

DATED: MAY 21, 1997

SIGNED BY: HUGH L. THOMPSON, JR.

Mr. Wayne K. Scharber
Deputy Commissioner
Tennessee Department of
Environment and Conservation
L & C Tower, 21st Floor
401 Church Street
Nashville, TN 37243-1532

Dear Mr. Scharber:

On May 2, 1997, 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 NRC's program.

Section 5, page 16, of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to those recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next review will be scheduled in four years, unless program concerns develop that require an earlier evaluation.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to working with you in the future.

Sincerely, /RA/

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Kenneth W. Bunting, Director
Division of Superfund

Michael H. Mobley, Director
Division of Radiological Health

Lawrence E. Nanney, Deputy Director
Division of Radiological Health

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF TENNESSEE AGREEMENT STATE PROGRAM

DECEMBER 2-6, 1996

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 December 2-6, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Florida. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period February 4, 1994 to December 6, 1996, were discussed with Tennessee management on December 6, 1996.

A draft of this report was issued to Tennessee for factual comment on March 11, 1997. The State of Tennessee responded in a letter dated April 10, 1997 (Attachment 1). The State's comments were incorporated into the final report. The Management Review Board (MRB) met on May 2, 1997, to consider the proposed final report. The MRB found the Tennessee radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Tennessee Department of Environment and Conservation (DEC) is the agency within Tennessee State government that regulates environmental issues and radiation hazards. The DEC Commissioner is appointed by and reports to the Governor of Tennessee. Within DEC, the radiation control program is administered by the Division of Radiological Health (DRH). The DRH organization chart is included as Appendix B. The Tennessee program regulated 563 specific licenses at the time of the review. In addition to the radioactive materials licenses, the DRH has also issued approximately 4500 registrations for machine-produced radiation which covers about 13,000 X-ray tubes used within the State. The DRH is also responsible for environmental surveillance, emergency planning, and response to emergencies. The review focused on the materials program as it is carried out under the Section 274b. of the Atomic Energy Act of 1954, as amended, Agreement between the NRC and the State of Tennessee.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the State on October 15, 1996. Tennessee provided its response to the questionnaire on November 14, 1996. A copy of that response is included as Appendix C to this report.

The review team's general approach for conduct of this review consisted of: (1) examination of Tennessee's response 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 review of selected files, (5) field accompaniments of four 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 non-common 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 review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common indicators, and Section 5 summarizes the review team's findings and recommendations.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on February 4, 1994, and the results were transmitted to Mr. J. W. Luna, on July 28, 1994. The DEC was informed that the NRC staff determined that at that time, the Tennessee program for regulation of agreement materials was adequate to protect public health and safety and was compatible with the regulatory program of the NRC. All of the recommendations were determined to be satisfactorily resolved and the issues were closed out as documented in the letter and follow-up report to Mr. J. W. Luna dated October 4, 1994.

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) Status of Materials Inspection Program, (2) Technical Staffing and Training, (3) Technical Quality of Licensing Actions, (4) Technical Quality of Inspections, and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on five factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, reciprocity and timely dispatch of inspection findings to licensees. This evaluation is based on Tennessee's questionnaire responses to this indicator, data gathered independently from the State's inspection data tracking system, and interviews with managers and staff.

Review of the State's inspection priorities showed that the State's inspection frequencies for various types, or groups of licenses are at least as frequent as similar license types, or groups, listed in the NRC Inspection Manual Chapter (MC) 2800 frequency schedule. Inspection frequencies under the State's system range from 6 months to five year intervals with two exceptions: generally licensed gauges/devices and in-vitro laboratories, possessing less than 200 microcuries of radioactive material, which are inspected initially and thereafter only for resolution of problems. NRC inspects these programs initially, and every five years thereafter, as resources allow. The State has six categories of licensees that are inspected on a six month frequency: nuclear laundries, disposal/processing facilities, incinerators, waste handlers (prepack and repack), and disposal facilities (burial). NRC inspects these categories of licensees on an annual basis.

In its response to the questionnaire, Tennessee indicated that as of December 6, 1996, only five core inspections of licensees located within the state were overdue by more than 25 percent of the State's established inspection frequency. Three of the licensees are inspected on a six-month frequency so, under NRC established frequency, these inspections would not have been considered overdue. As of the date of the IMPEP review, all five inspections were scheduled to be completed by March 1997. The State also indicated that

three core and seven non-core licensees located outside the State were overdue by more than 25 percent. The State indicated that the licensees had not performed work in the State and, therefore, the State was unable to perform the inspections. In addition, they indicated that license conditions had been placed on the out-of-State licenses that required the licensees to notify the State when work was scheduled to be performed within the State. Nevertheless, the team suggested that the State periodically remind licensees of the requirement to notify DRH before performing work within the State and verify that work has not been conducted within the State's jurisdiction. These numbers are well within the 10 percent criterion for overdue inspections of Management Directive 5.6.

The team reviewed the initial inspection dates for 11 of 32 new licenses that had been issued between March 1995 and February 1996. Ten of the 11 licensees were inspected within six-months of license issuance. One new licensee was inspected at seven months post issuance rather than at six months.

The timeliness of inspection result issuance was evaluated. The results of 19 inspections were reviewed. The typical procedure for issuing the results of an inspection is: (1) the inspector prepares a letter that is used to transmit the inspection results; (2) the transmittal letter is typically dated two weeks after the inspector finalizes the letter; (3) the letter is forwarded for supervisory review; and (4) the letter is transmitted to the licensee after at least two levels of supervisory review. The review indicated that of inspections reviewed, only 10 of the 19 letters transmitting inspection findings were dated within four weeks of the completion of the inspection. It was difficult to determine the dates the letters were issued due to the inspectors dating the letters prior to supervisory review. Twelve of the 19 inspection letters were issued between 6 to 18 weeks after the inspection; one inspection letter was dispatched within 4 weeks; and it was not possible to determine when the other five letters were dispatched. It is recommended that the State review the process for report issuance with the goal of increasing the timeliness of inspection report issuance.

The State reported in its response to the questionnaire that 139 requests for reciprocity were received between February 4, 1994 and October 29, 1996. The team was unable to determine how many of these reciprocity requests were received from the same licensee. DRH performed 33 reciprocity inspections during the review period. This is a significant increase over the number of reciprocity inspections that had been performed during previous review cycles. The State's goal is to inspect at least ten percent of the licensees who are authorized to perform licensable activities under reciprocal recognition of a radioactive materials license issued by the NRC, an Agreement State, or a Licensing State. The State has met this goal. The review team was unable, however, to compare the number of reciprocity inspections by category of licensee to the goals established in NRC MC 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States,' and inspection of agreement state licensees operating under 10 CFR Part 150.20," which is incorporated by reference into MC 2800. It is recommended that the State review the number of reciprocity inspections it is performing against the inspection goals established in MC 1220.

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

3.2 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level, technical qualifications of the staff, training, and staff turnover. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed DRH management and staff, and considered any possible workload backlogs.

The organization chart shows that DRH has a total of 89 positions. Effectively about 50% of the staff works in whole, or in part, on matters related to Agreement materials. DRH was authorized to fill only 59 positions at the time of the review. Mr. Michael H. Mobley is the Division Director and he has a Deputy Director, Mr. Lawrence R. Nanney. The Office of the Director is supported by an Administrative Services Section (seven personnel) which provides general office services and accounts receivable support to the Division. The Technical Services Section (eleven personnel) provides personnel and environmental monitoring, low-level waste monitoring, standards development and processing, and emergency preparedness and training support to the Division. The Enforcement Section includes 24 staff members working out of four Area Offices. The distribution of the staff is as follows: the Coordinator is located in the Nashville (Headquarters) Office; 4 persons are in the Nashville Area Office; 6 persons are in the Memphis Office; 3 persons are in the Chattanooga Office; and 10 staff members are in the Knoxville Office.

The Licensing, Registration and Planning Section (12 personnel) licenses and registers radioactive materials and radiation producing devices used within the State. Five individuals are directly involved in conducting the review of applications and issuing licenses for the radioactive materials used under the Agreement. Two individuals within the Radioactive Material Specific Licensing group also perform the reviews of sealed sources and devices (SS&D). A discussion of SS&D personnel training is covered in Section 4.2.2. Four individuals are involved in machine and device permitting activities. Two individuals provide planning, policy and regulatory guidance to the Division.

The DRH has established qualifications for its technical classifications, including Health Physicist 1 (HP1) and Health Physicist 3 (HP3). Applicants at the entry level, HP1, are required to have a baccalaureate degree in a physical or (appropriate) life science. They are usually assigned basic responsibilities in the program until sufficient training experience is obtained. They receive training in health physics, nuclear medicine uses, materials licensing, inspection procedures for radioactive materials or radiation producing devices, industrial radiography, well logging, emergency response, environmental monitoring, low-level radioactive waste management, and standards/procedures development. Increased training warrants their assignment to more complex responsibilities. HP1 staff are required to qualify as HP3 staff after two years employment, one year for an individual with an MS in Health Physics, or their employment is terminated. Individuals with a MS have a shorter qualification time to reach the HP3 level because they are given constructive credit for their advanced training in Health Physics.

The higher technical classifications provide a career progression: from HP3, one may progress to HP Supervisor 1 or 2; from HP Supervisor 1 or 2, one may progress to HP Field Office Manager, HP Manager 1, HP Consultant, or HP Manager 2; from HP Manager 1 or 2, one may progress to HP Manager 3.

DRH has a pragmatic approach to training and qualification. The position description for new personnel, HP1, includes a description of several courses, including several "core" courses, which a new employee is expected to complete. DRH trains individuals on a case-by-case basis factoring in the individual's basic experience and program needs. An individual training program is developed to meet these needs. The DRH has an aggressive program for monitoring and scheduling individual training. DRH uses a data base for planning, scheduling and monitoring individual training. Because of the limited access to NRC sponsored "core" courses and other training opportunities, it may take several years for the person without a Health Physics background to complete all "core" training requirements.

The State has attempted to accelerate some individual training by sponsoring employee attendance at courses such as the five week health physics course. The DRH has worked very closely with the Office of State Programs (OSP) to fill any sudden vacancies in NRC sponsored courses, especially those given in Chattanooga and Oak Ridge, to maximize their training opportunities.

DRH relies heavily on an apprenticeship approach to training its personnel. All new personnel are carefully coached and observed while performing various activities related to their position. When supervisors determine that an individual is competent in a particular area, e.g., fixed gauges, nuclear medicine, or industrial radiography, the individual is permitted to work with less supervision in that area. This is a very subjective process and the length of time spent developing an employee varies with the individual. An individual is not considered fully qualified in any area until there is consensus on this point among the management team. Interestingly, the DRH may not limit a new employee's first experiences to less complex licensed activities. Depending on the need, the DRH may start training an individual on very complex activities as a team member. As an employee gains more on-the-job experience and training and completes the two years required in the HP1 class, they achieve the journeyman (HP3) level of competency.

Personnel in the Licensing, Registration and Planning Section are assigned increasingly complex licensing case work under the direction of senior staff. They also accompany experienced inspectors during compliance inspections of complex licenses to gain field experience.

The inspection staff receives the same basic training as the licensing staff. Inspectors are required to demonstrate competence during accompaniments by the supervisor prior to being given permission to perform inspections independently. The DRH inspector accompaniment process and the team's findings are in Section 3.4. This information was verified through discussions with managers and staff, review of the questionnaire response, a review of organizational charts and a review of the position descriptions. The team determined that all staff utilized for the agreement materials program were technically qualified by evidence of their training and experience.

The DRH reported that ten employees had left the Division since the 1994 review. One individual retired. Seven employees left DRH for promotion, better compensation or to continue their education. Two individuals were removed for cause. Retaining qualified personnel is not believed to be a problem. The attrition noted in the State's response is considered to be normal given the size of the program. The DRH, however, is faced with the problem of filling vacant positions. All State government agencies are presently under a hiring freeze instituted in early 1995. Vacated positions cannot be filled. Strong justifications are necessary and the process is long and arduous. The State's response indicated that they are in the process of

requesting freeze releases for six positions at the time of the review. The DRH is projecting the loss of two positions from their organization within the next six months. This will reduce the total number of DRH positions to 87.

In summary, the State has a balanced licensing and inspection program with approximately equal number of individuals involved in each area. Few vacancies exist at the senior level. The DRH has developed a strategy for addressing the long term State-wide hiring freeze and is slowly filling vacant positions. DRH has criteria for hiring, training and developing members of the staff to assure a continued high level of performance. DRH management supports development and demonstrated a commitment to training during this review period.

Despite their commitment to training, the DRH has voiced a concern about the impact NRC's change in policy for funding Agreement State training will have on their program.

DRH is meeting all mission requirements through creative resource management. The replacement of personnel losses will increase the size of the staff and provide more flexibility in meeting an unexpected, significant event.

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

3.3 Technical Quality of Licensing Actions

The review team examined completed licenses and casework for 78 license actions in 23 specific license files, representing the work of five license reviewers. The license reviewers and supervisor were interviewed when needed to supply additional information regarding licensing decisions or file contents.

The license casework was selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The cross sampling included eight of the State's major licenses and included the following types: source and device manufacturing and distribution, industrial radiography, nuclear medicine, gamma knife, high dose rate remote afterloader, academic and nuclear pharmacy. Licensing actions reviewed included 3 new, 3 renewals, 69 amendments, and 3 terminations. Two of the new licenses, one renewal, and two of the terminations were major licenses. No major license termination involved decommissioning. The two terminations that were major licenses were commercial distributors of sealed sources. A list of these licenses with case specific comments can be found in Appendix D.

Licensing actions were reviewed for completeness, consistency, proper isotopes and quantities authorized, 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 of its conditions and tie-down conditions; and overall technical quality. Casework was reviewed for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports; product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits; peer or supervisory review as indicated; and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

Two exemptions issued were reviewed. One exemption was from the "Very High Radiation Area" posting requirement on a gamma knife facility door to lessen patient apprehension and the other was to permit the preparation and distribution of I-123 MIBG (non-AEA material) which does not yet have an Investigational New Drug (IND) or New Drug Application (NDA) from the Food and Drug Administration (FDA).

In general, the review team found that the licensing actions were thorough, complete, consistent, of acceptable or higher quality, and with health and safety issues properly addressed. Special license tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. Two exemptions were reviewed for this review period. Both of them had valid justifications. The licensee's compliance history was taken into account when reviewing renewal applications as determined from documentation in the license files and/or discussions with the license reviewers.

The review team found that terminated licensing actions were well documented, showing appropriate transfer records and survey records. A review of the licensing actions over the review period showed that almost all terminations were for licensees possessing sealed sources. These files showed that documentation of proper disposal or transfer was available.

The team found that licensees have been notified of the need to file for reciprocity on sites which are exclusive Federal jurisdiction according to All Agreement States Letter SP-96-022. All licenses which allow for temporary job sites have been amended to include a standard condition in accordance with the All Agreement States Letter SP-96-022.

Licenses were renewed on a five year frequency. Licensees are tied down to previously submitted applications, supporting documentation and updated information. The State is considering extending the renewal period for certain licensees under specific conditions. The category of licensee and the specific conditions that would be required for the renewal extension is currently being studied. Licenses that are under timely renewal are amended as necessary to assure that public health and safety issues are addressed during the period that the license is undergoing the renewal process.

The license reviewer passed each licensing action up through the supervisory chain for review. Some of the licensing actions performed by the licensing manager do not receive a peer review. This was determined not to be of concern since the licensing actions which did not receive a peer review were of a minor nature. Major licensing actions receive multiple reviews and input from all levels up through the Director.

The review team found that the current staff is well trained and experienced in a broad range of licensing activities. The casework was reviewed for adequacy and consistency with the NRC procedures. The State does not have official, written administrative procedures for licensing reviews. They follow their licensing guides during the review process to ensure that licensees submit the information necessary to support the license. The licensing guides were very similar to the NRC guides.

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.

3.4 Technical Quality of Inspections

The team reviewed the inspection reports and enforcement documentation for 19 inspections conducted during the review period. The casework included a review of the work of 13 materials inspectors from all field offices. The casework covered a range of license types to include medical, academic, and industrial licensees. Appendix E provides a list of the inspection cases reviewed with case-specific comments.

The inspection procedures and techniques utilized by the State were reviewed and determined to be consistent with the inspection guidance provided in MC 2800. It was found that the majority of the inspections performed by the State were unannounced. The inspection reports provided documentation of inspection findings in a consistent manner. For the most part, the field offices were consistent in how they were documenting inspections. The inspection form used by the inspectors provided documentation of the licensee's radiation safety organization, program scope, facilities, equipment, radiological safety procedures, personnel monitoring, exposure to radiation, receipts and disposal records, posting, labeling, independent measurements, general observations, and violations. The inspection form allowed inspectors to provide brief, clear, discussions of the inspection and relevant findings. The reports were sufficiently detailed to support escalated enforcement actions. The State's enforcement letters were formal in style, detail and language.

Inspectors sign all routine enforcement correspondence. All of the inspection results and routine enforcement letters were verified as having been reviewed and approved in accordance with applicable DRH policy before issuing the results to licensees.

Four inspector accompaniments were performed by a review team member during the period of October 31 and November 13-15, 1996. One inspector was accompanied during the early morning inspection of a nuclear pharmacy facility, and three other inspectors were accompanied to medical facilities. These accompaniments are also identified in Appendix E. All of the other fully qualified inspectors have been accompanied during previous reviews since 1990. On the accompaniments, the Tennessee inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was satisfactory, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

In response to the questionnaire, the State reported that 9 out of 13 individuals who are qualified to perform inspections were accompanied by supervisors during the review period. It was suggested that consideration be given to conducting accompaniments with the field office supervisors that are routinely performing inspections. The State's policy is to accompany each inspector at least once each calendar year.

It was noted that the State had a variety of portable instruments for routine confirmatory surveys and for use during incidents and emergency conditions. Instruments were calibrated annually by a consultant or by the instrument manufacturer. Laboratory samples are analyzed by Tennessee's Department of Health, Division of Laboratory Services, Radiochemistry Laboratory. The laboratory participates in the Environmental Protection Agency's cross-check program. Approximately 400 samples are analyzed quarterly by the laboratory for the Division of Radiological Health.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire regarding this indicator, reviewed the incidents reported for Tennessee's "Nuclear Material Events Database" (NMED) against those contained in the Tennessee files and reviewed in detail the casework of 13 incident files and 7 allegation files. In addition, the review team interviewed the Deputy Director, the Manager of Inspection and Enforcement Section, the Supervisor of the Knoxville Area field office, and the two staff persons responsible for tracking incidents and allegations, and for providing the NMED summary data to NRC.

Responsibility for initial response and follow-up actions to incidents and allegations involving licensed materials rests with the Inspection and Enforcement Section. Tennessee procedures require the prompt response by the DRH to each incident or allegation. Each incoming notification is discussed with management and staff as appropriate and the response is coordinated with the appropriate field staff including an on-site inspection as appropriate. The managers related that all incidents, complaints, and allegations are evaluated by management, followed up with an inspection if possible, and recorded and tracked in the computerized tracking system. The updated NMED system was provided to the State on October 31, 1996 and the State has designated one individual for entering the State's data onto the system. The State has begun submitting event information on diskettes, but the State did not have the modem installed and was unable to access the on line event information at the time of the review. The State has plans for addition of the modem for on-line data input.

The reviewer examined in detail the State's response and documentation to all 13 events listed in Appendix F and verbally discussed several other events with the Inspection and Enforcement Section Program Manager. This effort included the State's incident and allegation process, tracking system, file documentation, open records laws and policies, and notification of events to other Federal and State Agencies.

The review team found that the State's responses generally were well within the performance criteria. Responses were prompt and well-coordinated, and the level of effort was commensurate with health and safety significance. Health Physicists were dispatched to the site when appropriate. In general, the State took suitable corrective and enforcement actions, notified the NRC, other States, and other Agencies as appropriate, and followed the progress of the investigation through until close out. The team noted a difference in the reporting threshold between State reporting procedures of significant events to NRC with respect to the definition of significant events. The State defines a "significant event" as an event that is an abnormal occurrence or one where media interest is involved. The NRC defines a "significant event" as one that is required to be reported by the licensee on an immediate or 24 hours basis. This threshold difference in reporting events to NRC resulted in two events not being reported to NRC as significant events. In the State's April 10, 1997 response, the DRH provided additional perspective on their interpretation of the TN reporting procedures. However, the events were reported to NRC later during the routine exchange of information. The review team suggests that the State revise their definition of "significant event" to be consistent with the definition provided in NRC guidance on reporting

events, and which will provide uniformity in reporting events on a national basis.

Allegations were responded to promptly with appropriate investigations and follow-up actions. Concerned individuals' (CI) identity can be protected under the State's open record law to the extent that investigations can be protected while underway. Program management related that all confidential information is maintained in a file which is secured in a locked cabinet, and this was confirmed by the reviewer. In general, the State's response was determined by the review team to meet the indicator guidance. However, the State's procedures do not have specific details on how known alleged or CIs are notified concerning the actions taken by the State in response to the concerns, specifically when the notification is needed and whether the notification should be verbal or in writing. All allegations, which had been referred by Region II, were resolved. Although the State reportedly has experienced no problems with their current CI notification procedures and policy, the team suggested that the State revisit their procedures and determine if more formal notification procedures are needed with respect to notification of the CI of the actions taken and the results of the State's investigation.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery. Tennessee is not authorized pursuant to its Agreement with NRC to regulate uranium recovery operations and the State does not have a low-level radioactive waste disposal site. Therefore, only the first two non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

Based on previous reviews, the State's response to the questionnaire, and discussions with the staff and management, clear statutory authority exists which designates the Tennessee DRH as the State radiation control agency with authority over agreement materials. The State statute that provides this legal authority is Title 68, Chapter 202, of the Tennessee Code Annotated (TCA).

Along with their response to the questionnaire, the State provided the review team with copies of legislation that affects the radiation control program. The legislative authority has been reviewed during this, and previous reviews, and is considered adequate to protect public health and safety. Based upon discussions with staff, the management, and a review of the State's response to the questionnaire, the review team confirmed that there have been no changes that would negatively impact the regulation of agreement materials.

4.1.2 Status and Compatibility of Regulations

The Tennessee radiation control program's regulations are found in "Rules of the Department of Environment and Conservation," Chapters 1200-2-4 through

1200-2-12. The questionnaire documented that DRH rules adopted during any calendar year are subject to the "sunset" provisions on June 30 of the following calendar year, unless approved by the State Legislature. Management indicated that the "sunset provision" has not been a problem since all DRH regulations must be approved by the Legislature's Government Operations Committee (GOC). Historically, all regulations approved by the GOC have been passed by the legislature. The list of regulations provided with the State's response to the questionnaire was evaluated to determine the status of the Tennessee regulations.

Four NRC regulation amendments became effective since the 1994 review and were adopted by the State:

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, 70 amendments (56 FR 64980) which became effective on October 15, 1991. The State's rule became effective on December 28, 1996. NRC has reviewed this rule and has found it to be compatible with NRC's regulations.
- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715) which became effective on July 1, 1993. The DRH does not have an irradiator licensee nor have they received an application for an irradiator license. Therefore, the State does not need to implement the requirement at this time. DRH management has recognized the need to implement legally binding requirements should an application be received.
- "Definition of Land Disposal and Waste Site QA Programs," 10 CFR Part 61 amendment (58 FR 33886) which became effective on July 22, 1993. The State adopted this requirement on October 28, 1996. NRC has reviewed this rule and has found it to be compatible with NRC's regulations.
- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose not to adopt self-guarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provisions for financial assurance that include at least a subset of those provided in NRC's regulations, e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee). It is noted that TRH had a "Self-Guarantee" provision in place since 1987. NRC has reviewed this rule and has found it to be compatible with NRC's regulations.

The review team identified three regulations that have not been put into effect in the Tennessee program:

- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," 10 CFR Part 40 amendment (59 FR 36026) that became effective on July 1, 1994. The State of Tennessee does not have a uranium mill and this regulation is not required.
- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) which became effective on January 27, 1992. At the time of the February 1994 review, it was noted that the State's

regulations should be amended to include this requirement. It has not been adopted. The team confirmed that this regulation has been submitted twice to the Commissioner, Tennessee Department of Environment and Conservation. It is presently at the Commissioner's Office. The expected date of adoption of the proposed rule cannot be predicted. NRC is currently deferring compatibility findings for Agreement States that have not yet adopted a compatible QM rule, pending resolution of the issue of Agreement State compatibility. The team recommended that the DRH continue to closely follow the development of NRC's compatibility policy and the revision of 10 CFR Part 35 and, depending on the outcome, take appropriate action on this rule.

- "Decommissioning Recordkeeping Documentation of Restricted Areas and Spill Sites," 10 CFR Parts 30 and 40 (58 FR 39628) that became effective on October 25, 1993. Under this requirement a licensee must maintain records of spills or contamination events in or around their site or facility where they cannot remove radioactive material or may have spread to inaccessible areas. Licensees must maintain as-built drawings and modifications of structures and equipment, or records containing the relevant information, within their restricted areas where radioactive materials are used or stored. The drawings or records should include information about normally inaccessible areas such as buried pipes that may become contaminated.

Agreement States generally adopt regulations or impose legally binding requirements similar to NRC's to maintain compatibility. DRH management asserted that they did not adopt NRC's rule believing the State has an effective combination of mechanisms in place that exceeds NRC's requirement. Additionally, the team could not show that DRH had imposed a consistent, legally binding requirement equivalent to NRC's upon its licensees. Despite the lack of a regulation and the inability to specifically identify a legally binding equivalent the team did not find the State's performance lacking in this area. The review team recommended that DRH document the rationale supporting their decision and what legally binding requirements are used in place of an amendment to the DRH regulations. Pursuant to the team's request, DRH examined its procedures and practices and submitted an explanation of their position. Additionally, in the State's response dated April 10, 1997 the DRH committed to use legally binding requirements. The review team and the MRB believe that the rationale explains that DRH's license application, application review, inspection, license termination process, environmental monitoring procedures and record retention requirements provide a performance-based equivalent to NRC's requirement. In particular, provisions in other sections of Tennessee's regulations and in license conditions imposed on licensees contain requirements that satisfy the essential objectives of the NRC regulation.

Based on information DRH submitted and further explanation provided by the Division Director at the MRB meeting, a need does not exist for DRH to adopt a requirement similar to NRC's 10 CFR Part 30.35 (g) (1) and (2). The MRB's determination is that the State's procedures give adequate assurance that the intent of NRC's requirement will be met in this area. The review team agrees with the MRB's decision.

The review team examined the procedures used in the State's regulatory process and found that the public is offered the opportunity to comment on proposed regulations and participate in public hearings that follow the comment period. The procedures also require the proposed regulations, proposed hearing date,

hearing comments and analysis, and the final regulations to be placed on the Department's internet home page. Draft copies of the proposed regulations are provided to NRC during the rule development process and the final regulations are submitted to NRC.

DRH uses a computerized system to follow future regulatory actions. It is the intention of the DRH management to address these regulations in a timely fashion. At the time of the review the following items are on the regulatory agenda:

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994.
- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. This rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement State the flexibility to implement more stringent requirements if they so desire.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.
- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. Agreement States are expected to have an effective rule on the same date.

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

4.2 Sealed Source and Device Evaluation Program

In evaluating the State's SS&D evaluation program, the review team studied the information provided by the State relative to this indicator in their response to the questionnaire, reviewed the casework and background information of all certificates of registration issued since the February 1994 review, reviewed procedures and guidance, and interviewed the DRH staff and managers responsible for SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The review team reviewed the files of the seven new or revised SS&D registry sheets issued since the February 1994 review. The SS&D registry sheets issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G. The technical quality of the evaluations was good and there were no comments related to the technical quality.

The Tennessee Regulations for Radiation Protection provide a regulatory basis for the SS&D program. Tennessee regulations 1200-2-10-.10 and 1200-2-10-.13 define the approval criteria and the type of information to be submitted by the applicant for registration of sources and devices.

4.2.2 Technical Staffing and Training

The State reported that a three-person team with combined staff efforts equalling approximately 12 weeks per year are needed for performing safety evaluations. All persons performing safety evaluations have bachelor's degrees, and have been trained in health physics and have taken the NRC licensing course. The two senior reviewers have many years experience in performing safety evaluations and have attended the SS&D workshops for training. The reviewers demonstrated to the review team an ability to understand and interpret the information submitted by applicants as described in the performance criteria. The junior reviewer works under the supervision of the two senior members, and all evaluations receive at least one technical review by a supervisor and a second party concurrence by supervision.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

There have been no reported incidents involving sources or devices approved by the State.

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

4.3 Low-Level Radioactive Waste (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 LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host state for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Tennessee. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance with respect to each of the performance indicators to be satisfactory. Accordingly, the team recommended, and the MRB concurred in finding the Tennessee program to be adequate to protect public health and safety and compatible with NRC's program.

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

1. The team suggested that the State periodically remind licensees of the requirement to notify DRH before performing work within the State and verify that work has not been conducted within the State's jurisdiction (Section 3.1).
2. It is recommended that the State review the process for report issuance with the goal of increasing the timeliness of inspection report issuance (Section 3.1).
3. It is recommended that the State review the number of reciprocity inspections it is performing against the inspection goals established in MC 1220 (Section 3.1).
4. It was suggested that consideration be given to conducting accompaniments with the field office supervisors that are routinely performing inspections (Section 3.4).
5. The review team suggests that the State revise their definition of "significant event" to be consistent with the definition provided in NRC guidance on reporting events, and which will provide uniformity in reporting events on a national basis (Section 3.5).
6. The team suggested that the State revisit their procedures and determine if more formal notification procedures are needed with respect to notification of the CI of the actions taken and the results of the State's investigation (Section 3.5).
7. "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) which became effective on January 27, 1992. The team recommended that the DRH continue to closely follow the development of NRC's compatibility policy and the revision of 10 CFR Part 35 and, depending on the outcome, take appropriate action on this rule (Section 4.1.2).

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Tennessee DEC Organization Chart
Appendix C	Tennessee's Questionnaire Response
Appendix D	License File Reviews
Appendix E	Inspection File Reviews
Appendix F	Incident File Reviews
Appendix G	Sealed Source and Device Evaluation Reviews
Attachment 1	Tennessee's Response to Review Findings

APPENDIX A
IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Myers, OSP	Team Leader Technical Staffing and Training Legislation and Regulations
Richard L. Woodruff, RII	Response to Incidents and Allegations Sealed Source and Device Evaluation Program
Catherine Haney, NMSS	Status of Materials Inspection Program Technical Quality of Inspections
William Passetti, Florida	Technical Quality of Licensing Actions

APPENDIX B
ORGANIZATIONAL CHARTS

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE - RESPONSE