June 9, 2004

Ms. Karen Stachowski
Deputy Commissioner of Environment
Tennessee Department of Environment and Conservation
401 Church Street, 21st Floor, L&C Tower
Nashville, TN 37243-0435

Dear Ms. Stachowski:

On May 13, 2004, 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 program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's program. The MRB also directed that the increased monitoring of the Tennessee program be terminated.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendation for the State of Tennessee. We request your evaluation and response to recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Radiation Control Program and the excellence in program administration demonstrated by your staff, as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

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

Enclosure:
As stated

cc: Lawrence E. Nanney, Director
Division of Radiological Health

Robert Greger, CA
OAS Liaison to the MRB

bcc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield

Distribution: DCD (SP01) PDR (YES√)

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF TENNESSEE AGREEMENT STATE PROGRAM

February 23-26, 2004

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Tennessee radiation control program. The review was conducted during the period of February 23-26, 2004, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Maine. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period August 26, 2000 to February 26, 2004 for the indicators Staffing and Training, Technical Quality of Licensing, and Sealed Source and Device Evaluation Program and the period October 26, 2001 to February 26, 2004 for the other performance indicators were discussed with Tennessee management on February 26, 2004.

A draft of this report was issued to Tennessee for factual comment on March 25, 2004. The State responded by letter dated April 12, 2004. The Management Review Board (MRB) met on May 13, 2004 to consider the proposed final report. The MRB found the Tennessee radiation control program adequate to protect public health and safety and compatible with NRC's program.

The Tennessee Agreement State program is located in the Department of Environment and Conservation (the Department). The Department is divided into three program areas, State Parks and Conservation, Finance and Business Services, and Environment. The Division of Radiological Health (the Division) is located under the Deputy Commissioner for Environment who in turns reports to the Department Commissioner. The Division consists of the Office of the Director and four sections: Administrative Services, Licensing/Registration/Policy, Technical Services, and Inspections and Enforcement (I&E). Each section in the Division is headed by a Manager who reports to the Division's Deputy Director and Director.

Organization charts for the Department and the Division are included as Appendix B. The Tennessee program regulates approximately 550 specific licenses authorizing agreement materials. 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 State on November 25, 2003. The Division provided a response to the questionnaire on February 13, 2004. A copy of the questionnaire response can be found on NRC's Agency-wide Document Access and Management System using the Accession Number ML040620709.

The review team's general approach for conduct of this review consisted of: (1) examination of Tennessee's responses to the questionnaire; (2) review of applicable Tennessee statutes and regulations; (3) analysis of quantitative information from the Division's licensing and inspection data base; (4) technical evaluation of selected licensing and inspection actions; (5) field accompaniments of six Tennessee inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-

common performance indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review and the team's conclusions regarding close out of the recommendations. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the Division. A response is requested from the Division to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on August 25, 2000, ten recommendations were made and transmitted to John M. Leonard, Assistant Commissioner for Environment, on November 17, 2000. Additionally, during a follow-up IMPEP review which concluded on October 26, 2001, one additional recommendation was made and eight recommendations were closed (Numbers 2, 4 through 10 from the 2000 report). The final follow-up report was transmitted to Mr. Leonard on February 5, 2002. The team's review of the current status of all open recommendations follows:

Open recommendations from the 2000 IMPEP Review report:

Recommendation 1

> The review team recommends that the Division take actions to ensure that: (1) inspections are conducted in accordance with their assigned inspection frequencies; and (2) inspection reports are issued in a timely manner. (Section 3.1 of the 2000 report and Section 2.1 of the 2001 report)
>
> Current Status: The Division has taken actions to ensure that inspections are conducted in accordance with their assigned inspection frequencies. At the time of the review, there were no overdue inspections. With the exception of five reports issued by one inspector, all inspection reports are issued in a timely manner. Division management has committed to correct this weakness. See Section 3.2 for further discussion. This recommendation is closed.

Recommendation 3 (revised in 2001)

> The review team recommends that the Division ensure that inspection findings are fully supported in documentation of the inspection and that cited violations are fully supported in the inspection report. The review team also recommends that in order to enhance both the quality and documentation of inspections, the Division establish and implement additional guidance for ensuring consistent, appropriate, and prompt regulatory actions including incorporating root cause identification, especially of repeat violations. (Section 3.2 of the 2000 report and Section 2.2 of the 2001 report)

Current Status: The team reviewed the Division's inspection findings and determined that conclusions and violations were appropriately supported. The team observed during inspector accompaniments and noted during the review of inspection documentation that consistent, appropriate, and prompt regulatory actions were taken. The team also noted that inspections conducted by the Division incorporated root cause identification and addressed repeated violations. This recommendation is closed.

Open Recommendation from the 2001 follow-up IMPEP Review report

Follow-up Recommendation 1

The review team recommends that the Division establish a management plan for the development, tracking, and adoption of regulations in a timely manner, and to adopt the current regulations needed for adequacy and compatibility in accordance with the Office of State and Tribal Programs (STP) Procedure SA-201, "Review of State Regulations or Other Generic Legally Binding Requirements." (Section 3.1.2 of 2001 the report)

Current Status: The staff responsible for regulation development prepares a report for the Deputy Director on developing, tracking, and adopting regulations. The last two regulation review packages submitted by the Division to NRC for review have followed the guidance provided in STP Procedure SA-201, "Review of State Regulations or Other Generic Legally Binding Requirements." As noted in Section 4.1.2, when the five amendments reviewed by NRC in December 2003, and the three submitted for NRC's review on February 13, 2004 are adopted, Tennessee will have all necessary regulations adopted for adequacy and compatibility. In addition, the Division will have one regulation adopted before its due date. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

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, interviewed Division management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Division devotes a total of 19.5 full time equivalents (FTE) to the radioactive materials program, including administration but excluding clerical support. A total of 12.2 FTE is allotted to I&E and Technical Services Sections for radioactive materials compliance and emergency response programs. Inspection staff members are based out of four regional field offices in Nashville, Chattanooga, Memphis, and Knoxville. Inspection staff members also perform other duties including x-ray and other inspections for which the Division is responsible. Radioactive materials licensing and the sealed source and device evaluation programs have been allotted

5.6 FTE and are performed by the Licensing/Registration/Policy Section in the Nashville central office. The remaining FTE is allotted for administration and policy/regulatory guidance distributed between the Director's office and the Technical Services Section.

Eleven staff members left the Division during the review period and seventeen staff members were hired during the same period. Five of the individuals hired had previously worked for the Division. This turnover is approximately one-half of the staff turnover during the previous IMPEP review period (1996-2000). The Division currently has five vacant positions representing 2.5 FTE. Two of these positions were recently vacated when staff members were promoted into higher positions. The Division filled the vacant I&E Manager position by promotion in October 2003. Division management indicated that low initial salary for new hires make it very difficult to attract and retain qualified individuals. Important factors in the Division's ability to retain staff are economic conditions and the availability of other job opportunities. Based on the Division's overall performance, the review team concluded that staffing is adequate for the radioactive materials program.

Division management indicated that approximately 91.5 percent of the Division's funding is dedicated revenue from licensee fees with the balance from the State's general funds. In 2001, the Division increased fees to materials licensees by approximately 50 percent.

The qualifications of the staff were determined from the questionnaire, training records, and interviews of personnel. The Division has a documented training program which specifies minimum training requirements as well as supervisory sign off on the completion of training. The staff is well qualified from an education and experience standpoint. All staff have at least a Bachelor's degree in the sciences, or equivalent training and experience. All experienced technical staff members have taken the NRC courses deemed appropriate for their tasks. Division management indicated that training of new staff may be delayed due to current restrictions on out-of-state travel. In response to the out-of-state travel restrictions, the Division conducted an alternative training course to meet the medical core course requirement for inspectors and also sponsored the NRC's "Inspecting for Performance" course at an instate location. In the long term, both the review team and the Division believe that the lack of access to out-of-state training may degrade the technical quality of the program. The use of on-the-job training has also been used to supplement formal course work so that individuals may broaden their work experience.

In general, inspection staff members become qualified to complete x-ray tasks and are then trained to perform radioactive materials tasks, starting with the most simple and working towards the more complex. It is the goal of the I&E Manager to cross train most staff at all Regional Offices to conduct x-ray and materials inspections of the most common groups of licensees and registrants.

Tennessee does not have a radiation oversight board. No evidence of any conflict of interest issues was identified.

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.

3.2 Status of Materials Inspection Program

The team focused on five factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licensees, the timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The evaluation is based on the Division's questionnaire response relative to this indicator, data gathered independently from the Division's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

A review of the Division's inspection priorities revealed that the inspection frequencies for various types of licenses are at least as frequent as similar license types listed in the November 25, 2003 revision to NRC Inspection Manual Chapter (IMC) 2800. The Division has a goal to inspect waste processing, complex industrial, and manufacturing licensees once every six months, a greater frequency than listed in IMC 2800. The Division does not extend or compress inspection frequencies based on compliance history.

The Division normally inspects new licensees in accordance with guidance in the previous IMC 2800; within six months of receipt of radioactive material, but no later than one year after issuance of the license. Current NRC guidance in the revised IMC 2800 is to perform initial inspections within one year of license issuance. The Division intends to use the six month frequency as a goal, but plans to eventually adopt the new frequency.

In response to the questionnaire, the Division indicated that no core inspections were currently overdue by more than 25 percent of the NRC frequency. The team reviewed lists of information for all inspections conducted and all new licenses issued during the period and verified this information. The Division conducted 214 core inspections and 52 initial inspections in eliminating the inspection backlog identified since the 2001 follow-up review. Overall, only 10 routine core and initial inspections were conducted overdue since the 2001 follow-up review. Given the status of 28 percent overdue inspections conducted overdue or still overdue at the time of the follow-up review, the Division's efforts to address and correct this weakness are commendable.

The review team evaluated the timeliness of the communication of inspection results to the licensees by reviewing inspection data and files for 30 inspections throughout the Division's four regional inspection offices. For three of the offices, the random sampling indicated that results were communicated within 30 days after the date of the inspection, with one exception for a complex team inspection with multiple violations issued 3 months late. In one regional office, however, the reports of a single inspector were not issued within 30 days after the date of the inspection. The review team evaluated eight out of nine inspections conducted by this individual since the follow-up review. For five of these inspections, inspection results were communicated to the licensee two months to two years after the inspection was conducted. For the remaining three inspections evaluated by the review team, inspection findings had not been issued at the time of the review, including one inspection that was conducted approximately 3 years ago. The review team examined the timeliness for the remaining inspectors and identified no additional performance issues with the issuance of inspection findings for that region. The review team also noted that this region was identified during the 2000 review and 2001 follow-up review as having difficulty meeting the 30-day goal for issuance of inspection results.

The review team discussed this weakness with the I&E Manager and the Deputy Director and determined that this individual inspector had been assigned a significant number of inspections

to perform and had responded to several incidents. The individual accomplished the field work in a timely manner at the expense of the timely completion of the inspection documentation. The I&E Manager has committed to reinspect those licensees where the findings have not been issued and are significantly late. Tennessee management has committed to work with this specific inspector to assist with identification and elimination of the backlog of inspection documentation. With strong management commitment by the Division to address this area, the improved performance of the Division for this indicator since 2000 and the large majority of the inspection findings communicated to licensees in a timely fashion, the review team does not believe that a recommendation is warranted at this time.

The review team determined that the Division granted 21 core reciprocity licenses during the review period. The Division satisfied the 20 percent criteria prescribed in NRC IMC 1220 by conducting 10 inspections of core reciprocity licensees during the review period. In addition, the Division inspected 28 percent of non-core reciprocity licensees during the review period.

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 the Materials Inspection Program, was satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for a total of 23 radioactive materials inspections. The casework examined included inspections conducted by 16 current inspectors. The review team examined core inspections of various types including manufacturing and distribution, broad medical, medical private practice, medical - written directive required, medical - written directive not required, well logging and subsurface tracers, industrial radiography, service and maintenance, and nuclear pharmacy. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on casework reviewed, the review team noted that routine inspections covered all aspects of the licensee's radiation programs. The Division has revised its inspection field note forms and each Region is starting to utilize these during inspections. The review team found that inspection reports were generally thorough, complete, consistent, and of good quality, with sufficient documentation to ensure that the licensee's performance with respect to health and safety was acceptable. The inspection documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. The review team noted that some files did not contain an inspection report. This matter is discussed in detail in Section 3.2.

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 outlined in NRC's IMC 2800. Inspection reports cover all appropriate areas for each inspection type and addressed all relevant health and safety elements. The reports contain the inspector's narrative of what was observed and reviewed during the inspection. Inspection reports are reviewed by the Field Office Manager, generally within one week after the completion of the inspection. If no violations were observed, inspection results are generally sent to the licensee within two weeks of the completion of the inspection. If any violations were observed, a draft notice of noncompliance (NON) is prepared by the inspector.

All inspection correspondence is issued from the respective field office where the inspection was performed. For inspections conducted by Field Office Managers and any inspection involving a facility that has financial assurance for decommissioning, the I&E Manager will perform the second review on the inspection documentation and correspondence.

During the review period, supervisory accompaniments were conducted for all non-supervisory inspectors on an annual basis. The team found, however, that not all supervisory inspectors who routinely conduct inspections were accompanied. The I&E Manager has developed a plan to ensure that all personnel, particularly the field office managers, are accompanied annually. The Division expects to accompany all supervisory inspectors by the end of 2004. In addition, to improve the quality and efficiency of the inspection process and the overall communication among the Regional Offices, the I&E Manager has been holding monthly teleconferences with the Regional Field Office Managers to review inspection and enforcement issues.

The review team accompanied six Division inspectors from all four Regional offices during the week of November 17, 2003 during inspections of a medical institution licensed for diagnostic nuclear medicine, a nuclear pharmacy, and a sealed source manufacturer and distributor, as well as industrial radiography facilities. The accompaniments are identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate inspection techniques, as well as knowledge of the regulations and the specific license requirements for each licensee being inspected. The inspectors were well prepared and thorough in their review of the licensee's radiation safety programs. The inspections were adequate to assess radiological health and safety at the licensed facilities.

The Division has an adequate supply of survey instruments to support the current inspection program, as well as responding to incidents and emergency conditions. The Division has commercial contractors who calibrate their survey instruments on an annual basis. Appropriate calibrated survey instruments such as GM meters, scintillation detectors, ion chambers, and micro-R meters were observed to be available. Media samples collected by Division staff are analyzed by the radiochemistry laboratory in the Department of Public Health's Division of Laboratory Services located in Nashville. The laboratory is capable of a number of analyses including gamma spectroscopy, liquid scintillation, and low background gross alpha and beta counting.

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 20 materials licensing actions representing the work of five 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 and its 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 actions reviewed included the following types of licensees: industrial radiography, radioactive waste processing, broad scope research and development, medical institution - written directive required, contaminated metals processing, medical private practice, nuclear pharmacy, leak test service, and sealed source manufacturer. Licensing actions included two new, three renewals (including associated decommissioning financial assurance), one termination, and 14 amendments. A listing of the casework licenses evaluated with case-specific comments is enclosed in Appendix D.

All license reviewers have signature authority and sign their own licensing actions. The licensing staff generated licenses and correspondence with standardized conditions and formats. The Division issues licenses for a ten-year period under a timely renewal system. The review team noted that the licensing staff used the computer database effectively and efficiently to obtain needed information for completing licensing actions. Due to their prompt assignment, review, and resolution of incoming licensing requests, the licensing staff has effectively managed their casework.

The review team found that the licensing actions were thorough, complete, timely, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the license or sealed source and device registry files and are inspectable. Deficiency letters state regulatory positions, are used at the proper time, and identify deficiencies in the licensee's documents. Terminated licensing actions are well documented, showing appropriate transfer and survey records. The licensee's compliance history was taken into account during the review process and the review team found that there was good two-way communication between the licensing and inspection staffs regarding pertinent licensee information.

For each licensing action, licensing staff used the Division's licensing guides and completed a checklist specific to the type of license. Since the last review in 2000, the Division revised a number of their licensing guides and updated license conditions and specific licensing operating procedures. The team reviewed the Division's recently revised Medical and Industrial Radiography License Application Guides and found these documents were complete, well organized, available to licensing staff and are used.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Division's actions in responding to incidents, the review team examined the Division's response to the questionnaire relative to this indicator, reviewed the incidents reported for Tennessee in the Nuclear Material Events Database (NMED) against those contained in the Division's files, and evaluated the casework and supporting documentation for 12 materials incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the Division's

response to 12 allegations involving radioactive materials. Four allegations were referred to the Division by the NRC during the review period.

The incidents selected for review included the following event categories: contamination event, fire, damage to equipment, equipment failure, transportation, release of radioactive material, leaking source, and stolen radioactive material. The review team found that the Division's responses to incidents were complete and comprehensive. Initial responses were prompt and well-coordinated and the level of effort was commensurate with the health and safety significance of the event. The Division dispatched inspectors for on-site investigations when appropriate and took suitable enforcement and follow-up actions when indicated.

The responsibility for initial response and follow-up actions to materials incidents are assigned to the appropriate Regional office. A majority of incident notifications are received at the Regional offices, but all notifications are logged in and assigned a tracking number by the Division Director's office. For most incidents, the staff in the Regional offices decides on the appropriate response. For significant events, the Regional office will consult with Division management prior to taking action. The Regional office conducts the investigation of the incident and prepares appropriate documentation. The completed documentation is forwarded to the Deputy Director for final review and documentation including the entering of pertinent information into NMED.

The Division follows the NRC's "Handbook on Nuclear Material Event Reporting in the Agreement States" for the reporting requirements of incidents. Prior to the on-site review, the review team identified 39 reportable and 80 other incidents in NMED for Tennessee during the review period. Reports and follow-up information are generally submitted electronically monthly using the NMED software by the Deputy Director. Documentation for individual events are maintained in the incident files and include a tracking form, documentation on the Division's response to the incident, documentation if the event was entered into the local NMED database, and any follow-up correspondence with the NMED contractor. When the Division's local NMED events were compared to those events in the national database, the team noted that two reportable events were in the local database but not in the national database. The Division believed that the files for these two events were transferred to the NRC contractor along with other events that were incorporated into the national database. The NRC contractor could not locate these two events in the database or the transfer files.
Subsequently, the Division submitted the information for the two events to the NMED contractor.

In evaluating the effectiveness of Tennessee's actions responding to allegations, the review team examined the Division's questionnaire responses relative to this indicator and the Division's allegation procedure. The casework for 12 allegations were reviewed. During the review period, four allegations were referred to the State by the NRC and 14 were reported directly to the State. The Division evaluates each allegation and determines the proper level of response. The review of the casework and the files indicated that the Division took prompt and appropriate action in response to the concerns raised. Each of the allegations reviewed were appropriately closed, and the allegers were informed of the results when possible. There were no performance issues identified from the review of the casework documentation.

All communication with the Division is considered public record under Tennessee's Open Records Law. Any alleger requesting anonymity is informed that every effort will be made to

protect their identity, but it cannot be guaranteed. All investigations involving potential criminal activity are immediately brought to the attention of the Division's senior management for a determination if the case should be forwarded to the I&E Division for action.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Tennessee's performance with respect to the indicator, Response to Incidents and Allegations, was satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

Along with their response to the questionnaire, the Division provided the review team with the opportunity to review copies of legislation that affects the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in Title 68, Chapter 202-101 through 202-704 of the Tennessee Code Annotated. The Division is designated as the State's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed since being found adequate during the previous review, and found that the State legislation is adequate.

4.1.2 Program Elements Required for Compatibility

The Tennessee radiation control program's regulations 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 agreement materials, machine produced radiation, and accelerators. Tennessee requires a license for possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the 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. Tennessee has different 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 the Rulemaking Hearing Rules procedures, all 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 two-week period following the hearing. Any changes are made to the rules as needed and 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 after a waiting period of 75 days. After the rule becomes effective, representatives of the Division and the OGC are scheduled to appear before the Government Operations Committee of the legislature for the Committee's approval. Rules adopted during the year are subject to sunset on June 30 of the following calendar year, unless approved by the legislature.

In response to a telephone inquiry from a legal firm after the on-site review, STP identified that Tennessee's equivalent to 10 CFR Part 20.2003, "Disposal by Release into Sanitary Sewerage," a Category A compatibility requirement, is more restrictive. STP subsequently reviewed the Tennessee rule and sent comments to the Division in a letter dated April 12, 2004. During the MRB meeting held on May 13, 2004, the review team discussed with the MRB and Division staff that this regulation had originally been adopted prior to the 1991 revision to Part 20. Review of NRC files indicated that NRC corresponded with Tennessee on December 18, 1997 and again on December 23, 1998 in response to Tennessee's February 6, 1998 letter on the compatibility of this regulation. However, the 2000 IMPEP review team and the 2001 follow-up review team did not identify this inconsistency. The current review team also did not identify this inconsistency and did not discuss this issue during the on-site review, nor in the draft or proposed final reports. Shortly before the May 13, 2004 MRB meeting, the review team informed the Division of their intention of discussing this issue during the meeting. During the discussion, the Division Director indicated that the State disagreed with including discussion of this issue in the IMPEP report. Following consideration of the State's views, the MRB agreed with the review team's inclusion of discussion relating to this rule and the team's recommendation presented below, in the final IMPEP report. The Division Director indicated that after appropriate review and consideration by the Division, Tennessee will respond in writing to the April 12, 2004 letter. The review team recommends that the Division promptly adopt the current version 10 CFR 20.2003.

In his June 1, 2004 letter responding to the revised language in the final IMPEP report (Attachment 2), Lawrence E. Nanney requested that the recommendation above be changed to recommending that "the Division promptly respond to the letter dated April 12, 2004, in order to address the differences in the State's equivalent rule to 10 CFR Part 20.2003." Although the NRC acknowledges the Division's commitment to reply to the April 12, 2004 letter, the review team and the MRB believe that retaining the recommendation as originally proposed more clearly conveys the intent of the discussions held at the May 13, 2004 MRB meeting.

The team evaluated the Division's responses to the questionnaire, 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 NRC STP Regulation Assessment Tracking System. Since the follow-up IMPEP review, the Division adopted 16 amendments in one rule package that became effective in October 2002. NRC's review letter dated February 1, 2002 indicated that NRC had completed its review with comments on 15 final regulations. The review team found that 16 amendments were submitted to NRC by the State for review, but the amendments were not identified individually. On a cursory review by the team, it appears that the Division addressed all NRC comments in the February 2002 letter. During the on-site review, it was identified that the following regulation had not been reviewed by NRC:

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70

"Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997. Parts of this amendment are designated as A and/or B for compatibility. The State submitted their final regulation for this amendment for NRC review on April 7, 2004. The NRC sent one comment to the State on this final regulation in a letter dated May 6, 2004. If this comment is addressed, this regulation would meet the necessary compatibility criteria.

The team identified seven rules needed for compatibility. The NRC reviewed the State's proposed regulations for the following amendments in December 2003, and determined that they meet the NRC's compatibility requirements when the three comments identified are addressed. Presently, this rule package has been signed by the Department's Commissioner and is currently in the Attorney General's Office for review.

- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 45393) that became effective October 26, 1998. The State has drafted proposed regulations for this amendment and submitted them to the NRC for review on October 22, 2003.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR50127) that became effective November 20, 1998. The State has drafted proposed regulations for this amendment and submitted them to the NRC for review on October 22, 2003.

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000. The State has drafted proposed regulations for this amendment and submitted them to the NRC for review on October 22, 2003.

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

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

The State has drafted proposed regulations for the amendments identified below and submitted them to the NRC for review on February 13, 2004. The NRC sent comments to the State on these proposed regulations in a letter dated March 25, 2004.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR 30, 31 and 32, amendments (65 FR 79162), that became effective on February 16, 2001. The Division addressed the reporting requirements for generally licensed device distributors which was due by August 16, 2001 by amending the licenses for the State's distributors of generally licensed device in June 2001.

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

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

- "Medical Use of Byproduct Material," 10 CFR 20, 32,and 35, amendments (67 FR 20249), that became effective on April 24, 2003.

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

- "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments," 10 CFR 71 amendments (69 FR 3698), that will become effective on October 1, 2004.

During the 2000 IMPEP review, the review team found the State's performance for this indicator unsatisfactory based on the 17 overdue regulations needed for compatibility and no management plan to address regulations. During the 2001 follow-up review, the State's performance was found satisfactory with recommendations for improvement, based on development of a management plan, preparation and submittal to NRC of 15 proposed amendments addressing regulations needed for compatibility and that only three additional regulations were overdue. The current review team found the continued progress made by the Division in addressing regulation promulgation commendable.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Tennessee's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, was satisfactory.

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

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

In assessing the Tennessee SS&D evaluation program, the review team examined the information provided in response to the IMPEP questionnaire. The team reviewed selected new, amended SS&D evaluations and inactivations, 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 four individuals who perform SS&D evaluations as secondary duties. The Manager of Radioactive Materials Specific Licensing was the principal reviewer and the Manager of the Licensing/Registration/Policy Section served as a concurrence reviewer. These two individuals have several years of experience performing SS&D reviews. During the review period, two other license reviewers attended the NRC/State SS&D Workshop held in 2001. One individual is now fully qualified to perform SS&D evaluations after completing reviews of

new and amendment applications for a sealed source and a device in collaboration with a senior reviewer. The second individual has limited independent reviewer and signature authority. Both individuals have the proper training and qualifications in accordance with the Division's Training Policy and have documented training and authorizations in their training files.

All four individuals have many years of experience in health physics and have attended the NRC/State 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. This matter is discussed further in Section 4.2.2.

According to the Division's response to the questionnaire, the Division expends approximately 0.35 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 recommends that Tennessee's performance with respect to this sub-indicator, Technical Staffing and Training, be found satisfactory.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, 18 SS&D certificates related to byproduct materials were issued by the Division. The review team examined a total of 12 certificates and their supporting documentation including four new applications, seven amendments, and one inactivation representing the work of all four reviewers. The SS&D registration certificates examined by the review team are listed with case specific comments in Appendix F.

In 1997, a major distributor of gauging devices with byproduct materials that are manufactured in Germany moved to the State. This licensee currently has 16 active SS&D certificates issued by the Division which constitutes the majority of all byproduct material SS&D casework. The Division also evaluated the SS&D applications for other manufacturers and distributors, but a majority of these products use naturally occurring and accelerator produced materials.

Analysis of the files and interviews with the staff confirmed that the Division follows the recommended guidance from the NRC/State SS&D Workshop and NUREG-1556, Volume 3 issued in July 1998. The team found, however, that the reviewers did not consistently use the review checklist provided in NUREG-1556, Volume 3, Appendix C. The team determined that reviewers did not use the checklist for amendments but did use them for new applications. Appropriate standards, Regulatory Guides, and NRC SS&D training workshop references were available and generally used when performing SS&D reviews. The team found that the Division did not use the latest version of the applicable industrial standards in five of the cases reviewed.

For example, the team determined that the Division staff was not aware that the requirements of the standard ANSI/ISO/ASQ 9001-1994 "Quality Management Systems - Requirements" (ISO-9001) are no longer used and accreditation to the 1994 version became invalid in December 2002. SS&D manufacturers frequently use and are accredited by ISO 9001. The NRC position on the International Quality Standards is documented in the policy paper entitled "Approaches for Adopting More Widely Accepted International Standards" (SECY-03-0117, dated July 9, 2003). The paper primarily addressees the applicability of International Quality

Standards to Safety related items of commercial nuclear power plants, but the conclusions are also applicable for SS&Ds.

The Division was not aware of the NRC's position on ISO 9001 since it was not circulated outside the agency. The team also noted that the Division was depending on the industry and consensus standards listed in NUREG-1556, Volume 3 and was not aware of the revisions of some of these consensus standards. The use of the latest industry and consensus standards for the SS&D product evaluations is an important component to furthering national consistency in this area. The team recommends that NMSS and STP develop a procedure to identify and periodically notify the Agreement States of agency positions that affect SS&D evaluations and the revision of industry and consensus standards for SS&D product evaluations in an All Agreement States letter.

The review team concluded that the overall technical quality of the product evaluations varied. The review team found that the use of the checklist resulted in a significant improvement in the overall evaluation of the applications. Consequently, the overall technical quality of product evaluations for the new applications was better then major amendments and showed improvement over the review period. The review team and Division staff discussed this finding and staff indicated that they will consider also using the checklist for major amendments.

In three of the cases reviewed, the team found that the Division did not adequately follow-up and evaluate advanced engineering and materials of construction related information provided by the licensee. At the time of the review, the Division had no access to mechanical engineering expertise for seeking advice or a second opinion on unique engineering and materials related issues. 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.

The review team and Division staff discussed the need to closely follow the format for documenting product evaluation since the registry certificates are used nationally. For example, the team noted that some certificates did not have legible attachments or essential drawings available in English. The review team recommends that the Division prepare registration certificates consistent with the current version of NUREG-1556, Volume 3.

Based on the IMPEP evaluation criteria, the review team recommends that Tennessee's performance with respect to this sub-indicator, Technical Quality of the Product Evaluation Program, be found satisfactory with recommendations for improvements.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

There was one reported incident involving a registration certificate issued by the Division as indicated in Appendix E. The incident took place in Louisiana and involved the failure of the shutter on a Model LB 7442-CR level gauge mounted on a centrifuge which resulted in the one curie source coming out of the shield. The review team determined that the Division handled the incident promptly and appropriately, determining the root cause and notifying other licensees with the same device in a timely manner. As a result of the incident, the Division required the manufacturer to conduct additional vibrational tests on the failed model. The Division is still reviewing the results of these tests. The Division is considering submitting a technical assistance request to the NRC regarding some specific aspects of the test results. In

addition, the Division issued a revised SS&D registry sheet with a revised welding procedure for the shutter mechanism.

Based on the IMPEP evaluation criteria, the review team recommends that Tennessee's performance with respect to this sub-indicator, Evaluation of Defects and Incident Regarding SS&Ds, be found satisfactory.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Tennessee's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was satisfactory.

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 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 existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Tennessee has such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Tennessee. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team and the MRB found Tennessee's performance to be satisfactory for all seven performance indicators. Accordingly, the review team recommended and the MRB concurred in finding the Tennessee Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. The MRB also directed that the increased monitoring of the Tennessee program be terminated. Based on the results of the current IMPEP review, the review team recommended and the MRB agreed that the next full review should be in approximately four years.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation by the State.

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

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)

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)

Below is a recommendation, as mentioned in a earlier section of the report, for evaluation and implementation, as appropriate by the NRC.

1. The team recommends that NMSS and STP develop a procedure to identify and periodically notify the Agreement States of agency positions that affect SS&D evaluations and the revision of industry and consensus standards for SS&D product evaluations in an All-Agreement State letter. (Section 4.2.2)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Tennessee Organizational Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews
Attachment 1	April 12, 2004 Letter from Lawrence E. Nanney Tennessee's Response to Draft IMPEP Report
Attachment 2	June 1, 2004 Letter from Lawrence E. Nanney, Tennessee's Response to Revised Language in Final IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Duncan White, Region I	Team Leader Technical Staffing and Training Response to Incidents and Allegations
Kathleen Schneider, STP	Status of Materials Inspection Program Legislation and Program Elements Required for Compatibility
Robert Gattone, Region III	Technical Quality of Licensing Actions
Shawn Seeley, Maine	Technical Quality of Inspections Response to Incidents and Allegations Inspector Accompaniments
Ujagar Bhachu, NMSS	Sealed Source and Device Evaluation Program
Richard Woodruff, Region I	Inspector Accompaniments

APPENDIX B
TENNESSEE ORGANIZATION CHARTS

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APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Cardinal Health — License No.: R-19149-A05
Location: Nashville, TN — Inspection Type: Routine/Unannounced
License Type: Nuclear Pharmacy — Priority: 1
Inspection Date: 10/30/03 — Inspectors: GK, TB

File No.: 2
Licensee: Schlumberger — NRC License No.: 42-00090-03
Location: Oak Ridge, TN — Inspection Type: Reciprocity
License Type: Well Logging — Priority: 3
Inspection Date: 12/19/01 — Inspector: RM

File No.: 3
Licensee: Schlumberger — NRC License No.: 42-00090-03
Location: Point Pleasant, TN — Inspection Type: Reciprocity
License Type: Well Logging — Priority: 3
Inspection Date: 6/21/02 — Inspector: RM

File No.: 4
Licensee: CIS-US — MA License No.: MA-20-9734
Location: Chattanooga, TN — Inspection Type: Reciprocity
License Type: Service/Maintenance — Priority: 2
Inspection Date: 1/24/03 — Inspector: LP

File No.: 5
Licensee: CIS-US — MA License No.: MA-20-9734
Location: Knoxville, TN — Inspection Type: Reciprocity
License Type: Service/Maintenance — Priority: 2
Inspection Date: 1/21/04 — Inspector: NF

File No.: 6
Licensee: Elekta — GA License No.: GA-1153-1
Location: Memphis, TN — Inspection Type: Reciprocity
License Type: Service/Maintenance — Priority: 2
Inspection Date: 2/21/03 — Inspector: AG

File No.: 7
Licensee: Cardinal Health — License No.: R-47080
Location: Knoxville, TN — Inspection Type: Routine/Unannounced
License Type: Nuclear Pharmacy — Priority: 1
Inspection Dates: 11/13, 11/17/03 — Inspectors: MS, CJ

File No.: 8
Licensee: Cardinal Health License No.: R-47080
Location: Knoxville, TN Inspection Type: Routine/Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Dates: 9/9-20/02 Inspector: RM

File No.: 9
Licensee: Cardiology Consultants of Johnson City License No.: R-90040-F09
Location: Johnson City, TN Inspection Type: Routine/Unannounced
License Type: Medical Private Practice Priority: 3
Inspection Date: 4/24-25/03 Inspector: JT

File No.: 10
Licensee: Atom Sciences License No.: R-01094-J12
Location: Oak Ridge, TN Inspection Type: Initial
License Type: Research & Development Priority: 2
Inspection Date: 3/20/03 Inspectors: MA, MM, KG

Comment:
Inspection correspondence issued without supervisory review.

File No.: 11
Licensee: The Heart & Vascular Institute License No.: R-79282
Location: Memphis, TN Inspection Type: Initial/Unannounced
License Type: Medical-Written Directive Not Required Priority: 3
Inspection Date: 11/6/03 Inspectors: JG, AG

File No.: 12
Licensee: Tri-State Testing License No.: R-79210
Location: Memphis, TN Inspection Type: Routine/Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 8/20/02 Inspector: GS

File No.: 13
Licensee: Chattanooga Heart Institute License No.: R-33151-D13
Location: Chattanooga, TN Inspection Type: Initial/Unannounced
License Type: Medical-No Written Directive Required Priority: 3
Inspection Date: 8/7/03 Inspector: LP

File No.: 14
Licensee: Blount Memorial Hospital License No.: R-05021-L10
Location: Maryville, TN Inspection Type: Initial/Announced
License Type: Medical-Written Directive Required Priority: 3
Inspection Date: 8/27/02 Inspector: CJ

Comment:
Initial on-site inspection took place 15 months after issuance of license.

File No.: 15
Licensee: Vanderbilt University License No.: R-19021-E05
Location: Nashville, TN Inspection Type: Routine/Unannounced
License Type: Medical Broad Scope and Research Priority: 1
Inspection Date: 1/22-23/03 Inspectors: RP, SS, GK, RH, PR, TB

Comments:
a) Inspection performed 17 days overdue.
b) Inspection correspondence issued without supervisory review.

File No.: 16
Licensee: Baptist Dekalb Hospital License No.: R-21002-H06
Location: Smithville, TN Inspection Type: Routine/Unannounced
License Type: Medical-Written Directive Not Required Priority: 3
Inspection Date: 2/13/03 Inspector: FS

File No.: 17
Licensee: Baptist Dekalb Hospital License No.: R-21002-H06
Location: Smithville, TN Inspection Type: Special/Follow-up
License Type: Medical-Written Directive Not Required Priority: 3
Inspection Date: 5/6/03 Inspectors: FS

File No.: 18
Licensee: Baptist Memorial Hospital License No.: R-49002
Location: Ripley, TN Inspection Type: Initial/Unannounced
License Type: Medical-Written Directive Required Priority: 3
Inspection Date: 9/11/03 Inspector: AG

Comments:
a) Inspection correspondence issued without supervisory review.
b) Initial on-site inspection took place 13 months after issuance of license.

File No.: 19
Licensee: Heartcare License No.: R-79279
Location: Germantown, TN Inspection Type: Initial/Unannounced
License Type: Medical-Written Directive Not Required Priority: 3
Inspection Date: Logged in as 8/22/03 Inspector: AG

Comment:
Inspection correspondence not issued until 2/2/04.

File No.: 20
Licensee: Park Avenue Radiology Associates License No.: R-79202
Location: Memphis, TN Inspection Type: Routine/Unannounced
License Type: Medical-Written Directive Required Priority: 3
Inspection Date: Logged in as 4/24/01 Inspector: AG

Comment:
Violations were identified during the review, but inspection results have yet to be sent to licensee.

File No.: 21
Licensee: Jackson Madison County General Hospital License No.: R-57002
Location: Jackson, TN Inspection Type: Routine/Unannounced
License Type: Medical-Written Directive Required Priority: 2
Inspection Date: Logged in as 3/14/03 Inspector: AG

Comment:
Inspection documentation not completed.

File No.: 22
Licensee: Apex Cardiology License No.: R-57035
Location: Jackson, TN Inspection Type: Initial/Unannounced
License Type: Medical-Written Directive Not Required Priority: 5
Inspection Date: Logged in as 8/27/03 Inspector: AG

Comment:
Inspection documentation not completed.

File No.: 23
Licensee: Berthold Technologies License No.: R-01082-D02
Location: Oak Ridge, TN Inspection Type: Routine/Announced
License Type: Manufacturer and Distributor Priority: 5
Inspection Date: 9/19/01 Inspectors: CJ, AW, MM

INSPECTOR ACCOMPANIMENTS

The following inspection accompaniments were made as part of the on-site IMPEP review:

Accompaniment No.: 1
Licensee: Quality Control & Inspections, Inc. License No.: R-79255-I07
Location: Millington, TN Inspection Type: Routine, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 11/19/03 Inspector: GS

Accompaniment No.: 2
Licensee: General Physics Corporation License No. R-16020-L05
Location: Arnold Air Force Base, TN Inspection Type: Routine, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 11/20/03 Inspectors: GK, TB

Accompaniment No.: 3
Licensee: Aerospace Testing Alliance (ATA) License No.: R-16011-B07
Location: Arnold Air Force Base, TN Inspection Type: Routine, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 11/20/03 Inspectors: GK, TB

Accompaniment No.: 4
Licensee: Sanders Medical Products License No.: R-47154/R-47155
Location: Knoxville, TN Inspection Type: Routine, Unannounced
License Type: Research & Development; Manufacturer and Distributor Priority: 3
Inspection Date: 11/17/03 Inspector: NF

Accompaniment No.: 5
Licensee: Summit Medical License No.: R-47159-E06
Location: Knoxville, TN Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 3
Inspection Date: 11/18/03 Inspector: KG

Accompaniment No.: 6
Licensee: Cardinal Health License No.: R-33111
Location: Chattanooga, TN Inspection Type: Routine/Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 11/19/03 Inspector: LP

Comment:

Inspector looked at package certification results, but did not verify if actual shipping configurations were the same as those originally tested.

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: IveyCooper Services, LLC — License No.: R-33145-G11
Location: Chattanooga, TN — Amendment No.: NA
License Type: Industrial Radiography — Type of Action: New
Date Issued: 7/26/01 — License Reviewer: GB

Comment:

Training and experience for individual authorized to retrieve stuck radiography sources is not documented in license. The Division's licensing guide does not contain specific guidance for training and/or experience for individuals requesting authorization to conduct stuck source retrievals.

File No.: 2
Licensee: Edwards Pipeline Services, Inc. — License No.: R-02006-H11
Location: Tulsa, OK — Amendment No.: NA
License Type: Industrial radiography — Type of Action: New
Date Issued: 8/1/01 — License Reviewer: RP

Comment:

Training and experience for individual authorized to retrieve stuck radiography sources is not documented in license. The Division's licensing guide does not contain specific guidance for training and/or experience for individuals requesting authorization to conduct stuck source retrievals.

File No.: 3
Licensee: ToxCo — License No.: R-73023-C05
Location: Oak Ridge, TN — Amendment No.: 6
License Type: Contaminated Metals Processor — Type of Action: Amendment
Date Issued: 11/18/02 — License Reviewer: JG

File No.: 4
Licensee: Philotechnics, Ltd. — License No.: R-01084-A08
Location: Oak Ridge, TN — Amendment No.: 3
License Type: Radioactive Waste Processor — Type of Action: Amendment
Date Issued: 9/19/00 — License Reviewer: RP

Comment:

Tie-down condition authorizes that survey instruments be operated on the highest scale first and incrementally lowered to the lowest scale to avoid unnecessary radiation exposure which is contrary to good health physics practice.

File No.: 5
Licensee: University of Tennessee License No.: R-47005-H08
Location: Knoxville, TN Amendment No.: 59
License Type: Broad Scope Research and Development Type of Action: Amendment
Date Issued: 9/24/03 License Reviewer: CA

File No.: 6
Licensee: Shaw Pipeline Services, Inc. License No.: R-02006-H11
Location: Tulsa, OK Amendment No.: 1
License Type: Industrial Radiography Type of Action: Amendment
Date Issued: 10/4/01 License Reviewer: SK

File No.: 7
Licensee: Johnson County Health Center License No.: R-46002-A10
Location: Mountain City, TN Amendment No.: 3
License Type: Medical Type of Action: Amendment
Date Issued: 3/6/02 License Reviewer: SK

File No.: 8
Licensee: Manufacturing Sciences Corporation License No.: S-01046-L12
Location: Oak Ridge, TN Amendment No.: 74
License Type: Contaminated Metals Processor Type of Action: Renewal
Date Issued: 12/19/02 License Reviewer: CA

File No.: 9
Licensee: Aerojet Ordnance Tennessee License No.: S-90009-I11
Location: Jonesborough, TN Amendment No.: 137
License Type: Source Material Manufacturer and Distributor Type of Action: Renewal
Date Issued: 9/21/01 License Reviewer: JG

File No.: 10
Licensee: Duratek Services, Inc. License No.: R-73006-F13
Location: Oak Ridge, TN Amendment No.: 93
License Type: Radioactive Waste Processor Type of Action: Renewal
Date Issued: 6/19/03 License Reviewer: CA

Comment:

The renewed license did not include a letter from the previous amendment that contains some of the commitments made by the licensee regarding the control of access to high radiation areas.

File No.: 11
Licensee: Cardinal Health 412, Inc. License No.: R-19214-G06
Location: Nashville, TN Amendment No.: N/A
License Type: Nuclear Pharmacy Type of Action: Termination
Date Issued: 11/10/03 License Reviewer: RP

File No.: 12
Licensee: Erlanger Medical Center License No.: R-33091-E05
Location: Chattanooga, TN Amendment No.: 22
License Type: Medical - Written Directive Required Type of Action: Amendment
Date Issued: 12/31/03 License Reviewer: SK

File No.: 13
Licensee: Baptist Memorial Hospital License No.: R-79032-F04
Location: Memphis, TN Amendment No.: 177
License Type: Medical - Written Directive Required Type of Action: Amendment
Date Issued: 9/26/03 License Reviewer: GB

File No.: 14
Licensee: Dresden Medical Associates, P.C. License No.: R-92005-G13
Location: Dresden, TN Amendment No.: 2
License Type: Medical Private Practice Type of Action: Amendment
Date Issued: 1/30/04 License Reviewer: SK

File No.: 15
Licensee: Centennial Medical Center License No.: R-19111-A09
Location: Nashville, TN Amendment No.: 50
License Type: Medical - Written Directive Required Type of Action: Amendment
Date Issued: 2/23/04 License Reviewer: SK

File No.: 16
Licensee: Holston Valley Hospital and Medical Center License No.: R-82033-H04
Location: Kingsport, TN Amendment No.: 48
License Type: Medical - Written Directive Required Type of Action: Amendment
Date Issued: 2/6/04 License Reviewer: GB

File No.: 17
Licensee: ISCS/REMide License No.: R-63018-H09
Location: Clarksville, TN Amendment No.: 1
License Type: Leak Test Service Type of Action: Amendment
Date Issued: 2/11/04 License Reviewer: GB

File No.: 18
Licensee: Spectrum Techniques, Inc. License No.: R-01079-D06
Location: Oak Ridge, TN Amendment No.: 13
License Type: Manufacturer and Distributor Type of Action: Amendment
Date Issued: 1/26/02 License Reviewer: RP

File No.: 19
Licensee: State of Franklin Healthcare Associates, PLLC
Location: Johnson City, TN
License Type: Medical Private Practice
Date Issued: 1/02/04
License No.: R-90036-H03
Amendment No.: 15
Type of Action: Amendment
License Reviewer: RP

File No.: 20
Licensee: Methodist Healthcare - Fayette Hospital
Location: Somerville, TN
License Type: Medical Private Practice
Date Issued: 1/12/04
License No.: R-24002-J06
Amendment No.: 4
Type of Action: Amendment
License Reviewer: RP

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM

File No.: 1
Licensee: Tri-State Testing & Drilling, Inc. Licensee No.: R-33105
Site of Incident: Chattanooga, TN Incident Log No.: 01-217 (NMED #011082)
Date of Incident: 11/28/01 Type of Incident: Stolen Radioactive Material
Investigation Date: 11/28/01 Type of Investigation: On Site

File No.: 2
Licensee: Duratek Licensee No.: R-73008
Site of Incident: Oak Ridge, TN Incident Log No.: 01-221 (NMED #020135)
Date of Incident: 12/10/01 Type of Incident: Transportation
Investigation Date: 12/12/01 Type of Investigation: Phone

File No.: 3
Licensee: DSSI, Inc. Licensee No.: R-73014
Site of Incident: Kingston, TN Incident Log No.: 02-016 (NMED #021108)
Date of Incident: 1/19&24/02 Type of Incident: Release of Radioactive Material
Investigation Date: 1/25-28/02 Type of Investigation: Phone, Next Inspection

File No.: 4
Licensee: Erlanger Medical Center Licensee No.: R-33008-H06
Site of Incident: Chattanooga, TN Incident Log No.: 02-090 (NMED #030071)
Date of Incident: 7/5/02 Type of Incident: Release of Material and Contamination Event
Investigation Date: 7/10&16/02 Type of Investigation: On Site, Phone

Comment:
Event reported to NMED contractor in January 2003.

File No.: 5
Licensee: American Ecology Recycling Center Licensee No.: R-01037
Site of Incident: Oak Ridge, TN Incident Log No.: 02-127 (NMED #021115)
Date of Incident: 8/27/02 Type of Incident: Contamination Event
Investigation Date: 9/5/02 Type of Investigation: On Site

File No.: 6
Licensee: Duratek Licensee No.: R-73008
Site of Incident: Oak Ridge, TN Incident Log No.: 02-129
Date of Incident: 8/23/02 Type of Incident: Transportation
Investigation Date: NA Type of Investigation: Next Inspection

File No.: 7
Licensee: Volunteer NDT Corporation Licensee No.: R-33139
Site of Incident: Stilesboro, GA Incident Log No.: 02-179 (NMED #030512)
Date of Incident: 12/4/02 Type of Incident: Equipment Failure
Investigation Date: 12/30/02 Type of Investigation: Next Inspection

Comment:
State of Georgia has lead on investigation; Tennessee reviewed event at next inspection.

File No.: 8
Licensee: Baptist Memorial Hospital Licensee No.: R-79031-F04
Site of Incident: Memphis, TN Incident Log No.: 03-006 (NMED #030248)
Date of Incident: 1/8/03 Type of Incident: Leaking Source
Investigation Date: 1/13/03 Type of Investigation: Phone and Next Inspection

File No.: 9
Licensee: Vanderbilt University Medical Center Licensee No.: R-19021
Site of Incident: Nashville, TN Incident Log No.: 03-019 (NMED #030254)
Date of Incident: 1/31/03 Type of Incident: Equipment Failure
Investigation Date: 1/31 & 2/3/03 Type of Investigation: Phone and On Site

File No.: 10
Licensee: Ameristeel Corporation Licensee No.: General License
Site of Incident: Jackson, TN Incident Log No.: 03-082 (NMED #040087)
Date of Incident: 6/8/03 Type of Incident: Damage to Equipment
Investigation Date: 6/8/03 Type of Investigation: On Site

Comment:
Event reported to NMED contractor in February 2004.

File No.: 11
Licensee: Aerojet Licensee No.: R-90009
Site of Incident: Jonesborough, TN Incident Log No.: 03-130 (NMED #040068)
Date of Incident: 8/29/03 Type of Incident: Fire
Investigation Date: 9/4/03 Type of Investigation: Phone

Comment:
Event reported to NMED contractor in January 2004.

File No.: 12
Licensee: Radiological Assistance, Consulting & Engineering Licensee No.: R-79266
Site of Incident: Memphis, TN Incident Log No.: 03-100 (NMED #030561)
Date of Incident: 6/26/03 Type of Incident: Contamination Event
Investigation Date: 7/2/03 Type of Investigation: Site

File No.: 13
Licensee: Berthold Technologies Licensee No.: R-01082-D02
Site of Incident: Monsanto Corporation, Luling, LA NMED No.: #030565
Date of Incident: 6/29/03 Type of Incident: Equipment Failure and Loss of Control
Investigation Date: 6/03 to present Type of Investigation: On Site and Telephone

Comment:

The equipment failure involved a gauging device with a SS&D registry sheet issued by the Division.

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM

File No.: 1
Registry No.: TN-1031-D-101-B — SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies — Model No: LB 7400 Series
Date Issued: 12/4/03

Comments:

a) Certificate does not reflect the name change of sealed source manufacturer from Amersham Corporation to AEA Technologies QSA, Inc.
b) Some drawings in the file had notes annotated in a foreign language.
c) The certificate states “Attachment 2 is an outside view of a typical device which shows the mounting flange and the protection flange for the key lock. The label in this attachment has since been modified for this review.” It is not clear what has changed in the label and the comparative time frame of the review has not been specified.
d) The certificate states that ”The later version of the LB 7440/D/CR and the LB 7442 D/CR shields were manufactured without an installed collimator.” The later version was not specified and the date and/or the serial number was not stated when this change was made. Further in the certificate in the prototype testing section, a statement is made that incorrectly conveys a message that Models LB 7445 DE and LB 7446 DE were tested and that they are not part of this registry.
e) The statement “Furnish a copy of the general license, ensure a valid specific license” is not clear.
f) The definition of extreme vibration environment was not specified.
g) The drawings incorrectly made references to Logos of Berthold Technologies predecessors.
h) Registry attachments do not provide principle overall dimensions, and do not identify safety features and the location of the device labels.
i) Case checklist was not prepared for this amendment.

File No.: 2
Registry No.: TN-1031-S-103-S — SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies — Model No.: P2608-100
Date Issued: 5/25/01

Comments:

a) It is not clear whether the laser marked or stamped sealed sources were tested.
b) Certificate makes a reference to an expired version of ISO-9001 Quality Assurance standard.
c) Registry attachments do not provide principle overall dimensions, and do not identify safety features, as well as the location of the sealed source and the sealed source label or engraving.
d) Classification of the sealed source did not include the year that the standard was issued.

e) The certificate indicates that the sealed sources would be marked with letters “BT” presumably representing Berthold Technologies’s logo. However, the attachments to this registry indicate the logo as EG&G.
f) Case checklist was not prepared for this amendment.

File No.: 3
Registry No.: TN-1031-D-104-B SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No.: LB 300L Series
Date Issued: 3/14/03

Comments:
a) Certificate does not reflect the name change of sealed source manufacturer from Amersham Corporation to AEA Technologies QSA, Inc.
b) A copy of the latest Berthold ISO-9001 certification was not available.
c) Registry attachments do not provide complete overall dimensions and safety features, as well as the location of the device labels.
d) The statement “The operations and shock limits are dictated by the glass photo-multiplier tube of the detector” is not accurate since the detectors may not be attached to the structure inducing the vibrations and sealed source may be mounted on the structure.
e) The statement “Furnish a copy of the general license, ensure a valid specific license” is not clear.
f) The statement “Installation, replacement, removal from service and disposal of sealed sources containing radioactive materials used in the devices shall be performed only by the device manufacturer“ is not clear as one of the source manufacturers is foreign based and may not have a specific license to carry out these licensed activities.
g) Leak test frequency of three years to new devices was extended even with use of new sealed sources. The manufacturer did not provide the historical safe performance of these sources over an extended period of time as required.
h) The certificate indicates that “the sources can be withdrawn using a plier.” Generally licensed devices are required to be tamper proof.
i) Case checklist was not prepared for this amendment.

File No.: 4
Registry No.: TN-1031-D-105-B SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No: LB 379
Date Issued: 7/3/01

Comments:

a) A copy of the latest Berthold ISO-9001 certification was not available.
b) Registry attachments do not provide principle overall dimensions, and do not identify safety features, as well as the location of the sealed source and the sealed source label or engraving.

c) The statement “The operations and shock limits are dictated by the glass photo-multiplier tube of the detector” is not accurate since the detectors may not be attached to the structure inducing the vibrations and sealed source may be mounted on the structure.
d) The statement “Furnish a copy of the general license, ensure a valid specific license” is not clear.
e) The statement “Installation, replacement, removal from service and disposal of sealed sources containing radioactive materials used in the devices shall be performed only by the device manufacturer“ is not clear as one of the source manufacturers is foreign based and may not have a specific license to carry out these licensed activities.
f) The expected life of the devices was given as 10-15 years but the controlling factor for the life of device was not known.
g) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.
h) The basis of limiting the measuring path of devices must not exceed 145 p.s.i. was not provided.
i) An explanation for the importance of dropping the device on its base from three meters onto concrete was not provided.
j) Case checklist was not prepared for this amendment.

File No.: 5
Registry No.: TN-1031-D-111-B SS&D Type: Sulfur Analyzer
Manufacturer: Berthold Technologies Model No.: LB 375
Date Issued: 6/21/02

Comments:
a) Certificate did not reflect the name change of sealed source manufacturer from Amersham Corporation to AEA Technologies QSA, Inc.
b) A copy of the latest Berthold ISO-9001 certification was not available.
c) Curium-244 activity was increased and authorized from 10 millicuries to 110 millicuries but the acceptability of three year leak test frequency for the modified device with this new increased activity was not evaluated.
d) The details, material specifications of titanium and beryllium, and thickness of the entrance and exit gauge windows of the fluid gauge were not provided.
e) Conditions of normal use did not clearly define the basis and what is the maximum operating temperature at which the device can be safely used.
f) Certificate makes a reference to an expired version of ISO-9001 Quality Assurance standard.
g) The statement “Furnish a copy of the general license, ensure a valid specific license” needs clarification.
h) The certificate states that “Devices may be mounted by both specific and general licensees in accordance with guidance provide by Perkin Elmers Instrument, Inc.” instead of Berthold Technologies.
i) Isotopes used in these devices have a long half life. It was not clear from the review of the files as to how the 15-year device life was estimated.
j) The certificate states that ”We conclude Model LB 300 IRL ML Type II Series, as specified in this certificate is acceptable for distribution” whereas the certificate was issued only for a Model LB 375 only.

k) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.
l) Case checklist was not prepared for this amendment.

File No.: 6
Registry No.: TN-1031-D-112-B SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No.: LB 8110
Date Issued: 6/12/01

Comments:

a) Device shutter functional test frequency was not stated in the certificate.
b) For normal conditions of use the basis for the operating temperature and the rational for testing for 15,000 cycles was not available.
c) Case files did not have results of required licensee audits.
d) A copy of the latest Berthold ISO-9001 certification was not available.
e) The statement “Furnish a copy of the general license, ensure a valid specific license” needs clarification.
f) The statement “The sealed radioactive sources used in Model LB 8110 devices are well protected against airborne and other contaminants” is not supported or a justification provided.
g) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.
h) Case checklist was not prepared for this amendment.

File No.: 7
Registry No.: TN-1031-D-113-B SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No.: LB 7501
Date Issued: 06/18/01

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) Leak test specification was waived despite the quantity in the new device exceeded exempt quantities.
c) A copy of the latest Berthold ISO-9001 certification was not available.
d) The statement “Furnish a copy of the general license, ensure a valid specific license” needs clarification.
e) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.

File No.: 8
Registry No.: TN-1031-D-114-B SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No.: LB 7502
Date Issued: 8/22/02

Comments:
a) Not all dimensions were stated in dual units (Metric & English).

b) Leak test specification was waived despite the quantity in the new device exceeded exempt quantities. The details related to the stacking of 8 sources were not available.
c) A copy of the latest Berthold ISO-9001 certification was not available.
d) The statement “Furnish a copy of the general license, ensure a valid specific license” needs clarification.
e) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.

File No.: 9
Registry No.: TN-1031-D-115-S SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No.: LB 300 IS
Date Issued: 2/7/03

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) Certificate assigned a three-year leak test frequency although not requested from the licensee and the sources used in the device were approved elsewhere for a six-month frequency.
c) Number and dimensional details of cable and attachment methods to the sealed source device holder had insufficient information.
d) A copy of the latest Berthold ISO-9001 certification was not available.
e) The certificate requires the distributor to supply the users an appropriate operating and service manual. A copy of this manual was not available in the file.
f) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.

File No.: 10
Registry No.: TN-1031-D-116-B SS&D Type: Gamma Gauge
Manufacturer: Berthold Technologies Model No.: LB 7409-3
Date Issued: 4/24/03

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) Certificate assigned a three-year leak test frequency although not requested from the licensee and the sources used in the device were approved elsewhere for a six-month frequency.
c) A copy of the latest Berthold ISO-9001 certification was not available.
d) Label drawings carried notes in a foreign language.
e) The rational for setting operating conditions of the device is incorrectly based on the temperature limits of the detector and the vibration limits of the counter tube.
f) The statement “Installation, replacement, removal from service and disposal of sealed sources containing radioactive materials used in the devices shall be performed only by the device manufacturer“ needs to be clarified as one of the source manufacturers is foreign based and may not have a specific license to carry out these licensed activities.
g) Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.

File No.: 11
Registry No.: TN-1067-D-103-S SS&D Type: PET
Manufacturer: CTI Pet Systems, Inc. Model No.: ECAT-HRRT
Date Issued: 7/21/03

Comment:

Registry attachments did not provide all the principle overall dimensions, and did not identify safety features and the location of device labels.

File No.: 12
Registry No.: TN-8117-D-104-S SS&D Type: Gamma Gauge
Manufacturer: Eurotherm Corporation Model No.: TIAM 11
Date Issued: 9/00

Comment:

The certificate was incorrectly numbered the certificate as TN-8117-D-104. The correct number is TN-8117-D-**801**-S.

ATTACHMENT 1

April 12, 2004 Letter from Lawrence E. Nanney
Tennessee's Response to the Draft IMPEP Report

ML041140518

ATTACHMENT 2

June 1, 2004 Letter from Lawrence E. Nanney
Tennessee's Response to the Revised Language
in the Final IMPEP Report

ML041530609