

February 5, 2002

Mr. John M. Leonard
Assistant Commissioner for Environment
Department of Environment and Conservation
401 Church Street
L&C Tower, 21st Floor
Nashville, TN 37243-0435

Dear Mr. Leonard:

On January 22, 2002, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) follow-up report on the Tennessee Agreement State program. The follow-up IMPEP review was conducted on October 22-25, 2001. The MRB found the Tennessee program adequate but needs improvement, and compatible with NRC's program.

Based on the follow-up review, the Tennessee program has improved. Of the four indicators reviewed during the follow-up review, the MRB supported changing the performance rating to the next higher rating for three indicators (Technical Quality of Inspections, from unsatisfactory to satisfactory with recommendations for improvement; Response to Incidents and Allegations, from satisfactory with recommendations for improvement to satisfactory; and Legislation and Program Elements Needed for Compatibility from unsatisfactory to satisfactory with recommendations for improvement). The performance rating for the remaining indicator, (Status of Materials Inspection Program, unsatisfactory) will remain the same. The MRB concluded that the inspection program has made progress, but the timeliness of inspections, issuance of the reports, and some technical aspects of the inspection program are still in need of improvement.

Section 4.0, page 13, of the enclosed final report presents the follow-up IMPEP team's recommendations for the State of Tennessee. I request your evaluation and response to those recommendations within 30 days from receipt of this letter. In your response to the recommendations, we would like an outline of the actions and expected dates for operation of the program without a significant inspection backlog and the schedule for adoption of regulations needed for compatibility and adequacy.

Based on the results of the current IMPEP follow-up review, the next full review will be in approximately two years. Also the next periodic meeting will take place in one year and the Regional State Agreements Officer will conduct quarterly calls with Division management to follow the Division's progress.

John M. Leonard

- 2 -

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 J. Paperiello
Deputy Executive Director
for Materials, Research and
State Programs

Enclosure:

As stated

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

Lawrence E. Nanney, Director
Division of Radiological Health

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.

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cc: Milton H. Hamilton, Commissioner
Tennessee Department of Environment
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Lawrence E. Nanney, Director
Division of Radiological Health

bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrified

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STP-AG-26

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
FOLLOW-UP REVIEW OF THE TENNESSEE AGREEMENT STATE PROGRAM

October 22-25, 2001

FINAL REPORT

U. S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the follow-up review of the Tennessee Department of Environment and Conservation (the Department), Division of Radiological Health (the Division), conducted October 22-25, 2001. This follow-up review was directed by the Management Review Board (MRB) based on the results of the August 21-25, 2000 Integrated Materials Performance Evaluation Program (IMPEP) review. The MRB directed that a follow-up review of the common performance indicators, Status of Materials Inspection Program, Technical Quality of Inspections, and Response to Incidents and Allegations, and the non-common performance indicator, Legislation and Program Elements Required for Compatibility, be conducted in one year based on the unsatisfactory finding for three indicators and satisfactory with recommendations for improvement finding for the fourth indicator. The follow-up review also included evaluation of actions taken by the State to address the eight recommendations made during the August 21-25, 2000 IMPEP review.

The follow-up review was conducted by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the State of California. Team members are identified in Appendix A. The follow-up review was conducted in accordance with the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on September 3, 1997 (62 FR 46517), and the November 5, 1999, NRC [Management Directive 5.6](#), "Integrated Materials Performance Evaluation Program (IMPEP)."

A draft of this report was issued to Tennessee for factual comment on December 3, 2001. Tennessee sent factual comments by letter dated January 4, 2002 from Mr. Lawrence E. Nanney, Director, Division of Radiological Health, Tennessee Department of Environment and Conservation. The Management Review Board (MRB) met on January 22, 2002 to consider the proposed final report. The MRB found the Tennessee program adequate but needs improvement, and compatible with NRC's program.

Based on the follow-up review, the Tennessee program has improved. Of the four indicators reviewed during the follow-up review, the MRB supported changing the performance rating to the next higher rating for three indicators (Technical Quality of Inspections, from unsatisfactory to satisfactory with recommendations for improvement, Response to Incidents and Allegations, from satisfactory with recommendations for improvement to satisfactory, and Legislation and Program Elements Needed for Compatibility from unsatisfactory to satisfactory with recommendations for improvement). The performance rating for the remaining indicator, (Status of Materials Inspection Program, unsatisfactory) will remain the same. The MRB concluded that the inspection program has made progress, but the timeliness of inspections, issuance of the reports, and some technical aspects of the inspection program are still in need of improvement.

The Tennessee Agreement State program is administered by the Commissioner who reports directly to the Governor. The Division, which is located in the Department, is responsible for implementation of all radiation programs for the State including the Agreement State program. The organizational chart for the Division is presented in Appendix B. At the time of the follow-up review, the Tennessee program regulated approximately 565 specific licenses, including all types of major licensees except for uranium mill tailings.

Prior to the follow-up review, the NRC conducted a heightened oversight program for the Tennessee program. The program included Tennessee developing and submitting a program improvement plan in response to the 2000 IMPEP review, followed by bimonthly conference calls with NRC. Conference calls were held February 1, 2001, April 3, 2001, June 5, 2001, and August 8, 2001. The communications for the heightened oversight program are in Appendix C to this IMPEP report. Tennessee's actions and their status were reviewed in preparation for this follow-up review.

The review team's approach for conducting the follow-up review consisted of: (1) examination of the Division's actions during the period of heightened oversight; (2) in-depth review of the four program indicators identified above for the period of August 26, 2000 through October 25, 2001; (3) field accompaniments of five Division inspectors; (4) discussion of the status of the Division's actions to address the seven recommendations in the 2000 report; and (5) 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 the three common performance indicators, and one non-common performance indicator, for activities conducted during the period of August 26, 2000 through October 25, 2001. Preliminary results were discussed with Tennessee management on October 25, 2001.

Section 2 below discusses the results of the follow-up review of the Tennessee program for the three common performance indicators. Section 3 below discusses the results of the follow-up review of the Tennessee program for the one non-common performance indicator. Section 4 summarizes the review team's findings and recommendations resulting from the follow-up review. The Division's progress in addressing other recommendations from the 2000 review and general status of the program covered in a periodic meeting can be found in Appendix D.

2.0 COMMON PERFORMANCE INDICATORS

The follow-up review addressed three of the five common performance indicators used in reviewing both NRC Regional and Agreement State programs. The three indicators are: (1) Status of Materials Inspection Program, (2) Technical Quality of Inspections, and (3) Response to Incidents and Allegations.

2.1 Status of Materials Inspection Program

During the follow-up review, the review team evaluated actions taken by the Division in response to the finding of unsatisfactory made during the 2000 IMPEP review, as well as the status of the inspections performed since the 2000 review, and the current status of due and overdue inspections.

The team reviewed the timeliness of inspections performed since the last review period, the current and projected backlog of overdue inspections, and timeliness in communication of inspection results to licensees. The team reviewed data provided by the Division from their inspection tracking system to determine the timeliness of inspections, and reviewed inspection files to determine the date of the issuance of inspection results to licensees relative to the date of inspection.

The review team's evaluation of the Division's response to the first recommendation is presented below.

Recommendation 1

The review team recommends that the Division take actions to ensure that:

- (1) inspections are conducted in accordance with their assigned inspection frequencies;
- (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 of the 2000 report)

Current Status

In response to this recommendation, the Division prioritized the outstanding overdue inspections from the last review period, in order from the most overdue to the least overdue. This ensured that those inspections that had been most delinquent (up to 42 months overdue), were performed right away; however, it also had the result of creating a new backlog, as many inspections falling due and becoming overdue during this period were postponed to reduce the already existing backlog. This issue is discussed in more detail later in this section.

The Division has made some progress with respect to the timely communication of inspection results to licensees; however, they still experience significant delays in communication in one inspection region (one report was delayed for 10 months after the date of inspection). This issue is discussed in more detail later in this section.

The Division has made improvements in following up on the submission of inspection reports and related materials to the central office since the last review period. There is still a delay in the submission of reports in one region. The problems with the inspection tracking system identified during the last review have been corrected.

Since the last review period, the Division performed 128 core inspections which includes initial inspections. To evaluate the Division's materials inspection program, the team examined the status of 111 inspections which were not included in the previous review. There were 32 of 111 inspections (28.8%) that were overdue when performed. In addition, the Division will have another 24 inspections that will become overdue before December 31, 2001.

Of those core inspections performed overdue during the review period, the most delinquent inspection was performed 10 months after it became overdue, and the average delay was about three and one-half months beyond the date after which they became overdue. The most delinquent initial inspection was performed approximately twelve months after the date of license issuance, and the average delay for initial inspections performed on an overdue basis was nine months after license issuance.

In terms of the length of delay of core inspections, the Division has improved substantially over the last review period; however, they still have not been able to reduce the percentage of inspections

that are performed on an overdue basis. In fact, the Division has experienced an increase in the percentage of inspections performed on an overdue basis during this review period relative to the last (28.8% in 2001 versus 26% in 2000). The Division will be implementing a new database management system that will allow real time status for inspection information. Division management believes that this system should aid them in conducting the work in a more timely manner.

The review team evaluated the timeliness of the communication of inspection results to the licensees by initially reviewing approximately two inspection files for each inspector throughout the Division's four regional inspection offices. For three of the offices, the random sampling indicated that results were almost always communicated within 30 days after the date of the inspection, and the delays identified beyond 30 days were insignificant (one to five days). In one region, however, the initial review of two files indicated that the results of the inspections were not communicated to the licensee until approximately 180 days after the inspection. Due to the significant delay in these two cases, additional inspection files from this region were reviewed. In a review of 18 additional inspection files, there were 14 inspections for which the results were communicated to the licensee more than 150 days after the date of the inspection. In one case, the delay was 300 days after the date of the inspection. The team concluded that this regional office may not have adequate trained staff, thus impacting the timeliness for submission of inspection reports.

Based on the follow-up review, the team considers items (1) and (2) of this recommendation open until such time as the Division is able to reduce the percentage of inspections, performed on an overdue basis, below 10 percent for a period of at least one year, and until steps have been taken to ensure the timely communication of inspection results to the licensee and timely submission of these inspection reports to the central office, for all inspection regions.

The review team concludes that the materials inspection program has shown some improvement since the 2000 IMPEP review. However, due to the percentage of inspections still performed on an overdue basis, and the substantial delays in communicating results of inspections to the licensees in one inspection region, the review team believes that continued improvement in the program is needed. Based on the IMPEP evaluation criteria, the review team recommends that Tennessee's performance with respect to the indicator, Status of Materials Inspection Program, continues to be found unsatisfactory.

2.2 Technical Quality of Inspections

During the follow-up review, the review team evaluated actions taken by the Division in response to the finding of unsatisfactory made during the 2000 IMPEP review, as well as the status of the technical quality of inspections performed since the 2000 review.

The team evaluated inspection reports, enforcement documentation, and inspection field notes, interviewed inspectors for eight inspections conducted during the review period, and conducted five inspector accompaniments. The casework included five of the Division's materials license

inspectors, and covered inspections of various types of licensees including diagnostic nuclear medicine facilities, a high dose-rate remote afterloader device manufacturer performing a source replacement under reciprocity, nuclear pharmacies, academic, and industrial radiography. Appendix E lists the inspection casework files reviewed for completeness and adequacy and accompaniments including case-specific comments.

The following two recommendations, including the recommendation from the indicator, "Technical Staffing and Training" were evaluated together because training was a contributing factor to program deficiencies for the "Technical Quality of Inspections" indicator.

Recommendation 2

The review team recommends that the Division follow the Tennessee inspection policy and procedures. (Section 3.2 of 2000 report)

Recommendation 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 of 2000 report)

Current Status

In response to the 2000 IMPEP recommendations, the Division reviewed its inspection procedures and provided additional training to the staff on the conduct of inspections including performance-based concepts. The Division concluded that no changes were required in the procedure. The training was a combination of formal class work and meetings with regional staff. Topics covered were proper documentation of inspection findings, support for notices of non-compliance, timeliness of the conduct of inspections, and timeliness of issuance of inspection findings. The formal class training for Division inspection staff included an "Inspecting for Performance" course solely for Division staff (24 staff), "Inspection Procedures" course (9 staff), and "Root Cause and Incident Investigation" course (9 staff).

During the review period, each of the Division's regional area managers or the supervisors performed annual inspection accompaniments with each of their inspectors. The Division initiated in July 2001 documentation of these accompaniments as part of their on-the-job training program. The review team noted that three of the four regional area managers, who perform routine inspections, were not accompanied by Division management on an annual basis. The new Inspection and Enforcement Manager acknowledged that he was aware of the need to conduct the accompaniments, but did not conduct them due to other high priority work and the State travel restrictions. Division management stated their intention is to conduct annual accompaniments for all inspectors in the future.

Five inspectors were accompanied by an IMPEP team member during the weeks of September 3 and October 8, 2001. The accompaniments included inspections of a medical institution performing diagnostic nuclear medicine, a high dose-rate remote afterloader device manufacturer performing a source replacement under reciprocity, a blood bank using a self-

shielded irradiator and two firms performing industrial radiography. The facilities inspected are identified in Appendix D.

During the accompaniments, each inspector demonstrated appropriate knowledge of the regulations and the license requirements for the licensee being inspected. Each inspector used a combination of performance-based and compliance-based inspection techniques. The inspectors were well prepared for the inspection, and thorough in their audits of the licensee's radiation safety programs. Generally, Division inspectors observed licensed operations, conducted effective interviews with appropriate licensee personnel, requested appropriate demonstrations of licensee radiation safety practices, and conducted confirmatory radiation measurements. No poor health physics practices were observed during any of the accompaniments. The inspections were adequate to assess radiological health and safety at the licensed facilities.

The accompanying review team member observed two isolated instances where Division inspectors missed opportunities to observe certain licensed activities. These observations were discussed with individual inspectors and their managers after completion of their respective inspections. In each case, the Division inspectors and their managers were openly receptive to the observations and to suggestions regarding methods for observing licensed activities as part of conducting a performance-based inspection.

Recommendation 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 of 2000 report)

The inspection procedures utilized by the Division are described in "Division of Radiological Health's Inspection and Enforcement Policy and Procedures" and are generally consistent with the inspection guidance outlined in NRC's Inspection Manual Chapter (IMC) 2800. Inspection reports are in a format that covers all inspection areas for each inspection type.

Based on the casework reviewed, the review team noted that routine inspections covered the significant aspects of the licensees' radiation safety program. The review team found that the inspection reports were generally complete, with sufficient documentation to ensure that licensees' performance with respect to health and safety was acceptable. The documentation, with some exceptions, adequately supported violations cited in Notices of Non-compliance (NONs) issued to licensees.

The review of inspection documentation indicated that Division inspectors identified from zero to 16 violations in their reports. Three inspections identified from 8 to 16 violations, with one inspection having six repeat violations. The review team found that the language in the NONs sent to the licensees did not reflect increased regulatory concern over the number of documented violations. In one case, the inspector recommended in a memorandum that Division management consider escalated enforcement against the licensee. The cognizant regional area manager and the Inspections and Enforcement manager did review the case, but elected to not take any escalated enforcement. The Division has no criteria for consistently characterizing the severity of violations or for consistently determining when escalated enforcement should be considered.

Division management indicated that they had sent NRC's Severity Level system to the Tennessee Office of General Counsel (TN-OGC) for consideration in the development of a system for use by the Division.

A poorly performing licensee was not scheduled to be inspected any earlier than at the routine five year interval. Division personnel stated that while it was technically possible to amend scheduled future inspection dates, there was no Division policy or procedure to assist the staff in considering adjustments in the inspection frequency based on poor licensee performance. In discussions with Division management and staff, they agreed that development and implementation of a policy for adjusting inspection frequency up or down based on licensee performance would be useful to the program.

The review team reviewed three inspections in which repeat violations were identified. In general, the inspection reports did not document any inspector evaluation of the reasons why the violations had recurred or why the corrective actions previously described by the licensee were ineffective in preventing the recurrence of the violations. The review team discussed with Division staff and management the need to understand and document the root cause of repeat violations, especially those that may suggest systemic weakness in a licensee's radiation safety program. The review team offered to provide example language that the Division could use to develop and implement standard language to be added to the text of NONs for communicating the Division's heightened regulatory concern over the number and the nature of repeat violations.

An NON issued for several violations was not supported by the associated inspection report which did not contain the inspector's basis for the violations, nor a discussion of the inspector's review of the program areas in which these violations were identified. For another inspection file, a supplemental letter asked the licensee to commit to specific corrective actions, including a specific item to be documented for which there was no regulatory basis. Two other NONs identified citations against the license's "tie-down" condition and lacked specific information about the regulatory requirement being cited as well as specific information about how the requirement was violated. The review team discussed with Division management and staff the usefulness of additional guidance to the inspection staff on (1) the structure and content of NONs to improve the consistency of NONs, (2) the regulatory basis for cited violations, and (3) the supporting documentation for each violation which should be included in the inspection report documenting the finding. The review team discussed with the Division that they may want to review standard violation language developed by the NRC and other Agreement States and consider modifying and adopting standard violation citations. The review team also discussed with Division management and staff the importance of ensuring senior licensee management attended close-out meetings at the conclusion of inspections that either document a large number of violations, repeat violations, or violations that would represent a serious radiation safety concern.

During the January 22, 2002 MRB meeting, the MRB directed the review team to expand Recommendation 3 to indicate that the review team's concerns are not limited to documentation of inspections. Based on these discussions, the review team has expanded Recommendation 3 from the 2000 IMPEP review to read as follows: "The review team recommends that the Division ensure that inspection findings are fully supported in documentation of the inspection and that cited violations are fully supported in the inspection report. The review team also recommends that in order to enhance both the quality and documentation of inspections, the Division establish

and implement additional guidance for ensuring consistent, appropriate, and prompt regulatory actions including incorporating root cause identification, especially of repeat violations.”

The Division has an adequate number and variety of appropriately calibrated radiation survey instruments distributed to each of the regional area offices to support the current inspection program. Available radiation survey instrumentation include G-M meters, scintillation detectors, ion chambers and micro-R meters. Radiation survey instruments are calibrated at least annually by Division personnel.

Based on the evaluation performed during the follow-up review, the review team recommends that the previous Recommendations 2 and 5 be closed and that the revised Recommendation 3 remain open.

The review team concludes that the technical quality of the inspection program has shown improvement since the 2000 IMPEP review based on the limited items identified during inspection accompaniments and review of inspection documentation. Although the 2000 IMPEP report found the performance with respect to this indicator to be unsatisfactory, the review team is proposing a change in the finding from the 2000 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 changed to satisfactory with recommendations for improvement.

2.3 Response to Incidents and Allegations

During the follow-up review, the team evaluated actions taken by the Division in response to the finding of satisfactory with recommendations for improvement made during the 2000 IMPEP review, as well as the status of the Division’s performance since the 2000 review.

The team reviewed the Division’s revised “Complaint/Allegation/Incident (CAI) Event Investigation Procedure,” and examined six investigations completed during the review period, all of which were reported in the Nuclear Material Events Database (NMED). A list of the incident casework examined with the case-specific comments is included in Appendix E. The team also reviewed the Division’s response to six allegations involving radioactive materials, including three allegations referred to the Division by the NRC during the review period.

The review team’s evaluation of the Division’s response to Recommendations 6, 7 and 8, is presented below. The recommendations are discussed together, as the Division’s responses to these recommendations are related.

Recommendation 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 3.4 of 2000 report)

Recommendation 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 3.4 of 2000 report)

Recommendation 8

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. (Section 3.4 of 2000 report)

Current Status

In response to these recommendations, the Division instituted a supervisory review by the Deputy Director of all closed investigations and allegations to ensure that properly documented evaluations were included in the final investigation or allegation package, that all other relevant information was included in the final investigation or allegation package, and that allegations had been appropriately closed out with the alleged.

The review team evaluated six events, including a fire, the receipt of a contaminated shipment, two unplanned contamination events, lost sources, and a therapeutic misadministration. The review team found the Division's response to incidents were complete and comprehensive. Initial responses were prompt, well coordinated, and the level of effort was commensurate with the health and safety significance. The Division dispatches inspectors for onsite investigations when appropriate, and took suitable enforcement and follow-up actions. In each of the six files, the inspector's reports generally provided adequate detail including root cause to support the resolution of the investigation. All incident files had been reviewed by the Deputy Director prior to closing each incident file.

The review team also evaluated six allegation files, three of which were referred to the Division by the NRC. The three allegations received directly by the Division, and their subsequent investigation, were very well documented. The casework indicated that the Division took prompt and appropriate action in response to the concerns raised. Two of these three were closed out in writing with the alleged. The file for the third allegation documented diligent attempts by the inspector to contact the alleged with the results, and was closed only after those attempts failed. A review of the allegations referred to the State by the NRC Region II office indicated that there were no outstanding NRC issues related to the referrals, and that the State had been very responsive to the Regional requests when replies were needed to close out the allegations.

Based on the follow-up review, the review team considers these recommendations closed.

The review team concludes that the Division's response to incidents and allegations has improved since the 2000 IMPEP review and no performance issues were identified. 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 changed to satisfactory.

3.0 NON-COMMON PERFORMANCE INDICATOR - LEGISLATION AND PROGRAM ELEMENTS REQUIRED FOR COMPATIBILITY

3.1.1 Legislation

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

3.1.2 Program Elements Required for Compatibility

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

Division representatives related that there had been no changes to the process for the adoption or amendment of regulations. Under the Rulemaking Hearing Rules procedures, all proposed rules are reviewed internally by the Department's 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, sent to the Attorney General's Office for review, and become effective 75 days after being filed with the Secretary of State. After the rule becomes effective, representatives of the Division and the OGC may 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.

During the 2000 IMPEP review, this indicator was found to be unsatisfactory and one recommendation applicable to regulations was made by the team. The status of the actions taken by the Division to address the finding and recommendation is provided below.

Recommendation 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 of 2000 report)

Current Status

The Division provided the NRC with a package of proposed regulations on February 28, 2001. The proposed regulations were reviewed for compatibility and adequacy, and the NRC comments were provided verbally to a staff person on April 4, 2001, and to the Division by letter dated June 8, 2001. A public hearing was held on the rulemaking on April 23, 2001 in Nashville, Tennessee. Eight of nine NRC comments regarding compatibility were incorporated into the proposed regulations. At the time of this follow-up review, the rulemaking package was under review by the State Attorney General's Office. When approved, the package will be filed with the Secretary of State and become effective 75 days later. The team discussed with Division managers the need to provide the "as published" regulations to NRC for review as requested in the Office of State and Tribal Programs (STP) Procedure SA-201, "Review of State Regulations or Other Generic Legally Binding Requirements."

The review team noted that the comment that had not been addressed was identified as the provisions of 10 CFR 34.42(a). This provision is designated as a category "C" for compatibility, and needed to be adopted by June 27, 2000. The Division management stated that this provision was inadvertently missed and would be adopted in the next rule package.

The team also compared data obtained from the STP State Regulation Status tracking system with the rulemaking package and information provided during the review. The rulemaking package above did not address all of the regulations needed for compatibility and in particular those regulations designated as H&S that are needed for adequacy. The following rules were identified as needed for compatibility and/or adequacy.

- ! "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 and will initiate rulemaking as appropriate when the new Part 35 becomes effective. The team believes this action is appropriate.
- ! "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995. 10 CFR 30.35 and 30.36 provisions are H&S compatibility categories needed for adequacy.
- ! "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. Provisions of this rule are H&S categories needed for adequacy.
- ! "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39058) that became effective August 20, 1997. Provisions of this rule are designated as A and/or B for compatibility, or H&S for adequacy.
- ! "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35, 36 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998. Provisions in this rule are designated either as category A, B, C, or H&S.

Regulations needed in the future were identified as follows:

- ! “Respiratory Protection and Controls to Restrict Internal Exposures,” 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55525) that became effective February 2, 2000.
- ! “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.
- ! “New Dosimetry Technology,” 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001.
- ! “Requirements for Certain Generally Licensed Devices Containing Byproduct Material” 10 CFR Parts 30, 31, and 32 amendments (65 FR 791629) published December 18, 2000 that became effective February 16, 2001. Provision of this rule are designated as A or B for compatibility and require early implementation (6 months).

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. The team discussed Management Directive 5.9, the rules needed for compatibility, and the rules designated as H&S that are needed for adequacy. The review team noted that several rules have not been adopted within the 3 year time frame, and the Division did not have a plan for the timely consideration, tracking, and adoption of rules needed for compatibility and for adequacy. The team also believes that the Division needs to evaluate all H&S category rules identified above to determine if the Tennessee rules address the essential objectives for adequacy, and amend their rules, as appropriate.

The review team identified that there was a misunderstanding within State staff of the requirements for adopting regulations needed for adequacy. Through discussions with Division management and review of the NRC guidance documents, this misunderstanding was addressed. Based on these considerations, the review team has reworded Recommendation 9 from the 2000 IMPEP review for clarity to read as follows: “The review team recommends that the Division establish a management plan for the development, tracking, and adoption of regulations in a timely manner, and to adopt the current regulations needed for adequacy and compatibility in accordance with the STP Procedure SA-201, “Review of State Regulations or Other Generic Legally Binding Requirements.”

During the January 22, 2002 MRB meeting, the review team informed the MRB that the final rules package had been submitted to NRC on December 21, 2001 for review. These rules will be published in February 2002. The review team noted that no additional changes were made to the package since the preliminary review in October 2001. Based on the preliminary acceptability of this rule package, the review team recommended and the MRB concurred that the preliminary finding for this performance indicator would be changed from unsatisfactory to satisfactory with recommendations for improvement. In the letter issued February 1, 2002, the NRC found this regulation package compatibility with the exception of the comments noted in the letter. 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 changed to satisfactory with recommendations for improvement.

4.0 SUMMARY

The follow-up review team evaluated Tennessee's performance in responding to three unsatisfactory and one satisfactory with recommendations for improvement findings and resolving the specific recommendations made during the 2000 IMPEP review for the three common and one non-common performance indicators, Status of Materials Inspection Program, Technical Quality of Inspections, Response to Incidents and Allegations, and Legislation and Program Elements Required For Compatibility. The follow-up review team concludes that the inspection program has made progress, but the review team noted that the timeliness of inspections, issuance of the reports, and some technical aspects of the inspection program are still in need of improvement. The development of a plan and use of an effective regulation tracking system to ensure timely issuance of compatible and adequate regulations would resolve the regulation issue. Based on this information, the review team recommended and the MRB concurred in finding the Tennessee program to be adequate but needs improvement and compatible with NRC's program.

Based on the status of the Tennessee program, the follow-up review team recommended and the MRB concurred that the Tennessee Agreement State program receive a full IMPEP review in two years with a periodic meeting in about one year. Also, the Regional Agreement State Officer will conduct at least quarterly calls with the Division management to go over the status/progress of reducing the overdue inspections, to discuss activities to improve documentation supporting inspection findings, and to discuss development of a plan for updating State regulations. At the periodic meeting, the status of the Division's actions to address the findings and recommendations can be evaluated. The detailed evaluation (casework review) would follow one year later (routine IMPEP).

Below is a summary list of open recommendations from the 2000 report and the new recommendations from this follow-up review.

Open Recommendations from the 2000 IMPEP report:

Recommendation 1

The review team recommends that the Division take actions to ensure that:

- (1) inspections are conducted in accordance with their assigned inspection frequencies; and
- (2) inspection reports are issued in a timely manner. (Section 3.1 of 2000 report; Section 2.1 of follow-up report)

Recommendation 3 (revised)

The review team recommends that the Division ensure that inspection findings are fully supported in documentation of the inspection and that cited violations are fully supported in the inspection report. The review team also recommends that in order to enhance both the quality and documentation of inspections, the Division establish and implement additional guidance for ensuring consistent, appropriate, and prompt regulatory actions

including incorporating root cause identification, especially of repeat violations. (Section 3.2 of 2000 report; Section 2.2 of follow-up report)

New recommendations from the follow-up review:

Follow-up Recommendation 1

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

LIST OF APPENDICES

Appendix A	IMPEP Follow-up Review Team Members
Appendix B	Division of Radiological Health Organizational Chart
Appendix C	Heightened Oversight Program Correspondence
Appendix D	Periodic Meeting Summary Including Status of Other Recommendations from the Previous Review
Appendix E	Inspection Casework Reviews and Accompaniments
Appendix F	Incident Casework Reviews
Attachment	January 4, 2002 Letter from Lawrence E. Nanney Tennessee's Response to Follow-Up Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

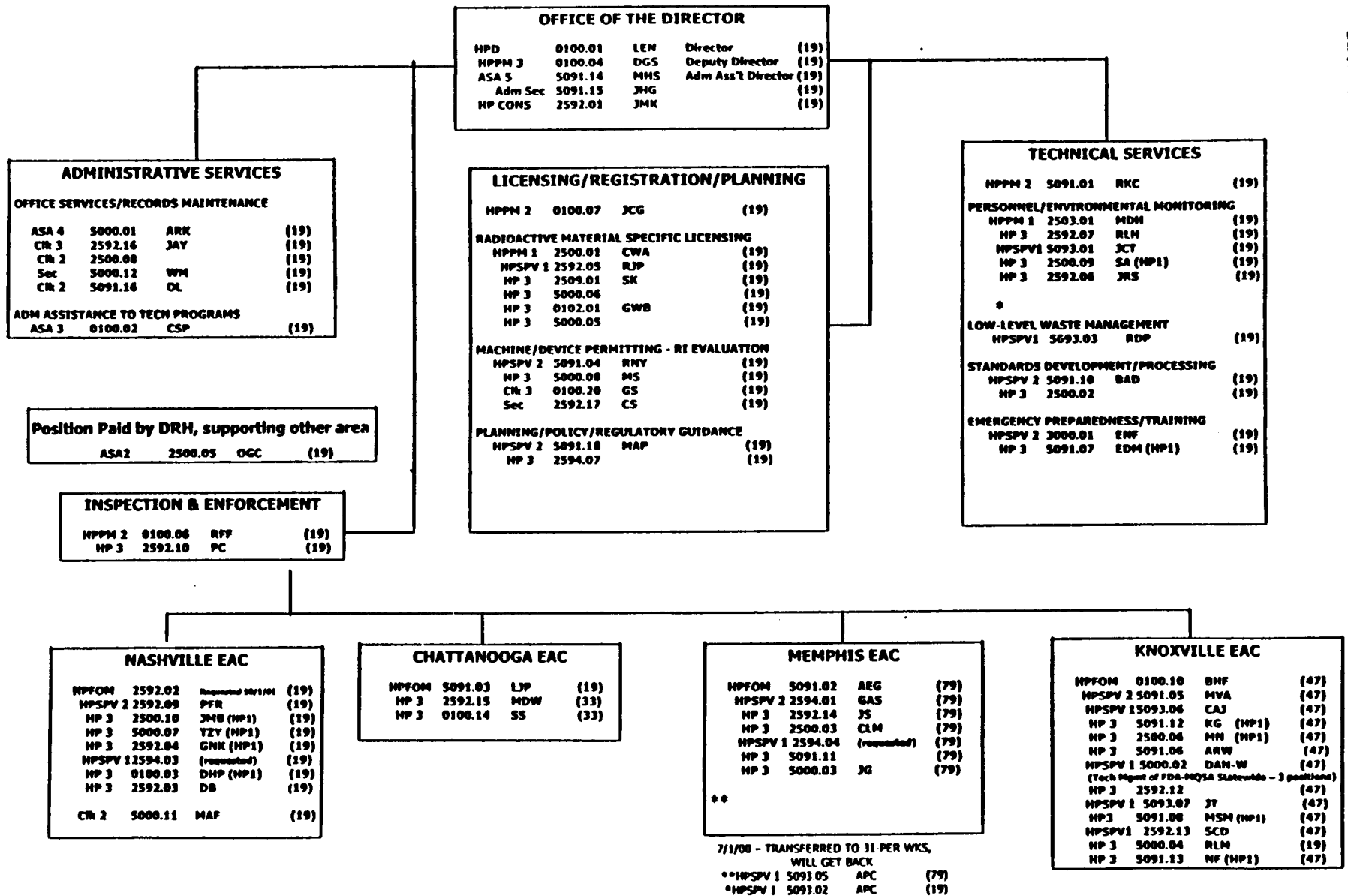
Name	Area of Responsibility
Dennis Sollenberger, STP	Team Leader
Barbara Hamrick, CA	Status of Materials Inspection Program Response to Incidents and Allegations
Richard Woodruff, Region II	Legislation and Program Elements Required for Compatibility
John Pelchat, Region II	Technical Quality of Inspections Inspector Accompaniments

APPENDIX B

TENNESSEE ORGANIZATIONAL CHART
FOR THE DIVISION OF RADIOLOGICAL HEALTH
(ML013310611)

DIVISION OF RADIOLOGICAL HEALTH (327.32)

October 22, 2001



APPENDIX C

HEIGHTENED OVERSIGHT PROGRAM CORRESPONDENCE

Minutes of Bimonthly Conference Calls:

1. February 1, 2001 conference call minutes.
2. April 3, 2001 conference call minutes.
3. June 5, 2001 conference call minutes.
4. August 8, 2001 conference call minutes.

Letters from/to Tennessee:

1. January 2, 2001 letter from J. Leonard to C. Paperiello, responding to the November 27, 2000 final IMPEP report including actions to address recommendations in the report. (ML010120195)
2. January 29, 2001 letter from C. Paperiello to J. Leonard requesting additional information for the program improvement plan. (ML010260424)
3. March 26, 2001 letter from L. E. Nanney to D. Sollenberger, second bimonthly progress report. (ML010940237)
4. May 22, 2001 letter from L. E. Nanney to D. Sollenberger, third bimonthly progress report. (ML013300612)
5. July 20, 2001 letter from D. Shults to D. Sollenberger submitting a copy of Tennessee's "Inspection and Enforcement Policy and Procedures" manual. (ML012150118)
6. July 31, 2001 letter from L. E. Nanney to D. Sollenberger, fourth bimonthly progress report. (ML012190331)

MINUTES: TENNESSEE TELECONFERENCE OF FEBRUARY 1, 2001

These minutes are presented in the same general order as the items were discussed in the meeting. The participants were as follows:

Dennis Sollenberger, STP
Kathleen Schneider, STP
Richard Woodruff, RII
L. Edward Nanney, TN
Debra Shults, TN
John Politte, TN

Frederick Combs, STP
Lance Rakovan, STP
Barbara Hamrick, CA
Johnny Graves, TN
Roger Fenner, TN
Ruben Crosslin, TN

1. **Letter to J. Leonard and Requested Information Program Improvement Plan to include Management Commitments.** Mr. Sollenberger discussed the proper management level for correspondence with the State. Mr. Sollenberger and Mr. Nanney discussed a table to track the State's progress including updating due dates. Mr. Nanney stated that he was hoping to have the format ready, but it was not at the time of the call.

2. **Status of Actions in January 2, 2001 Letter.**

Inspection Program. Mr. Sollenberger stated the need to know problems with the inspection program ASAP. Ms. Shults reported that of the 48 inspections overdue at the time of the review, 15 had not been completed (7 in-State and 8 out-of-State). She also reported that at the time of the call there were 42 overdue inspections. The State reported that they are working on two tracking systems (one internal and one interdepartmental) and that there doesn't seem to be any problems at this time. State staff are currently performing audits of files from the last two years in an attempt to ensure that files are consistent with each other.

Training Program. The State reported that they are following the NRC/OAS Training Working Group Report in their attempts to create a written training program, and that NRC will have the opportunity to comment on the program in concurrence with State staff. The State hopes to provide a draft approximately March 1, 2001.

Incidents and Allegations. Mr. Sollenberger discussed the need to review policy and procedures as they are drafted. State staff attendance at the Root Cause Course was discussed.

Items Needed for Compatibility. The State commented a package containing 12 of the 18 regulations required for adoption was out for comment to staff members. The State was hoping to move the regulations out of the office the week following the teleconference. STP staff and the State discussed the "D/H&S" Compatibility Category and the need to adopt regulations under this category.

SS&D Reviewer Qualification. The upcoming SS&D Workshop was discussed, including the need for only 2 State attendees and the expense of hotel rooms.

3. **Discussion of Changes to Items or Dates for Completion.** STP staff and the State discussed regulation review by NRC and STP Procedure SA-201.
4. **Contents of Future Status Reports (Due 2 weeks prior to next call).** Mr. Sollenberger stated that he would share the tracking table he was using with the State. The need to get all State commitments down on paper was highlighted, as well as the need for a procedure detailing the expectations of both NRC and States during a period of heightened oversight.
5. **Date for Next Conference call (date and time).** The next call was set up for Tuesday, April 3 at 10:00 am EST.

MINUTES: TENNESSEE TELECONFERENCE OF APRIL 3, 2001

These minutes are presented in the same general order as the items were discussed in the meeting. The participants were as follows:

Dennis Sollenberger, STP
Lance Rakovan, STP
Barbara Hamrick, CA
Debra Shults, TN
Roger Fenner, TN
Billy Freeman, TN
Steve Seegar, TN

Paul Lohaus, STP
Richard Woodruff, RII
L. Edward Nanney, TN
Johnny Graves, TN
Barbara Davis, TN
Mary Helen Short, TN
Melissa Wolford, TN

1. Status of Actions in January 2, 2001 Letter.

Inspection Program. Ms. Shults reported that staff members are attending a number of NRC-sponsored courses such as Inspecting for Performance, Inspection Procedures, and Root-Cause/Incident Investigation. She stated that at the time of the call there were 65 inspections due, 27 of which were overdue. She also stated that of the 48 inspections overdue at the time of the review, only 4 have yet to be completed. These inspections should be conducted by the end of the month. In terms of staff turn-over, Ms. Shults stated that two staff members had left the program and three had been hired. She noted that the program has the potential to hire five additional staff members. She stated that Tennessee is on schedule with their inspection procedure evaluation.

Training Program. The State said that a copy of the draft revision to their training program would be sent to Mr. Sollenberger for review.

Incidents and Allegations. Mr. Sollenberger and Ms. Hamrick commented that they had received and reviewed revised incident and allegation procedures.

Items Needed for Compatibility. Mr. Woodruff stated that he is currently reviewing the package of regulations submitted by the State. He noted that he is about three fourths of the way done and has no significant comments thus far. He promised to review the results of the review with State staff prior to sending the results to NRC Headquarters. The State was asked to follow the guidance in STP Procedure SA-201, including highlighting regulations that have been revised, to help expedite the review process. The importance of adopting regulations designated as "D/H&S" was discussed. Mr. Lohaus noted that the criteria in Management Directive 5.6 for a satisfactory rating for the common performance indicator, Legislation and Program Elements Required for Compatibility, includes adopting regulations necessary for both compatibility and health and safety. The State noted that they are attempting to achieve compatibility as quickly as possible. The adoption of the financial assurance rule was discussed.

SS&D Reviewer Qualification. The State mentioned that they are working on a set of qualifications for SS&D reviewers that would not necessarily require attendance at the

NRC SS&D Workshop. Mr. Nanney discussed the budget problems faced by the Tennessee program and the importance of management support.

2. **Discussion of Changes to Items or Dates for Completion.** Mr. Sollenberger noted that there have been no changes to expected completion dates.
3. **Future Status Reports.** Mr. Sollenberger and the State discussed the format for progress reports.
4. **Date for Next Conference call (date and time).** The next call was set up for Tuesday, June 5 at 10:00 am EDT.
5. **Additional Topics.** Mr. Lohaus asked for clarification on a statement made in the State's progress report on the increased interaction with NRC. Mr. Nanney noted the State's emphasis on improving programmatic obligations. Mr. Lohaus asked for clarification on how the NRC could lessen the number of interruptions and improve the heightened oversight process. Mr. Lohaus and Mr. Nanney discussed the heightened oversight process and areas of possible difficulty and confusion. The State asked if IMPEP team members' guidance forms completed during the review could be shared with States. Mr. Lohaus said he would consider the request. Mr. Freeman commented that IMPEP team members should give more directions with their comments and should focus on making all comments performance-based. He also stated that he would be more than willing to come to the main office for the follow-up IMPEP review to ensure proper communication with team members.

The State commented on the need for IMPEP team members to fully discuss findings with State staff during the onsite review, especially the need to discuss matters with regional staff members in larger programs. Mr. Lohaus agreed and indicated that STP would re-enforce the importance of this issue during the upcoming IMPEP training as well as revising the language in the STP procedures dealing with reviewing IMPEP indicators.

MINUTES: TENNESSEE TELECONFERENCE OF JUNE 5, 2001

The minutes are presented in the same general order as the items were discussed in the meeting. The participants were as follows:

Dennis Sollenberger, STP
Douglas Collins, RII
Johnny Graves, TN
Roger Fenner, TN
Mary Helen Short, TN

Paul Lohaus, STP
L. Edward Nanney, TN
Barbra Davis, TN
Anthony Hogan, TN
John Politte, TN

1. Status of Actions in January 2, 2001 Letter

Inspection Program. Mr. Nanney reported that the 48 in-state licenses that had been overdue previously were all inspected now. Six out-of-state licenses cannot be inspected until they conduct work in Tennessee. In the month of May, 19 inspections were completed. He stated that there was a correction for the number of in-state licenses. The May 22 letter stated that there were 8 in-state licenses. In actuality, there are 5 in-state licenses. Furthermore, as of the first of June only 2 are overdue. Mr. Sollenberger inquired as to whether or not Tennessee had modified their inspection procedure and if the staff was knowledgeable of the new policies. He expressed a desire to have the staff understand the policies before NRC begins the follow-up review by initiating accompaniments of Tennessee inspectors. Mr. Nanny responded that he thought that Tennessee might be ready, but was not certain. Mr. Lohaus requested that the State's expectation for the conduct of inspections be communicated to him by some means. Mr. Nanney agreed to make arrangements to do this, but stated that he felt it was unclear what was wanted in the inspection program. It was also agreed that a follow-up phone call should be arranged to further discuss Tennessee's procedures once they had sent a summary of those procedures. It was agreed that Tennessee's procedures would be reviewed and any specific problems could be addressed during an offline follow-up discussion.

Training Program. Mr. Nanney stated that the training policy would be completed and approved in June. He also reported that Debra Shults was meeting with Roger Fenner to discuss the program's implementation. Mr. Sollenberger said that the documentation of the training program would be evaluated as part of the follow-up review.

Incidents and Allegations. Mr. Sollenberger commented that he had reviewed the incidents and allegations procedures and that they looked acceptable. The implementation of these procedures will be reviewed during the follow-up review.

Items Needed for Compatibility. Mr. Sollenberger expressed regret for not having been able to send out the final comments on the package of regulations sooner. Mr. Lohaus arranged to have them faxed later in the day. Tennessee stated that Mr. Woodruff had already discussed the comments with them. Barbara Davis stated that a public hearing had occurred and no one appeared. Also, a comment period was held and one letter was

received and addressed. Tennessee expects TN-OGC to follow up in approximately 5 - 6 weeks.

SS&D Reviewer Qualification. Mr. Sollenberger stated that NRC would review the SS&D qualifications and documentation for the reviewers during the follow-up review.

2. **Discussion of Changes to Items or Dates for Completion.** No dates have changed. The regulations are being developed on the dual track as discussed earlier.
3. **Future Status Reports.** Tennessee will submit a status report prior to the August 8, 2001 conference call.
4. **Date for Next Conference Call (date and time).** The next call was set up for Tuesday, August 7 at 10:00 am EDT. Following the conference call Debra Shults called and requested that the call be moved to Wednesday, August 8, 2001 at 10:00 Eastern, 9:00 central time.
5. **Additional Topics.** Mr. Sollenberger requested a list of inspections for July and August and a list of qualified inspectors be sent to him. Mr. Nanney agreed to do so. Mr. Sollenberger also recommended that accompaniments be spaced between the four regions. Anthony Hogan stated that there would be drills during the last week of August. As such, that period would not be convenient for accompaniments. The follow-up review will be scheduled in September or, if need be, October.

Mr. Lohaus informed the State that sharing IMPEP forms with States was under consideration.

MINUTES: TENNESSEE TELECONFERENCE OF AUGUST 8, 2001

The minutes are presented in the same general order as the items were discussed in the meeting. The participants were as follows:

Dennis Sollenberger, STP
Lance Rakovan, STP
L. Edward Nanney, TN
Johnny Graves, TN
Anthony Hogan, TN
Mary Helen Short, TN

Paul Lohaus, STP
John Pelchat, RII
John Politte, TN
Debra Shults, TN
Billy Freeman, TN
Other TN staff

1. Status of Actions in January 2, 2001 Letter

Inspection Program. Mr. Sollenberger commented that NRC had received the State's July 20, 2001 letter including a copy of their "Inspection and Enforcement Policy and Procedures" manual. Mr. Pelchat noted that he would work with the State to schedule inspector accompaniments in September. Mr. Nanney commented that the State's tracking system was still in the design phase, but they expect that it will be operational by the end of October. The State noted that 17 inspections were completed in July. Six overdue in-State inspections are still incomplete, as well as nine out-of-State inspections which can be completed only if the licensees enter the State again to perform licensed actions.

Training Program and Incidents and Allegations. Mr. Sollenberger discussed what the State could expect during the upcoming follow-up review.

Items Needed for Compatibility. The status of the State's regulation adoption was discussed. The State noted that the staff member that usually handles regulation adopted has been out due to illness. It was estimated that a complete review of regulations would take approximately 3-4 weeks. The State noted that adoption of the "H&S" rules has been delayed due to the staff member's absence.

SS&D Reviewer Qualification. No discussion.

2. Date for Next Conference Call (date and time). It was agreed that there was no need for another conference call as long as inspector accompaniments and the follow-up review could be scheduled without complications.

3. Potential Timeframe for Inspection Accompaniments and Follow-up Review. Mr. Pelchat and the State discussed possible weeks for the inspector accompaniments. The weeks of October 22 and 29 were suggested for the onsite follow-up review. Mr. Sollenberger noted that the team expects the review to start Monday afternoon with the exit meeting Thursday afternoon. The team will not be looking at licensing or SS&D. The State and Mr. Sollenberger discussed having a day during the review when all State

inspectors would be available to talk with review team members, if necessary. Mr. Pelchat noted that he plans to debrief with the field office manager and the inspector after each accompaniment. Mr. Sollenberger noted that he would contact the State about the week for the review after he had the chance to talk with the rest of the review team.

4. **Additional Topics.** Mr. Freeman noted that there was still some confusion on the part of the State as to what should be done with some of the comments made in the IMPEP report. Mr. Sollenberger noted that some of the comments may have resulted from lack of communication between the review team and State staff during the onsite review. Mr. Pelchat promised he will work hard to keep communications open and clear. All parties agreed to move forward and not focus on past issues. Mr. Nanny stated that he appreciates the promise of open communication and believes that his program will do well during the upcoming review.

Mr. Sollenberger summarized the actions the review team intends to take due to this teleconference: (1) The review team will complete their examination of the inspection procedure and will call if there are any questions; (2) Mr. Pelchat will work with the State to schedule inspector accompaniments for September; and (3) Mr. Sollenberger will get back to the State with a proposed date for the review (The review was scheduled for the week of October 22, 2001).



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
L & C Tower, 21st Floor
401 Church Street
Nashville, TN 37243-1530

January 2, 2001

Carl Paperiello
Deputy Executive Director
for Materials, Research and
State and Tribal Programs
Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike, 3rd Floor
Rockville, MD 20852

OSP
01 JAN 12 PM 3:29

Dear Mr. Paperiello:

This letter is in response to your letter dated November 27, 2000. In that letter, you requested a program improvement plan addressing recommendations in Section 5 of the enclosed final IMPEP report. We have reviewed the recommendations and offer the following:

Recommendation:

1. The review team recommends that the Division take actions to ensure that:

(1) inspections are conducted in accordance with their assigned inspection frequencies:

Response: On October 1, 2000, a new Inspection and Enforcement Manager was named by the Division. Since that time, the new Manager has worked closely with the Field Office Managers to institute proactive management of the program. The I & E Manager held a meeting on December 5-7, 2000, with the four Field Office Managers in which was discussed, among other topics, the importance of meeting the inspection frequency requirements. Inspection status is now being monitored in the Central Office by the I & E Manager on a monthly basis.

1. (2) inspection reports are issued in a timely manner:

Response: Work is on-going toward developing an inspection tracking system to uniformly monitor the issuance of inspection reports and to track replies and follow-up correspondence. It is hoped that this system will be functional by April 1, 2001. Our expectation is that, with the continued effort of the Field Office Managers and the active involvement of the I & E Manager, any problem cases which arise during the interim will be detected and dealt with in a timely manner.

ML010120195

Carl Paperiello
January 2, 2001
Page 2

1. (3) inspection reports and associated information are filed in a manner that the information can be easily retrieved, and:

Response: The problem identified by the review team was primarily one of document control in the Central Office. We are addressing the backlog of inspection reports and related materials that occurred over the past few years in the Central Office due to poor management. An audit of the license files in the Central Office to ensure that all materials from the past two inspections are in the files will be completed by July 1, 2001. The Director's Office will ensure that a backlog does not develop in the future and that materials are filed in a timely manner. While we believe that significant document control problems do not exist in the Environmental Assistance Centers (EACs), the I & E Manager will verify this as part of the periodic audit function in those field offices.

1. (4) deficiencies in the inspection tracking system are corrected.

Response: The review team identified a tracking problem for Priority 7 licensees. The report stated that "...the 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 has passed. Priority 7 licensees 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." This is not entirely correct. The only Priority 7 licenses that are not issued an expiration date are *in-vitro* licenses. For a period of time, the computer did not include these licenses in the tracking system, but this problem has been corrected.

Recommendation:

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

Response: We believe that our inspectors are inspecting in accordance with our current policy and procedures manual, as DRH has interpreted the meaning of terminology adopted from NRC guidance. However, the need for additional training has been recognized by the new management team. The Division has contracted with the NRC's Technical Training Center to provide the "Inspecting for Performance-Materials Version" course to all the I & E staff in the Tennessee program. This course will be held February 13-15, 2001, in Chattanooga, Tennessee. The Division will then revise and clarify its policy and procedures manual. Revision of the manual will be completed by June 1, 2001. In the meantime, the new I & E manager will meet with all I & E staff in the individual EACs to ensure that we are following our current policy and procedures.

Carl Paperiello
January 2, 2001
Page 3

Recommendation:

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.*

Response: At the December meeting of the I&E Manager and the Field Office Managers, this topic was discussed at length and the need for more thorough documentation of cited violations was emphasized. This issue will be further addressed in training sessions (see 2 above).

Recommendation:

4. *The review team recommends that the Division develop and document a training and qualification program which addresses the training requirements in the NRC/Organization of Agreement States Training Working Group Report or the NRC Inspection Manual Chapter 1246.*

Response: The Division's training team will conduct a meeting by February 1, 2001, to initiate the development of a training qualification and documentation program. The program will be completed by July 1, 2001.

Recommendation:

5. *The review team recommends that the inspection staff be trained in the Division's policies and procedures in the conduct of inspections.*

Response: See 2 and 3 above.

Recommendation:

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.*

Response: The Division's "Complaint/Allegation/Incident (CAI) Event Investigation Procedure" was revised in October 2000 and issued with supplemental guidance in December 2000 to ensure that the investigation and evaluation of the licensee's actions are complete. Since additional courses have been added in Chattanooga, we are encouraged at the possibility of getting several staff members into the "Root Cause and Incident Investigation" course during this NRC fiscal year. We have identified additional staff to submit for attendance at these courses and are hopeful of favorable consideration.

Recommendation:

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.*

Carl Paperiello
January 2, 2001
Page 4

Response: This recommendation was implemented by the revision of the Division's CAI procedure referenced in 6 above.

Recommendation:

8. The review team recommends that supervisory reviews be conducted to ensure thoroughness of investigations of allegations, including that allegations are closed with the alleged.

Response: This recommendation was implemented by the revision of the Division's CAI procedure referenced in 6 above.

Recommendation:

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."

Response: During the review visit, it was reported that our regulations were being amended in their entirety. Upon peer review in the Division, it was determined that changes included in the package of regulations, as then constituted, would have imposed an excessive and unnecessary workload on portions of the Division staff. We have identified those rules which would have contributed to this problem, and a revised package containing the following rules will be approved by the Division for introduction into the promulgation process by January 31, 2000:

Frequency of Medical Examinations for Use of Respiratory Protection Equipment

Low-Level Waste Shipment Manifest Information and Reporting

Performance Requirements for Radiography Equipment

Radiation Protection Requirements: Amended Definitions and Criteria

Clarification of Decommissioning Funding Requirements

10 CFR Part 71: Compatibility with the International Atomic Energy Agency

Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act

Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State

Carl Paperiello
January 2, 2001
Page 5

Licensed Industrial Radiography and Radiation Safety – Requirements for Industrial Radiography Operations

Radiological Criteria for License Termination

Also: (future regulations needed)

Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14

Deliberate Misconduct of Unlicensed Persons

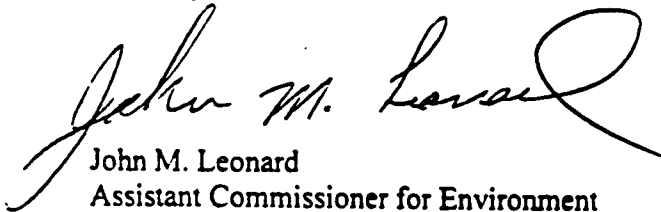
Recommendation:

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.

Response: All persons conducting principal and concurrent reviews for SS&D registrations will be fully qualified and will have documented authorizations to perform these reviews on file.

If you have any questions concerning these responses, please contact Eddie Nanney at (615)532-0360.

Sincerely,



John M. Leonard
Assistant Commissioner for Environment

cc: Milton H. Hamilton, Jr., Commissioner, Environment & Conservation
Lawrence E. Nanney, Director, Division of Radiological Health



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

January 29, 2001

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

Dear Mr. Leonard:

Thank you for your January 2, 2001 letter responding to the recommendations in the final Integrated Materials Performance Evaluation Program (IMPEP) report sent to you by letter dated November 27, 2000. Your letter is responsive to the IMPEP recommendations and identifies actions that Tennessee staff has taken or will take to address the recommendations. However, we asked that a program improvement plan be developed and your response does not appear to fully address several aspects of a program improvement plan. A program improvement plan should include: (1) management commitments, (2) program responsibilities, (3) specific objectives to be addressed to improve each program element, (4) estimated dates when commitments will be met, and (5) an estimated date when the program will be satisfactory under the IMPEP criteria. The NRC staff will discuss the responses and the additional information needed to complete a program improvement plan with Mr. Nanney and his staff as we conduct the heightened oversight program. We request that, following these initial discussions under the heightened oversight program, Mr. Nanney submit a revised program improvement plan that addresses the item identified above.

As stated in our November 27, 2000 letter, the heightened oversight program will include bimonthly conference calls and a follow-up review. We have worked with Mr. Nanney and scheduled the first bimonthly conference call for February 1, 2001 at 9:00 CST (10:00 EST). The agenda for the call will be developed with Mr. Nanney and his staff. The follow-up review will be conducted in the August - October 2001 time frame.

We appreciate the positive actions that you and your staff have taken and are continuing to implement with regard to our recommendations. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

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

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

Lawrence E. Nanney, Director
Division of Radiological Health

ML010260424



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
Division of Radiological Health
3rd Floor, L & C Annex, 401 Church Street
Nashville, TN 37243-1532
Phone: 615-532-0360, Fax: 615-532-7938, E-mail: enanney@mail.state.tn.us

March 26, 2001

Mr. Dennis Sollenberger
Office of State and Tribal Programs
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. ^{Dennis}Sollenberger:

As requested in Dr. Paperiello's letter dated November 27, 2000, to Mr. John Leonard of this Department, I am submitting the second of the requested bimonthly progress reports addressing the IMPEP team's suggestions and recommendations. This letter and its attachments update our January 2, 2001 response and provide the specific information requested in Dr. Paperiello's letter dated January 29, 2001, and your email of March 9, 2001. Attachment 1 follows the Program Improvement Plan outline provided, and addresses the specific questions posed. Attachment 2 is the completed status chart.

Since the IMPEP review, the Division has expended considerable resources, in both staff time and dollars, to improve the three areas found unsatisfactory by the review team: Status of Materials Inspection Program, Technical Quality of Inspections, and Legislation and Program Elements Required for Compatibility.

Of the 48 licenses that were found to be overdue by IMPEP criteria, all but four of those inspections have been performed. All of the Priority 1 licenses from that list have been inspected. Tennessee has 560 specific licenses, and of those, 73 licenses have inspection frequencies of one year or less (six months). These inspections require trained staff and, as the review team pointed out, turnover of inspection staff has been significant. Five freeze waiver requests for inspection positions were recently approved by Department management. Since the review, three new inspectors have been hired, but it will take time to train these personnel in radioactive material inspection techniques.

In the area of technical quality of inspections, the team delivered a finding of unsatisfactory. Although we did not agree with many of the particulars of this finding, we have taken several measures to understand the viewpoint of the team, and to make performance improvements in this area. The Division sent 24 inspectors to the "Inspecting for Performance-Materials Version" class in February 2001 at full cost for tuition and per diem expenses. We sent 9 staff members to the "Inspection Procedures" class in March 2001. We have 8 staff members attending the "Root

Mr. Dennis Sollenberger
March 26, 2001
Page 2

Cause and Incident Investigation" course in March 2001. We have 5 staff members currently attending the five-week "Applied Health Physics" course in Oak Ridge. We are also sending two licensing staff members to the SS&D workshop in Boston in April 2001.

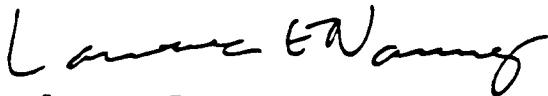
All of these staffing and training expenses have occurred at a time when Tennessee state government is suffering a significant revenue shortfall. These actions demonstrate that the management of the Tennessee Department of Environment and Conservation, as well as that of DRH, are committed to maintaining adequate staffing and providing sufficient training in order to ensure that quality inspections are performed and that licensing actions are conducted by fully qualified individuals.

The Division has scheduled a public hearing for the compatibility-required regulations in April 2001. This rulemaking hearing is one of several currently being planned and conducted. Recently, a hearing was conducted regarding supplemental fees for our licensees and registrants to address critical revenue needs of DRH. Another is planned regarding changes in our x-ray inspection program. We are aggressively moving these regulations through the State process.

All these measures are being undertaken at a time when personnel changes in three levels of management have occurred. As was documented during the review, all three of these managers had been in their current positions nine months or less. We have been trying to make this transition as smooth as possible, however, meeting our programmatic obligations while at the same time responding to numerous inquiries of the review team and NRC management has frequently been challenging. In addition to the materials program, Tennessee has almost 4700 x-ray registrants to regulate. We handle over 150 reported incidents involving radiation each year. We also monitor the environment at three NRC-licensed facilities and participate in emergency response drills at these facilities. We monitor the environment and participate in annual emergency response drills with the facilities at the U. S. Department of Energy's Oak Ridge Reservation. We are contracted to the U. S. Food and Drug Administration to perform MQSA inspections, as well as other compliance inspections, for them. Tennessee has a unique and diverse radiological health program, and we intend that it remain a quality program. We are committed, as we believe our recent history well documents, to making whatever changes may prove to be necessary to continue the program improvements which are underway.

If you have any questions, please contact me at (615) 532-0360.

Sincerely,



Lawrence E. Nanney
Director

Program Improvement Plan:

Overall Management Commitments:

What is being done differently to prevent a reoccurrence?

Changes in management ensure better communication between the Manager and the field staff; tracking of inspections and letters by the Central Office.

Changes in responsibility / accountability

New I&E Manager as of October 1, 2000.

Changes in staff support

(Responses to Specific Recommendations should be addressed as part of the discussion)

I&E Program to include incidents and allegations:

Dec 2000 meetings: What was discussed in meetings? Minutes or summary?

Need for increased communication with I&E Manager and field staff; procedural changes; better documentation in inspection reports; increased training, both formal and OJT; consistency in inspection procedures between field offices.

What information is being provided to I&E manager on a monthly basis?

The quarterly due / overdue list is provided to the Manager and the field staff. Inspections are reported to the Manager on a monthly basis. Inspection letters requiring the review of the Manager are forwarded as they are written.

Inspections due

65 remain due as of March 31, 2000.

Inspections conducted

60 done from January 1, 2001 to March 23, 2000.

Inspections overdue / by how much / when to be conducted?

Of the original overdue list, only 4 remain to be inspected, two of which will be done by March 31, 2001 and the other two by April 30, 2001. Twenty-seven (27) are overdue as of March 31, 2000 — 9 of those are out-of-state licensees. Sixteen of the other eighteen will be completed by April 30.

What results have been observed in performance?

How are actions being tracked while new system is developed?

Manually and by the in-house computer system.

Items needed for Compatibility:

Regulations needed

The 12 rules that we identified in our letter of January 2, 2001, have been through peer review and the public hearing is set for April 23, 2001. The notice of this hearing appeared in the Tennessee Administrative Register this month.

Dates to be adopted

After the hearing, the final rules will undergo review by the Department's legal staff. We will not be able to set a date until that review is completed.

Expected date when program will complete items needed for compatibility

See above.

Other Items:

Training Program Documentation

Establish overall training policy

Draft training policy is under review. Second draft to be sent to staff by March 31, 2001.

Establish qualifications for licensing, inspection, SS&D, others

Qualifications will be addressed in the policy.

Timeline to meet these qualifications

Timelines will be addressed.

SS&D Qualification

All persons conducting principal and concurrent reviews for SS&D registrations will be fully qualified and will have documented authorizations to perform these reviews on file. Two licensing staff will attend the SS&D Workshop the week of April 2, 2001.

ISSUE	STATE RESPONSE	COMPLETION TIME	STATUS
Overall Management Commitment	Not addressed in 01/02/2001 letter		Ongoing
1.(1) Insp. Freq.	Mtg/FOM 12/5-7/00; mon. by I&EM monthly	Ongoing	Ongoing
1.(2) Insp.rpt timely	INSP TRKG SYS dev.	04/01/2001 for SYS developmt, ongoing for perf	Ongoing Manual tracking by I & E Management
1.(3) Filing of repts	Audit file to ensure last 2 yrs info are in the files	07/01/2001	Ongoing
1.(4) Initial Insp based on expiration dates	The system has been corrected to assign initial inspection within 6 mon.	prior to 01/02/2001	Completed.
2. Follow insp proced	Trng for staff thru IFP Mtngs with staff Revision of IP Policy&P	02/13-15/2001 Ongoing 06/01/2001	Completed Ongoing 9 staff attended Insp. Proc. 3/12/01-3/16/01
3. Sup for Insp Findgs	Discussed in Mang Mtg Will be discd in trng	12/2000 TBD	Ongoing
4. Doc for Trng Prog	Initiate Dev. Documentation done	02/01/2001 07/01/2001	Ongoing
5. Trng on TN Insp P	See 2 above	See 2 above	Ongoing
6. Incident Doc	Revised CAI proc./addl guidance Trng on Root Cause	10/2000 TBD	Completed 8 staff will attend Root Cause Course 3/26/01
7. Formal Closure of Incident files	Covered in CAI proc Implementation of CAI	10/2000 Ongoing	Completed Ongoing
8. Superv. review of Allegations	Covered in CAI proc. Implementation of CAI	10/2000 Ongoing	Completed Ongoing
9. Adopt regs	Package of 12 regs to begin process(out of Div) other 6 regs not addressed yet Date for progrr compat.	01/31/2001 Not stated Not stated	Package out of Division awaiting scheduled 4/23/01 public hearing
10. SS&D staff quals	Staff will be fully qualified	Not stated	Two staff members will attend SS&D Training 04/02/01



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
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May 22, 2001

Mr. Dennis Sollenberger
Office of State and Tribal Programs
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Sollenberger:

As requested in Dr. Paperiello's letter dated November 27, 2000, to Mr. John Leonard of this Department, I am submitting the third of the requested bimonthly progress reports addressing the IMPEP team's suggestions and recommendations.

Since the IMPEP review, the Division has expended considerable resources, in both staff time and dollars, to improve the three areas found unsatisfactory by the review team: Status of Materials Inspection Program, Technical Quality of Inspections, and Legislation and Program Elements Required for Compatibility.

Of the 48 licenses that were found to be overdue by IMPEP criteria at the time of the review, all of the in-state licenses have been inspected. Six out-of-state licenses from that list have not been inspected and will remain on the list until inspection opportunity is presented by their performance of work in Tennessee. There are eight in-state licenses overdue for inspection. Of our eleven out-of-state licenses, nine are overdue. Nineteen licenses were inspected in the month of April. At our conference call in June, we will report the number of inspections performed in May.

Two staff members attended the NRC's "Transportation of Radioactive Materials" course in Chattanooga in April. Two license reviewers attended the SS & D workshop in Boston in April. Also, one of the reviewers participated in a device review with an authorized reviewer in accordance with our training criteria. All staff members will attend 8 hour OSHA refresher training on May 23, 2001.

The Division conducted a public hearing on April 23, 2001, for the compatibility required regulations. Comments were received and evaluated, and responses were recently provided. The final regulations are expected to be signed out of this office within days.

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Mr. Dennis Sollenberger
May 22, 2001
Page 2

If you have any questions, please contact me at (615) 532-0360.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence E. Nanney". The signature is fluid and cursive, with the first name "Lawrence" written in a larger, more prominent script than the last name "Nanney".

Lawrence E. Nanney
Director

APPENDIX D

PERIODIC MEETING SUMMARY INCLUDING STATUS OF OTHER RECOMMENDATIONS FROM THE PREVIOUS REVIEW

A periodic meeting was held with Division management by Dennis Sollenberger, Team Leader, and Richard Woodruff, Regional State Agreements Officer, during the follow-up review pursuant to STP Procedure [SA-116](#), "Periodic Meeting with Agreement States Between IMPEP Reviews." Those topics normally documented during the periodic meeting that were reviewed and documented as part of the follow-up review will not be discussed in this Appendix. The following topics were discussed.

Action on Previous Review Findings

The August 2000 IMPEP report made ten recommendations for action by the Division. Eight of these recommendations were discussed in earlier sections under their respective indicators. The status of the remaining three comments is discussed below.

Recommendation 4

The review team recommends that the Division develop and document a training and qualification program which address the training requirements in the NRC/OAS Training Working Group Report or NRC Inspection Manual Chapter 1246.

Current Status

The Division developed a training policy document that included individual training summaries and on-the-job documentation sheets. The policy was issued effective on July 1, 2001. It was distributed for implementation to all license reviewers and inspectors by internal memorandum on July 12, 2001. The individual training files had been set up. However, the individual training history sheets had not been completed at the time of the follow-up review. The review team recommends that this recommendation be closed with the implementation of the individual qualification sheets being reviewed during the next IMPEP review.

Recommendation 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.

Current Status

Two individuals attended the April 2-6, 2001 SS&D workshop. These individuals were also assigned SS&D amendment casework under the direct supervision of their manager. The assignments were completed and evaluated by the supervisor, training was documented, and the individuals approved for independent SS&D device amendment assignments. The individuals will perform new device assignments under management supervision as new device applications are received. The review team recommends that this recommendation be closed.

Program Strengths and/or Weaknesses

The Division management related that the strength of the program was in the senior, experienced managers, and that the staff had good attitudes concerning inspection and enforcement issues.

The Division reported good support from the Department and legislature. This support is in the form of stable sources of funding, and adequate administrative, legal, and laboratory services.

The Division was able to increase the materials license fees by 50% which are earmarked for the Division. The Division funding is now approximately 92% fee based.

Staff retention and salaries are still issues. Since the August 20, 2000 review, seven staff have left the program and 10 staff have been hired. Although this appears to be a positive staff gain for the program, two staff who left the program were senior inspectors (one was a regional manager). The Department received a step increase for all employees and an additional step increase for the licensing staff. They are also trying to get an additional step increase for all staff. A step increase is between 4-5%.

Out of State travel has been either restricted or prohibited. The Division Director was unable to attend the Annual Meeting of the Organization of Agreement States, and staff participation was not permitted at out-of-State training locations. The only exception was for two individuals to attend the SS&D workshop for training in April of 2001.

The Division identified staff training needs in Industrial Radiography and Medical Uses. The team leader discussed options that may be available to the program from Oak Ridge Institute for Science and Education (ORISE) or through State supported educational institutions.

Feedback on NRC's Program

No significant issues were identified. The Division Director noted that the IMPEP review had helped their program, that their program had benefitted from the exchange of information received from the IMPEP team members.

Status of Program and/or Policy Changes

There have been no significant changes in the organizational structure of the Division of Radiological Health as described in the 2000 IMPEP review. An updated organizational chart is attached to the follow-up report as Appendix B.

No significant changes were noted or discussed concerning legislative changes or the redistribution of responsibilities with respect to the agreement materials program. A new manager is in charge of the Inspection and Enforcement program.

Impact of NRC Program Changes

The NRC representatives discussed the status of the new 10 CFR Part 35 amendment, security issues, the status of the NRC web site and the passcode needed for access to the site.

Internal Program Audits and Self-Assessments

The Division managers reported that currently no self-assessments were being performed; however, the Materials Supervisor at the Memphis regional office had shared his experiences on IMPEP teams with the other staff and in planning for the previous IMPEP review. Peer reviews are conducted on all licenses issued, and all inspection reports receive at least one level of supervisory review. Enforcement letters receive the same type of reviews and are issued out of the field office. Feedback is also being provided to the inspectors through the Inspection and Enforcement Manager, and during training and inspector accompaniments. See additional discussion under Section 2.2 of the follow-up report.

Status of Allegations Previously Referred

This is discussed in Section 2.3 of the follow-up report.

Nuclear Material Events Database (NMED) Reporting

A general discussion was held with the representatives concerning the NMED reporting system. The Division was informed that upgraded software had been installed by the INEEL contractor, and that Sam Petijohn, at NRC, could be contacted for training and installation of the new software in Tennessee.

ATTACHMENT

January 4, 2002 Letter from Lawrence E. Nanney
Tennessee's Response to Follow-Up Draft IMPEP Report

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