

Mr. John M. Leonard
Assistant Commissioner for Environment
Tennessee Department of Environment
and Conservation
401 Church Street, 21st Floor, L&C Tower
Nashville, TN 37243-1530

November 27, 2000

Dear Mr. Leonard:

On November 7, 2000, 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 IMPEP review was conducted August 21-25, 2000. The MRB had received for consideration the comments in Mr. Nanney's letter dated October 23, 2000. The MRB found the Tennessee program adequate but needs improvement, and not compatible with NRC's program. Because of the significance of the concerns, the MRB recommends heightened oversight of the Tennessee program. I request that bi-monthly conference calls take place with the appropriate Tennessee and NRC staffs to discuss the status of the program. The Office of State and Tribal Programs will coordinate the bi-monthly conference calls. I request that, two weeks prior to the calls, you submit a brief status report on the activities conducted since the last report and the necessary statistical data.

I also request that you prepare and submit a program improvement plan that addresses the recommendations in Section 5 of the enclosed final report. I request that this report be submitted within 30 days of this letter. Upon review of the program improvement plan, the staff will schedule the first conference call and a more detailed outline for the status reports. I request the initial conference call be scheduled and conducted no later than February 1, 2001.

Based on the results of the current IMPEP review, a follow-up review will be scheduled during the period August - October 2001. The follow-up review will cover the State's action on the recommendations from the August 2000 review.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your continuing support of the Division of Radiological Health. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl Paperiello
Deputy Executive Director
for Materials, Research and
State and Tribal Programs

Enclosure:
As stated
cc: See next page

John M. Leonard

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cc: Milton H. Hamilton, Commissioner
Department of Environment and Conservation

Lawrence E. Nanney, Director
Division of Radiological Health

Edgar D. Bailey, CA
Agreement State Liaison to
The Management Review Board

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF TENNESSEE AGREEMENT STATE PROGRAM

August 21-25, 2000

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 August 21-25, 2000, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of California. 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 25, 1998, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period December 7, 1996 to August 25, 2000 were discussed with Tennessee management on August 25, 2000.

A draft of this report was issued to Tennessee for factual comment on September 22, 2000. The State responded in a letter dated October 23, 2000. At the time of the review, the review team found Tennessee's performance to be satisfactory for the common performance indicators Technical Staffing and Training, Technical Quality of Licensing Actions and Sealed Source and Device Evaluation Program; satisfactory with recommendations for improvement for the indicator, Response to Incidents and Allegations; and unsatisfactory for the indicators, Status of Materials Inspection Program, Technical Quality of Inspections, and Legislation and Program Elements Required for Compatibility. Because of the significance of the concerns, the team recommended that a program of heightened oversight be implemented to assess the progress of the State in implementing corrective actions.

On September 13, 2000, Mr. Carl Paperiello, NRC, and other NRC staff discussed by telephone with Mr. John Leonard, Assistant Commissioner for Environment, and his staff, the significance of the teams findings and NRC's understanding of the State's commitments made during the team's exit meeting on August 25, 2000. This conversation was documented in a October 2, 2000 letter to Mr. Leonard from Mr. Paperiello.

The Management Review Board (MRB) met on November 7, 2000 to consider the proposed final report. The MRB concurred in the individual findings by the review team for each indicator. Based on the Tennessee actions to date and the commitments by the Division Director, the MRB concurred in the review team's recommendation for a program of heightened oversight to assess the progress of the State in implementing corrective actions. The MRB found the Tennessee radiation control program was adequate, but needs improvement, and not compatible with NRC's program.

The MRB directed that a program improvement plan be submitted in addition to the responses to the recommendations found in Section 5, that a follow-up review be conducted during the period August - October 2001, that bimonthly conference calls take place with Tennessee staff, and that written progress reports be submitted two weeks prior to each call.

The Tennessee Agreement State program is administered by the Division of Radiological Health (the Division) within the Department of Environment and Conservation (DEC). Organization charts for the DEC and the Division are included as Appendix B. At the time of the review, the Tennessee program regulated 559 specific licenses, including gauges, medical, academic, industrial, manufacturing, and waste broker/processor. The review focused on the materials program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, (AEA) 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 June 16, 2000. The State provided a response to the questionnaire on July 31, 2000. During the review, discussions with the State staff resulted in the responses being further developed. A copy of the questionnaire responses is included as Appendix G to the proposed final 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 licensing and inspection actions; (5) field accompaniments of five 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 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 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 State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous routine review, which concluded on December 6, 1996, three recommendations and four suggestions were made and the results transmitted to Mr. Wayne K. Scharber, Deputy Commissioner, Tennessee Department of Environment and Conservation on May 21, 1997. The periodic meeting resulted in recommendation for the closure of all three of the recommendations. The team's review of the current status of these recommendations is as follows:

1. 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).

Current Status: The Division has developed and implemented a revised policy for issuance of inspection reports and correspondence. This recommendation is closed. This issue is evaluated further in Section 3.1 and a new recommendation is made.

2. It is recommended that the State review the number of reciprocity inspections it is performing against the inspection goals established in Manual Chapter 1220. (Section 3.1)

Current Status: The Division has issued revised guidance to the technical staff regarding increased reciprocity inspections by priority of inspection, and has started tracking the inspections. This recommendation is closed.

3. "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).

Current Status: The Division is monitoring the development and status of the 10 CFR Part 35 revision. The Commission has approved the final rule which is expected to be published in Spring 2001. We believe that the Division conserving rulemaking resources to address the new Part 35 is appropriate. The recommendation is closed. This issue is addressed in Section 4.1.2.

During the 1996 review, four suggestions were made concerning: (1) periodic reminder for out-of-State licensees of the requirement to notify the Division before performing work within Tennessee; (2) conducting accompaniments of field office supervisors that routinely perform inspections; (3) revising Tennessee's definition of "significant event" to provide national consistency; and (4) revisit procedures for notification of the concerned individual of actions taken and results of the State's investigation. The team determined that the State considered the suggestions and took appropriate actions.

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 Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

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

A review of the Division's inspection priorities revealed that the inspection frequencies for the various types of licenses are the same or more frequent than similar license types listed in NRC Inspection Manual Chapter (IMC) 2800. The Division does not extend or compress inspection frequencies based on compliance history. The Division does attempt to inspect certain types of licensees at a greater frequency than listed in NRC IMC 2800. These licensees are all waste processing licensees, and the Division's goal is to inspect them once every six months.

In response to the questionnaire, the Division indicated that 31 core inspections were overdue by more than 25% of the NRC frequency. By the time of the IMPEP review, this number had been reduced to 21 core inspections. A review of the Division's data indicated that during this review period, 68 of 257 core inspections (26%) were overdue by more than 25% of the NRC frequency when they were performed. At the time of the review, there were six licensees requiring inspection on an annual basis that were overdue by more than 25% of the NRC frequency. Of these six, four were nuclear pharmacies, and were overdue by 17 to 42 months.

With respect to new licensees, the team evaluated the Division's inspection data tracking system and determined that 73 initial inspections of new licensees were performed during the IMPEP review period. Of these 73, there were 41 (56%) that were performed more than six

months after the license had been issued. In addition, at the time of the IMPEP review there were 10 initial inspections that had not yet been performed, although the licenses had been issued more than six months prior to the review. The team identified a tracking problem for Priority 7 licensees. The inspection data tracking system calculates when the initial inspection is due by looking at the expiration date of the license, and back-calculating to the date of issuance, then calculating six months from that date, and assigning it as overdue when that date is passed. Priority 7 licensees in Tennessee are not assigned an expiration date. Therefore, the date when the initial inspection is overdue is not properly entered into the inspection data tracking system. However, of the 41 initial inspections that were performed more than six months after the issuance of the license, only 11 were Priority 7 licensees.

Regionally, there were substantial differences with respect to the number of inspections, routine and initial, that were performed on an overdue basis. In the Memphis office, 21 out of 28 (75%) of the core inspections performed were overdue, while in the Chattanooga office, no core inspections were overdue when performed during this IMPEP review period.

The timeliness of the issuance of inspection findings was evaluated by randomly selecting from each of the regional offices approximately seven inspection reports spanning the IMPEP review period. Of the 29 reports reviewed, there were 12 where the inspection letter and Notice of Non-compliance, if applicable, were dispatched to the licensee more than 30 days after the inspection. Of these 12, six were dispatched more than 60 days after the inspection, including one being up to 12 months late at the time of the review, but still not issued.

The Division requires that the inspection findings be delivered to the Nashville office for maintenance in the central files. However, this policy is not consistently followed by the regional offices, as there were numerous cases where file documentation was missing. Some of the reports from regional offices outside of Nashville were sent to Nashville at the Deputy Director's request for the IMPEP team's review. In one case, the team requested a copy of the inspection report for an inspection performed June 18, 1997, as entered in the inspection data tracking system, but the Deputy Director stated that no inspection had actually been performed during that period. The data in the tracking system was in error. That licensee is currently overdue for inspection.

In another eight cases, there were inspections performed in the Memphis region during March 1998, but no reports could be located, either in the central files or in the regional offices. The Deputy Director stated that she believed the inspections were completed, but never approved by the supervisor, and Division staff would continue to look for them. Several other reports could not be located during the on-site IMPEP review. One report (February 1998) was missing for a Priority 1 licensee. A second report (May 2000) for this licensee was still in the process of being prepared while the review was being conducted, although the inspection had been performed three months earlier. A report for an inspection (August 1999) in response to an allegation for a Priority 1 licensee and the Notice of Non-compliance were never reviewed and released to the licensee or the allegor. The Division should ensure that all completed inspection records are properly filed in the central office. This would reduce the number of missing inspection reports. The Division has developed a plan for completing those inspections that are currently overdue and was searching for the missing records at the time of the review. The staff turnover in the inspection program has contributed to problems in performance of the inspection program.

The Division reported that 180 requests for reciprocity were received between January 1, 1997 and August 18, 2000. The team did not determine how many of these reciprocity requests were

received from the same licensee. The Division performed 67 reciprocity inspections during the review period. This is a significant improvement over the 33 inspections performed out of 139 requests made during the previous review cycle. The Division's goal is to perform reciprocity inspections at the same frequency as that prescribed by NRC IMC 1220. This goal was not met in all cases (i.e., for all categories of licensees, for each year in the review period), however on average, over the review period, the Division did meet this goal.

The review team recommends that the Division take actions to ensure that: (1) inspections are conducted in accordance with their assigned inspection frequencies; (2) inspection reports are issued in a timely manner; (3) inspection reports and associated information are filed in a manner that the information can be retrieved; and (4) deficiencies in the inspection tracking system are corrected.

During the MRB meeting, the Division Director noted that the Priority 1 overdue inspections had been performed since the onsite review. In addition, the Division had selected a new Inspection and Enforcement (I&E) supervisor to oversee the management of the inspection program.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed some of the inspection staff. The evaluation included reviewing 21 radioactive materials inspections (for 17 licensees) conducted during the review period. The casework included fourteen inspectors, representing each of the State's four regional offices, and covered inspections of nine types of licensees (hospitals, mobile nuclear medicine, gamma knife, industrial radiography, well logging, radiopharmacy, waste processors, decontamination services providers, and portable gauges). Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

The Division's inspection procedures are consistent with the inspection guidance outlined in NRC IMC 2800. Inspection reports are in checklist format with space for limited narrative input that would adequately cover all inspection areas. The Division has specific inspection forms for the various types of licensees. Full narrative reports (instead of the checklist format) are normally completed for large, complex licensees, such as waste processors. All inspection reports receive supervisory review. Central Office Management only reviews inspection reports from Priority 1 licensees requiring financial assurance, notices of non-compliance involving licenses-for-delivery, and any inspections performed by Field Office Managers.

During the review period, inspector accompaniments were performed by supervisory staff and central office management. The review team determined that only two inspectors had not been accompanied in calendar year 1999, one of whom was a field office manager who also conducted inspections and performed accompaniments of inspection staff in his region. This did not appear to affect the overall performance of the inspection program.

Based on casework and interviews of selected inspection staff, the review team determined that most routine inspections do not adequately assess licensees' radiation protection programs. The inspection reports document a compliance-based inspection technique that focuses heavily,

and in many cases exclusively, on record reviews. Of the 21 inspection reports reviewed, 13 did not include any documentation of observation of licensed activities or interviews of licensee personnel who performed those activities. The review team found that inspection reports were of low quality, with insufficient documentation to ensure that licensee performance with respect to health and safety was acceptable. The documentation in the inspection reports typically did not support the violations transmitted to licensees. Of the 55 violations identified in the casework reviewed, 35 were not supported, and in some cases were contradicted, by information in the inspection reports. None of the inspection reports discussed the relative safety significance or root causes of the violations identified to licensees. In many cases, the notices of non-compliance did not establish that a violation occurred, i.e., the “requirement” statement addresses performance of a task and the “contrary to” statement indicates that records of the results of the tasks were not available.

Five Division inspectors were accompanied during inspections by a review team member during the week of July 31, 2000. The accompaniments included two medical licensees and three radiography licensees. These accompaniments are also identified in Appendix C.

During four of the accompaniments, the inspectors did not demonstrate appropriate inspection techniques. The inspectors focused exclusively on record reviews and did not observe any activities in progress or conduct any substantive interviews of licensee personnel regarding their knowledge of routine operating and emergency procedures. In one instance, the inspector did not tour the licensee’s facilities until after the normal licensed activities for the day had ended, approximately five hours after initially arriving onsite. Two inspectors did not interview any licensee personnel who actively performed licensed operations.

Except for the one industrial radiography inspection where the inspector observed activities at a temporary job site, none of the inspectors assessed the radiological health and safety performance of the licensees inspected. These inspectors did not demonstrate through their inspection activities knowledge of the State’s Inspection and Enforcement Policy and Procedure which directs inspectors to obtain information through “...selective direct observation of work in progress, interviews of workers and management personnel, confirmatory measurements, and examination of selective records and procedures to...” determine whether licensed activities are conducted safely. In addition, under Section 1000.08 of the policy and procedure, inspection staff are advised that inspection effort expended against various portions of regulatory requirements should be commensurate with their relative importance to safety. During four of the five accompaniments, the inspectors’ expenditure of resources was on activities that were of little importance to safety (i.e., record retention).

Due to the inspection program not fully addressing the health and safety aspects of licensee’s operations, the review team has the following recommendations:

The review team recommends that the Division follow the Tennessee inspection policy and procedures.

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.

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

unsatisfactory.

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program 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 State's questionnaire responses relative to this indicator, interviewed program management and staff, and considered any possible workload backlogs.

At the time of the review, the Division had a total of 72 staff positions. Approximately 36 of these staff contribute to the Agreement State portion of the program for a total of 1.1 full time employees (FTE) in administration, 7.8 FTE in licensing, 9.8 FTE in inspection, and 2.4 FTE in emergency response. The Division is managed by a Director and Deputy Director (with 2 administrative and 1 technical staff in the Director's office) with three technical sections (Technical Services, Inspection and Enforcement, and Licensing, Registration, and Planning) as well as an Administrative Services Section (7 staff) which provides general office services and management of accounts receivable. The Technical Services Section (13 staff) provides personnel and environmental monitoring, low-level waste monitoring, standards development and processing, and emergency preparedness and training.

The I&E Section (32 staff) is divided into four regional offices (Memphis (6), Nashville (9), Chattanooga (3), and Knoxville (13)) and a program manager in Nashville. The I&E Section conducts all inspections for materials and radiation machines.

The Licensing, Registration and Planning Section (14 staff) conducts the licensing of radioactive materials and registration of radiation producing devices used within the State. Eleven staff are involved, in part, in conducting the review of license applications and issuance of licenses for radioactive materials covered under the Agreement. Two staff, other than the managers in the Section, review Sealed Source and Device applications. This activity will be discussed further in Section 4.2.2.

All health physics staff are required to have a bachelors degree in physical, engineering, or life sciences. They are usually assigned basic responsibilities in the program until sufficient training and experience is obtained. The Division has established a tracking system for all training for the staff. They receive training in health physics, nuclear medicine uses, materials licensing, inspection procedures for materials or radiation producing machines, industrial radiography, emergency response, and regulations and office procedures. Although not all staff have attended every course, the program has sufficient expertise to execute the program. The Division has limited funding (\$14K) for out-of-State travel. This limits their participation in certain out-of-State training courses which over time degrades the technical quality of the program. They have used on-the-job training to supplement the course work so that individuals may broaden their work areas. The Division does not have a documented training program or plan which specifies minimum training requirement as well as supervisory sign off on completion of that training. The review team recommends that the Division develop and document a training and qualification program which address the training requirements in the NRC/Organization of Agreement States Training Working Group Report or NRC Inspection Manual Chapter 1246.

The Division has experienced significant staff turnover. During the review period, they hired 24 new staff and 23 staff have left the program. About half of the staff that left the program worked

in the radioactive materials program. Several of the staff working in the x-ray portion of the program were being trained to become materials inspectors. The majority of the staff that left the Division had about 3 years or less with the Division. Therefore, several of the positions have been filled more than once during the evaluation period. This has required significant training resources as well as on the job training effort to get the new staff prepared to contribute to the Division. The new staff are typically trained to begin in the x-ray program. As their training progresses they may be moved to a position in the materials program.

The Director of the Division retired in November 1999 and the Deputy Director was selected to succeed him in January 2000. The Technical Services manager was selected to be the new Deputy Director in July 2000. The Inspection and Enforcement manager was moved to a staff technical position in July 2000 and at the time of the review these two management positions were in the process of being filled. At the time of the review, there were seven vacancies (4.1 FTE) in the inspection program and two vacancies (1.3 FTE) in the licensing program. The current vacancies in the inspection program account for about 40% of the staff assigned to the materials inspection program. The Division has requested hiring freeze waivers for their vacant positions and has attempted to hire qualified individuals. This has not always been successful since several times there were no qualified individuals on the register when it was accessed. The low salary (\$21K) for an initial hire is not a sufficient salary to attract qualified individuals. Without a significant salary increase, which is not likely given the current financial condition of the State of Tennessee that was discussed during the exit meeting, the current staffing issues will persist. At the exit meeting, upper management indicated that some salary incentives may be available for some entry level positions and the Division management expressed an interest in pursuing this as an option. The high turnover and training workload on existing staff has adversely impacted the program, specifically the "Status of Materials Inspections," "Technical Quality of Inspections," and "Incident and Allegations" indicators. The review team recommends that the inspection staff be trained in the Division's policies and procedures on the conduct of inspections.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 25 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated 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 authority. The files were checked for retention of necessary documents and supporting data. A separate review evaluated one licensing action in detail, including an onsite visit to the State offices and licensed facility. Based on the results of this specific case review, the team looked at the programmatic process for documentation of telephone calls and meetings with licensees. In addition, particular attention was given to review of the State's process for review and approval of sampling and monitoring

programs, release criteria, and detection limits. The evaluation conducted of this licensing action will be issued as a separate report.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period. The cross-section sampling included the following types: waste processing; broad scope licenses; decontamination services; industrial radiography; medical (institutions and private practices performing diagnostic and/or therapeutic nuclear medicine, brachytherapy, strontium-90 eye applicator, gamma stereotactic surgery); nuclear pharmacy; nuclear laundry; laboratory research and development; portable gauges; leak test, calibration and other services; source material; and sealed neutron PuBe source. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

The following licensing actions that were completed during the review period were reviewed: 8 new licenses, 3 renewals, 33 amendments, and 3 terminations, for a total of 47 licensing actions. During the review period, extensions of the license expiration date were issued to nearly all licensees, so few renewals were done. Two sets of amendments were generated by the State to certain classes of licenses: 1) to add a license condition to all radiography licenses for approval to use the optically-stimulated luminescent dosimeters; and 2) to add a license condition to all medical facilities authorized to perform therapeutic nuclear medicine describing the new patient release criteria. In discussions with State management representatives, it was noted that one licensee has filed for bankruptcy and was unable to sell or re-organize. For this facility, the State has drawn on the funds provided by the facility's financial assurance in order to decommission the facility.

The casework evaluation indicated that the Division staff follows appropriate licensing guides during the review process. Generally, deficiencies were addressed by letters containing appropriate regulatory language. Each license reviewer has proper signature authority to sign their own licensing actions. Overall, the review team found that the licensing actions were thorough, complete, consistent, of high quality and properly addressed health and safety issues.

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 Division's "Complaint/Allegation/Incident (CAI) Event Investigation Procedure," and evaluated selected incidents reported for Tennessee in the Nuclear Material Events Database (NMED) against those contained in the Tennessee files. A list of the incident casework examined with the case-specific comments is included in Appendix E. The team also reviewed the State's response to 14 allegations involving radioactive materials including 10 allegations referred to the State by the NRC during the review period.

The Division had 64 reportable radioactive materials incidents during the review period and 14 were selected for review. The incidents included: leaking sources; a misadministration; contamination events; fires; and an occupational overexposure. All incidents in the Division files were in the NMED records. The NMED records reflected the information in the Division files.

The review team found that the Division has an incident response and allegation procedure in place, but that it is not routinely practiced in a detailed fashion. The resolution of potential health and safety issues was marginal. The Division made notifications to the NRC, and other Agreement State programs as required.

The Division's CAI procedure requires that each "staff member involved in an event . . . prepare a written report documenting the activities in which (s)he was involved," including, "all relevant information," and that these reports be "forwarded to the CAI coordinator, where they will be made part of the file for each event." In four of the fourteen cases reviewed, there was no written report by the inspector(s) involved. All four of these cases appeared to have had the potential for serious consequences. In all four cases, the incident file did not contain any indication that the Division had evaluated the licensee's response or corrective actions. Two of these four incidents occurred at the same licensed facility, within three months of one another, and both involved fires in the ventilation system sparked by cutting torches. In three additional incident files, significant information was missing, including laboratory sample analysis results, documentation of the decontamination of an unlicensed facility, information necessary to assess the public dose consequences of a release, and assessments of individual doses resulting from the incidents.

In the remaining seven incident files that were reviewed, the written reports and supplementary documentation appeared to support the conclusions reached by Division staff and the actions taken were appropriate and timely. In two of these cases, the Division pursued escalated enforcement actions, including the imposition of fines.

The missing information was discussed with the Deputy Director, who also functions as the CAI coordinator, and she stated that the Division does not have a formal procedure for closing incident files. This appears to have contributed to the missing information identified in half of the incident files reviewed during the on-site IMPEP review. The CAI coordinator felt that the activities had been conducted but that the information had not been assembled in the incident files.

The review team recommends that the Division ensure that independent, documented evaluations of the licensee's actions and root cause analyses are completed as part of an incident investigation.

The review team recommends that the Division formally close incident files, including a review to ensure that all the necessary documentation is included in the file.

The Division's procedure for responding to incidents includes a section specifically related to allegations. The State law currently does not provide anonymity to persons bringing complaints forward to the Division. Information in the Division's files is open to the public, and anonymity can only be preserved if the complainant's name does not become a part of any record. The procedure also requires that when a complainant is known to the Division, a response to that person be made providing the results of the investigation. If the complaint was made in writing, the response is to be made in writing. If the complaint was made verbally, the response may be verbal or in writing, but should be documented in the file.

The team reviewed 10 of the 12 allegations referred to the State by the NRC, and four allegations delivered directly to the State. With respect to the two referred by NRC that were not reviewed, both were referred within the two months prior to the on-site IMPEP review. One was still with

the field office, and the investigation had not been completed, and the other did not involve AEA material.

The review team found that the Division's response to the allegations referred by the NRC were handled in a timely and appropriate manner, with two exceptions. In one case, the investigation was performed during the course of a full inspection, approximately three months after the referral. In addition, the results of this inspection, including a Notice of Non-compliance was written, but never delivered to the licensee. The Deputy Director said this report had been submitted for supervisory approval, but was apparently misplaced and never approved for release. In the second case, the allegation was investigated approximately one and one half months after the referral, and the results of the investigation were not transmitted to the complainant until another two and one half months after that because, according to the investigation, the "report was misplaced in [the] Central Office."

The review team found that with respect to those allegations received directly by the Division, the responses appeared timely and appropriate. However, in three out of the four cases, there was no documentation of responses providing the results of the investigation to the complainants. The review team recommends that supervisory reviews be conducted to ensure thoroughness of investigations of allegations, including that allegations are closed out with the alleged.

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 with recommendations for improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing 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 uranium recovery, 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 applies 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. Under the Rulemaking Hearing Rules procedures, all proposed rules are reviewed internally by the Department's Office of General Council (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, 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 will be 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. Historically, all rules approved by the OGC have been approved by the legislature with the passage of appropriate legislation.

The team evaluated Tennessee'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 information concerning the adoption of regulations with data obtained from the Office of State and Tribal Programs (STP) Regulation Assessment Tracking System.

The Division has not adopted any regulations needed for compatibility since the 1996 review. The Division drafted some of the rules needed for compatibility, but the rules were never adopted and the rules were not provided to STP for review. The team identified rules needed for compatibility as follows:

- ! "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) which became effective on January 27, 1992. The Division is monitoring the development and status of the 10 CFR Part 35 revision. The Commission has approved

the final rule which is expected to be published in Spring 2001. We believe that the Division conserving rulemaking resources to address the new Part 35 is appropriate.

- ! "Decommissioning Recordkeeping and License Termination," 10 CFR Parts 30 and 40 amendment (58 FR 39628) that became effective October 25, 1996. This rule was drafted in February 1998 then removed from consideration by the Division.
- ! "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994. This rule was drafted in December of 1996 then removed from consideration by Division.
- ! "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 was drafted in April of 1998.
- ! "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that became effective March 1, 1998. Agreement States were expected to have an effective rule on the same date and this rule is designated as category B for compatibility.
- ! "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995. This rule is designated as category B for compatibility. The Division incorporated 60 FR 28323 in all radiography licenses by license condition in January 1997. The team did not verify during the review that the license condition covered all of the regulatory requirements.
- ! "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995. Certain definitions in this rule are designated as category A for compatibility.
- ! "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 28323) that became effective November 24, 1995.
- ! "Medical Administration of Radiation and Radioactive Materials," 10 CFR Part 35 amendment (60 FR 48623) that became effective November 24, 1995.
- ! "10 CFR Part 71: Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendments (60 FR 50248 and 61 FR 28724) that became effective April 1, 1996. This rule is designated as category B for compatibility.
- ! "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1996.
- ! "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65120) that became effective January 9,

1997. This rule was drafted in October of 1998.

- ! “Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997. The Division incorporated this jurisdictional requirement in temporary jobsite licenses by license condition in April, 1996. The team did not verify during the review that the license condition covered all of the regulatory requirements.
- ! “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997. The Part 20 amendment is designated as category A compatibility. The Division put a license condition on medical licenses that authorized therapeutic dosages of radiopharmaceuticals that allowed the use of the new patient release criteria. The license condition was not reviewed for completeness. The Division is proceeding to adopt the rule in the next revision.
- ! “Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947) that became effective June 27, 1997. Parts of this rule are designated as category B for compatibility.
- ! “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.

Regulations needed in the future were identified as follows:

- ! “Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea,” 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998. This rule was reportedly drafted by the Division in February 1998 and is designated as category B for compatibility.
- ! “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 35, 36 amendments (63 FR 39347 and 63 FR 45393) that became effective October 26, 1998. Definitions changes in this rule are designated as category A for compatibility.
- ! “Transfer for Disposal and Manifests: Minor Technical Conforming Amendment,” 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998. This amendment is designated as category B for compatibility.
- ! “Deliberate Misconduct by Unlicensed Persons,” 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.
- ! “License for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections,” 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998. Portions of this rule are designated as category B for compatibility.

- ! “Termination of Transfer of Licensed Activities: Recordkeeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1999.
- ! “Respiratory Protection and Controls to Restrict Internal Exposures,” 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000. Portions of this amendment are designated as category B for compatibility.
- ! “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment (65 FR20337) that became effective May 17, 2000. Portions of this amendment are designated as category B for compatibility.

It is noted that Management Directive 5.9, Handbook, Part V, (1)(C)(III) provides that regulations issued prior to September 3, 1997 should be adopted by the State as expeditiously as possible, but not later than three years after the September 3, 1997 effective date of the Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

During the review, Division staff reported that the Tennessee regulations were being revised in their entirety and estimated that at least six months would be needed for their adoption after they were approved by Division management. The review team recommends that the Division adopt the regulations needed for compatibility as expeditiously as possible and provide the proposed regulations to the STP for compatibility review in accordance with the procedure SA-201 “Review of State Regulations.”

Based on the IMPEP evaluation criteria, the review team recommends that Tennessee’s performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found unsatisfactory.

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

In assessing the State's SS&D evaluation program, the review team examined information provided by the State in response to the IMPEP questionnaire on this indicator. A review of selected new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff's use of guidance documents and procedures, interviewed the two Managers and staff involved in SS&D evaluations, and verified the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The Division has processed two new registrations, and amended 19 other registrations since the last review. The review team selected the two newly issued SS&D registry certificates and nine other registrations for review. The review included all amendments, supporting documentation, licenses, and inspections associated with each of the registrations selected. The certificates reviewed covered the period since the last program review in December of 1996 and represented cases completed by all reviewers. The SS&D certificates issued by the Division and evaluated by the review team are listed with case-specific comments in Appendix F.

Analysis of the files and interviews with the staff confirmed that the Division follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3,

issued July 1998. Appropriate review checklists were used to assure all relevant materials have been submitted and reviewed. Checklists were contained in the registration files. All pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were confirmed to be available and were used when performing SS&D reviews.

The registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The review team determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of an accident.

4.2.2 Technical Staffing and Training

The manager of the Radioactive Materials Specific Licensing Section is the principal reviewer and signs all registration sheets. A concurrence review is performed by the manager of the Licensing/Registration/Planning Branch. The principal reviewer and the concurrence reviewer both have Bachelor of Science degrees, many years of experience in health physics; licensing; inspections; performing SS&D reviews; and both have attended the NRC/State SS&D workshops. Two experienced license reviewers are being trained to perform SS&D reviews under the direct supervision of the principal reviewer. These trainees were determined by the team during interviews to be fully trained license reviewers, adequate to perform limited SS&D reviews under the direct supervision of the principal reviewer, and the case specific registration reviews performed during this review period. However, the trainees have not attended the SS&D workshops which would assist in qualifying them to sign the registration sheets as a reviewer. Signatures and reviewer qualifications were discussed with the principal reviewer. The principal reviewer confirmed that the trainees had only performed work under his direct supervision and that the trainees would be sent to the next SS&D workshop scheduled for FY 2001 providing funds are available. The qualification of the trainees have not been fully documented as discussed under Section 3.3 and the SS&D managers acknowledged the need for additional authorization documentation for the reviewers. The managers are committed to maintaining a high degree of quality in their SS&D reviews. The review team recommends that all persons conducting principal and concurrent reviews for SS&D registrations be fully qualified and have documented authorizations on file.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No significant incidents or defects related to SS&Ds were reported with these devices (products) during the review period. The team also verified that there were no reported incidents through discussions with the SS&D reviewers and a review of the incidents as discussed under Section 3.5. An on-line search by manufacturer utilizing the NMED system was conducted by the team prior to the review, and no incidents were identified that were related to any malfunctioning devices or products considered during this review.

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 that Tennessee's performance to be satisfactory for the indicators, Technical Staffing and Training, Technical Quality of Licensing Actions, and Sealed Source and Device Evaluation Program. The review team found Tennessee's performance to be satisfactory with recommendations for improvement for the indicator, Response to Incidents and Allegations. The review team found Tennessee's performance to be unsatisfactory for the indicators, Status of Materials Inspections, Technical Quality of Inspections, and Legislation and Program Elements Required for Compatibility. Accordingly, the review team recommended and the MRB concurred in finding the Tennessee Agreement State Program to be adequate, but needs improvement and not compatible with NRC's program. The review team recommended and the MRB concurred that a program of Heightened Oversight be implemented to assess the progress of the State in implementing corrective actions discussed at the exit meeting and the MRB meeting. The MRB requested the State prepare and submit a program improvement plan which addresses the recommendations below. The MRB also requested that the State submitted bi-monthly status reports and participate in bi-monthly conference calls to discuss the progress to date on the State's action plan. The initial conference call should be scheduled no later than February 1, 2001.

Based on the results of the current IMPEP review, the review team recommended and the MRB concurred that a follow-up review will be scheduled during the period August - October 2001.

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

RECOMMENDATIONS:

1. The review team recommends that the Division take actions to ensure that: (1) inspections are conducted in accordance with their assigned inspection frequencies; (2) inspection reports are issued in a timely manner; (3) inspection reports and associated information are filed in a manner that the information can be retrieved; and (4) deficiencies in the inspection tracking system are corrected. (Section 3.1)
2. The review team recommends that the Division follow the Tennessee inspection policy and procedures. (Section 3.2)
3. 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. (Section 3.2)
4. The review team recommends that the Division develop and document a training and qualification program which address the training requirements in the NRC/Organization of Agreement States Training Working Group Report or NRC Inspection Manual Chapter 1246. (Section 3.3)
5. The review team recommends that the inspection staff be trained in the Division's policies and procedures on the conduct of inspections. (Section 3.3)
6. The review team recommends that the Division ensure that independent, documented evaluations of the licensee's actions and root cause analyses are completed as part of an incident investigation. (Section 3.5)
7. The review team recommends that the Division formally close incident files, including a review to ensure that all the necessary documentation is included in the file. (Section 3.5)
8. The review team recommends that supervisory reviews be conducted to ensure thoroughness of investigations of allegations, including that allegation are closed out with the allegor. (Section 3.5)
9. The review team recommends that the Division adopt the regulations needed for compatibility as expeditiously as possible and provide the proposed regulations to the STP for compatibility review in accordance with the procedure SA-201 "Review of State Regulations." (Section 4.1.2)
10. The review team recommends that all persons conducting principal and concurrent reviews for SS&D registrations be fully qualified and have documented authorizations on file. (Section 4.2.2)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Tennessee Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source & Device Casework Reviews
Attachment 1	Tennessee Comments on the Draft IMPEP Report dated October 23, 2000

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Dennis Sollenberger, STP	Team Leader Technical Staffing and Training
Richard Woodruff, Region II	Sealed Source and Device Evaluation Program Legislation and Program Elements Needed for Compatibility
Jamnes Cameron, Region III	Technical Quality of Inspection Inspection Accompaniments
Betsy Ullrich, Region I	Technical Quality of Licensing Actions
Barbara Hamrick, California	Response to Incidents and Allegations Status of Materials Inspections Program

APPENDIX B

TENNESSEE

DEPARTMENT OF ENVIRONMENT AND CONSERVATION

ORGANIZATION CHART

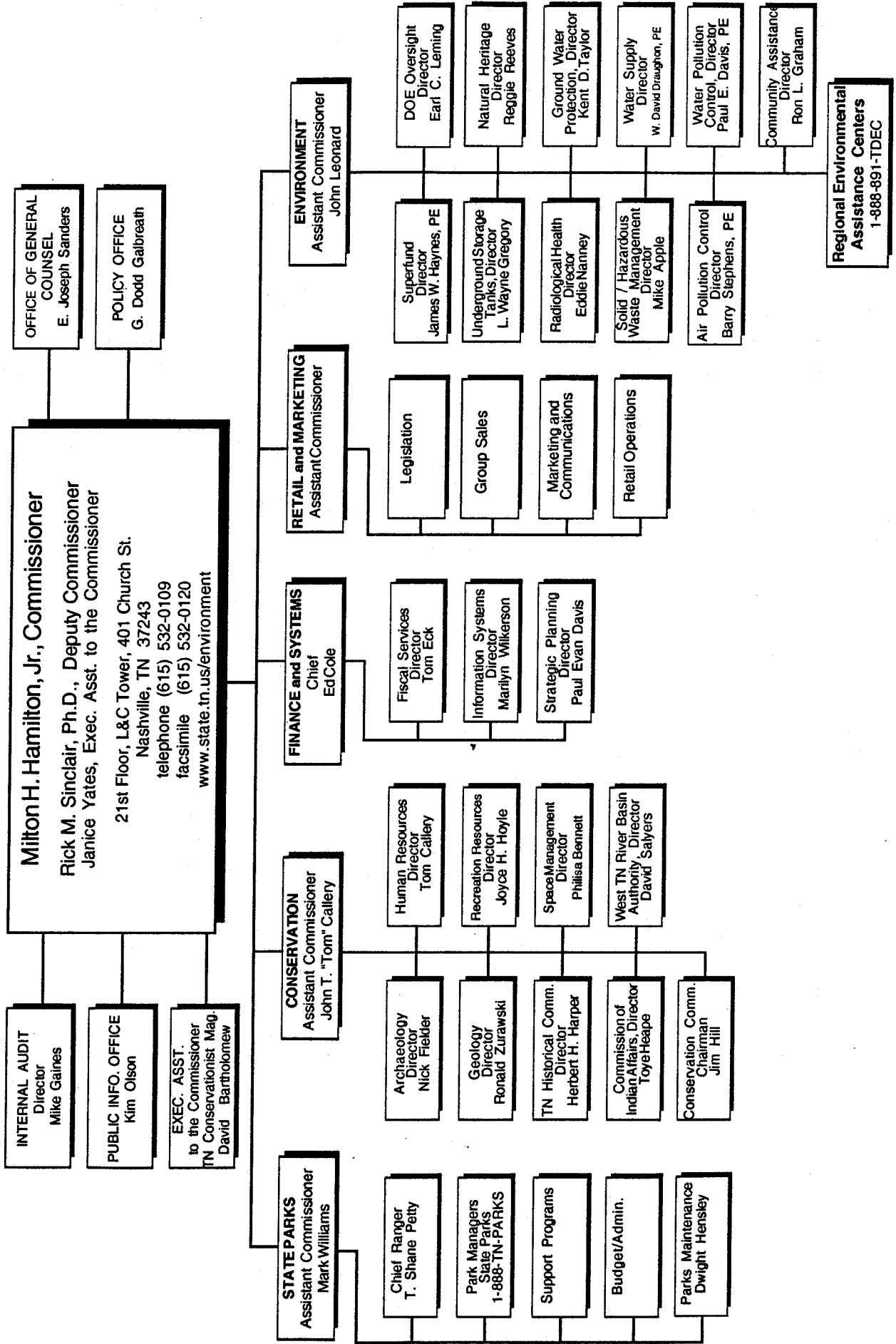
and

DIVISION OF RADIOLOGICAL HEALTH

ORGANIZATIONAL CHART

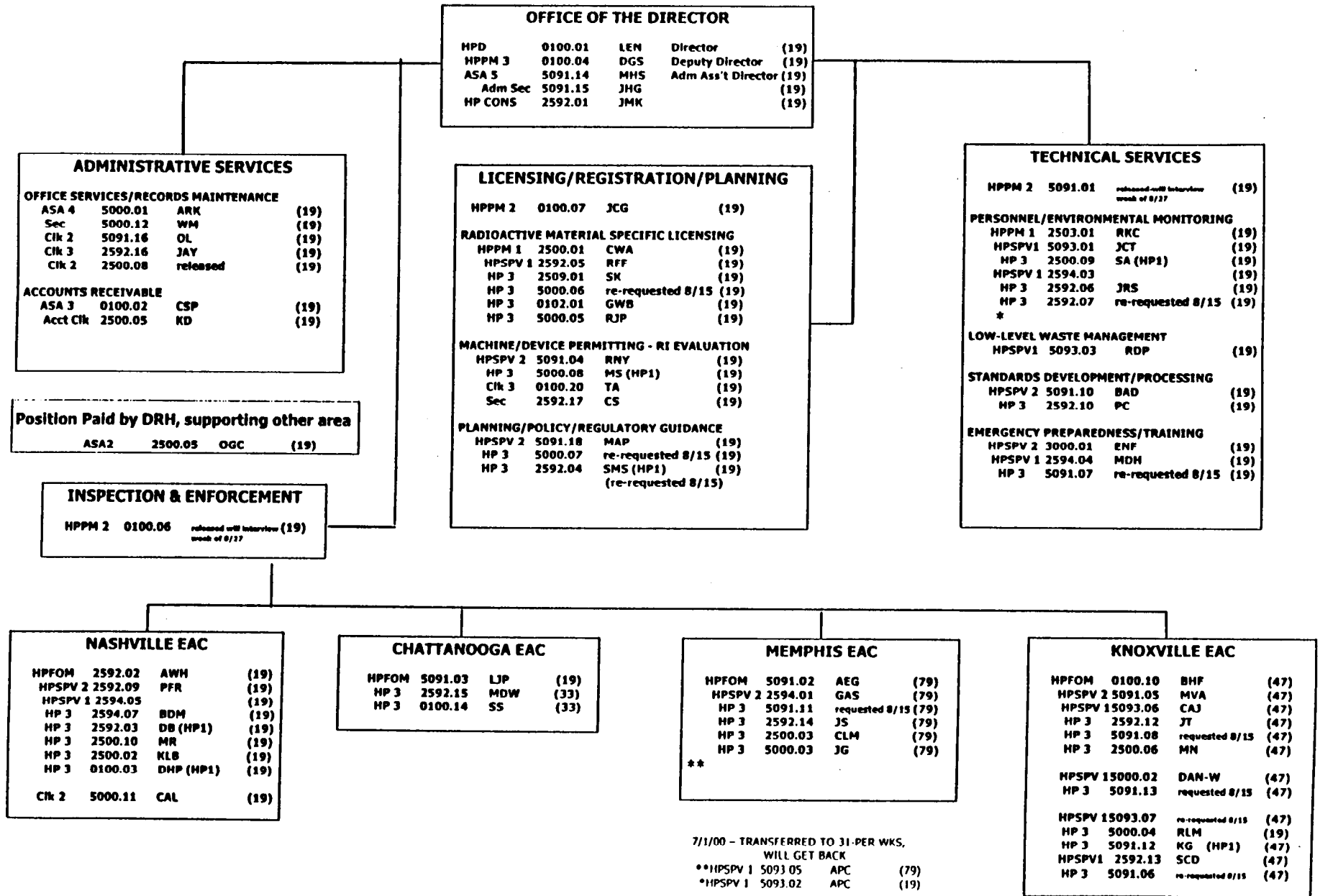
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TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION



DIVISION OF RADIOLOGICAL HEALTH (327.32)

August 16, 2000





STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

L & C Annex, 3rd Floor
401 Church Street
Nashville, Tennessee 37243-1532
(615) 532-0364

October 23, 2000

Mr. Paul H. Lohaus, Director
Office of State and Tribal Programs
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Lohaus:

I am responding to your letter dated September 22, 2000, to Mr. John Leonard. We have reviewed your letter and the attached draft IMPEP report which documents the preliminary findings from the review of the Tennessee Agreement State program conducted by your team during the week of August 21-25, 2000. Attached are our comments regarding the accuracy of the report.

It should be noted that the majority of the comments relate to Section 3.2 Technical Quality of Inspections and to Attachment C, Inspection Casework Reviews. In our discussions during and after the Review Team's visit to Tennessee, I expressed the concern that most of what we were hearing about this portion of the review was anecdotal. I stated that we were looking forward to seeing the casework so that we could try to understand the basis for the findings which were being formulated.

Having now had that opportunity, I must point out that we disagree with a large number of the specifics in this indicator. We feel that this finding places an inappropriate emphasis on doing inspections in accordance with NRC's SOPs, rather than those we currently use. Our SOPs have been in place for many years, and have not in the past come under such criticism. While they are no doubt due for an update, we believe that they are the standard against which technical quality should be judged. On that basis, we submit that the suggestions we have offered, if accepted, will improve the technical accuracy of the report.

00 OCT 24 PM 5:10

OSP

Thank you for the opportunity to provide these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence E. Nanney". The signature is written in a cursive style with a large initial "L" and a long, sweeping underline.

Lawrence E. Nanney
Director

ATTACHMENT

3.1 Status of Materials Inspections

- Page 4. P. 1. L 1 Remove “not” and add an “s” to require.
- Page 4. P. 1. L 2 Sentence should begin with “Some of the reports....”
- Page 4. P. 2. L 5 Sentence begins “Two reports....were missing...” The report dated May 2000 was not missing. it was being prepared by the principal inspector in that field office.
- Page 4. P. 2. L 8 Sentence begins “The staff turnover...” Sentence should end at the semicolon. The Division does have a clear policy that requires all correspondence relating to all inspection findings be delivered to the Central Office for maintenance in the central files. The inspection reports were sent to the Central Office from the field offices for maintenance in the Central Office files per policy. The fact that the reports were not filed in the license files was not due to a lack of a clear policy.

3.2 Technical Quality of Inspections

- Page 4. P. 6. L 2 Sentence should be changed to reflect that the inspectors were not interviewed for all 21 radioactive materials inspections conducted during the review period. The statement “...and interviewed inspectors for 21 radioactive materials inspections (for 17 licensees)...” implies that they were interviewed regarding each inspection. Had this actually occurred, many of the items which we believe were erroneously included in the casework findings, and to which we respond here, might not have been included in the first place.
- Page 5. P.1. L 6 Sentence beginning “All notices of non-compliance...” should be deleted. Central Office Management only reviews inspection reports from Priority 1 licensees requiring financial assurance, licenses-for-delivery notices of non-compliance, and any inspections performed by Field Office Managers.
- Page 5. P. 3. L 6 Sentence beginning “The review team...” The term “low quality” is subjective and pejorative and has no clear meaning in this context.

- Page 5. P. 3. L 11 Sentence beginning "None of the inspection reports..." is factual, however, it is irrelevant. We have not yet adopted the concepts of performance-based inspections and routine inspector evaluation of safety significance and root cause of violations into our inspection SOPs. While this is in large part due to the fact that we have been extremely limited in our ability to get staff into both the Inspecting for Performance and the Root Cause Investigation courses, that too is irrelevant. It is relevant that, wherever these concepts are referenced in these review findings, we are being penalized for not following the NRC's SOPs, while it has been portrayed that we are not following our own SOPs.
- Page 5. P.5. L 5 Sentence beginning "In one instance..." The tour of the facility was during normal work hours, but after the last patient had been scanned.
- Page 6.P.1. L 5 Sentence beginning " In addition, under Section 098.05 of..."should read, "under Section 1000.08"
- Page 7. P.4. L 1 Sentence beginning "The Division Director retired..."and the following two sentences should be deleted. Replace the first three sentences with the following: "The Director of the Division retired in November 1999 and the Deputy Director was selected to succeed him in January 2000. The Technical Services manager was selected to be the new Deputy Director in July 2000. The Inspection and Enforcement manager was moved to a staff technical position in July 2000 and these two management positions are in the process of being filled."
- Page 10. P. 7. L 2 Sentence beginning "However, in three out of..." can not be substantiated since there is no documentation in Appendix E as to what specific allegations the review team is referencing.
- Page 12. Bullet 7 Add: "The Division incorporated 60 FR 28323 in all radiography licenses in January 1997."
- Page 13. Bullet 5 Add: "The Division incorporated this jurisdictional requirement in temporary jobsite licenses in April, 1996."

Appendix C. Inspection Casework Reviews

File No.: 1

At the time of the NRC review team visit the report was still in draft form and was in the process of management review when requested by the NRC review team. The report had not been fully reviewed but notes and omissions were noted on the draft report and was provided to the NRC review team with their full knowledge that it was an incomplete document. Several of the items noted in the review of this report reflect the draft status of the report. The information that is noted as not in the report was available in the inspector's notes and was included in the final document after management review.

Page C.2. File No. 5

a) Observations are not always possible in low-workload facilities. This is a small hospital with one technician performing 30 – 40 scans per month.

b) 1. The citation in the letter states: "Records for linearity tests which were to be conducted during the second quarter of 1999 were not available for review."

This is how we cite. If no records are available to prove tests were performed, then there is no proof tests were performed.

2. Requirement is for records to be maintained. If there is not a ring badge report then the licensee is still required to estimate dose and maintain a record. The ring badge record was not available.

3. The licensee's representatives were the nuclear medicine tech and the Director of Imaging Services. In a small hospital where use of radiation is limited, these individuals would certainly know if this type of training was taking place. The licensee's response clearly indicates that this training was not being performed.

c) Violation # 2 was not disputed by the licensee. They offered an explanation as to why there was no record from the processor.

d) The information on our internal inspection reports is sufficient to perform inspections in accordance with our SOP's. These forms and the method of completing these forms have been used for years (through other NRC reviews and one previous IMPEP review) without any substantial changes. The comment reflects the reviewer's opinions which we do not share.

Page C.2. File No. 6

a) Sentence beginning "Report indicated..." The inspection report did indicate that work had been performed in Alabama with two sources which were still in Alabama at the time of inspection. The licensee accepted the violation and stated they would make corrections.

Page C.3. File No. 7

Inspection date: 4/20/00

b) The inspector requested the RSO who was not present. They were provided with the acting RSO and an authorized user to conduct the inspection.

Inspection date: 8/5/99

b) In paragraph 28 of the inspection report, the records were noted as not being on file that resulted in the items of non-compliance 1 and 2.

c) The inspector requested the RSO who was not present. They were provided with the acting RSO and an authorized user to conduct the inspection.

Page C.3. File No. 8

The inspection dated 8/14/97 was performed by BAS (Barbara Shrader) not MW.

Page C.4. File No. 9

a) 1. The inspection report clearly identifies items that were untrackable by the licensee. B-25 boxes and drums. The licensee could not identify how long these packages had been on site or what they contained. This is an ongoing problem at this facility and has been the subject of numerous meetings with our office. The licensee is a very large facility with literally hundreds (if not thousands) of packages on site at any one time. The only feasible way to monitor the length of package storage is to require an auditable tracking system. The citation is accurate because there was no way for the licensee to demonstrate compliance.

2. How can an inspector be expected to total up hundreds of packages of material and figure out by observation how much radioactive material exists in an unpackaged state? Without a tracking system as discussed above activity on site is not auditable. Citation is valid.

3. It is not our policy to not cite for self-identification nor is it our policy to credit for self-identification and correcting as does the NRC.

4. The information the reviewer indicates is missing is not relevant. The licensee was required to but did not perform the bioassays.

5. The report goes into great detail about what the license requires (continuous sampling), what was being done (only 2 samples of each type for 10-12 burns, no sampling for the high temperature burn), why this was currently happening (reduction of HP staff and a change in procedures). The technical violation is clear – sampling of air effluent is not being performed during burn operations and the amount of radioactive material released by the facility cannot be determined.

7. "Seventh violation was for failure to demonstrate compliance with the public dose limits. The violation is not substantiated." This is deemed incorrect in that the inspection report states on page 3, 5th paragraph, item #7. "The dose to the member of the public calculation was not available for 1999.", and on page 6, item #27. "Dose to the Member of the Public...the 1999 dose calculation was not completed...no time estimates were received during the exit interview as to when this calculation would be available". The review team's report goes on to refer to the inspector's report as follows: "The report includes the results of the annual TLD fence-line monitoring. The highest recorded dose was 170 millirem in a year, with an occupancy factor of 1. A license condition allows 500 millirem in a year based on TLD results." Although this is true, it is irrelevant in that the inspector did not cite against the 500 mR/year limit, rather against the SRPAR requirement to demonstrate compliance with the member of the public limit which is 100 millirem TEDE, not limited to an occupancy of 1. The 500 mR/yr limit is a separate requirement imposed by license condition which must also be met.

Page C.5. File No. 11

a) 1. "Report states that record of inventory not available. not that it was not performed." Paragraph 20 (8)(d) of the inspection report states that quarterly physical inventories were not performed and were not documented. The citation is consistent with our procedures. The records were not available to indicate that the inventories had been performed. A record of the inventory is the only proof that it has occurred. Since the number of sources that the licensee can possess is variable (no single source to exceed xxx curies" for each of 3 different cameras) the licensee is required to keep records for any and all sources.

a) 2. The third violation in the inspection letter is worded "...requires in part that reports received from the TLD processor be kept for inspection by Division..." The citation reads: "TLD records were not available" and they were not all available. In addition exposure information from other types of dosimeter results were available.

a) 3. "The fourth violation was for failure to leak test sealed sources at six month intervals..." A licensee must have records of the initial leak test after receipt or of the manufacturer's leak test sent with the camera. Neither was available.

Page C.6. File No. 12

b) RSO was unavailable at the time of inspection but was involved in the response to the items noted.

Page C.6. File No. 13

a) 1. Paragraph 27 of the inspection report indicated the licensee's own area monitors showed a 700 mR/yr exposure in 1997 and 500 mR/yr for 1998 at the generator area and they had made no assessment which included this information and stack release data of iodine to determine compliance with the 100 mrem/yr limit. The statement "Empirically, it appears that no one likely would have exceeded the limit" by the reviewer ignores the data presented in the report of the licensee's own data in paragraph 27. our own independent survey data in paragraph 32 of the inspection report, and the fact that this is next to a glass wall which separates it from the uncontrolled area outside of the building.

a) 2. License condition 36 requires that the doors to the hot lab area (restricted) be maintained locked to prevent couriers' access and maintain contamination control. This

was the license condition violated and was cited as such. The doors were documented and observed as unlocked to the hot lab area and were noted in paragraph 22 in the inspection report. The citation was substantiated.

a) 3. Each violation of the failure to monitor was addressed immediately upon observing the failure to monitor. Since several drivers were coming and going during the inspection each incident was addressed as it occurred. This indicated a need for refresher training concerning this license requirement and that was noted to the RSO by making it a citation, addressing it at each incident observed and corrected, and during the closeout meeting as documented in the inspection report paragraph 19.

a) 4. The refrigerator and L-block were labeled with "Caution Radioactive Material" labels and were located in an unrestricted area (an area free of contamination and radioactive materials that the licensee had dedicated as such) of the facility as documented in their license. The labels should have been defaced or removed and documentation of the release survey showing no contamination be provided which they were not able to do. Our independent surveys noted in Paragraph 32 indicated no contamination in the office areas that included these items.

b) The response of the licensee dated 7/12/99 indicates not only the expansion of the restricted area but the relocation of waste and generator areas as a method to lower exposure rates to members of the public (in a letter dated May 17, 1999). The letter also indicates that this will put them into compliance with the regulations, correcting the cited violation, which was failure to ensure compliance with the limit.

Page C.7. File No. 14

a) "Cannot determine by inspection report if any interviews were conducted." The persons interviewed during this inspection were the Radiation Safety Officer, medical physicist, physicist, and oncology nurse as documented in the inspection report.

Page C.7. File No. 15

a) The RSO is the president and owner of the company.

Page C.8. File No. 16

a) 1. Leak tests were performed and reviewed but they were not being done on a six-month interval as noted in the

inspection report. The relevance of the reviewer's questions is unclear.

a) 2. The licensee committed to wearing personnel monitors in the initial application. License condition 23 of the license requires them to have badging. If they have badging, they are required by SRPAR to maintain the records. This is what was cited in the inspection report and letter.

a) 3. Licensees are required to maintain receipt and disposal records of the gauges they possess for review by the Division. The failure to maintain the records for review is a violation of license condition 20.

a) 4. The licensee indicated this person is an authorized user and the license requires in Condition 15.A. that they maintain a copy of the training certificate. This is a violation of the license.

b) Note that in paragraph 21 of the report the manager is Jay Richardson, Jr. This is a family business and the RSO Jay Richardson III is a member of management.

Page C.9. File No.17

a) 1. It is not incumbent on the inspector to go to the landfill and sample what has been sent there by the licensee to determine if they are within the concentration limits. It is also not incumbent on the inspector to take raw data and perform the necessary analysis to determine compliance. The license requires the licensee to show compliance and that is done through records. At the time of the inspection the records provided did not establish compliance for past shipments. The licensee agreed to our request and suspended the operation until a better understanding of the records could be ascertained. The licensee did not know nor were they able to show that they were in compliance on the day of the inspection.

a) 2. "Third violation was for failure to" The reviewer takes issue with the inspector's wiping technique and documentation of the area wiped for the survey without having any factual knowledge about the actual technique used. The reviewer notes that "...it is difficult to establish that the inspector's wiping technique **exactly approximated** (sic, emphasis added) 100 square centimeters." The reviewer goes on to suggest that the

inspector overwiped areas. The inspection report specifically points out "all swipes that were taken over an area of 100 sq. cm except for MVA 451 which was a Large Area Wipe". The swipes designated as taken over a 100 sq.cm area were in fact taken over a 100 sq. cm area (at least as close to 100 sq.cm as any health physicist can obtain with the 4 inch square "S" swipe technique which is an industry recognized standard) and were not gross swipes as the reviewer suggests. This comment represents nothing other than the reviewer's opinion, and is completely unsubstantiated.

a) 3. The basis of the 45-day limit is not something the inspection report would ever address. A careful review of the license would show that the 45 day limit has been discussed and negotiated over a long period of time. The inspector is to determine if all casks are within the 45 day limit and cite the facility if they are not.

a) 4. In Tennessee when we establish a clear limit of 5 pCi/gm. the limit is 5 pCi/gm. The licensee accepted that limit. Under our current SOPs, the inspectors determine compliance and cite if not in compliance.

a) 5. The amendment in question was for a procedure (including this monitor) to replace an existing procedure that the licensee could not make operate properly. The issues involving the stack monitoring at this facility have been ongoing for quite some time. While the inspector is not expected under current SOPs to comment on the safety impact, the safety impact of unmonitored stack releases should be implicitly clear. Being "hampered" to bring a facility into compliance is not accepted as an excuse for non-compliance. The remote alarm was committed to by the licensee in the amendment request and we expect commitments to be met.

a) 7. The report shows that the tests were over one month late and that the test failed when it was finally performed. The test was repeated on the next day and again failed. The facility did not get an acceptable test until almost 2 months later. All of this is in the inspector's report.

a) 8. The monitoring for these isotopes had not been performed. The citation is correct.

- a) 9. This comment is of no significance with respect to Tennessee SOPs, but the following responses are considered appropriate:

Citation # 11

These storage casks were transportation casks on loan to the licensee. The length of time authorized had been negotiated with the licensee by the licensing staff prior to the amendment. The licensee had not requested an extension and was still using the casks. Under our SOPs this is a violation of the license and was cited.

Citation #12

The citation was as follows:

12. SRPAR 1200-2-5-.113(1) requires, in part, that each container of radioactive materials shall bear a clearly visible label which shall bear the radiation caution symbol and the words "CAUTION - RADIOACTIVE MATERIAL" and include information that will permit individuals handling, or working in the vicinity of the container, to take precautions to avoid or minimize exposures (i.e. radiation level information).

Contrary to the above, containers of radioactive material in outside storage were not provided with adequate labeling in that containers were labeled with incorrect radiation level information which did not reflect the radiation levels associated with the current contents of the containers.

The safety significance should be obvious without elaboration.

Inspector Accompaniments

Page C.11, Accom. #2

The Radiation Safety Officer explained at the time of inspection that the source was used in February 2000 with no plans to use it the rest of the year.

- a) 9. This comment is of no significance with respect to Tennessee SOPs, but the following responses are considered appropriate:

Citation # 11

These storage casks were transportation casks on loan to the licensee. The length of time authorized had been negotiated with the licensee by the licensing staff prior to the amendment. The licensee had not requested an extension and was still using the casks. Under our SOPs this is a violation of the license and was cited.

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The safety significance should be obvious without elaboration.

Inspector Accompaniments

Page C.11. Accom. #2

The Radiation Safety Officer explained at the time of inspection that the source was used in February 2000 with no plans to use it the rest of the year.

Page C.11. Accom. #3

The Radiation Safety Officer, who is the radiographer on this license, was interviewed at the time of inspection.

Page C.12. Accom. #5

a) This is incorrect. The inspector upon arrival at the facility went to the Administration office and was then directed to the RSO to conduct the inspection. (This was confirmed by the NRC reviewer to the inspector's supervisor at the time of the NRC review). No items of health and safety were noted by the inspector or by the NRC reviewer and the RSO decided not to include any higher management for the exit meeting.

b) This statement is incorrect. The inspector followed the inspection SOP which states on page 9 of the SOP in 1000.08 that selective direct observations of work in progress be conducted. The reviewer notes in the review of File 1 that he observed surveys being conducted by the inspector at which time pointed questions were asked of the workers concerning training and activities in which they were engaged. The reviewer indicated to the inspector's supervisor during the NRC review that observations, questions of workers and surveys were performed. In regard to the therapy dose administration not being observed, the inspector inquired about observing the procedure, the nuclear medicine technician asked that the patient's (an elderly female who was only partially clothed) right to privacy be respected, and the inspector concurred. The reviewer did not attempt to determine the reason for not observing the therapy dose. The inspector repeatedly asked the reviewer if he could clarify anything or answer any questions on the inspection activities. The reviewer did not comment at the time.

c) This is incorrect. The inspector spoke with several personnel during the inspection and during the performance of their duties. The inspector asked questions concerning the activities in which they were involved, about how surveys were performed, and if training was adequate, including Declared Pregnant Worker issues. The inspector also asked the technician who was performing the therapy procedure to walk through verbally the method and procedures he would follow to administer the dose and perform the exam.

License Casework Review

Page D.3. File No. 11

Comment a) "Licensee letter dated 11/29/99 refers to telephone calls from reviewer 11/29/99 and 5/5/00 but no record of telephone calls in the file." This comment needs clarification in that a licensee letter dated 11/29/99 could not reference a telephone conversation that took place on 5/5/00. The situation is: Amendment 50 references letters dated 4/21/00, with attachments, and 5/8/00, with attachment. The letter dated 5/8/00 includes a copy of a letter dated 11/29/99 (which is referenced in Amendment 49) which references a phone call between the licensee and the staff reviewer on 11/29/99. The letter clearly states the discussion in the phone conversation; therefore, the acceptance of the letter by reference by the staff reviewer is the documentation of the phone call. The letter dated 5.8/00 references a phone call between license reviewer and the licensee documenting that a particular issue concerning the request of 4/21/00 (and the additional clarification of 5.8/00) was already taken care of (namely in Amendment 49 concerning financial assurance); the acceptance by the reviewer of the letter with this discussion and its subsequent reference in Amendment 50 is the documentation of the phone call.

Appendix E. Incident Casework Reviews

File No. 1

a) We do not understand the sentence beginning "The reported levels of Am-241...." The laboratory results of the swipes in our file taken by our inspector indicate six out of the nine swipe samples indicated Am-241 with no detectable Bi-214 and Pb-214. The other three swipes (from floor areas) contained no detectable Am-241, but normal concentrations of Bi-214 and Pb-214. The Am-241 concentrations ranged from 5.3 pCi/wipe to 1753 pCi/wipe. The Pb-214 and Bi-214 ranged from 10.3 pCi/wipe to 13.3 pCi/wipe.

Page E.2. File No.4

a) "There was no written report by the inspector involved in this investigation." In fact, there were two copies of the same report in the file written by the inspector involved in this investigation.

b) "This event appears significant enough to have required an on-site response." However, the inspector documents in

the written report (which is a part of the file) that the stack analyses indicate no RAM release. In addition, the licensee's report dated 6/30/98 (also in the file), states that stack samples showed no release of radioactive material. Although the reviewer does not mention this, it should be noted that this incident was determined to not meet the incident reporting criteria as defined in SRPAR 1200-2-5-.141.

c) In the reviewer's comments under item d), there are quotations around a statement from the licensee's report as follows: "three hours of decon in P-4 – water, sludge and filter media". However, the actual statement in the file reads: "Decon Operations and Health Physics Began a clean-up of Parcel 4 Storage Area-Retrieving Filter Media, water & sludges.-clean-up took about 3 hours". It was not interpreted that this "clean-up" was exclusively radioactive decontamination, but rather simply a clean-up of the mess that was present, some decontamination and some non-radioactive clean-up. The inspector was notified the day after the event occurred. At that time the recovery operation was complete. Sufficient information was submitted by the licensee to close this event. A site visit was not deemed necessary.

Page E.3. File No. 6

a) "There was no written report by the inspector involved." There were two reports from two individuals involved in this incident in the file.

Page E.5. File No. 12

The type of investigation should be changed from "phone" to "site visit" as recorded in the file. The enforcement document in the file states that inspections were conducted by staff on 3/2/99 and 3/3/99.

Page E.6. File No. 14

Site of incident should be changed from "Not recorded" to "President's Island – Ergon" as recorded on the front sheet of the incident report.

Appendix F. Sealed Source & Device Casework Reviews

File No. 5

The telephone conversation clarifying certain details of the device was documented. No further letter documentation was considered necessary.