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

August 6, 2008

Mr. Paul Sloan
Deputy Commissioner
Bureau of Environment
Tennessee Department of Environment
and Conservation
401 Church Street
First Floor, L & C Tower
Nashville, TN 37243-0435

Dear Mr. Sloan:

On July 15, 2008, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Tennessee Agreement State Program. The MRB found the Tennessee Agreement State Program adequate, but needs improvement, to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 18, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review of the Tennessee Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for April 2010.

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

Sincerely,

/RA/

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

Enclosure:
Tennessee Final IMPEP Report

cc w/encl.: Lawrence E. Nanney, Director
Tennessee Division of
Radiological Health

John Parker, New Mexico
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE TENNESSEE AGREEMENT STATE PROGRAM

April 21-25, 2008

FINAL REPORT

Enclosure

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 21-25, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Ohio. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of February 27, 2004, to April 25, 2008, were discussed with Tennessee managers on the last day of the review.

A draft of this report was issued to Tennessee for factual comment on May 29, 2008. The State responded by letter on June 25, 2008, from Lawrence E. Nanney, Director, Division of Radiological Health (the Division). A copy of the State's response is included as an attachment to this report. The Management Review Board (MRB) met on July 15, 2008, to consider the proposed final report. The MRB found the Tennessee Agreement State Program to be adequate, but needs improvement, to protect public health and safety and compatible with NRC's program.

The Tennessee Agreement State Program is administered by 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 Senior Director of Air Programs, who reports to the Deputy Commissioner for Environment, 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 program regulated 591 specific licenses. The review focused on the 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 State of Tennessee.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Division on January 22, 2008. The Division provided a response to the questionnaire on April 8, 2008, and an updated response to the questionnaire on April 18, 2008. Copies of the questionnaire responses can be found in the NRC's Agencywide Document Access and Management System using the Accession Number ML081490544.

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 five of the Division's inspectors; and (6) interviews with staff and managers to answer questions or clarify issues. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Agreement State program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current review for 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 and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 26, 2004, the team made three recommendations in regard to program performance that were transmitted to Ms. Karen Stachowski, Deputy Commissioner for Environment, on June 9, 2004. The current status of the recommendations is as follows:

1. The review team recommends that the Division promptly adopt the current version 10 CFR 20.2003. (Section 4.1.2 of the 2004 IMPEP review report)

   Current Status: The Division adopted a rule equivalent to 10 CFR Part 20.2003 that became effective July 7, 2006. The Division submitted the rule to the NRC for a compatibility review on July 27, 2006. On September 1, 2006, the NRC responded without comment. This recommendation is closed.

2. The review team recommends that the Division acquire or provide a mechanism for staff to have access to expertise commensurate with the complexity of SS&D casework. (Section 4.2.2 of the 2004 IMPEP review report)

   Current Status: The Division adopted a procedure for accessing expertise as outlined in a letter to the NRC dated July 14, 2004. During the review period, the Division generally resolved questions about sealed source and device (SS&D) reviews internally. The Division utilized the procedure to acquire technical assistance from the NRC concerning a device evaluation in 2004. This recommendation is closed.

3. The review team recommends that the Division prepare registration certificates consistent with the current version of NUREG-1556, Volume 3. (Section 4.2.2 of the 2004 IMPEP review report)

   Current Status: The Division incorporated changes in its preparation of registration certificates such that they are consistent with the format and style of NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration." This recommendation is closed; however, a new related recommendation is opened in Section 4.2.2 of this report.

In addition to the above, the 2004 review team made one recommendation to the NRC. Consistent with current practice, NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) will track and address this recommendation separately from this report.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing 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 responses relative to this indicator, organizational chart and staffing plan, interviewed Division management and staff, reviewed job descriptions, the training policy, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Division is comprised of Office of the Director and four Sections: the Administrative Services Section, the Inspection and Enforcement Section, the Licensing/Registration/Policy Section, and the Technical Services Section. The Office of the Director, the Administrative Services Section, the Licensing/Registration/Policy Section and the Technical Services Section are located at the Central Office in Nashville. Inspection, enforcement and incident response activities are conducted primarily through four field offices located in Nashville, Chattanooga, Memphis, and Knoxville. Inspection and enforcement activities are coordinated by the Inspection and Enforcement Section Manager, located at the Knoxville Field Office.

At the time of the review, there were 38 individuals with various degrees of involvement in the radioactive materials program, totaling 20.4 full time equivalents (FTE). This staffing level does include administration; however, excludes clerical support. The review team noted that inspection and licensing staff may also be involved with x-ray or other regulatory activities. At the time of the review, the Division had five vacancies. The vacancies included two staff positions at the Central Office, one staff position at the Nashville Field Office, one supervisory position at the Memphis Field Office, and one supervisory position at the Knoxville Field Office. The five vacancies account for an additional 1.95 FTE, bringing the full staffing total to approximately 22.4 FTE for radioactive materials activities.

The five vacant positions are currently frozen. At the time of the review, the Division was preparing to petition the Department to fill one position at the Central Office. A portion of the FTE for this position would be allotted to compatibility activities. The Division was not seeking to fill the remaining four frozen positions which include three slots for inspectors at the Field Offices and one staff position at the Central Office. The review team discussed with Division management the prospect of filling currently vacant positions.

During the review period, 11 staff members left the Division and 11 staff members were hired. At the time of the review, two staff members had been with the Division for less than 1 year, and a total of eight had been with the Division for 2 years or less. An additional four individuals were hired and then left the Division within the review period. Although these individuals were primarily assigned to x-ray duties, Division managers stated that the loss of these individuals

affected the materials program because personnel performing materials-related duties are used to balance the workload. The Division's turnover can be primarily attributed to competition with local industry and other agencies for qualified staff. Low starting salary and limited opportunities for advancement appear to be contributing factors to the turnover, according to Division managers.

The high turnover rate has been a historic problem within the Department. Division managers are concerned that the current economic situation may result in additional staff losses. The review team determined that the staff turnover and unfilled positions likely contributed to weaknesses observed in the inspection program and the adoption of regulations, as discussed later in this report. An insufficient number of staff members who were formerly approved to perform specific tasks by the Department in the areas of inspection and regulatory review appears to be the root cause for late inspections and the untimely adoption of regulations needed for compatibility. Increased security and emergency response activities have been putting additional strain on the Division's available resources. The review team discussed the high turnover rate with Division staff and managers, as well as potential solutions such as employee recruitment and retention incentives.

Subsequent to the review, the Division Director informed the NRC of the direct impact to the Division resulting from a Statewide initiative to reduce operating costs. The initiative calls for a Statewide reduction of 2,000 filled positions, primarily by means of voluntary buyouts, to be followed by a reduction in force, if necessary, to meet that goal. For the Division, the goal is to eliminate four currently filled positions; however, the five currently frozen vacant positions have not been affected by the Statewide initiative. At the time of the review, the review team determined that the Division's staffing level was adequate to achieve the Division's mission of protecting public health, safety, and security; however, in light of these staffing cuts and potential additional staff losses, the Division's performance with respect to inspections, licensing actions, and response to incidents and allegations could be adversely impacted. The review team recommends that the State evaluate the Division's projected staffing level and take appropriate action to ensure that the Division has adequate resources to achieve its primary objective of protecting public health, safety, and security.

The Division has a written training program that is consistent with the guidance in the NRC/Organization of Agreement States Training Working Group Recommendations for Agreement State Training Programs, dated 1997; however, the training program was put in place in July 2001 and has not been revised or reviewed since. The review team found that the training program does not specify minimum training and qualification requirements. The review team also found that qualification practices and documentation are not consistent throughout the Division. The review team looked at 14 staff training files, including managers and staff from the Central Office and the Field Offices. Training and qualification information was either missing or incomplete in most files. The review team found that some files from the Knoxville Field Office were complete, with detailed notes and other documentation demonstrating training, and included a qualification journal, which indicates what types of licenses the inspector is qualified to perform. The review team observed that this documentation is not part of the training program; therefore, it is not used in the other offices. The review team determined that the Division's written training program does not meet the current needs of the Division. 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.

Discussion with Division managers and staff revealed that no specific training was defined for license reviewers except the courses listed in Appendix B of the training program and on-the-job training of reviewing progressively more complex licenses with the approval of more senior license reviewers. Staff stated that some courses which could contribute to the training of license reviewers and inspectors were not listed on the Appendix B form. The review team noted that the training program does not include the radioactive material security training course. The review team recommends that the State review the training policy to ensure that it meets current and future needs of the staff and revise the policy, as appropriate, to include on-the-job training and security training.

Overall, the staff is well qualified from an education and experience standpoint. All new staff members have at least a Bachelor's degree in a science. Experienced technical staff members have taken the NRC courses or equivalent; however, as discussed above, the documentation was not complete in all cases. Division managers indicated that training of staff is no longer the challenge it had been in previous years due to the State more readily approving out-of-State travel and the NRC's revised policy on funding Agreement State training. On-the-job training has also been used to supplement formal course work so that individuals may broaden their work experience. The Division Director supports staff training opportunities, as well as participation in Federal and State working groups.

Division management indicated that approximately 90 percent of the Division's funding is dedicated revenue from licensee and x-ray registrant fees with the balance from appropriated funds. In 2001, the Division increased fees to materials licensees by approximately 50 percent. Fees have not been increased since that time.

Tennessee does not have a radiation oversight board.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Tennessee's performance with respect to the indicator, Technical Staffing and Training, was satisfactory, but needs improvement.

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 managers and staff.

The review team verified that the Division's inspection priorities for various license types were at least as frequent as similar license types listed in NRC's Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." The Division does not extend or compress inspection frequencies based on compliance history.

The review team determined that the Division conducted approximately 397 routine inspections of Priority 1, 2, and 3 licensees and 161 initial inspections during the review period. The Division performed 36 of these inspections overdue by more than 25 percent of the inspection priorities listed in IMC 2800, ranging from 1 month to 107 months overdue. Fourteen Priority 1, 2, and 3 or initial inspections were overdue at the time of this review, ranging from 1 month to 65 months overdue. Based on this data, the review team calculated that approximately 9 percent of the Priority 1, 2, and 3 and initial inspections were either completed overdue or were overdue at the time of the review.

The review team was concerned about the length of time some of the inspections were overdue. The review team discussed this issue with the Deputy Division Director and the Inspection and Enforcement Section Manager and determined that the major factors that contributed to the length of time some of these inspections were overdue included frequent staff turnover, especially at one field office, and the amount of time needed to train new staff. Other contributing factors included changing to a new inspection tracking system, which was not completely utilized by all regional inspection staff until recently; inadvertent mischaracterization of some inspection priority codes (e.g., some Priority 3 licensees were coded as Priority 5 licensees and were not inspected at the correct interval); and initial inspections of new program codes for existing licensees were not identified as due within 12 months. In addition, a few of the inspections were counted as overdue even though the inspections were completed. The inspection documentation could not be located so the Division considered these inspections to be overdue and committed to reinspect those licensees where the findings have not yet been issued. This issue was identified during the previous review in 2004. Division managers committed to using their electronic inspection tracking system, DRH Track, to monitor the inspection due dates for upcoming inspections to ensure that the inspections are performed prior to their due date. The Division has assigned all of the overdue inspections and plans to schedule and conduct the inspections as soon as possible.

The review team evaluated the timeliness in providing inspection findings to licensees by reviewing inspection data and files for 51 inspections, covering a cross-section of the staff and regional inspection offices. Twenty-two of the inspection reports were issued greater than 30 days after the date of the inspection. Two of the regional offices account for 17 of these reports. The review team discussed this issue with the Deputy Division Director and the Inspection and Enforcement Section Manager and determined that the regional field office managers are responsible for ensuring inspection reports are issued in a timely manner. The review team determined that staffing turnover and competing priorities (e.g., incident response, non-materials inspections) affected the issuance of some of the reports. Division managers and the regional managers have committed to using DRH Track to monitor the due dates for inspection reports and ensure that the reports are issued to licensees in a timely manner. There is a strong management commitment by the Division to take action to improve the timely performance of inspections and timely issuance of inspection reports to licensees. The review team believes that the Division can successfully correct the weaknesses in the materials inspection program.

Over the review period, the Division granted 65 reciprocity permits that were candidates for inspection based on 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 met or exceeded the goal of inspecting 20 percent of all candidate licensees

operating under reciprocity in each of the 4 years covered by the review period. The Division conducted 32 inspections of candidate reciprocity licensees during the review period.

The review team determined that the Division adequately planned for the initial set of Increased Controls inspections of affected licensees. The review team evaluated the Division's prioritization methodology and found it acceptable. The Division identified 44 licensees who are subject to the Increased Controls and had completed 51 Increased Controls inspections at the time of the review.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Tennessee's performance with respect to the indicator, Status of Materials Inspection Program, was satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 15 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by 18 Division inspectors and covered a wide variety of inspection types, including: broad scope academic, industrial radiography, waste disposal service providers, nuclear pharmacy, Increased Controls, mobile nuclear medicine, and limited scope medical programs. 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 the licensees' radiation safety programs. The review team found that inspection reports were generally thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. Inspection report 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 described in "Division of Radiological Health's Inspection and Enforcement Policy and Procedures" and are generally consistent with the inspection guidance found in IMC 2800. After the inspectors complete inspection reports, the reports are previewed and signed by the respective Field Office Manager. Once signed, completed actions are sent to the licensee. The Division's goal is to issue all inspection reports within 30 days of the inspections.

All inspection correspondence is issued from the respective field office where the inspection was performed. For inspections conducted by Field Office Managers, the Inspection and Enforcement Manager will perform the second review on the inspection documentation and correspondence. Findings were clearly stated and documented. If any violations are identified, a draft notice of noncompliance is prepared by the inspector. The review team also noted that inspection correspondence involving the Increased Controls was appropriately labeled as sensitive information and withheld from public disclosure.

During the review period, supervisory accompaniments were conducted for all inspectors on an annual basis, including supervisory inspectors.

The Division maintains an adequate supply of appropriately calibrated survey instrumentation to support its inspection program, as well as to respond to radioactive materials incidents and emergency conditions. The Division has commercial contractors who calibrate the majority of their survey instruments on an annual basis. The remaining instruments are sent to the manufacturer for calibration. The Division uses the Tennessee Department of Public Health's radiochemistry laboratory in Nashville for analysis of media samples collected by Division inspectors. The laboratory is capable of a number of analyses, including gamma spectroscopy, liquid scintillation counting, and low background gross alpha and beta counting. The Division sends samples to private laboratories for any laboratory services that cannot be performed in the Department of Public Health laboratory.

The review team accompanied five of the Division's inspectors during the weeks of April 7 and April 14, 2008. The Division's inspectors performed inspections at an industrial radiography facility and limited scope medical institutions. All inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Tennessee's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined the completed licenses and casework for 21 materials licensing actions which represented the work of 5 license reviewers. The licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license, license conditions and tie-down conditions, and overall technical quality. Casework was evaluated for adherence to good health physics practices, reference to appropriate regulations, supporting documents, peer or supervisory review and proper signature authorities. 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 that were completed during the review period. The sample focused on the State's new licenses, amendments, renewals, terminations, and the incorporation of Increased Controls into licenses. The sample included the following types of licenses: industrial radiography, radioactive waste processing, decommissioning and decontamination service provider, broad scope medical/research and development, medical institution - written directive required, well logging, fixed gauge, portable gauge, veterinary, nuclear pharmacy and medical institution - emerging technology. Licensing actions included 6 new licenses, 4 renewals, 1 termination, and 10

amendments. A list of the casework licenses evaluated, with case-specific comments, can be found in Appendix D.

Each of the five license reviewers tracked their licensing actions electronically. Due to the prompt assignment, review, and resolution of incoming licensing requests, the licensing staff effectively managed their casework. The review team identified no backlog of amendments or new applications during the review period. The Division issued license renewals associated with medical, industrial radiography, portable gauge and waste processors for a 10-year period under a timely renewal system. Other types of licenses were reviewed on a similar 10-year period; however, the license was extended without requiring the licensee to submit a complete renewal application. The Division was incorporating the extended licenses into the timely renewal process in a systematic method.

All license reviewers have signature authority and sign their own licensing actions. The licensing staff generates licenses and correspondence with standardized conditions and formats. The review team noted that the licensing staff used the computer database effectively and efficiently to obtain needed information in order to complete licensing actions. The review team found that the licensing actions were thorough, complete, timely, consistent, and of high quality with health, safety and security issues properly addressed. License tie-down conditions were stated clearly and backed by information contained in the license or sealed source and device registry files. To obtain additional information from the licensees or applicants, the license reviewers primarily used formal deficiency letters that stated regulatory positions and referenced the established guidance document for the respective licensed activity and specifically identified the deficiencies in the licensee's documents.

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 a number of their licensing guides. The review team acknowledged that the Division authorizes a number of unique licenses, identified as waste processors. These activities are primarily regulated by the Division for the entire country. The Division has unique talents, experience and expertise associated with licensing these types of activities. 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.

During the review period, the Division implemented NRC's recently revised pre-licensing guidance. The pre-licensing checklist and worksheets were adequately completed. The review team found that the Division had followed the guidance for the new licenses issued since it was adopted. Pre-licensing visits were not conducted, which was consistent with the guidance for these licensees.

Because not all of the recent regulatory changes issued by the NRC had been adopted as Tennessee regulations, the Division had imposed a number of the regulations by license conditions. Some examples included the security requirements for portable gauges and guidance for medical emerging technologies. In addition, the Division sent Radiological Information Notices to its licensees, similar to the NRC's Regulatory Issues Summaries. One example included a Radiological Information Notice dated January 25, 2007, which addressed

the change in the NRC regulations regarding medical physicists. The notice encouraged medical physicists to request an amendment so they may be named on the license as an authorized medical physicist under the State of Tennessee qualification requirements. The Increased Controls had been incorporated by license condition into each of the required licenses. Additionally, the Division had received notification on April 14, 2008, from FSME that the State of Tennessee's proposed license condition for the fingerprinting order was compatible with the NRC's license condition. The Division indicated that it would start implementing the revised license condition.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Tennessee's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the 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 10 radioactive materials incidents. The incidents selected for review included medical events, lost radioactive material, damaged equipment, reported overexposures, and equipment failures. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Division's response to eight allegations involving radioactive materials, including four allegations referred to the State by the NRC during the review period.

When notification of an incident is received, the responding technical staff members, in consultation with their supervisor or manager, determine the appropriate level of initial response. Technical staff members are authorized to respond to the site of an incident without obtaining supervisor or manager approval if the incident requires notification to the Division in 24 hours or less. 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 appropriate situations and took suitable enforcement and followup actions when necessary.

The review team identified 35 radioactive materials incidents in NMED for Tennessee during the review period of which 34 required reporting to the NRC's Headquarters Operations Center. The review team evaluated the Division's timeliness in reporting incidents and found that, following notification from the licensee, the Division reported 30 of the 34 incidents within the required time frame. Of the remaining four cases, two incident reports were delayed due to the delayed discovery of situations which required reporting; one was delayed during holidays; and the other was delayed due to the unusual circumstances of the incident. The review team noted that in responses to more significant incidents, the Division issued a simplified charter to guide the response activities. The charter document identified issues to be resolved and information to be collected. The Division's response procedure does not address charters. The review team also noted that the Division does not close incidents until all compliance issues are resolved and enforcement action, if required, is completed.

The review team noted that the Tennessee incident files included events involving electronic radiation sources and other events to which staff respond but are not reportable under NRC regulations. The review team found that incident information in NMED for Tennessee was up to date and complete, with the exception of three recent incidents not yet closed. The Division's Complaint/Allegation/Incident (CAI) Coordinator maintains the incident files. The Deputy Division Director provides information electronically to the NRC's contractor responsible for maintaining NMED. The Division's Event Investigation Procedure requires coordination of responses among the Deputy Division Director, the CAI Coordinator, the responding staff and the responding staff's supervisor. The procedure addresses timely reporting of events to the NRC Headquarters Operations Center and entering event information into NMED.

In evaluating the effectiveness of Tennessee's response to allegations, the review team evaluated the casework for four NRC-referred allegations, as well as four other allegations reported directly to the State during the review period. The review team determined that the Division took prompt and appropriate action in response to all concerns raised. All of the allegations reviewed were appropriately closed, and the affected individuals were notified of the actions taken. Although the Division makes every effort to protect an alleger's identity, Tennessee law requires the allegation files to be public records, and made available to the public upon request. For this reason, the Division avoids recording the name of an alleger in the file records.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Tennessee's Agreement does not relinquish NRC authority for a Uranium Recovery Program, so only the first three non-common performance indicators were applicable 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.

During the 2004 review, the review team examined the procedures used in the Division's regulatory process and found that the public and other interested parties are offered an opportunity to comment on proposed rules. During this review, the review team verified that no changes have been made to the 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 Rules procedures. Under these procedures, proposed rules are reviewed internally by 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 for a 2-week period following the hearing. 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 75 days after filing. After the 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.

Current NRC policy requires that Agreement States adopt equivalent regulations or legally binding requirements no later than 3 years after an NRC amendment becomes effective. The following NRC amendments are overdue for adoption:

- "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), that was due for Agreement State adoption by April 29, 2008.

The Division developed a documented plan for adopting above regulations. As noted in Section 3.4 of this report, the Division has used license conditions as legally binding alternatives to regulations to impose safety and security requirements on licensees for several of the requirements in these amendments; however, the Division has not submitted all of the license conditions to the NRC for a compatibility review.

In addition, the following portions of NRC amendments are overdue for adoption:

- The 30.35 portion of "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.

- The 30.35 portion of "Timeliness in Decommissioning Material Facilities," 10 CRF Parts 30, 40, and 70 amendment (59 FR 36026), that was due for Agreement State adoption by August 15, 1997.

- The 30.35 portion of "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.

- The 30.35 portion of "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.

During a previous MRB, there was a misunderstanding on the part of both the NRC and Division staff which resulted in the four rules above being omitted from the Tennessee regulations. The misunderstanding involved the MRB's acceptance of Tennessee's handling of another portion of the NRC rulemaking as compatible. It was later discovered that the portion accepted by the MRB did not include these sections. Because of the misunderstanding, the review team is not considering these as overdue in its evaluation of this indicator. The Division plans to include the rules in a package scheduled to be submitted to the NRC for review by the end of 2008.

The review team identified the following NRC amendments that will need to be addressed in the future:

- "National Source Tracking System," 10 CFR Part 20 amendment (71 FR 65865; 72 FR 59162), that is due for Agreement State adoption by January 31, 2009.

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

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

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

- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31 32, and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.

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

At the time of the review, the Division had two draft rulemaking packages at different stages in the process, as documented in the Division's rulemaking plan. The first package will address two overdue amendments and two upcoming amendments. This package was with Department management for their review and was scheduled to be submitted to NRC for a compatibility review within a month of the IMPEP review. The second package was under development and was scheduled to be submitted to NRC by the end of 2008. The second package will address the remaining overdue amendments and one upcoming amendment.

Division managers and staff were aware of the regulations that are overdue and those that need to be adopted in the near future. The Division appeared to have a well formulated plan to address rules that were late for adoption and those becoming due. The review team learned that one staff member is considered proficient in the maintenance of the regulations and legislation and dedicates 0.35 FTE to those tasks. Division managers and staff noted that the low FTE allotted to compatibility, with only one new individual with limited regulatory review experience assigned to the task, was the contributing factor to the backlog. The review team discussed with Division managers the prospect of dedicating additional FTE to compatibility-related tasks, and of establishing means to address the timely adoption of required rules and regulations.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Tennessee's performance with respect to the indicator, Compatibility Requirements, was satisfactory, but needs improvement.

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

In reviewing this indicator, the review team used three subelements to evaluate the Division's performance regarding the SS&D Evaluation Program. The 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 Program, the review team examined the information that the Division provided in response to the IMPEP questionnaire. The review

team conducted a review of selected new, amended SS&D evaluations, deficiency letters, interactions with the applicant, and supporting documents covering the review period. The review team noted the Division's use of guidance documents and procedures, interviewed the staff involved in the evaluations, and verified the use of regulations and license conditions to enforcement commitments made in the applications.

4.2.1 Technical Staffing and Training

The Division has five individuals who perform SS&D evaluations as secondary duties. During the review period, one new SS&D reviewer attended the NRC SS&D Workshop held in 2006. The individual is now fully qualified to perform SS&D evaluations after completing several reviews in collaboration with a senior reviewer. The individual has the proper training and qualifications in accordance with the Division's Training Policy. The new SS&D reviewer has documented training and authorization in the training files. All five SS&D reviewers have attended the NRC SS&D Workshop. The current SS&D reviewers have extensive health physics experience for the performance of SS&D reviews. None of these individuals have formal engineering training.

According to the Division's response to the questionnaire, the Division expends approximately 0.45 FTE on SS&D evaluations. The review team concluded that the current SS&D staffing level is adequate for the needs of the Division.

Based on the IMPEP evaluation criteria, the review team recommended that Tennessee's performance with respect to the subelement, Technical Staffing and Training, was satisfactory.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Division issued 50 SS&D certificates. The review team examined 14 certificates and their supporting documentation including 3 new applications, and 11 amendments. The review team's casework evaluations covered 10 unique products (sources or devices) and all 5 of the Division's SS&D reviewers. Appendix F contains a list of the SS&D registration certificates, with case specific comments, examined by the review team.

Analysis of the files and interviews with the staff confirmed that the Division follows the recommended guidance from the NRC SS&D Workshop and NUREG-1556, Volume 3, Revision 1, issued in April 2004. Appropriate standards, Regulatory Guides, and NRC SS&D training workshop references were available to staff when performing SS&D reviews.

The review team concluded that the overall technical quality of the product evaluations varied. The team found that the reviewers did not consistently use the review checklist provided in NUREG-1556, Volume 3, Appendix A. The review team found that the use of the checklist resulted in a significant improvement in the overall evaluation of the applications. The overall technical quality of product evaluations for new applications that used a complete checklist was better than amendments that used only a single page of the checklist regarding the portion being amended, if it was used.

Through the casework evaluations, the review team identified repeated problems with respect to thoroughness; consistency with American National Standards Institute (ANSI) standards and NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations. Specific examples include:

- Failure to specify in measurable terms the temperature and vibration limits in certain devices that may have been a contributing factor to multiple device failures (four unique products);

- Reporting of dose rate measurements that are not consistent with ANSI and NUREG-1556, Volume 3, with respect to using maximum activity and scatter radiation for shutter closed measurements (seven unique products);

- Use of product principal use codes that are outdated or inconsistent with NUREG-1556, Volume 3, Appendix C use codes (six unique products);

- Lack of rule-required justifications on file for leak test frequencies greater than 6 months (six unique products);

- Inadequately addressed label durability or content (two unique products); and

- Omission of dose profile of radionuclide added to device (two amendments of one unique product).

These issues were discussed with the Division managers and staff. The review team recommends the Division establish a means to ensure evaluations are conducted with thoroughness; consistency with ANSI standards and NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations.

Based on the IMPEP evaluation criteria, the review team recommended that Tennessee's performance with respect to the subelement, Technical Quality of the Product Evaluation Program, was satisfactory, but needs improvement.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Division’s response to the questionnaire, the review team examined a selected sample of incidents or failures regarding SS&D registered products that occurred during the review period. The review examined events that occurred within the State of Tennessee, as well as events nationwide that occurred within the review period involving equipment or sources registered by the Division.

There were several incidents involving devices registered by the Division and one open investigation during the last IMPEP that was subsequently closed.

During the last IMPEP, the Division was still evaluating a device failure regarding the Berthold Technologies LB 7400 series device. The Division sought technical assistance from the NRC regarding the device evaluation. The Division issued an amended SS&D registration on February 25, 2005.

In the response to the questionnaire, the Division reported that the State of Georgia notified the Division in 2006 of three occurrences of stuck shutters on Berthold Technologies LB 7400 series devices. These events were due to severe vibration leading to lead buildup on the shutter and one with environmental corrosion. The Division also reported in the questionnaire that Berthold Technologies informed them in August 2007 of an application where the Berthold Technologies LB 7400 series device that had stuck shutters due to lead powder buildup from vibration issues. During the IMPEP, the Division informed the review team that Berthold Technologies had just advised them there was another problem with the Berthold Technologies LB 7400 Series device with lead buildup due to vibration causing the shutter to stick in another specific use application and that the manufacturer is preparing to add another model to the device series as a corrective action.

The review team noted that the Division reviewed the incidents and corrections as presented by the manufacturer in a timely manner. The review team determined that the Division adequately reviewed the root causes of the individual incidents within the scope of the individual usage applications at the time of failure; however, the review team concluded that the Division did not fully evaluate the root causes of these failures, which become apparent in the repeated nature of these device failures. The review team noted that the manufacturer had not specified the vibration limits in measurable terms that the devices would be expected to withstand for the entire expected life of the devices, and consequently the information was not identified in the limitations and normal conditions of use in the registration certificates.

Based on the IMPEP evaluation criteria, the review team recommended that Tennessee's performance with respect to the subelement, Evaluation of Defects and Incident Regarding SS&Ds, was satisfactory, but needs improvement.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Tennessee's performance with respect to the indicator, SS&D Evaluation Program, was satisfactory, but needs improvement.

4.3 Low-level Radioactive Waste (LLRW) 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 LLRW as a separate category. Those States with Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. 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. At this time, there are no plans for a commercial 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, Tennessee's performance was found satisfactory for four performance indicators and satisfactory, but needs improvement, for the following performance indicators: Technical Staffing and Training, Compatibility Requirements, and SS&D Evaluation Program. The review team made four recommendations regarding program performance. Accordingly, the review team recommended, and the MRB agreed, that the Tennessee Agreement State Program be found adequate, but needs improvement, to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

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

1. The review team recommends that the State evaluate the Division's projected staffing level and take appropriate action to ensure that the Division has adequate resources to achieve its primary objective of protecting public health, safety, and security. (Section 3.1)

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. (Section 3.1)

3. The review team recommends that the State review the training policy to ensure that it meets current and future needs of the staff and revise the policy, as appropriate, to include on-the-job training and security training. (Section 3.1)

4. The review team recommends the State establish a means to ensure evaluations are conducted with thoroughness; consistency with ANSI standards and NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations. (Section 4.2.2)

LIST OF APPENDIXES AND ATTACHMENT

APPENDIX A

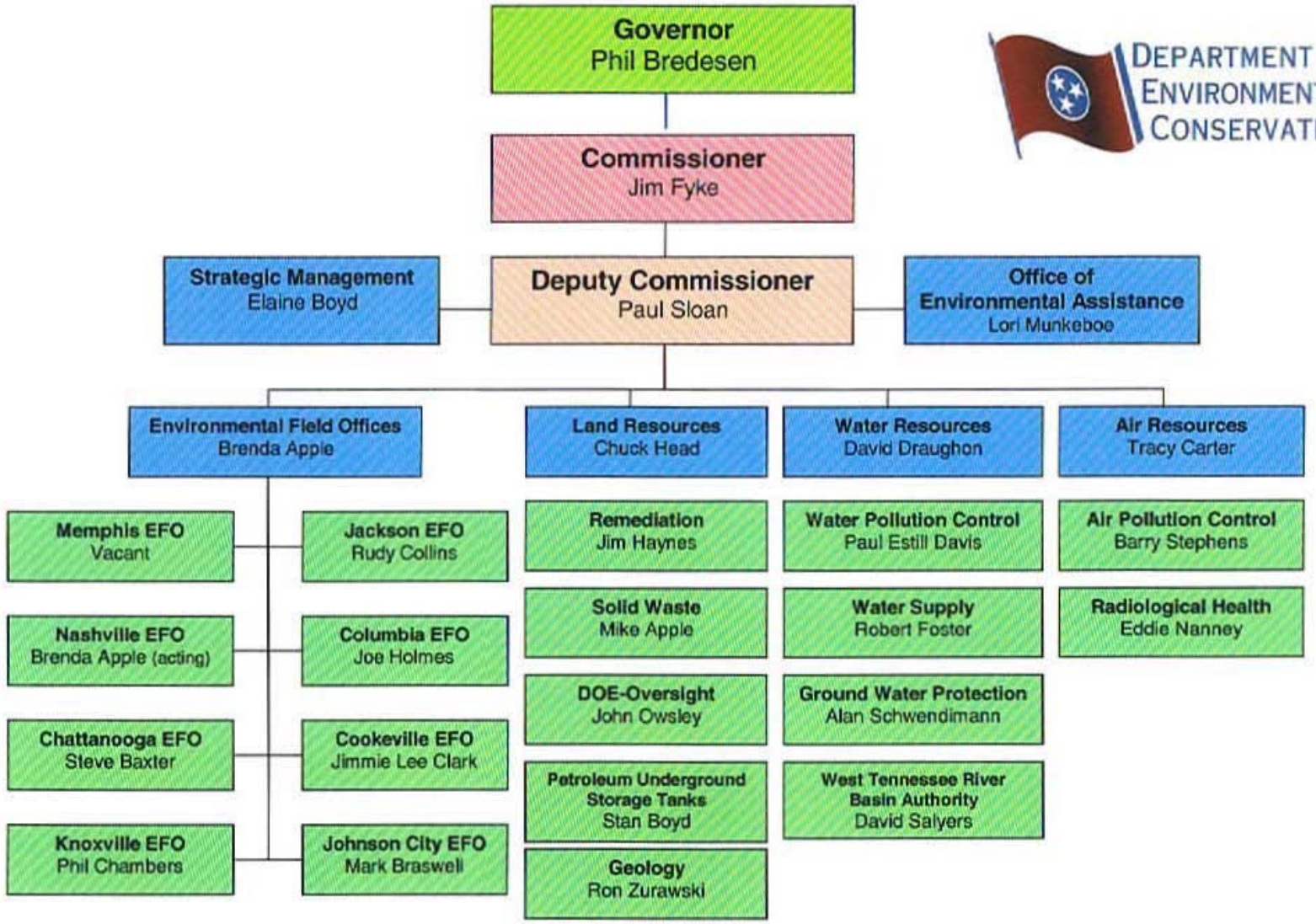
IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Richard Blanton, FSME	Team Leader Technical Quality of Incident and Allegation Activities
Joshua Palotay, FSME	Technical Staffing and Training Compatibility Requirements
Donna Janda, Region I	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Bryan Parker, Region I	Inspector Accompaniments
Rachel Browder, Region III	Technical Quality of Licensing Actions
Karl Von Ahn, Ohio	Sealed Source and Device Evaluation Program

APPENDIX B

TENNESSEE ORGANIZATION CHARTS

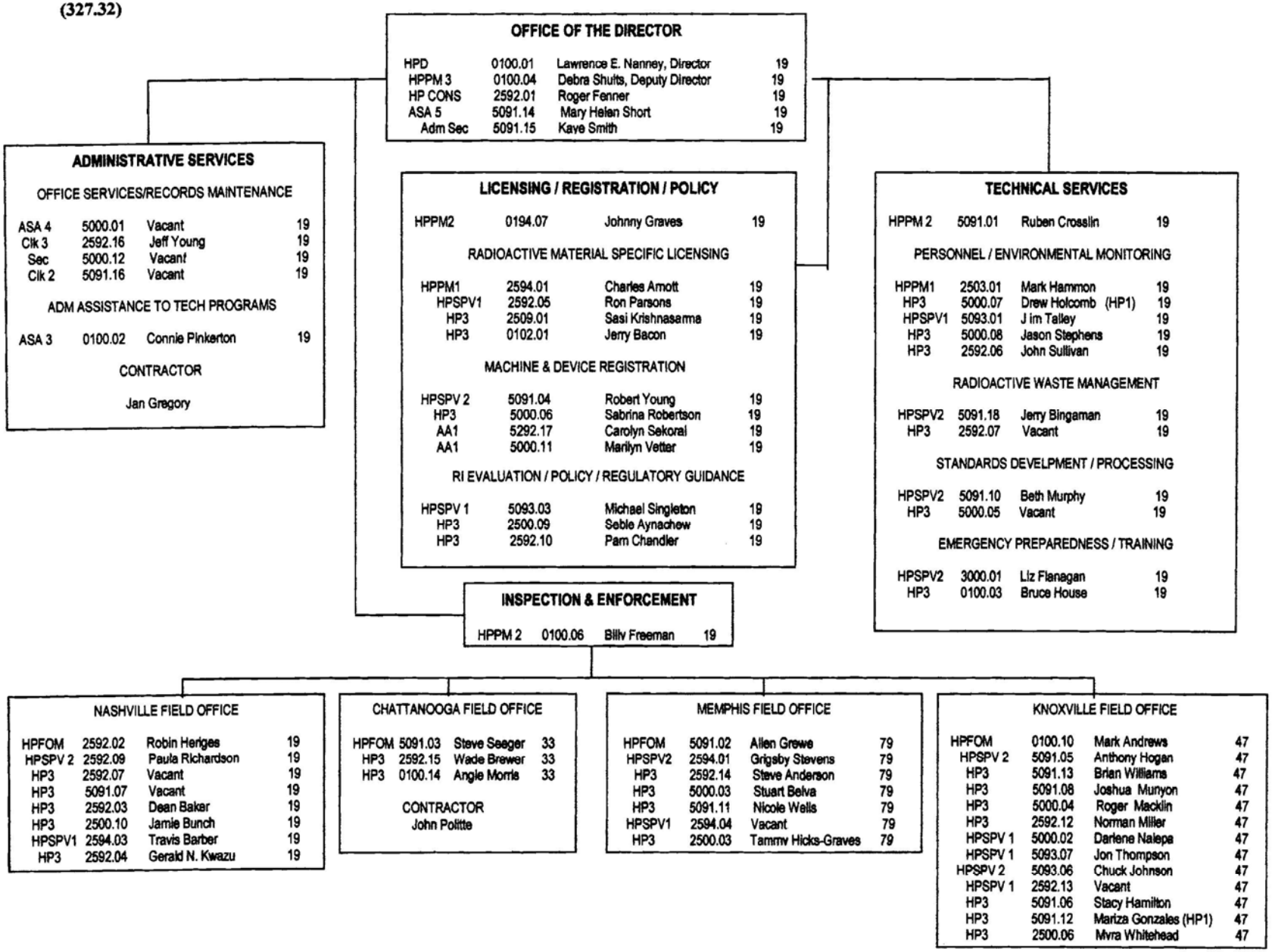
ADAMS ACCESSION NO.: ML081500401



TENNESSEE DEPARTMENT of ENVIRONMENT and CONSERVATION
BUREAU of ENVIRONMENT ORGANIZATION CHART
www.tdec.net

DIVISION OF RADIOLOGICAL HEALTH

(327.32)



APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: World Testing, Inc. License No.: R-95009-K16
Inspection Type: Routine/Special, Announced Priority: 2
Inspection Date: 12/7/06 Inspectors: GK, TB

File No.: 2
Licensee: Regional Medical Center of Memphis License No.: R-79177-H05
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 8/28/07 Inspector: AG

File No.: 3
Licensee: Duratek Services, Inc. License No.: R-73006-F13
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 2/20-22/08 Inspectors: JT, JM, BW, NM

Comment:
Inspection report was dispatched to the licensee 45 days after the inspection.

File No.: 4
Licensee: Ivy Cooper Services, LLC License No.: R-33145-G11
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 11/17/05 Inspectors: SS, CB

File No.: 5
Licensee: Mobile Tech Service License No.: R-54007-H15
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 6/29/07 Inspectors: WB, SS

File No.: 6
Licensee: Vanderbilt University License No.: R-19021-H09
Inspection Type: Routine, Unannounced Priority: 3
Inspection Dates: 12/13-14/06 Inspectors: GK, RH, et al

Comments:
a) Management review of the inspector's observations and findings was not documented.
b) Inspection report was dispatched to the licensee 37 days after the inspection.

File No.: 7
Licensee: Memorial Health Care System License No.: R-33120-L15
Inspection Type: Initial, Unannounced Priority: 2
Inspection Date: 2/2/07 Inspector: SS

Comments:
a) Inspection report did not document scope of high dose-rate remote afterloader (HDR) program, inspector observations, independent surveys, or interviews with workers for new HDR license.
b) Management review of the inspector's observations and findings was not documented.

File No.: 8
Licensee: Cardinal Health 414, Inc. License No.: R-33111-I14
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 12/8/04 Inspectors: SS, JP

File No.: 9
Licensee: American Industrial Testing License No.: R-79210-L15
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 11/27/06 Inspectors: GS, SB

Comment:
Management review was conducted after the inspection report was dispatched to the licensee.

File No.: 10
Licensee: Radiosurgical Center of Memphis License No.: R-79245-G17
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/24/05 Inspectors: AG, BF

Comment:
Inspection report was dispatched to the licensee 49 days after the inspection.

File No.: 11
Licensee: University of Tennessee Memphis License No.: R-79019-J09
Inspection Type: Routine, Announced Priority: 3
Inspection Dates: 11/13-14/07 Inspector: LP

Comment:
Inspection report noted that the previous inspection was conducted on April 26, 2001; however, the review team found no documentation of this inspection. The last documented inspection was performed on January 30 and February 5-7, 1996.

File No.: 12
Licensee: Duratek Services, Inc. License No.: R-73006-F13
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 2/23-24, 3/1/06 Inspector: JT

Comment:
Inspection report was dispatched to the licensee 75 days after the inspection.

File No.: 13
Licensee: East Tennessee Ambulatory Services Center, LLC License No.: R-90047-A16
Inspection Type: Initial, Announced Priority: 2
Inspection Date: 12/1/06 Inspector: SH

Comment:
Inspection report was dispatched to the licensee 49 days after the inspection.

File No.: 14
Licensee: Ivy Cooper Services, LLC License No.: R-33145-G11
Inspection Type: Initial/Special, Announced Priority: 1
Inspection Date: 12/20/06 Inspector: SS

File No.: 15
Licensee: Baptist Hospital of East Tennessee License No.: R-47188-J14
Inspection Type: Initial/Special, Announced Priority: 2
Inspection Date: 11/2/06 Inspector: MA

Comment:
Inspection report was dispatched to the licensee 40 days after the inspection.

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: World Testing, Inc. License No.: R-95009-K16
Inspection Type: Routine/Special, Announced Priority: 1
Inspection Date: 4/8/08 Inspectors: GK, TB

Accompaniment No.: 2
Licensee: Regional Medical Center at Memphis License No.: R-79177-J16
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/9/08 Inspector: SB

Accompaniment No.: 3
Licensee: St. Mary's Jefferson Memorial Hospital
License No.: R-45008-C16
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 4/15/08
Inspector: MW

Accompaniment No.: 4
Licensee: Wellmont Health System
dba Bristol Regional Med. Ctr.
License No.: R-82009-J15
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Dates: 4/16-17/08
Inspector: SH

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Bristol Metals, LLC — License No.: R-82057-B14
Type of Action: New — Amendment No.: N/A
Date Issued: 2/20/04 — License Reviewer: RP

File No.: 2
Licensee: Eagle Testing Co. — License No.: R-33155-I14
Type of Action: New — Amendment No.: N/A
Date Issued: 9/14/04 — License Reviewer: RP

File No.: 3
Licensee: MedVet Memphis — License No.: R-79291-J15
Type of Action: New — Amendment No: N/A
Date Issued: 10/18/05 — License Reviewer: Not recorded

File No.: 4
Licensee: PSC Metals, Inc. — License No.: R-33163-J16
Type of Action: New — Amendment No: N/A
Date Issued: 10/16/06 — License Reviewer: RP

File No.: 5
Licensee: St. Francis Hospital — License No.: R-79104-I15
Type of Action: Amendment — Amendment No.: 117
Date Issued: 3/8/06 — License Reviewer: GB

Comment:

The license amendment authorized HDR for two authorized users, as requested. Based on the way the license was written, three additional physicians were inadvertently authorized for HDR. The Division is going to amend the license to accurately reflect each physician's authorizations.

File No.: 6
Licensee: St. Francis Hospital — License No.: R-79104-I15
Type of Action: Amendment — Amendment No.: 120
Date Issued: 6/26/07 — License Reviewer: SK

File No.: 7
Licensee: Copper Bain Medical Center — License No.: R-70002-L14
Type of Action: Amendment — Amendment No.: 3
Date Issued: 2/4/08 — License Reviewer: RP

File No.: 8
Licensee: Vanderbilt University — License No.: R-19021-I15
Type of Action: Renewal — Amendment No.: 116
Date Issued: 9/6/05 — License Reviewer: RP

File No.: 9
Licensee: Vanderbilt University — License No.: R-19021-I15
Type of Action: Amendment — Amendment No.: 122
Date Issued: 1/18/07 — License Reviewer: CA

File No.: 10
Licensee: Precision Nuclear, LLC — License No.: R-90046-K15
Type of Action: Amendment — Amendment No.: 3
Date Issued: 10/11/06 — License Reviewer: SK

File No.: 11
Licensee: Baptist Hospital of East Tennessee — License No.: R-47188-J14
Type of Action: New — Amendment No.: N/A
Date Issued: 10/11/04 — License Reviewer: RP

File No.: 12
Licensee: JANX Integrity Group — License No.: R-19219-H17
Type of Action: Renewal — Amendment No.: 9
Date Issued: 8/3/07 — License Reviewer: SK

File No.: 13
Licensee: Energy Solutions, LLC — License No.: R-01105-L07
Type of Action: Termination — Amendment No: 1
Date Issued: 12/20/07 — License Reviewer: CA

File No.: 14
Licensee: Environmental Dimensions, Inc. — License No.: R-01103-C17
Type of Action: New — Amendment No: N/A
Date Issued: 3/7/07 — License Reviewer: CA

File No.: 15
Licensee: RACE, LLC — License No.: R-79273-H16
Type of Action: Renewal — Amendment No: 51
Date Issued: 8/17/06 — License Reviewer: CA

File No.: 16
Licensee: Duratek Services, Inc. — License No.: R-73006-F13
Type of Action: Amendment — Amendment No: 112
Date Issued: 3/10/08 — License Reviewer: CA

File No.: 17
Licensee: TOXCO, Inc.
Type of Action: Renewal
Date Issued: 5/19/06
License No.: R-01037-E16
Amendment No: 164
License Reviewer: JG

File No.: 18
Licensee: The LPA Group Incorporated
Type of Action: Amendment
Date Issued: 3/17/08
License No.: R-15006-A18
Amendment No: 1
License Reviewer: RP

File No.: 19
Licensee: Cardinal Health 414, Inc.
Type of Action: Amendment
Date Issued: 1/18/08
License No.: R-19149-B15
Amendment No: 101
License Reviewer: RP

File No.: 20
Licensee: Regional Hospital of Jackson
Type of Action: Amendment
Date Issued: 5/17/04
License No.: R-57011-A09
Amendment No: 55
License Reviewer: RP

File No.: 21
Licensee: Rusty's Well Services, Inc.
Type of Action: Amendment
Date Issued: 9/29/05
License No.: R-18009-C07
Amendment No: 10
License Reviewer: GB

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Saint Francis Hospital — License No.: GL-337
Date of Incident: 3/25/04 — NMED Log No.: 040213
Investigation Date: 3/29/04 — Type of Incident: Medical Event
Type of Investigation: Site

File No.: 2
Licensee: Professional Service Industry (PSI) — License No.: R-19014
Date of Incident: 4/03/04 — NMED Log No.: 040636
Investigation Date: 4/05/04 — Type of Incident: Damaged Equipment
Type of Investigation: Site

File No.: 3
Licensee: American Tissue — License No.: GL
Date of Incident: 6/30/04 — NMED Log No.: 050252
Investigation Date: 6/30/04 — Type of Incident: Lost/Stolen material
Type of Investigation: Site

File No.: 4
Licensee: Scientific Inspection Technology, Inc. — License No.: R-33092
Date of Incident: 8/9/04 — NMED Log No.: None
Investigation Date: 8/10/04 — Type of Incident: Potential loss of control
Type of Investigation: Site

File No.: 5
Licensee: Cardinal Health — License No.: R-47080
Date of Incident: 12/2004 — NMED Log No.: 050585
Investigation Date: 2/15/05 — Type of Incident: Overexposure
Type of Investigation: Site

File No.: 6
Licensee: University of Tennessee — License No.: R-47005
Date of Incident: 2/14/05 — NMED Log No.: None
Investigation Date: 3/12/05 — Type of Incident: Lost/Stolen material
Type of Investigation: Telephone

File No.: 7
Licensee: FedEx (Non-licensee) — License No.: None
Date of Incident: 4/11/05 — NMED Log No.: None
Investigation Date: None — Type of Incident: Lost/Stolen material
Type of Investigation: None

File No.: 8
Licensee: S&ME.
Date of Incident: 6/24/05
Investigation Date: 6/24/05
License No.: R-05018-H05
NMED Log No.: 050653
Type of Incident: Loss of control
Type of Investigation: Site

File No.: 9
Licensee: Nucor Steel.
Date of Incident: 2/8/08
Investigation Date: 3/7/08
License No.: None
NMED Log No.: None
Type of Incident: Lose of control
Type of Investigation: Telephone

File No.: 10
Licensee: Duratek, Inc.
Date of Incident: 1/16/08
Investigation Date: 1/17/08
License No.: R73008
NMED Log No.: 080046
Type of Incident: Release of material
Type of Investigation: Telephone

APPENDIX F

SS&D CASEWORK REVIEWS

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

File No.: 1
Registration No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Applicant Name: Berthold Technologies, USA, LLC — Type of Action: Amendment
Date Issued: 2/25/05 — SS&D Reviewers: CA, JG

File No.: 2
Registration No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Applicant name: Berthold Technologies, USA, LLC — Type of Action: Amendment
Date Issued: 1/2/07 — SS&D Reviewers: CA, JG

Comment:
No checklist was used.

File No.: 3
Registration No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Applicant name: Berthold Technologies, USA, LLC — Type of Action: Amendment
Date Issued: 8/15/07 — SS&D Reviewers: GB, RP

File No.: 4
Registration No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Applicant name: Berthold Technologies, USA, LLC — Type of Action: Amendment
Date Issued: 10/22/07 — SS&D Reviewers: SK, CA

Comments:
a) For open shutter measurements – the dose rates were made of in-beam measurements instead of scatter measurements – applies to all prior registrations as well (see ANSI N43.8 and NUREG-1556, Volume 3).
b) Registration certificate did not indicate a transition date (and/or serial numbers) for design changes to describe older devices in use.
c) The environmental conditions not described in measurable terms.

File No.: 5
Registration No.: TN-1031-D-108-S SS&D Type: Gamma Gauge
Applicant name: Berthold Technologies, USA, LLC Type of Action: Amendment
Date Issued: 4/19/05 SS&D Reviewers: CA, JG

Comments:
a) Amendment added Cesium-137 radionuclide to device approved for Cobalt-60, but no dose profiles were obtained or added to device registration.
b) The one dose profile summary provided in registration is for 8 mCi of Cobalt-60 in one model size, but maximum loading limit for device is 300 mCi.
c) Registration certificate did not indicate a transition date (and/or serial numbers) for design changes to describe older devices in use.
d) The temperature and vibration limitations for device based on detector environmental limits when the detector is not an integral part of the device.

File No.: 6
Registration No.: TN-1031-D-108-S SS&D Type: Gamma Gauge
Applicant name: Berthold Technologies, USA, LLC Type of Action: Amendment
Date Issued: 7/10/06 SS&D Reviewers: RP, CA

Comments:
a) Registration certificate was not updated for the conditions of use, or to add Cs-137 dose profile.
b) No checklist was used.

File No.: 7
Registration No.: TN-237-S-103-S SS&D Type: Sealed Source
Applicant name: Siemens Medical Solutions, USA Type of Action: Amendment
Date Issued: 5/9/06 SS&D Reviewers: SK, RP

Comments:
a) Cover page principal use code was listed as “Instrument Calibration and Transmission Determinations,” the principal use code (from NUREG-1556, Volume 3, Appendix C) should have been “(X) Medical Reference Sources.”
b) The radiation profile using non-standard isodose lines was for a 1.5 mCi Ge/Ga-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.

File No.: 8
Registration No.: TN-237-S-104-S SS&D Type: Sealed Source
Applicant name: Siemens Medical Solutions, USA Type of Action: Amendment
Date Issued: 5/1/07 SS&D Reviewers: GB, RP

Comments:
a) Cover page principal use code was listed as “instrument calibration and transmission determinations;” the principal use code should have been “(X) Medical Reference Sources.”
b) Radiation profiles in Attachment 3 & 4 of registration were for a 3.38 mCi Ge-68 source, but the maximum loading was 10 mCi.

File No.: 9
Registration No.: TN-1031-D-118-S SS&D Type: Gamma Gauge
Applicant name: Berthold Technologies, USA, LLC Type of Action: New
Date Issued: 8/7/06 SS&D Reviewers: CA, JG

Comments:
a) Vibration and shock limitations are defined by the scintillation detector system, not the device. The detector system is not an integral part of the device.
b) The source is stated to be able to withstand the temperature limitations (up to 400 deg C) in the dip tube (dry well), but no temperature limits were defined for the device. The melting point of lead in the device is 327 deg C.
c) Environmental conditions of use and limitations were not described in measureable terms.

File No.: 10
Registration No.: TN-1067-D-104-S SS&D Type: Transmission Assembly
Applicant name: Siemens Medical Solutions, USA Type of Action: New
Date Issued: 10/19/06 SS&D Reviewers: SK, RP

Comments:
a) Cover page principal use code listed as “(B) Medical Radiography” which was discontinued in 2004, principal use code should have been “(X) Medical Reference Source.”
b) Labeling – when the sealed source is installed, the label must be transferred from the source pig to the device, a requirement of use not described in the registration certificate.
c) The label may not be able to withstand the normal conditions of use.
d) Under external radiation levels, the stated value for 100 cm in the closed position had the value for the maximum dose rate at the opening (transcription error).

File No.: 11
Registration No.: TN-1031-D-117-B SS&D Type: Moisture Gauge
Applicant name: Berthold Technologies, USA, LLC Type of Action: New
Date Issued: 4/28/05 SS&D Reviewers: CA, JG

Comments:
a) Cover page principal use code was "(D) Moisture Gauge" instead of "(H) General Neutron Source Application."
b) The maximum dose rate in the open shutter position, for both gamma and neutron, were for in-beam dose rates instead of scatter dose rates.

File No.: 12
Registration No.: TN-237-S-105-S SS&D Type: Line Source
Applicant name: Siemens Medical Solutions, USA Type of Action: Amendment
Date Issued: 5/10/06 SS&D Reviewers: SK, RP

Comments:
a) Cover page principal use code listed as "(B) Medical Radiography" which was discontinued in 2004; principal use code should have been "(X) Medical Reference Source."
b) Radiation profile dose rates were stated for 3.1 mCi and 4.02 mCi Ge-68 sources, but the maximum source activity is 30 mC.
c) Registration certificate did not indicate a transition date (and/or serial numbers) for design changes to describe older devices in use.

File No.: 13
Registration No.: TN-1067-D-101-S SS&D Type: Scanner Holder
Applicant name: Siemens Medical Solutions, USA Type of Action: Amendment
Date Issued: 5/25/2006 SS&D Reviewers: SK, RP

Comments:
a) Cover page principal use code listed as "(B) Medical Radiography" which was discontinued in 2004; principal use code should have been "(X) Medical Reference Source."
b) Radiation dose rate profile was for a 15 mCi Ge-68 source loading, but the maximum device loading activity is 30 mCi.
c) The FDA approval summary information was included in the file, but not identified in the device registration.

File No.: 14
Registration No.: TN-1031-D-104-B
Applicant name: Berthold Technologies, USA, LLC
Date Issued: 2/21/08
SS&D Type: Gamma Gauge
Type of Action: Amendment
SS&D Reviewers: RP, CA

Comments:

a) In the conditions of normal use and safety analysis sections, the environmental limitations were based on the detector limits, and not that of the device. The detector is not an integral part of the device.

b) The prototype testing stated that the device was subjected to a vibration test of 50 Hz for 90 minutes, but did not indicate the corresponding amplitude (displacement) of the vibration.

ATTACHMENT

June 25, 2008, Letter from Lawrence E. Nanney
Tennessee's Response to Draft IMPEP Report

ADAMS Accession No.: ML081830728

STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION

DIVISION OF RADIOLOGICAL HEALTH
L & C Annex, 3rd Floor
401 Church Street
Nashville, TN 37243-1532
Phone: 615-532-0360, Fax: 615-532-7938, E-mail: Eddie.Nanney@state.tn.us

June 25, 2008

Mr. Richard Blanton
Health Physicist
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Dear Mr. Blanton:

I am responding to your letter dated May 29, 2008, to Mr. Paul Sloan. We have reviewed the draft IMPEP report, which documents the preliminary findings of the review team. Attached, please find our comments and suggestions regarding certain aspects of the draft report. We appreciate the opportunity to clarify these points.

We also appreciate, very much, the professionalism and courtesy demonstrated throughout the week by you and your review team. It was a pleasure working with you, and with the NRC management representatives, as well, who participated in the latter stages of the review and the closeout meeting on April 25, 2008.

Sincerely,

Lawrence E. Nanney
Director
Division of Radiological Health

cc: Mr. Paul Sloan, Deputy Commissioner, TDEC

Attachments

ATTACHMENT

3.1 Technical Staffing and Training

Page 4. P.1. L 4 — Remove the phrase "... and SS&D programs, ..." During this review period, the Licensing section did not experience any staff turnover nor were there any vacant positions in the section.

Page 4. P.1. L 6 — Remove the phrase "...and weaknesses in the preparation of SS&D certificates" for the same reason as cited above.

Page 5. P.2. L 2 — Sentence should end after "sciences". We do not accept equivalent training and experience in lieu of a Bachelor's degree in the sciences.

Page 5. P.3. L 2 — Insert "and x-ray registrant fees" after the words "licensee fees".

4.1.2 Program Elements Required for Compatibility

Page 12, P.2, bullet 4 — "National Source Tracking System – Sterilization Requirements" is not applicable in Tennessee. The NRC has already recorded this as not applicable on our SRS data sheet.

Page 13, Bullet 5 — "Security Requirements for Portable Gauges..." needs to be removed from the list. The Division sent the portable gauge license condition to the NRC for review and it was accepted with no comments on 5/13/08. The NRC has recorded this on our SRS data sheet.

Page 14, P 1, L 2 — The remainder of the paragraph following the first use of the word "condition" should be deleted. As noted above, on 5/13/08, the NRC accepted the portable license condition without comment. The NRC has recorded this on our SRS data sheet.

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

4.2.1 Technical Staffing and Training

Page 15, P 1, L3 — The individual referenced has not completed a review of a new application for a sealed source in collaboration with a senior reviewer.

Appendix C, Inspection Casework Reviews

File No. 10 "Management review was conducted after the inspection report was dispatched to the licensee." Documentation in the Field Office file indicates the inspection letter was dated 3/21/05, management approval was received 4/13/05 and the letter was mailed 4/14/05.

File No. 12 "Management review was conducted after the inspection report was dispatched to the licensee." Documentation in the Field Office file indicates the inspection letter was dated 3/17/06, management approval was received 5/12/06, and the letter mailed on 5/15/06.

File No. 13 "Management review was conducted after the inspection report was dispatched to the licensee." Documentation in the Field Office file indicates the inspection letter was dated 12/15/06, management approval was received 1/18/07, and the letter mailed on 1/19/07.

File No. 15 "Management review was conducted after the inspection report was dispatched to the licensee." Documentation in the Field Office file indicates the inspection letter was dated 12/11/06, management approval was received 12/12/06, and the letter mailed on 12/12/06.

Note: License No. listed on the report is incorrect. The number is R-47188-J14.

Appendix D, License Casework Reviews

File No. 6 The Division has updated this license to further restrict physician use of Y-90 Sirspheres, but has decided to continue this authorization for the physicians which we had previously approved for this use regardless of case number. This authorization was made before the advent of NRC's three cases for approval. We have begun to use the three case criteria for Y-90 for new applicants.

Appendix F, SS&D Casework Reviews

File No. 1 a) We do not understand why the vibration limits listed in the Prototype Testing section of the registration are not considered to be measurable items. (See attachment related to TN-1031-D-101-B dated February 25, 2005.)

b) We do not consider a check list necessary for every amendment to a registration. A check list was not used in this case since the focus of the amendment was an issue related to an incident.

File No. 6 — The registration date is July 10, 2006.

File No. 7 — The registration date is May 9, 2006.

c) The leak test frequency justification accepted was found in the application file which was in a folder separate from the registration. Appropriate page 8 is attached.

d) The working life declaration was found as above.

File No. 8 — a) Principle use code was "instrument calibration and transmission determinations." "Cylinder Source" was device type.

c) Although no leak test frequency justification was made, we accepted the one year frequency as part of the application submitted in 1991 for this NARM registration.

File No. 11 — b) We accepted their 3 year leak test proposal submitted as Item 23 in their answer to our deficiency letter. Appropriate page attached.

File No. 12 — The only request in this amended registration was a name change for the manufacturer/distributor.

b) and c) These criteria were established in 2001 for this NARM registration.

File No. 13 — c) See item 7 c).

DEVICE TYPE: Gamma Gauge for Density and Fill Level Measurement

LABELING: (Continued)

belt or microwave instruments. All metal labels are made of stainless steel. Other labels may be made of mylar, PVC-Polymer, or coated polyester film. Metal labels are riveted in place, and the other labels are secured in place by adhesive.

DIAGRAMS:

See Attachments 1, 2, and 3.

CONDITIONS OF NORMAL USE:

The scintillation counter is the limiting factor with respect to temperature. The specified operating range is -4 degrees F to 122 degrees F (-20 degrees C to 50 degrees C). All the devices have been evaluated for this temperature range.

PROTOTYPE TESTING:

The LB 7400 Series of devices has been in use in the USA since 1985. The manufacturer conducted tests of the device design in August 1996. These tests were conducted with devices that are not part of this registry, but are similar in design. They are Models LB 7445 DE and LB 7446 DE. The tests consisted of endurance (15,000 shutter operations), operating temperature (-20 degrees C to 200 degrees C), vibration (50 Hz for 90 minutes), thermal (800 degrees C), and free fall (9 meters, 27 feet). Test results appear to indicate that the integrity of the devices was maintained. It is stated that no design changes were made as a result of the tests.

Models LB 7440 CR, 7442 CR, and 7444 CR were tested for vibration at an acceleration of 1.5 g in 3 principal axes for approximately 1.5 hours in each axis. The frequency ranged from 5 to 200 Hertz at a sweep rate of 4 Hz per minute. Single amplitude ranged from 12.5 mm at 5 Hz to 0.0093 mm at 200 Hz. No evidence of damage to the device was seen. The only result of the vibration was a loosening of the transport screw that did not have its usual wire seal to secure it.

The Amersham/**AEA Technology/QSA, Inc.** Model CDC.P4, CKC.P4, and CDC.93 sources have received ANSI N542-1977 classifications of C66646, C66646, and C64545 respectively.

DEVICE TYPE: Gamma Gauge for Density and Fill Level Measurement

LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

Conveyor bell applications are limited to the use of 30 mCi (1.11Gbq) of Cs-137 maximum. In addition, conveyor belts are fitted with metal barriers to prevent access to the beam.

The devices may be locked in the open position. General licensees are provided instructions to not lock the device in the open position. Specific licensees should have in place appropriate procedures which will ensure the devices will not be locked in the open position.

Devices may be installed, relocated, maintained, or repaired by the distributor, or other persons authorized in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State to perform these services. Devices may be mounted by both specific and general licensees in accordance with guidance provided by Berthold Technologies U.S.A., LLC. The device must remain in the sealed and locked closed condition at all times during the mounting process and may only be unlocked prior to commissioning in the presence of the distributor or other persons specifically licensed for device installation.

The handling, storage, use, transfer, or disposal of devices used under a specific license shall be determined by the licensing authority. Devices used under the general license shall be governed by the requirements of "SRPAR" 1200-2-10-.10 or equivalent regulations of the U.S. NRC or an Agreement State. **CR versions of the device should not be installed in vibration environments where acceleration, frequency, and single amplitude exceed the values referenced in the PROTOTYPE TESTING section of this registration. For a continuous vibration environment, the registrant could not apply the above tests or confirm that these test results would guarantee a certain life span of the device. They did state that the tests were valid for comparison to a severe vibration environment, and that the test parameters far exceed those encountered in most installations. They stated that no failure of the device due to vibration had been noted except for the single welded shutter CR version. These have now been fully replaced with the double welded CR version.**

Installation, replacement, removal from service and disposal of sealed sources containing radioactive material used in devices shall be performed only by the device manufacturer, or other persons authorized in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement state to perform these services. Sources for disposal shall be shipped directly to the manufacturer in Germany, or to other persons authorized in a specific license issued by the U.S. Nuclear Regulatory Agency or an Agreement State to receive and

- Clean-up

At the end of the operation or shift, reusable items are cleaned as needed and stored in the fume hood. Protective clothing is checked for contamination and stored for reuse if appropriate. Waste items are collected in suitable containers and stored for later disposal.

As already mentioned, just prior to distribution each source is leak tested and a leak-test certificate prepared (see Appendix D). A copy of the certificate goes with the source and a copy is retained. Sources will be distributed only to recipients authorized by the appropriate regulatory authority to receive such sources. A file will be maintained of all authorized recipients and the sources they have received.

A full quality assurance program has been implemented as recommended in ANSI N542. Appendix B, and as per NARM 10F.

3.2 Installation, Removal, and Service of Sources

Normally more than one line source will be used at each client site. Authority is needed to allow CSI to install the line sources in the calibration device. Line sources do not require installation per se, but CTI Services personnel may be asked to demonstrate its use to the client and check out the system operation. Also, during equipment servicing, the sources will be inspected and repositioned if out of alignment.

3.3 Leak Testing of Sources

This subsection has two purposes: to request approval for annual leak testing of the model LS sources and to request authority to perform source leak tests.

Because of the 287-day half-life of the Ge-68 in the Model LS sources, their useful life is about 1 year. Consequently, these sources are normally replaced every year and the old source disposed as radioactive waste. Furthermore, the ceramic matrix prevents leakage from the outer containment in the traditional sense. Even with substantial damage to the model LS source containers, there is often no loss of radioactive material. If there is a loss of material, it is in the form of a dry, visible granular material that can be removed very easily. Finally, these sources are used under relatively stress-free non-industrial conditions that reduce the likelihood of damage. Therefore, CSI requests authority to specify annual leak testing of these sources. With annual leak testing, all sources will be tested prior to distribution and most will be disposed at the end of one year without further testing. If a source is used for greater than 1 year, it will be leak tested at the end of one year. Any source used after one year will be leak tested every 6 months.

Prior to shipping sources to clients, CSI is required to leak test and certify each source. During field servicing, some clients may request a leak test or the service engineer may have a concern that a leak test could confirm or relieve. Therefore, CSI requests authority to leak test all sources before shipment - see Appendix D for an example leak test certificate - and to provide client site leak tests. Leak test samples will not be mailed back or, otherwise, returned to CSI for analysis. Leak tests will be done by wiping the source with a damp filter disk or swab and counting the sample in a reproducible calibrated geometry with a beta-gamma sensitive instrument such as a "pancake" probe and suitable counter. A sensitivity of at least 0.005 μCi will be obtained and detected activities exceeding 0.005 μCi will be reported. Activities below 0.005 μCi will be reported as <0.005 μCi. The counting instrument will be fully calibrated at least annually (within 13 months) and source checked at least once during each day used. All leak test samples with detectable activity will be disposed as radioactive waste.

3.4 Repair of Sources

During installation or other client site service, CSI may encounter sources with minor damage that can be easily repaired without compromising radiation safety or source quality. Such repair activities may also occur at CSI. All such activities will be done with appropriate contamination controls and exposure

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ITEM 20 Setting up the LB 7410 for measurement is done in the same fashion as our other measurement systems. A count rate from the device detectors is read into a separate evaluation unit. Comparisons between the count rates and actual lab values are used do develop the slope factor (sensitivity) for the measurement. This is what we typically call device calibration. This is usually done in a separate area away from device itself. This calibration procedure can be performed by the customer or by the manufacturer when training the end user. There are no other calibrations necessary that would involve dismantling the device to make any adjustments to it. If it is suspected that the electronics within the device itself are not performing properly, the device would then need to be removed by a properly licensed person and returned to the manufacturer for diagnosis.

ITEM 21 Berthold Technologies U.S.A., LLC will provide device training for any of our customers who request training. If the end user is a General Licensee, Berthold Technologies is required to provide device operation training and radiation training as it applies to our devices at the customer site, before the system can be put into use. If the end user is a specific licensee, the obligations under their own operating license with their governing body would dictate whether Berthold Technologies would be required to provide specific device training. A copy of our General Licensee training manual and the specific device instructions contained in the LB 7410 operations manual have been included with this correspondence.

ITEM 22 All Berthold Technologies products associated with a device registration are shipped to our location in Oak Ridge for inspection before distribution to the end user. The procedure for the inspection has been previously submitted to the Department. No registered devices are dropped shipped by the manufacturer to the end user.

ITEM 23 The primary containment of the Am-241/Be source pellets is inside a double encapsulated stainless steel shell. Each encapsulation is welded closed to isolate the source material from the outside environment. The source capsule is housed in the stainless steel source holder (drawing 36746) inside the LB 7410. The source support disc (drawing 37569) and a spring ring keep the source capsule inside the source holder. The LB 7410 is composed of a stainless steel outer shell. Most of the components inside the outer shell are constructed of polyethylene for shielding purposes. The Am-241/Be source material is composed of the AM-241 being mixed with beryllium powders and the mixture then being pressed into pellets. The LB 7410 was not tested to a maximum temperature during prototype testing. In the event of high temperatures associated with a fire melting the polyethylene, the stainless steel outer shell would contain the source holder keeping the source capsule from reaching the outside environment. The maximum pressures that the LB 7410 was tested to would be the pressure test associated with the type A tests that were performed on the device. The maximum quantity of the source material for the LB 7410 is 300 millicuries. The radiotoxicity group for the source is listed to be A in the manufacturers registration. None of the LB 7410 devices currently in use have experienced any problems because of an extended leak test interval. The proposed source capsule to be used for the LB 7410 is the same as the source capsule used on our Sulfur Analyzer, TN-1031-D-111-B. The method of containment of the source is similar in the LB 375 Sulfur Analyzer. The leak test interval for the LB 375 is three years and we have no knowledge of any problems associated with an extended leak test interval on that device.