

DATED: JUL 28, 1994; SIGNED BY RICHARD L. BANGART

Mr. J. W. Luna, Commissioner
Department of Environment and Conservation
344 Cordell Hull Building
Nashville, TN 37203

Dear Mr. Luna:

This is to transmit the results of the NRC review and evaluation of the Tennessee radiation control program conducted by Mr. Richard L. Woodruff, Regional State Agreements Officer, Region II, which was concluded on February 4, 1994. The results of this review were discussed with you, Mr. Wayne K. Scharber, Assistant Commissioner, Mr. Kenneth W. Bunting, Administrator, Land and Radiation Programs Administration, Mr. Michael H. Mobley, Director, Division of Radiological Health, and Mr. Lawrence E. Nanney, Deputy Director, Division of Radiological Health.

As a result of our review of the Tennessee Radiation Control Program and the routine exchange of information between the NRC and the State, including the information you sent to us in letter dated December 17, 1993, NRC staff has determined that the State's program for regulating agreement materials is adequate to protect the public health and safety and is compatible with the regulatory program of the NRC.

During this review, we found significant improvements in the Tennessee Agreement State program. We are pleased with the progress and improvements that have been made. Specifically, we noted that the State's regulations have been updated and made compatible with the NRC 10 CFR Part 20, "Standards for Protection Against Radiation;" and the overdue inspection backlog has been eliminated. In addition, the personnel reclassification package was approved which included salary adjustments for radiation control personnel, and additional personnel were hired. It is also commendable that the State independently contracted with Oak Ridge Institute for Science and Education (ORISE) to conduct a five week Health Physics training course for 20 new personnel. We believe that the State's program has benefitted from these improvements.

Please note that there has been a change made in the format of this letter from our previous review letters. This letter summarizes the findings regarding all 30 program indicators as opposed to only discussing those indicators where deficiencies were noted. Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs.

Enclosure 2 is a summary of the review findings where recommendations are made for improvements in the radiation control program. This enclosure contains documentation on the: Scope of Review, Conclusion, Status of Program Related to Previous NRC Findings, Current Review Assessments and Recommendations, and Summary Discussions with State Representatives. Recommendations were made on three indicators; however, the findings that resulted in these recommendations are not considered significant enough to affect the findings of adequacy and compatibility. We request specific written responses from the State on the recommendations in Enclosure 2 within 30 days of this letter. We recognize the delay in our issuance of this letter; if you require more than 30 days to respond, please inform us of your revised response date.

Enclosure 3 presents a summary of the review findings where the State has adequately satisfied the indicator. Please note that the regulations that will need to be adopted by the State to maintain compatibility, as identified under the Indicator "Status and Compatibility of Regulations," are indicated in this enclosure. A written response to the items in Enclosure 3 is not required.

We appreciate your cooperation with this office and the courtesy and cooperation extended by your staff to Mr. Woodruff and the other NRC representatives during the review.

A copy of this letter and the enclosures are provided for placement in the State Public Document Room or otherwise be made available for public examination.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As Stated

cc w/encls:
Wayne K. Scharber, Assistant Commissioner
Department of Environment and Conservation
Kenneth W. Bunting, Administrator
Land and Radiation Programs Administration
Michael H. Mobley, Director
Division of Radiological Health
NRC Public Document Room
State Public Document Room

Enclosure 2 is a summary of the review findings where recommendations are made for improvements in the radiation control program. This enclosure contains documentation on the: Scope of Review, Conclusion, Status of Program Related to Previous NRC Findings, Current Review Assessments and Recommendations, and Summary Discussions with State Representatives. Recommendations were made on three indicators; however, the findings that resulted in these recommendations are not considered significant enough to affect the findings of adequacy and compatibility. We request specific written responses from the State on the recommendations in Enclosure 2 within 30 days of this letter. We recognize the delay in our issuance of this letter; if you require more than 30 days to respond, please inform us of your revised response date.

Enclosure 3 presents a summary of the review findings where the State has adequately satisfied the indicator. Please note that the regulations that will need to be adopted by the State to maintain compatibility, as identified under the Indicator "Status and Compatibility of Regulations," are indicated in this enclosure. A written response to the items in Enclosure 3 is not required.

We appreciate your cooperation with this office and the courtesy and cooperation extended by your staff to Mr. Woodruff and the other NRC representatives during the review.

A copy of this letter and the enclosures are provided for placement in the State Public Document Room or otherwise be made available for public examination.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:

As Stated

*See previous Concurrence Obtained on First draft of Report

** Concurrence Obtained on Final Report

Distribution: Next page

OFC	RII:SAO	RII:DRSS	RA:RII	OSP:SA	OSP:DD	AEOD:
NME	RWoodruff	JStohr	SEbnetter	CMAupin	PLohaus	RTripathi
DTE	3/7/94* 6/27/94** 7/15/94**	3/15/94*	3/14/94*	3/10/94* 6/08/94** 6/27/94** 7/15/94**	06/08/94** 7/15/94**	05/16/94*

OFC	NMSS:D	OGC	OSP:D	DEDS	EDO		
NME	RBernero	FCameron	RBangart	HLThompson	JMTaylor		
DTE	06/13/94**	6/22/94**	07/19/94**	07/ /97	07/ /97		

g:\chm\94letter.tn

cc w/encls:

Wayne K. Scharber, Assistant Commissioner
Department of Environment and Conservation
Kenneth W. Bunting, Administrator
Land and Radiation Programs Administration
Michael H. Mobley, Director
Division of Radiological Health

J. W. Luna

3

NRC Public Document Room
State Public Document Room

bcc w/encls:
The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque

Distribution:

DIR RF
EDO RF
H. Thompson, DEDS
R. Bernero, NMSS
S. Treby, OGC
F. Cameron, OGC
H. Newsome, OGC
R. Bangart, OSP
P. Lohaus, OSP
C. Maupin, OSP
J. Stohr, RII
R. Woodruff, RII
R. Trojanowski, RII
DCD (SP01)
S. Droggitis, OSP
E. Jordan, AEOD
R. Tripathi, AEOD
Tennessee File

PDR (YES ____ NO____)

APPLICATION OF "GUIDELINES FOR NRC REVIEW OF
AGREEMENT STATE RADIATION CONTROL PROGRAMS"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs," were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories. Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need of improvement in particular program areas is critical. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period. The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Act, as amended.

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND RECOMMENDATIONS FOR THE TENNESSEE RADIATION CONTROL
PROGRAM FOR THE PERIOD
DECEMBER 13, 1991 TO FEBRUARY 4, 1994

SCOPE OF REVIEW

The twenty-sixth program review of the Tennessee Agreement State program was held during the period of January 31 - February 4, 1994 in Nashville, Tennessee. The program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992 and the internal procedures established by the Office of State Programs. The State's program was reviewed against the 30 program indicators provided in the policy statement.

A questionnaire containing the thirty indicators with specific questions addressing each indicator was sent to the State prior to the review. This review included the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the Program managers and staff members, review team observations, licensing and inspection casework file reviews, and inspector accompaniments.

The State was represented by Michael H. Mobley, Director, Division of Radiological Health and his staff. Selected license and compliance files were reviewed by Richard L. Woodruff, Regional State Agreements Officer, Region II, and Jay Henson, Radiation Specialist, Region II. Incident files and procedures were reviewed by Dr. Raji Tripathi, Office of Analysis and Evaluation of Operational Data (AEOD). Area Field Office visits and accompaniments of five State inspectors were made by Mr. Woodruff during the periods of January 11-14 and January 19-20, 1994. A summary meeting regarding the results of the review was held on Friday, February 4, 1994.

CONCLUSION

The Tennessee program for Agreement Materials is adequate to protect public health and safety, and is compatible with NRC's regulatory program for similar materials.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in a letter to Commissioner Luna dated March 6, 1992. A follow-up review was conducted on August 31 - September 3, 1992 and the results were reported to Commissioner Luna in a letter dated October 30, 1992. A mid-review visit meeting was held with the State during the period of June 7-9, 1993. All of the comments and recommendations made following the 1991 review and the 1992 follow-up review have been satisfactorily resolved and closed out as documented in the 1992 follow-up report. These findings are presented below.

1. Status of the Inspection Program (Category I indicator)

Comment from the 1991 Routine Review

Data provided by the DRH shows that the program has 130 licenses that are overdue for inspection. Of these, 15 are priority I licenses that are overdue by more than 50 percent of their normal inspection intervals. They range from 12 to 38 months overdue. The DRH also has 24 priority IV licenses that are overdue for their initial inspection.

The DRH has a plan for inspection of certain "priority classes" of licenses and X-ray facilities as staff resources become available. This plan calls for

the integration of the X-ray inspections into the inspection schedule for material licenses. The first "priority class" includes all of the material licenses that are inspected on a six month frequency. The second "priority class" includes essentially all of the medical X-ray facilities. The third "priority class" includes all of the materials licenses with inspection intervals of one to three years that are overdue by more than 50% of their inspection interval. The remaining priority I through III materials licenses that are overdue, and priority IV and V materials licenses that are overdue by more than 50% of their inspection interval comprise "priority class" four. The fifth "priority class" includes veterinary X-ray facilities and the remaining priority IV and V material licenses that are overdue. The sixth "priority class" includes all priority VII material licenses.

It was noted that the area office supervisors are the only persons that are fully trained to perform material license inspections. When combined with other supervisory duties, major X-ray facility inspections, and training new personnel, the lack of qualified inspectors reduces the effectiveness of the above inspection plan. In some instances, the area offices inspection schedules have not progressed beyond the second "priority class" facilities, which allows the overdue materials licenses to become more overdue.

Recommendation from the 1991 Routine Review

It is recommended that the DRH reevaluate the inspection plan and assign material licenses in priorities I through III that are overdue by more than 50% of their inspection frequencies, and the material licenses that have never been inspected, to a higher "priority class."

Status from the 1992 Follow-up Review

On July 29, 1992, the Inspection and Enforcement Manager developed a new schedule for the inspection of materials licensees. The schedule places more emphasis on the inspection of licenses in priorities I through III that are overdue by more than 50% of their inspection frequencies, licenses that have never been inspected, and priority IV and V licenses that are overdue by more than 100% of their inspection frequencies. The inspection plan also has a "matrix" that projects the inspection workload for each of the four Area Compliance Offices over the next eighteen months. The plan calls for the inspection of 476 licenses over the next eighteen months, and the backlog to be eliminated by the end of the 1993 calendar year.

Recommendation from the 1992 Follow-up Review

We recommend that the DRH continue with the implementation of the revised inspection plan for the elimination of the overdue inspections.

Current Status

Based upon inspection data provided to the reviewer, the State has completely eliminated the backlog of overdue inspections. This item is closed.

2. Staff Continuity (Category II Indicator)

Comment from the 1991 Routine Review

The program has lost 23 technical staff members within the past four years, 12 within this review period. Data maintained by the DRH indicates that 18 of the 23 technical staff listed "salary" as a reason for leaving the program.

The 23 staff lost also represent over 45 years of technical experience lost, and 97 weeks of technical training lost from the program.

During the 1989 review, we recommended that the job classifications and respective salary ranges be reviewed and upgraded as needed to provide better staff continuity. This recommendation was revisited again during the 1990 follow-up review, and Mr. Scharber stated that a reclassification package was being actively pursued.

During the visit in July of 1991, we learned that the reclassification package had been submitted in final form to the Bureau of Environment Office on January 24, 1991, and that the package had received a favorable review by the personnel office staff. However, during this review we learned that the reclassification package is still in the Commissioner's Office and that no action has been taken.

The average of the mid-range salaries for entry level positions in the other seven southeastern Agreement States is \$27,015.00 annually. The current salary ranges provided by the DRH reveals that the mid-range salary for the entry level position Environmental Specialist I is \$19,050.00 or \$7,965.00 below the comparable salary in the other southeastern States.

Recommendation from the 1991 Routine Review

We recommend that the State expedite to the maximum extent practicable the reclassification of the DRH technical staff positions, and to upgrade the salaries accordingly.

Status from the 1992 Follow-up Review

The Program Director and his managers could not provide written documentation concerning the status of the personnel package that addresses the reclassification of the DRH staff. However, our discussions revealed that new job descriptions were submitted to the Personnel Department during the months of May and June, and that position audits have been conducted in three of the Area Offices. We also understand that all Environmental Specialist positions are being reevaluated, and that personnel action to reclassify the staff to Health Physicist positions could be expected by the first of the year.

Recommendation from the 1992 Follow-up Review

We again recommend that the State expedite to the maximum extent practicable the reclassification of the DRH technical staff positions, and to upgrade the salaries accordingly.

Current Status

The reclassification package was approved and implemented in December of 1993. The Environmental Specialist positions were reclassified as Health Physicist, along with an increase in salaries. This item is closed.

3. Additional Comment from 1992 Follow-up Review

The State's Radiation Control Program should have the capability to identify isotopes that are found in the environment as contaminated materials and or articles. A portable multiple channel analyzer (MCA) is recommended to provide timely and accurate information capabilities for the program. Several instances have occurred in recent years where this type of instrument

capability was needed, and would have saved considerable resources if the instrumentation had been available. During our exit meeting with the staff, we learned that the State had considered acquiring a portable MCA type instrument.

1992 Follow-up Recommendation

We recommend that the State follow through with their efforts to purchase a portable MCA for use under routine and emergency conditions.

Current Status

The Program Director indicated that a portable multiple channel analyzer has been purchased. This item is closed.

CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 27 of these indicators. Recommendations were made on three indicators; however, the findings that resulted in these recommendations are not considered significant enough to affect the findings of adequacy and compatibility. These three indicators are discussed below. The remaining 27 indicators are discussed in Enclosure 3. A questionnaire containing the 30 indicators with specific questions addressing each indicator was sent to the State prior to the review. The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the Program managers and staff members, review team observations, licensing and inspection casework file reviews, and inspector accompaniments. Specific assessments and recommendations are as follows:

1. Inspection Frequency (Category I)

NRC Guidelines¹

The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations. The minimum inspection frequency including for initial inspections should be no less than the NRC system.

Assessment

A comparison was made of the inspection frequencies utilized by the State and those utilized by NRC. In general, the State utilizes the same inspection frequencies as the NRC, except for waste processors and decontamination facilities that are inspected on a 6 month frequency as compared to an annual NRC frequency, and three source material facilities, one research and development facility, one rare earth extraction and processing facility which are inspected on an annual basis as compared to a 3 year NRC frequency.

The State was notified in January 1994 that the NRC inspection frequency for medium and high dose afterloading devices had changed to an annual frequency,

¹The guideline statements are a summary of the guideline provisions provided in the May 28, 1992 policy statement, "Guidelines for NRC Review of Agreement State Radiation Control Programs."

which was within a week of the NRC routine review. Thus, the State did not have sufficient time to change its written inspection frequency before the review was conducted. However, it was noted by the reviewer that the State had already instituted a practice of inspecting these devices on an annual basis.

Recommendation

We recommend that the State update its written inspection procedures and its inspection program to reflect an annual inspection frequency for afterloader device users. The State should also track these inspections specifically.

2. Licensing Procedures (Category II)

NRC Guidelines

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.

Assessment:

From the review of licensing files and discussions with staff, it was determined that the Program essentially utilizes NRC policy guidance and procedures for the evaluation of applications and the writing of the license document. Standard licensing guides have been developed and are available for the applicant's use. The State acknowledged the receipt of the draft Licensing Guide for Remote Afterloading Devices. Standard license conditions are also utilized for uniformity. Copies of NRC's standard licensing conditions, and license review checklists were provided to the Program on diskettes for their information. The casework was reviewed for technical adequacy of application review, significant errors and omissions, utilization of licensing procedures and standard conditions, and documentation.

As noted in the above NRC Guideline, standard license conditions should be used to expedite and provide uniformity in the licensing process. Tennessee's standard license conditions do not require Remote Afterloading Device sources to be returned to the manufacturer/distributor for disposal, as recommended in the licensing guide.

Also, a standard license condition is needed on all Nuclear Pharmacy licenses that requires "an authorized user to be physically present whenever licensed material is used," as discussed in NRC FC Directive 410-4. The State currently only requires material to be used "under the supervision of an authorized user," which is different from the NRC requirements. The State reported that problems with the "use" of material had not been noted.

Recommendation

We recommend that the State's licenses and standard license conditions be updated to require the return of remote afterloading device sources to the manufacturer/distributor for disposal and that the nuclear pharmacy licenses be updated to require "an authorized user to be physically present whenever licensed material is used."

3. Status of Inspection Program (Category I)

NRC Guidelines

The State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. When backlogs occur, management should develop and implement a plan to reduce the backlog.

Assessment

The computerized inspection due listing was reviewed and updated by the RCP to reflect inspections performed during 1994. The Program does not have any inspections that are overdue for inspection. The status of the inspection program is assessed monthly and on a quarterly basis, and the inspections due assignments are generated on a semi-annual basis.

The State previously recognized the need to decrease emphasis on reciprocity inspections to reduce the overall inspection backlog as set out in their inspection action plan. As noted above, the program does not have any overdue inspections. Therefore, we believe increased emphasis should now be placed on reciprocity inspections. According to the State's response to the questionnaire, 200 reciprocity notices were received in 1993 and only one reciprocity inspection was conducted. Given that the action plan has been effective in eliminating the backlog and a large number of reciprocity notices have been received, the State should increase its efforts in conducting reciprocity inspections.

Recommendation

The RCP should increase its efforts to inspect reciprocity licensees, especially those performing industrial radiography.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review was held on Friday, February 4, 1994, with Commissioner Luna, and Messrs. Wayne K. Scharber, Assistant Commissioner for the Environment; Kenneth W. Bunting, Administrator, Land and Radiation Programs; Michael H. Mobley, Director, Division of Radiological Health; and Lawrence E. Nanny, Deputy Director, Division of Radiological Health.

In general, the reviewer discussed the scope of the review, and the progress the State had made since the last review. Specifically, the State was commended on (1) the adoption and update of regulations needed for compatibility including the revised regulations equivalent to 10 CFR Part 20; (2) the Program's efforts to eliminate the inspection backlogs; (3) the reclassification of the technical personnel to Health Physicist; (4) the salary increases; and (5) the excellent support for specialized Health Physics training of the technical staff.

The Organizational changes in the Office of State Programs were discussed, and the Commissioner was informed that the reviewer would recommend findings of adequacy and compatibility, and that a letter confirming the review would be forthcoming.

In reply, Commissioner Luna discussed at length his support for the Program and their efforts to develop a quality Program.

SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED BY THE TENNESSEE
RADIATION CONTROL PROGRAM FOR THE PERIOD
DECEMBER 13, 1991 TO FEBRUARY 4, 1994

The assessments below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the Program managers and staff members, review team observations, licensing and inspection casework file reviews, and inspector accompaniments. The State fully satisfies the following indicators:

1. **Legal Authority (Category I)**

NRC Guidelines

Clear statutory authority should exist, designating a State radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement.

Assessment

Based on previous reviews and the State's response to the questionnaire, clear statutory authority exists which designates the Tennessee Division of Radiological Health as the State radiation control agency with authority over agreement materials. The State statutes that provide this legal authority is Title 68, Chapter 23, of the Tennessee Code Annotated (TCA).

2. **Status and Compatibility of Regulations (Category I)**

NRC Guidelines

The State should adopt regulations to maintain a high degree of uniformity with NRC regulations. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable, but no later than 3 years after the effective date.

Assessment

The State was provided a chronology of regulation amendments that are needed for compatibility for comparison with the Tennessee regulations that have been adopted. This chronology was compared with the Tennessee regulations, and the amendments that were adopted by the State since the last (December 1991) review were assessed for compatibility.

The State's regulations are compatible with the NRC regulations up to the 10 CFR Parts 30, 31, 34, 39, 40, and 70 amendments on "Notification of Incidents" (56 FR 40757) that became effective on October 15, 1991 and should be adopted by October 15, 1994.

In addition, we would like to bring to the State's attention other regulations that will be needed for compatibility. These rules are:

- "Quality Management Program and Misadministrations", 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992 and will need to be adopted by January 27, 1995.
 - "Licenses and Radiation Safety Requirements for Irradiators", 10 CFR Part 36 (58 FR 7715) that became effective on July 31, 1993 and will need to be adopted by July 31, 1996.
 - "Licensing Requirements for Land Disposal of Radioactive Waste," 10 CFR Part 61 amendment (58 FR 33886) that became effective on July 22, 1993 and will need to be adopted by July 22, 1996.
 - "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993 and will need to be adopted by October 25, 1996.
3. **Location of the Radiation Control Program Within the State Organization (Category II)**

NRC Guidelines

The RCP should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management.

Assessment

The Organizational chart depicting the Program relative to other health and safety programs was reviewed. The RCP is located in the State organization parallel to other health and safety programs. The Commissioner of the Department is at the cabinet level of the State's organization and reports directly to the Governor. In addition, adequate access to appropriate levels of State management is maintained by the Program Director who is the State Liaison Officer appointed by the Governor.

4. **Internal Organization of the RCP (Category II)**

NRC Guidelines

The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy.

Assessment

The internal organizational chart was reviewed and the organizational structure was discussed with the Program Director. The results of the review and discussions with staff indicated that the RCP is organized toward achieving an acceptable degree of staff efficiency and to place appropriate emphasis on major program functions. For example, there has been considerable growth in staff since the last review and the State RCP has been modified to accommodate the increase in staff. In early 1991, the RCP staff consisted of 41 positions and in 1993, the RCP staff was increased to 74 positions, which was an increase of approximately 83%. To accommodate this significant growth, organizational changes occurred within two of the major technical sections,

Licensing/Registration/Planning, and Technical Services. These changes were done to further develop the organization, for staff efficiency and for better communication in the execution of the program.

Lines of supervision from the Director, Division of Radiological Health, to the Assistant Director, Division of Radiological Health, to the Managers of the Licensing and Registration Section and the Inspection and Enforcement Section are specific to provide execution of program policy.

5. **Legal Assistance (Category II)**

NRC Guidelines

Legal staff should be assigned to assist the RCP or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP program, statutes, and regulations.

Assessment

Based upon the State's response to the questionnaire and discussions with staff, legal assistance to the RCP is adequate. During the review period, the RCP utilized legal assistance as needed for enforcement cases, and issues concerning regulations, fees, civil penalties, and financial assurance issues. The Attorney General's Office has assigned a full time attorney to the Department, and the Program Director stated that the Attorneys' involvement enabled the timely adoption of the State's equivalent regulations to 10 CFR Part 20 and other regulations.

6. **Technical Advisory Committees (Category II)**

NRC Guidelines

Technical Committees, Federal Agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems.

Assessment

At the present time, Tennessee does not have technical advisory committees. However, the State indicated that when assistance is needed, under the State's Administrative Procedures Act, the Division must solicit comments from Professional Societies (such as the Tennessee Radiological Society), etc., during the updating of regulations. In addition, the Program manager related that other State Agencies, the NRC and other Federal Agencies, and consultants would be called upon for assistance as needed.

The reviewer did not note any unique or technically complex problems where the State should have used resources other than those indicated above and found the information provided by the State in this area to be adequate to satisfy this indicator.

7. **Contractual Assistance (Category II)**

NRC Guidelines

States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have procedures and mechanisms in place for acquisition of technical and vendor services necessary to support these

functions that are not otherwise available within the RCP. The RCP should avoid the selection of contractors which have been selected to provide services associated with the low-level radioactive waste facility development or operations.

Assessment

This indicator was not evaluated because the State, at present, does not have a low-level waste disposal regulatory program.

8. **Quality of Emergency Planning (Category I)**

NRC Guidelines

The State radiation control program (RCP) should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc. Periodic drills should be performed to test the plan.

Assessment

The RCP has a written emergency response plan for incidents. Aspects of the emergency plan were submitted to the NRC for review as part of the documentation requested for the review of the Tennessee Multi-Jurisdictional Radiological Emergency Response Plan For Watts Bar Nuclear Plant. In addition, the RCP has been involved in five emergency exercises since the last review, which included each of the Tennessee Valley Authority reactors.

According to the response from the State in the questionnaire, the emergency communications list was last revised in September 1993 and the emergency plan was revised in October 1993. In addition, the emergency plan was tested in a drill on October 6-7, 1993 for the Watts Bar facility.

9. **Budget (Category II)**

NRC Guidelines

Operating funds should be sufficient to support program needs such as staff travel necessary to conduct an effective compliance program, including routine inspections, follow-up or special inspections (including pre-licensing visits) and responses to incidents and other emergencies, instrumentation and other equipment to support the RCP, administrative costs in operating the program including rental charges, printing costs, laboratory services, computer and/or word processing support, preparation of correspondence, office equipment, hearing costs, etc., as appropriate.

Assessment

Funding is sufficient to support the radioactive materials program. The total budget for fiscal year 93-94 for the Division of Radiological Health is \$3,875,300.00 and the radioactive materials program was allocated \$1,829,000 of this budget; this figure does not include the management and administrative aspects of the program. The radioactive materials program received \$1,959,000.00 from radioactive materials fees. The materials program is 90 percent funded by fees and these funds are credited to a special fund for the Division's use.

10. Laboratory Support (Category II)NRC Guidelines

The RCP should have the laboratory support capability in-house, or readily available through established procedures, to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, etc., on a priority established by the RCP.

Assessment

Although the laboratory support was not inspected during this review, the laboratory support services have not significantly changed since the previous reviews as noted from discussions with staff and from the responses to the questionnaire. Based upon discussions with the State and previous reviews of the RCP in this area, all work that requires laboratory analysis is performed by the Bureau of Laboratory Services. The laboratory has the capability of performing bioassays, and analyzing environmental samples collected during radiological inspections. In addition, the Bureau of Laboratory Services equipment and procedures are evaluated by the Independent Measurements Section from the NRC Region II Office on an annual basis.

The State indicated in responding to the questionnaire that there have not been any serious problems in obtaining timely and accurate results from the laboratory. The reviewer used previous information and information from the State to determine that laboratory support is adequate.

11. Administrative Procedures (Category II)NRC Guidelines

The RCP should establish written internal procedures to assure that the staff performs its duties as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies, decommissioning and license termination, fee collection, contacts with communication media, conflict of interest policies for employees, exchange of information and other functions required of the program. Administrative procedures are in addition to the technical procedures utilized in licensing, inspection, and enforcement.

Assessment

The internal procedures were reviewed and discussed with the supervisors and the technical staff. Special attention was given to the review of the procedures for handling proprietary information, allegations, incident tracking, misadministrations, and enforcement procedures. As a result of our review, the procedures were determined to be adequate to assure that the staff performs the duties required and to provide a high degree of uniformity and continuity in regulatory practices.

12. Management (Category II)**NRC Guidelines**

Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquiries, regulation revisions). Supervisory review of inspections, reports and enforcement actions should also be performed.

Assessment

A review of licensing files, enforcement files, and inspection files along with discussions with staff and the review of the State's response to the questionnaire was used in developing this assessment. From these various sources, it was determined that monthly reports on the status of licensing and enforcement actions are developed for management review. Area Field Offices are audited on an annual basis. All licensing actions receive a supervisory review, and all inspection reports and enforcement cases receive supervisory review. In addition, all inspectors receive supervisory accompaniments at least annually.

13. Office Equipment and Support Services (Category II)**NRC Guidelines**

The radiation control program (RCP) should have adequate secretarial and clerical support. States should have a license document management system that is capable of organizing the volume and diversity of materials associated with licensing and inspection of radioactive materials.

Assessment

Based upon the response to the questionnaire, discussions with staff and observations of the technical staff, the RCP has an adequate administrative support staff which is supervised by the Deputy Director. With regard to managing licensing and inspection documents, the RCP reviewers utilize computers to generate licensing documents and each license has its own disk on which the license with amendments is stored. The State also indicated that inspection letters are generated using a system with stored paragraphs that minimizes typing by technical staff. Presently, there is some sharing of communal computers; however, the RCP is rapidly installing computers in order to reach the goal of a computer for every technical staff member.

14. Public Information (Category II)**NRC Guidelines**

Inspection and licensing files should be available to the public consistent with State administrative procedures. It is desirable, however, that there be provisions for protecting from public disclosure proprietary information and information of a clearly personal nature.

Assessment

From the review of the State's procedures and discussions with staff, the reviewer determined that the State operates under an open records law which requires all records, except those containing proprietary information, to be open to the public. In addition, the State has administrative procedures for

handling and protecting "proprietary information" and for the storage of proprietary information in a locked file.

15. **Qualifications of Technical Staff (Category II)**

NRC Guidelines

Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel including the director of the radiation protection program should be commensurate with the type of licenses issued and inspected by the State.

Assessment

The qualifications of the technical staff were reviewed and all of the technical staff have degrees in the sciences. The training and experience of the technical staff, including the senior personnel and managers is commensurate with the licenses issued and inspected by the State.

16. **Staffing Level (Category II)**

Professional staffing level should be approximately 1 to 1.5 person-year per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel.

Assessment

The Division currently has 62 full-time employees located in the Nashville office (44) and in the Area Offices in Knoxville (9), Chattanooga (3), and Memphis (6). The staffing includes 43 technical staff members (including first-line supervisors), and 19 other managers and administrative support staff. Of the technical staff, approximately 12.1 FTEs are currently being utilized in the materials program for 542 licenses, or 2.2 FTE per 100 licenses.

17. **Staff Supervision (Category II)**

NRC Guidelines

Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel. Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy. Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Assessment

A review of the training and experience of the senior personnel and first line supervisors indicates that these personnel are adequate to provide guidance to junior and senior personnel. It was determined that supervisors make appropriate work assignments in accordance with training and experience needed to perform the assigned task, and supervisors monitor the progress of the assignments and the completed actions.

18. Training (Category II)**NRC Guideline**

Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices. The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology. The RCP staff should be afforded opportunities for training that is consistent with the needs of the program.

Assessment

All of the senior personnel and most of the junior personnel have attended the NRC core courses. The RCP also utilizes short courses and workshops sponsored by other Agencies to the extent possible. In addition to the four persons which attended the NRC sponsored five week "Health Physics Course" in 1992, the State independently contracted with the Oak Ridge Institute for Science and Education (ORISE) for a five week "Health Physics Course" for an additional twenty State personnel. This course was conducted at State expense exclusively for the Tennessee staff without any NRC funding or involvement.

19. Staff Continuity (Category II)**NRC Guideline**

The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications and should be comparable to similar employment in the geographical area.

Assessment

The program lost four persons from the materials radiation control program over the calendar years 1992 and 1993. The State has taken measures to reduce staff turnovers by granting a 2 percent increase in salaries on July 1, 1993 and a 4 percent increase which was effective on January 1, 1994. In addition, on December 16, 1993, all Environmental Specialists in the Division were reclassified to Health Physicists. This reclassification was accompanied by salary increases for the technical staff. All technical staff received salary increases during this review period that ranged from 18.8 percent to a maximum of 57 percent. The average increase was 34 percent.

20. Technical Quality of Licensing Actions (Category I)**NRC Guidelines**

The RCP should assure that essential elements of applications have been submitted to the agency, and which meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions.

Assessment

Twenty-six license files were selected for casework review. The Program currently has thirty-eight major licenses and the State conducted three pre-licensing visits to major licensees during the review period. The review sample included major licenses that have never been sampled and those having major amendments. The sample contained eleven of the major licenses (one waste processor, one incinerator, four manufacturing and distribution, three nuclear pharmacies, and two decontamination services). The remainder of the sample contained four terminated license close-outs, one (the only) well logging license, four industrial radiography licenses, one private cardiology license, one private nuclear medicine license, one private brachytherapy license, one institutional brachytherapy license, one institutional diagnostic license, and one institutional teletherapy license. No significant comments from the review of the above indicated licenses were noted and the technical quality of licensing actions were found to be adequate.

21. **Adequacy of Product Evaluations (Category I)**NRC Guidelines

RCP evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC, State, or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users. Approval documents for sealed source or device designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Assessment

The Program issued two Sealed Source and Device registry sheets during this review period. The registrations are as follows:

- TN-363-D-102-S, manufactured by HNU Systems, Inc., using NARM material in a fluorescence analyzer type device
- TN-212-D-101-S, manufactured by Science Applications International Corporation, using by-product material in a rapid ashmeter type device

The device sheets evaluations were found to be clear, complete, and accurate. The State had proper documentation, and used appropriate guides (ANSI standards) for their evaluation.

22. **Inspector's Performance and Capability (Category I)**NRC Guidelines

Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to

supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections.

Assessment

All State Inspectors have been accompanied by supervisors since the last review, and the junior inspectors train with the senior inspectors on team inspections. All senior inspectors have been accompanied by the reviewer within the past two years. Five inspectors were accompanied by the NRC reviewer during this review, two from the Knoxville Area Office, one from the Chattanooga Area Office, and two from the Memphis Area Office. The accompaniments were as follows:

Date(s): January 11-12, 1994
 Inspector(s): Roger L. Macklin (lead) and Larry A. Helveston
 Licensee: Johnson City Medical Center
 Location: Johnson City, TN
 License No: R-90004-D93
 License Type: Institutional Medical and Brachytherapy

Date: January 13, 1994
 Inspector: Robert A. Schaeffer
 Licensee: Inspection Service, Inc.
 Location: Hixson, TN
 License No: R-33089-E98
 License Type: Industrial Radiography, Fixed facility

Date: January 19, 1994
 Inspector: Janice E. Harkins
 Licensee: The West Clinic
 Location: Memphis, TN
 License No: R-79216-B95
 License Type: Private Medical, Diagnostic

Date: January 19, 1994
 Inspector: Griggs Stevens
 Licensee: MQS Inspection, Inc.
 Location: Memphis, TN
 License No: R-79026-J97
 License Type: Industrial Radiography, Fixed location

The inspectors were prepared for the inspections and they conducted the inspections in a thorough manner. The Tennessee radioactive materials inspectors appear to be competent to evaluate health and safety problems and to determine compliance with State regulations and requirements. The reviewer did not note any discrepancies with the inspectors findings.

23. Responses to Incidents and Alleged Incidents (Category I)NRC Guidelines

Inquiries should be promptly made to evaluate the need for on-site investigations. Investigation (or inspection) results should be documented and enforcement action taken when appropriate. State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations.

Assessment

All of the incident files for the 1992 and 1993 calendar years were collected from the State. These files were previously distributed to the Office of State Programs and the AEOD. The incidents for 1993 were reviewed by Dr. Raji Tripathi from the AEOD, including the file and data systems utilized by the State, and the regulations related to incident reporting requirements. The State's incident reporting system, with emphasis on medical misadministrations, was discussed with the Program Manager and the Program staff. The Program maintains logs of misadministrations, complaints, allegations, and events along with the summary forms that are used for file documentation. The procedures for handling complaints, misadministrations, and allegations have been updated and the tracking system is maintained on the computer.

The RCP inspectors were observed to make appropriate inquiries of licensee staff concerning misadministrations and events during the inspection accompaniments. Also, the inspectors review safety committee minutes, consultant reports, and other records as appropriate to determine if misadministrations have occurred. The files indicate that 91 events occurred during the 1993 calendar year, of which 27 events were misadministrations and the State performed 39 on-site investigations. This guideline was adequately satisfied.

24. Enforcement Procedures (Category I)NRC Guidelines

Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Written procedures should exist for handling escalated enforcement cases of varying degrees.

Assessment

The State has taken escalated enforcement action on four licensees since the previous review. Only one of these actions is still pending at the time of the review. The Program has a lawyer from the State's Office of Attorney General assigned full time to the Department. The enforcement procedures were reviewed and practices were reviewed during the casework reviews. The RCP satisfies the requirements of this Guideline Indicator.

25. Inspection Procedures (Category II)**NRC Guidelines**

Inspection procedures and guides, consistent with current NRC guidance, should be used by inspectors to assure uniform and complete inspection practices and provide technical guidance in the inspection of licensed programs.

Assessment

The reviewer determined through discussions with staff, accompaniments of State inspectors, review of compliance files and examination of the State's response to the questionnaire that the Tennessee inspection procedures are consistent with current NRC guidance and satisfies the guideline. All of the materials inspectors have become familiarized with NRC procedures and guidance in conducting inspections by attending the Office of State Programs sponsored Inspection Procedures Course. It was determined that the RCP utilizes the Inspection Guidance provided by NRC, and the reviewer provided the State with updated copies of the NRC Manual Chapters 2800 and 87100 during the review. In addition, as evidenced during the accompaniments of inspectors, and the review of compliance casework, the procedures assure uniform and complete inspection practices and provides technical guidance for the overall Tennessee inspection program, since these procedures are utilized statewide by the different Area Field Offices.

26. Inspection Reports (Category II)**NRC Guidelines**

Inspection reports should uniformly and adequately document the results of inspections and identify areas of the licensee's program which should receive special attention at the next inspection. Reports should also show the status of previous noncompliance and the independent physical measurements made by the inspector.

Assessment

Twenty inspection reports from the compliance files were selected for the casework review. This casework review included reports from each Area Field Office and each compliance inspector. The casework consisted of two manufacturing and distribution licenses, one low-level waste processor, one commercial incinerator facility, one well logging license, three industrial radiography licenses, two nuclear pharmacy licenses, three institutional medical licenses, two institutional medical with brachytherapy licenses, one teletherapy license, one medical private clinic, one mobile nuclear medicine license, and two portable gauge licenses. All of the reports uniformly and adequately documented inspections, which included documentation of independent measurements made by the inspectors.

Only isolated comments were developed from the casework reviews and these comments were not indicative of any generic issues or problems. These comments were discussed with the technical staff at the conclusion of the review.

27. Confirmatory Measurements (Category II)

NRC Guidelines

Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements.

Assessment

The inspection reports were reviewed for documentation concerning confirmatory measurements and independent measurements. It was determined that the Area Field Offices had a sufficient number of calibrated portable instruments, including emergency kits. The Program utilizes a Nashville based commercial calibration facility for the routine calibration of instrumentation. The Program also has purchased a portable multichannel analyzer for use, and this closes out a comment from the previous review.