Failure
Type of Investigation: Site

Comment: Incident reported late to NMED, in 2012.

File No.: 9
Licensee: Construction Materials Laboratory
Date of Incident: 5/4/10
Investigation Date: 5/5/10
License No.: R-47079
NMED No.: 120169
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

Comment: Incident reported late to NMED, in 2012.

File No.: 10
Licensee: Saint Thomas Hospital
Date of Incident: 5/22/10
Investigation Date: 5/22/10
License No.: R-19190
NMED No.: 120174
Type of Incident: Contamination
Type of Investigation: Site

Comment: Incident reported late to NMED, in 2012.

File No.: 11
Licensee: Federal Express
Date of Incident: 11/23/10
Investigation Date: 11/23/10
License No.: Non-licensee
NMED No.: 110101
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 12

Licensee: Eberline Services
Date of Incident: 1/12/11
Investigation Date: 1/13/11
License No.: R-01063
NMED No.: N/A
Type of Incident: RAM Release
Type of Investigation: Site

File No.: 13
Licensee: K & S Associates, Inc.
Date of Incident: 1/18/11
Investigation Date: 1/24/11
License No.: R-19075
NMED No.: 120279
Type of Incident: Leaking Source
Type of Investigation: Site

Comment: Incident not reported to the NRC Headquarters Operations Center or to NMED. [Note: reported to NRC HOC on 4/30/12 and subsequently to NMED]

File No.: 14
Licensee: World Testing
Date of Incident: 3/3/11
Investigation Date: 3/4/11
License No.: R-95009
NMED No.: 120171
Type of Incident: Equipment Failure
Type of Investigation: Site

Comment: Incident was not reported to the NRC Headquarters Operations Center and was reported late to NMED, in 2012. [Note: reported to NRC HOC on 4/30/12]

File No.: 15
Licensee: University of Tennessee-Knoxville
Date of Incident: 3/22/11
Investigation Date: 3/23/11
License No.: R-47005
NMED No.: N/A
Type of Incident: Contamination
Type of Investigation: Telephone

Comment: Incident was not reported to NMED.

File No.: 16
Licensee: St. Jude Children's Research Hospital
Date of Incident: 5/17/11
Investigation Date: 5/18/11
License No.: R-79037
NMED No.: N/A
Type of Incident: Equipment Failure
Type of Investigation: Telephone

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: TN-1031-D-119-B — SS&D Type: Gamma Density Gauge
Applicant Name: Berthold Technologies — Type of Action: New
Date Issued: 7/30/08 — SS&D Reviewers: CA, JG

Comment: The registration indicates that it is possible to lock the shutter of the device in the open position. The ability to lock the shutter in the open position should be better clarified within the certificate, including the safety aspects of this practice.

File No.: 2
Registry No.: TN-0799-D-102-B — SS&D Type: Density Gauge
Applicant Name: Energy Technologies, Inc. — Type of Action: Amendment
Date Issued: 9/15/08 — SS&D Reviewers: RP, CA

Comment: Isotope labels on the device radiation profiles were transposed.

File No.: 3
Registry No.: TN-1031-S-110-S — SS&D Type: Gamma Source
Applicant Name: Berthold Technologies — Type of Action: Amendment
Date Issued: 1/26/09 — SS&D Reviewers: RP, CA

File No.: 4
Registry No.: TN-1031-D-104-B — SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies — Type of Action: Amendment
Date Issued: 3/11/09 — SS&D Reviewers: CA, JG

File No.: 5
Registry No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies — Type of Action: Amendment
Date Issued: 5/6/09 — SS&D Reviewers: CA, JG

File No.: 6
Registry No.: TN-1031-D-109-S — SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies — Type of Action: Amendment
Date Issued: 12/2/09 — SS&D Reviewers: RP, CA

File No.: 7
Registry No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies — Type of Action: Amendment
Date Issued: 10/14/10 — SS&D Reviewers: GB, RP

File No.: 8
Registry No.: TN-1031-D-119-B SS&D Type: Gamma Density Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 11/15/10 SS&D Reviewers: CA, JG

File No.: 9
Registry No.: TN-1031-D-104-B SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 3/1/11 SS&D Reviewers: CA, JG

File No.: 10
Registry No.: TN-1031-D-113-B SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 5/9/11 SS&D Reviewers: RP, CA

File No.: 11
Registry No.: TN-1031-D-114-B SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 5/9/11 SS&D Reviewers: RP, CA

File No.: 12
Registry No.: TN-0237-S-103-S SS&D Type: Medical Reference Source
Applicant Name: Siemens Medical Solutions Type of Action: Amendment
Date Issued: 8/12/11 SS&D Reviewers: SK, RP

Comments:

a) The principle use code for this device should have been “(X) Medical Reference Source” rather than “Instrument Calibration and Transmission Determinations.”
b) The radiation profile, using non-standard isodose lines, was for a 1.5 mCi Ge-68 source, much less than the maximum activity of 10 mCi.
c) The expected useful life of the source was not obtained or otherwise indicated on the registration certificate.
d) These corrections were suggested during the previous IMPEP review.

File No.: 13
Registry No.: TN-1031-S-120-S SS&D Type: Gamma Source
Applicant Name: Berthold Technologies Type of Action: New
Date Issued: 9/1/11 SS&D Reviewers: RP, CA

File No.: 14
Registry No.: TN-1031-D-101-B SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 10/3/11 SS&D Reviewers: RP, CA

Comments:

a) The registration indicates that it is possible to lock the shutter of the device in the open position. The ability to lock the shutter in the open position should be better clarified within the certificate, including the safety aspects of this practice.
b) Information on the length of the expected working life of the device and supporting testing information was not requested in the review process.

File No.: 15
Registry No.: TN-1031-D-104-B SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 10/3/11 SS&D Reviewers: RP, CA

Comment: Information on the length of the expected working life of the device and supporting testing information was not requested in the review process.

File No.: 16
Registry No.: TN-1031-D-119-B SS&D Type: Gamma Density Gauge
Applicant Name: Berthold Technologies Type of Action: Amendment
Date Issued: 10/3/11 SS&D Reviewers: RP, CA