DATED: SEPTEMBER 18, 1995 SIGNED BY: RICHARD L. BANGART

Donald E. Williamson, M.D. State Health Officer Department of Public Health 434 Monroe Street Montgomery, AL 36130-3017

Dear Dr. Williamson:

This is to transmit the results of the NRC review and evaluation of the Alabama radiation control program. This review, which concluded on June 23, 1995, was conducted by Mr. Richard L. Woodruff, Regional State Agreements Officer, Region II. The results of this review were discussed in a meeting with Mr. James W. Cooper, Director, Bureau of Health Care Standards and Mr. Kirksey E. Whatley, Director, Division of Radiation Control, on June 23, 1995.

As a result of our review of the State's program and the routine exchange of information between the NRC and the State, staff has determined that, at this time, the Alabama program for regulation of certain Atomic Energy Act (AEA) materials is adequate to protect the public health and safety. However, a finding that the program is compatible with NRC's program is being withheld because the State has not adopted the rule entitled "Quality Management Program and Misadministrations" (QM) amendment, which was to be adopted by January 27, 1995. We recognize that during the April 1995 Managers' Workshop that NRC indicated the promulgation of the QM rule would be assessed as to whether it should continue to be a basis for a finding of compatibility and that your staff has deferred a final completion of the QM rule pending completion of our assessment. The safety benefits of the QM rule and the need for consistent requirements among NRC and Agreement State regulations indicate the necessity for Agreement States to promulgate equivalent QM rules. Accordingly, the status of QM rule promulgation will continue to serve as a basis for a finding of compatibility. The staff is, however, evaluating methods to increase the flexibility of Agreement States in the implementation of the QM rule such as flexibility to expand definitions in the QM rule to include non-AEA radiation treatment modalities, to establish more restrictive reporting requirements covering additional diagnostic misadministrations, to determine the method by which a licensee would be required to submit its quality management program and to determine the timing of that submittal.

Please note there has been a change in the format of this letter from our previous review letters. This letter summarizes the findings regarding all 30 program indicators. Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 summarizes the status of previous review findings and current review findings and

recommendations. We request specific responses from the State on the findings and recommendations in Enclosure 2 within 30 days of this letter. Enclosure 3 presents a summary of the review findings where the State has adequately satisfied the indicators. A response to the items in Enclosure 3 is not required.

We were pleased with the improvements that have been made in the program since our last review. Specifically, we noted that the State does not have any licensing or inspection backlogs, that the State promptly took action and adopted compatible regulations following the 1993 review, and that other recommendations from the 1993 review have been resolved.

I appreciate the courtesy and cooperation extended to Mr. Woodruff by your staff during the review.

Sincerely,

Richard L. Bangart, Director Office of State Programs

Enclosures:

- Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"
- Status of Previous Findings and Summary of Review Findings and Recommendations for the Alabama Radiation Control Program (July 23, 1993 to June 23, 1995)
- Summary of Assessment of Indicators Fully Satisfied by the Alabama Radiation Control Program (July 23, 1993 to June 23, 1995)

cc w/encl: K. Whatley
State Liaison Officer

recommendations. We request specific responses from the State on the findings and recommendations in Enclosure 2 within 30 days of this letter. Enclosure 3 presents a summary of the review findings where the State has adequately satisfied the indicators. A response to the items in Enclosure 3 is not required.

We were pleased with the improvements that have been made in the program since our last review. Specifically, we noted that the State does not have any licensing or inspection backlogs, that the State promptly took action and adopted compatible regulations following the 1993 review, and that other recommendations from the 1993 review have been resolved.

I appreciate the courtesy and cooperation extended to Mr. Woodruff by your staff during the review.

Sincerely,

Richard L. Bangart, Director Office of State Programs

Enclosures:

- 1. Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"
- 2. Status of Previous Findings and Summary of Review Findings and Recommendations for the Alabama Radiation Control Program (July 23, 1993 to June 23, 1995)
- 3. Summary of Assessment of Indicators Fully Satisfied by the Alabama Radiation Control Program (July 23, 1993 to June 23, 1995)

cc w/encl: K. Whatley

State Liaison Officer

bcc w/encl: The Chairman

Commissioner Rogers

<u>Distribution</u>:

DIR RF PLohaus EDO RF JMTaylor, EDO HLThompson, DEDS RBangart SDroggitis CMaupin FCameron, OGC HNewsome, OGC RA, Region II RSAO, Region II CPaperiello, NMSS MSchwartz, OGC TCombs, OCA RSLO, Region II PDR (Yes_X__ NO___) DCD (SPO1) Alabama File

*See previous concurrence.

OFC	ORA:RSAO*	DRSS:RII*	RA:RII*	OSP:SPM*	OSP:DD*		
NME	RWoodruff	BMallett	SEbneter	CHMaupin:vb	PLohaus		
DTE	07/11/95*	7/12/95*	7/13/95*	08/16/95	08/18/95		
OFC	NMSS:D*	OGC*	OSP:D*	DEDS*			
NME	CPaperiello	FCameron	RBangart	HLThompson		 	
DTE	08/24/95	08/28/95	09/12/95	09/15/95	! ! !		-
G:\CHM\95LETTER.AL				OSP	CF CODE: SP-	-AG-1	•

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 <u>Federal Register</u> 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. 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. Comments on Category I indicators that are not significant will not be used as a basis for withholding of findings of adequacy or compatibility.

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. Pursuant to Section 274j of the Act, the Commission may terminate or suspend all or part of its agreement with a State if the Commission finds such termination or suspension is required to protect the public health and safety, or the State has not complied with one or more requirements of section 274 of the Act.

STATUS OF PREVIOUS FINDINGS AND SUMMARY OF REVIEW FINDINGS AND RECOMMENDATIONS FOR THE ALABAMA RADIATION CONTROL PROGRAM JULY 23, 1993, TO JUNE 23, 1995

SCOPE OF REVIEW

The 22nd regulatory program review with Alabama representatives was held during the period of June 19-23, 1995, in Montgomery, Alabama. This 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. The review included discussions with program management and staff, technical evaluation of selected license and compliance files, review of the State's policies and procedures, and the evaluation of the State's responses to an NRC questionnaire that was sent to the State in preparation for the review.

The State was represented by Mr. Kirksey E. Whatley, Director, Division of Radiation Control (DRC), Bureau of Health Care Standards, Department of Public Health; Mr. James L. McNees, Director, Radioactive Materials Compliance Branch, DRC; and Mr. David K. Walter, Radioactive Materials Licensing Branch, DRC.

Selected license and compliance files were reviewed by Mr. Richard L. Woodruff, Regional State Agreements Officer, Region II. Mr. Woodruff also visited the Department of Environmental Management, Field Operations Division Central Laboratory, on June 23, 1995.

CONCLUSION

The State's program for regulation of certain Atomic Energy Act radioactive materials is, at this time, adequate to protect the public health and safety. However, a finding that the program is compatible with NRC's program is being withheld because the State has not adopted the rule entitled "Quality Management Program and Misadministrations" (QM) amendment, which was to be adopted by January 27, 1995.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in a letter to Dr. Williamson dated December 9, 1993. All comments and recommendations made at that time were satisfactorily addressed and resolved, as documented during our visit on July 26-28, 1994.

CURRENT REVIEW FINDINGS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 29 of these indicators. These 29 indicators are discussed in Enclosure 3. A questionnaire containing the 30 indicators with specific questions pertaining to each indicator was sent to the State prior to the review.

1. <u>Status and Compatibility of Regulations</u> (Category I)

NRC Guidelines

The State must have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards, effluent limits, waste manifest rule and

certain other parts), Part 61 (technical definitions and requirements, performance objectives, financial assurances) and those required by UMTRCA, as implemented by Part 40.

The State should adopt other 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.

The radiation control program (RCP) has established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC.

Opportunity should be provided for the public to comment on proposed regulation changes (required by UMTRCA for uranium mill regulation.)

Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

Assessment

The State adopts regulations in accordance with the State's Administrative Procedure Act of 1981. The procedures provide for public hearings and comments, and proposed regulations are also provided to the NRC for comment prior to adoption.

The Alabama regulations for Radiation Control, Chapter 420-3-26, were reviewed for uniformity and compatibility during the July 1994 visit and prior to this review. The Alabama regulations are compatible with the NRC's regulations up to the provisions on "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992 and was to be adopted by January 27, 1995. However, a finding that the program is compatible with NRC's program is being withheld because the State has not adopted the rule entitled "Quality Management Program and Misadministrations" (QM) amendment, which was to be adopted by January 27, 1995. We recognize that during the April 1995 Managers' Workshop that NRC indicated the promulgation of the QM rule would be assessed as to whether it should continue to be a basis for a finding of compatibility and that your staff has deferred a final completion of the QM rule pending completion of our assessment. The safety benefits of the QM rule and the need for consistent requirements among NRC and Agreement State regulations indicate the necessity for Agreement States to promulgate equivalent QM rules. Accordingly, the status of QM rule promulgation will continue to serve as a basis for a finding of compatibility. The staff is, however, evaluating methods to increase the flexibility of Agreement States in the implementation of the QM rule.

In addition, we would like to bring to the State's attention the following regulations that will be needed for compatibility purposes:

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) that became effective on July 1, 1993 and will need to be adopted by July 1, 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.

- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994, and will need to be adopted by January 28, 1997.
- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994, and will need to be adopted by August 15, 1997.
- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 65243, and 60 FR 322) that became effective on January 1, 1995 and will need to be adopted by January 1, 1998.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective on March 13, 1995 and will need to be adopted by March 13, 1998.
- "Low-Level Waste Shipment Manifest Information and Reporting", 10 CFR Parts 20 and 61 amendments (60 FR 15649) that becomes effective on March 1, 1998 and will need to be adopted by March 1, 1998.

<u>Recommendation</u>

We recommend that DRC adopt the QM rule as soon as possible and any other regulation needed for a compatibility finding.

SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

A summary meeting regarding the results of the review was held on June 23, 1995. The following persons were present during the summary meeting: Mr. James W. Cooper, Director, Bureau of Health Care Standards; Mr. Kirksey E. Whatley, Director, Division of Radiation Control; and Mr. James L. McNees, Director, Radioactive Materials Compliance Branch.

The scope of the review was discussed and the State was informed that the review findings would be reported to the State in a letter signed by the Director, Office of State Programs. The State was informed that Status of Regulations is a Category 1 indicator, and that the findings regarding compatibility for the medical QM rule would be determined by the Commission. The State was also informed that the absence of any other significant Category I comments would indicate that the State's program is adequate to protect public health and safety. The State was informed that the reviewer concurred that there were no licensing or inspection backlogs, and that the previous recommendations had been addressed and resolved.

In reply, Mr. Cooper related that he would pass the information along to Dr. Williamson and the State would respond to our written comments.

SUMMARY OF ASSESSMENT OF INDICATORS FULLY SATISFIED BY THE ALABAMA RADIATION CONTROL PROGRAM JULY 23, 1993, TO JUNE 23, 1995

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, reviewer observations, review of the State's policies and procedures, and licensing and inspection casework file reviews. The State fully satisfies the following indicators:

1. <u>Legal Authority</u> (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.

States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA.

States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulations for low-level waste management and disposal. The statutes should also provide regulatory program authority and provide for a system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur. 1

<u>Assessment</u>

The State's response to the questionnaire was reviewed and discussions were held with the Director of the Division of Radiation Control (DRC) concerning any changes to the State's statutory authority for the regulation of agreement materials since the previous review. An updated copy of the Radiation Control Act (Title 22, Chapter 14, Radiation) was obtained and reviewed. The Act was revised in 1988 to allow the State to enter into a low-level waste compact and for the regulation of low-level waste generators. The State Board of Health is designated as the State radiation control agency responsible for protecting public health and safety, including the development of regulations, collection of fees, issuance of orders, determination of compliance, and impoundment of sources. Copies are on file in the NRC Region II Office.

 $^{^{1}}$ The level of separation (e.g., separate agencies) should be determined for each State individually.

2. <u>Location of the Radiation Control Program Within the State Organization</u> (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.

Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Assessment

A copy of the organizational charts were provided and reviewed. There have been no changes in the organizational relationship between the Department of Health and the Governor's Office since the previous review. The State Health Officer is appointed by the State Committee of Public Health, serves as chairman of the State Board of Health, and represents the State Board of Health to the Governor.

All Agreement State functions are contained within the Department of Public Health, Bureau of Health Care Standards, DRC. The program is parallel to other health and safety programs. The DRC is located in the Bureau of Health Care Standards, along with the Division of Planning & Program Development, the Division of Licensure & Certification, and the Division of Emergency Medical Services. The DRC program director has appropriate access to Department management.

3. <u>Internal Organization of the RCP</u> (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.

Where regional offices or other government agencies are utilized, the lines of communication and administrative control between these offices and the central office (Program Director) should be clearly drawn to provide uniformity in licensing and inspection policies, procedures and supervision.

Assessment

The internal organizational charts for DRC were received and reviewed. There have been no changes in the organizational structure relative to the State Health Department. The DRC is composed of five branches, the Radioactive Materials Licensing Branch, the Radioactive Materials Compliance Branch, the X-Ray Compliance Branch, the Emergency Planning and Environmental Monitoring Branch, and the Naturally Occurring Radioactive Materials Branch. The organization provides emphasis on major program functions, specific lines of supervision and staff efficiency.

4. <u>Legal Assistance</u> (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.

<u>Assessment</u>

The response to the questionnaire was reviewed and discussions relative to legal assistance were held with management staff. Legal assistance is available, as needed, from the General Counsel assigned to the Department of Health, and management related that the support has been excellent. The current counsel has been assigned to the Health Department for several years.

5. <u>Technical Advisory Committees</u> (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.

A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The Committee should represent a wide spectrum of medical disciplines. The Committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans.

Procedures should be developed to avoid conflict of interest, even though Committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

<u>Assessment</u>

The program utilizes two advisory committees, the Medical Radiation Advisory Committee, and the Radiation Advisory Board of Health.

The Radiation Advisory Board of Health consists of 10 members appointed by the Governor for staggered terms of 6 years. Membership comes from the fields of Radiology, Medicine, Health Physics, Dentistry, Chiropractic medicine, Veterinary medicine, and from the University of Alabama, Auburn University, and the Associated Industries of Alabama. The committee meets at the discretion of the State Health Officer who is also the chairman. There have been no formal meetings of the Advisory Board since the 1993 review, as the business can be handled through the mail. Program management related that this method has been effective, and more efficient for the board members.

The Medical Radiation Advisory Committee has two members that are in addition to the physicians on the Advisory Board. This committee is utilized to evaluate medical uses and physician training and experience. The Committee also usually handles business by mail and conference calls which allows for licensing staff consultation with the committee on an as needed basis, thus more efficient than periodic formal meetings.

6. <u>Contractual Assistance</u> (Category II)

NRC Guidelines

Because of the diversity and complexity of low-level radioactive waste disposal licensing and regulation, 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 LLW facility development or operations.

<u>Assessment</u>

The State does not have a LLW site and is not a host State for a site; therefore, this indicator is not currently applicable to the program review.

7. Quality of Emergency Planning (Category I)

NRC Guidelines

The State RCP should have a written plan in response to incidents at licensee facilities which takes into account such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.

The plan should define the responsibilities and actions to be taken by State agencies. The plan should be specific as to persons responsible for initiating response actions, conducting operations and cleanup.

Emergency communication procedures should be adequately established with appropriate local, county, and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the plan while in draft form.

The plan should be reviewed annually by program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

<u>Assessment</u>

Based upon discussions with management staff and emergency response personnel located in the DRC, the program has a comprehensive emergency plan for all types of radiological emergencies. The Radiological Emergency Response Plan was revised effective May 19, 1994 and utilizes the Alabama Emergency Management Agency, and County and City governments. A copy of the plan is on file in the Region II Office.

The plan is tested during exercises around the Browns Ferry, Bellefonte, and Farley nuclear power facilities. The last full scale test was for the Farley plant on December 14-15, 1994. A practice exercise was conducted on the Browns Ferry facility on June 14, 1995, and a DRC critique of the exercise was conducted on Monday, June 19, 1995 in the DRC Office.

The emergency communication list is updated as needed, and the current listing is dated June, 1995. A copy was obtained and reviewed. Copies of this listing are mailed to all licensees and other interested parties. The program has a 24 hour pager number, and each manager/supervisor is on the list and is expected to respond as appropriate to the type of incident. All of the licensing and materials staff are experienced and have been trained in

responding to incidents. Materials incidents are normally supervised by a supervisor or a senior inspector. A review of the incident files indicated that the response to incidents was timely, appropriate to the type of incident, and utilized persons trained in the response plan.

8. <u>Budget</u> (Category II)

NRC Guidelines

Operating funds should be sufficient to support program needs, such as staff travel necessary to the conduct of an effective compliance program, including routine inspections, follow-up or special inspections, (including prelicensing 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. States regulating the disposal of low-level radioactive waste facilities should have adequate budgetary resources to allow for changes in funding needs during the LLW facility life cycle. After appropriations, the sources of program funding should be stable and protected from competition from or invasion by other State programs.

Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

<u>Assessment</u>

A review of the questionnaire response and discussions with the program managers indicated that the program has sufficient monetary resources (\$1,603,450) for carrying out the regulatory program. Currently, the materials program (\$327,103) is 100% funded through fees. The fee schedule is coded in the Alabama regulations, and by law, Alabama can assess fees at 75% of those fees assessed by NRC. Thus, the Alabama fees will fluctuate as the NRC fees are adjusted.

Program managers related that the NRC proposal to eliminate inspection fees for materials license inspections, could have a negative impact on the DRC funds being recovered from inspection fees. The Program Director related that this issue had been discussed with the State Health Officer (SHO), and that the SHO had agreed in principle to adjusting future DRC monies with appropriated funds, if needed.

9. <u>Laboratory Support</u> (Category, II)

NRC Guidelines

The RCP should have 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.

In addition, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have access to laboratory support for radiological and non-radiological analyses associated with the licensing and regulation of low-level waste disposal, including soils testing, testing of environmental media, testing of engineering properties of waste packages and

waste forms, and testing of other engineering materials used in the disposal of low-level radioactive waste. Access to laboratory support should be available on an "as needed" basis for nonradiological analyses to confirm licensees' and applicants' programs and conditions for nonradiological testing should be prescribed in plans or procedures.

Assessment

Laboratory support is provided under contract with the State of Alabama Department of Environmental Management Laboratory (ADEM) located adjacent to the EPA, Eastern Environmental Radiation Facility, Montgomery, Alabama. An Agreement between the Health Department and ADEM provides for radiological analyses to be performed at the ADEM Central Laboratory, and specifies the monetary terms, scope of the services, and a quality assurance program associated with the analyses. Based upon a visit to the laboratory, the ADEM laboratory has technical procedures and equipment to analyze all types of environmental media for alpha, beta, and gamma emitters. Samples can be shared with EPA and NRC as appropriate.

A review of the questionnaire response and discussions with the DRC managers indicate that the ADEM Laboratory provides timely and accurate results on confirmatory measurement samples.

The DRC has also completed a State wide survey of selected sanitary sewer systems. The results of this survey project are under preparation, and will be provided to the Region II Office when completed.

10. <u>Administrative Procedures (Category II)</u>

NRC Guidelines

The RCP should establish written internal policy and administrative procedures to assure that program functions are carried out 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, and inspection and enforcement.

<u>Assessment</u>

The DRC maintains administrative procedures prepared by the Department and the Bureau, and also maintains procedures developed in the DRC. The DRC updates the procedures as needed. The Program Director related that the only changes occurred on January 5, 1994 with the addition of procedures for "Handling of Misadministration Reports and Investigations of Misadministrations" number 255, and number 256 "Handling Allegations From Members of the Public and Licensees." These procedures were reviewed during the 1994 review-visit. The updated Procedures Manual Index was obtained for the Regional files. Based upon the response to the questionnaire, discussions with the staff, the cross check of the Procedures Manual Index and the Manual, and the review of procedures number 255 and 256, it was determined that the DRC meets the requirements of this guideline.

11. 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).

RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services, and funding.

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, low-level radioactive waste disposal facilities, large scope, Type A Broad, and those which have the potential for significant releases to the environment) should receive second party review (supervisory, committee, consultant). Supervisory review of inspections, reports, and enforcement actions should also be performed.

For the implementation of very complex licensing actions, such as initial license review, license renewals and licensing actions associated with a low-level radioactive waste disposal facility, there should be an overall Project Manager responsible for the coordination and compilation of the diverse technical reviews necessary for the completion of the licensing action. The Project Manager should have training or experience in one or more of the main disciplines related to the technical reviews which the Project Manager will be coordinating, such as health physics, engineering, earth science, or environmental science.

When regional offices or other government agencies are utilized, program management should conduct periodic audits of these offices.

<u>Assessment</u>

The Compliance Branch Director and the materials license reviewer prepare monthly reports concerning the status of the inspection activities and licensing actions. The Program Director reviews and signs all licensing actions after consultation with the license reviewer. The Compliance Branch Director reviews and signs all compliance letters and the inspection reports after consultation with the respective inspector. The Compliance Branch Director also maintains a log of the inspector accompaniments including a summary of the activity, and a memorandum is placed in the inspector's personnel file. Staff meetings are held on a weekly basis or as necessary to resolve issues and for informational purposes.

Based upon the response to the questionnaire, discussions with program managers and staff, review of reports, review of casework files, review of the accompaniment log and crosschecks with the compliance files, and attendance at a staff meeting, the reviewer determined that the criteria of this guideline indicator were being satisfied.

12. Office Equipment and Support Services (Category II)

NRC Guidelines

The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to larger (greater than 300-400 licenses) programs. Similar services should be available to regional offices, if utilized.

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.

Professional licensing, inspection, and enforcement staff should not be used for fee collection and other clerical duties.

<u>Assessment</u>

Each DRC clerical staff member, each manager and supervisor, and the materials licensing staff and inspection staff have a personal computer (PC). Currently, the PCs are not on a "network"; however, the Program Director related that the Department would be moving to a new office building in 1996, and plans are to have all employees on a network, and the DRC would have communications capability for the internet system and other systems as appropriate. Several word processing and database software programs are available to the staff. Collection of fees are handled by a specific administrative person, and in accordance with Health Department procedures.

The response to the questionnaire, discussions with administrative and technical staff, demonstrations of the technical staff on their knowledge and use of the computers, and work performed by the administrative staff during the review, demonstrated that the program meets the requirements of this guideline indicator.

13. 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.

Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws during the process of major licensing actions associated with UMTRCA and low-level radioactive waste in permanent disposal facilities.

<u>Assessment</u>

The State's response to the questionnaire, discussions with staff, and observations, confirmed that inspection and licensing files are available to the public under Alabama procedures. Proprietary information, personal and medical information can be withheld as appropriate. The DRC maintains a locked safe for proprietary information. Press releases are prepared and released with the assistance of, and through the Department's Public Information staff.

14. 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. For States regulating uranium mills and mill tailings, staff training and experience should also include hydrology,

geology, and structural engineering.² For programs which regulate the disposal of low-level radioactive waste in permanent facilities, staff training and experience should include civil or mechanical engineering, geology, hydrology, and other earth science, and environmental science. In both types of materials, staff training and experience guidelines apply to available contractors and resources in State agencies other than the RCP.

Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Assessment

The qualifications of the technical staff were reviewed and all technical staff members involved with the materials licensing and inspection activities have at least a Bachelor of Science degree in the physical and/or life sciences. The Program Director and Compliance Branch Director have master degrees and two other managers have engineering and master degrees. The written job descriptions have been previously reviewed, and the Program Director related that no changes have occurred in the descriptions since the previous review. The review of the questionnaire response, discussions with managers, and documentation on file confirmed that the program meets the criteria of this guideline indicator.

15. <u>Staffing Level (Category II)</u>

NRC Guidelines

Professional staffing level should be approximately 1-1.5 person-years per 100 licenses in effect. RCP must not have less than two professionals available with training and experience to operate 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.

For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years of effort, including consultants, are needed to process a new mill license (including in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978.

States which regulate the disposal of low-level radioactive waste in permanent disposal facilities should allow a baseline RCP staff effort of 3-4 professional technical person-years (in addition to the two professionals for the basic RCP indicated in the first bullet of this indicator). However, in some cases, the level of site activity may be such that a lower level is adequate, particularly if contractor support is on call. In any event, staff resources should be adequate to conduct inspections on a routine basis during operations of the LLW facility, including inspection of incoming shipments and licensee site activities and to respond to emergencies associated with the site. During periods of peak activity, additional staff or specialty consultants should be available on a timely basis.

9

² Additional guidance is provided in the Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement (46 FR 7540, 36969 and 48 FR 33376).

<u>Assessment</u>

A review of the response to the questionnaire and discussions with the Program Director and the Compliance Branch Director confirmed that the program has adequately trained staff to carry out the regulatory functions of the DRC. The Materials program has five full time technical staff in addition to the Program Director, three persons in the Emergency Planning and Environmental Monitoring Branch, and two engineers in the Naturally Occurring Radioactive Materials Branch. Information provided indicates that 4.35 FTEs were utilized in 401 specific materials licenses, or a ratio of approximately 1.1 FTE per 100 licenses. The engineers and some of the emergency response personnel are being cross trained to perform materials inspections if needed.

16. <u>Staff Supervision (Category II)</u>

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.

<u>Assessment</u>

A review of the questionnaire response, casework files, and discussions with staff confirmed that all licenses are signed by the Program Director, and that all enforcement actions are reviewed and signed by the Compliance Branch Director. During the review, several instances were noted where the technical staff discussed licensing and compliance issues with each other and the managers, and provided confirmation of good communication among the staff concerning policy and regulatory issues. Documentation in the files confirmed that junior personnel are not allowed to perform work independently until approved by the supervisor for that level of work.

17. Training (Category II)

NRC Guidelines

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 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.

<u>Assessment</u>

A listing of all personnel by training courses was received and evaluated. All of the senior materials licensing and inspection personnel have attended the NRC core courses, the five week health physics course, and numerous workshops. The junior personnel also have attended the core courses and are

attending other NRC courses as they become available. All personnel have also received training in emergency planning and in use of the various computer software programs utilized by staff. A review of the response to the questionnaire and discussions with staff confirms that the program meets the criteria of this guideline indicator.

18. Staff Continuity (Category II)

NRC Guidelines

Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries.

Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area.

The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

<u>Assessment</u>

The program reported that no turn over in staff has occurred since the last review and this was confirmed with a comparison of the organizational charts. All personnel received an increase in salary in 1994. The salaries were confirmed to be comparable to equivalent positions in other Agreement States in the geographical area.

19. <u>Technical Quality of Licensing Actions (Category I)</u>

NRC Guidelines

The RCP should assure that essential elements of applications have been submitted to the agency, and that these elements 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. Additionally, in States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet State licensing requirements for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures, and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be adequately documented, including safety evaluation reports, product certifications, or similar documentation of the license review and approval process.

Pre-licensing visits should be made for complex and major licensing actions.

Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions.

The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

<u>Assessment</u>

Sixteen license files were selected for casework review. The program currently has 401 licenses, of which 19 are considered major licenses. The review sample included all new major licenses that have not been reviewed, and consisted of four nuclear pharmacy, one broad academic, one broad medical, one generally licensed device (GL) distribution, one decontamination facility, two industrial radiography including fixed and temporary locations, three institutional medical, one mobile nuclear medicine, one private nuclear medicine (cardiology), and one private therapy facility with a High Dose Rate (HDR) unit. From the review of the casework, it was determined that essential elements of the applications and the backup documentation met the current regulatory guidance to establish the basis for issuance of licenses. The DRC does not have a licensing backlog, and all licenses are issued by one license reviewer, with consultation and approval by the Program Director. All major licenses receive a pre-license visit before the license is issued.

20. 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.

The RCP should review manufacturer's information on labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy.

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.

Approval documents for radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste for disposal should be complete and accurate as to the use, capabilities, limitations, and site specific restrictions associated with each product.

Assessment

The program has not performed any product evaluations during this review period. Therefore, no product evaluation, source, or device files were reviewed. Discussions were held with the sealed source and device (SS&D) reviewer in DRC concerning reference materials and checklist provided by NRC for SS&D reviews, and it was confirmed that these referenced materials and procedures were available and would be followed for review of SS&Ds.

21. <u>Licensing Procedures (Category II)</u>

NRC Guidelines

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

In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should have program specific licensing guides, plans, and procedures for license review and policy memoranda which relate to specific aspects of waste disposal. The program should include the preparation of safety evaluation reports, product certifications, or similar documentation of license review and approval process.

License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions.

The present compliance status of licensees should be considered in licensing actions.

Under the NRC Exchange-of-Information program, evaluation sheets, service licenses, and licenses authorizing distribution to general licensees and persons exempt from licensing should be submitted to NRC on a timely basis.

Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process.

Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

<u>Assessment</u>

The DRC utilizes State licensing guides patterned after NRC policy guidance and procedures for the evaluation of applications and the writing of the license document. The guides and standard conditions were determined to be equivalent to those utilized by NRC. Updated licensing policies and standard conditions utilized by NRC were provided electronically to the State license reviewer. The casework was reviewed for technical adequacy of application review, significant errors and omissions, utilization of licensing procedures and appropriate license conditions, consideration of the applicable licensee's enforcement history and status, and documentation. The casework review confirmed that the licensing procedures are adequate to protect public health and safety and are consistent with NRC policies.

22. 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. The inspection program in all States should provide for the inspection of licensee's waste generation activities under the State's jurisdiction.

In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should include provisions for preoperational, operational, and post-operational facility inspections. The inspections should cover all program elements which are relevant at the time of the inspection and be performed independently of any resident inspector program. In addition, inspections should be conducted on a routine basis during the operation of the low-level radioactive waste facility, including inspection of incoming shipments and licensee site activities.

The RCP should maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available.

At least semiannual inspection planning should be done for the number of inspections to be performed, assignments to senior versus junior staff, assignments to regions, identification of special needs and periodic status reports. When backlogs occur, the program should develop and implement a plan

to reduce the backlog. The plan should identify priorities for inspections and establish target dates and milestones for assessing progress.

Assessment

The program's computerized licensing and inspection data system was reviewed. The program does not have any inspection backlog as determined from a review of the computer file and a spot check of information from the casework files. All inspections are planned on a quarterly basis, and the status of the inspection program is assessed each month. A review of the casework and the system verified that licenses and inspections are coded properly and the information from inspections promptly entered into the tracking system.

In addition to the questionnaire response, the State reported receiving 26 license reciprocity requests during the period since the 1993 review. The requests included 14 radiography, 17 portable gauge, 6 well logging, 4 gauge service, 3 teletherapy and HDR service, 1 calibration service, and 2 waste pick-up licenses. Of these reciprocity requests, the DRC conducted 10 inspections, of which 6 of the 14 radiography licenses were inspected. It should be noted that under Alabama regulations, licensees can operate under reciprocity in State jurisdictional areas for only 30 days in any calendar year, after which the licensee must obtain an Alabama license.

23. Inspection Frequency (Category I)

NRC Guidelines

The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations, e.g., major processors, broad licensees, and industrial radiographers should be inspected approximately annually. Smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency, including for initial inspections, should be no less than the NRC system.

<u>Assessment</u>

A comparison was made of the inspection frequencies utilized by the DRC and those utilized by NRC. The DRC frequencies were verified to be the same as the NRC frequencies utilized in 1994. An electronic copy of the Manual Chapter 2800 dated April 17, 1995 was provided to the Compliance Branch Director. This material dated April 17, 1995 apparently had not been sent to the State for their use. The Compliance Branch Director related that the inspection frequencies would be adjusted in their inspection system.

24. <u>Inspector's Performance and Capability (Category I)</u>

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.

For the inspection of complex licensed activities such as permanent low-level radioactive waste disposal facilities, a multidisciplinary team approach is desirable to assure a complete compliance assessment.

The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Assessment

All materials inspectors have been accompanied by supervisors since the last review as verified from the review of the State's Inspector Accompaniment Log and spot checked in the inspector reports. The junior inspectors train with the senior inspectors on team inspections, as verified by the casework documentation and discussions with the staff. All materials inspectors have been accompanied by NRC during the past three reviews, except for one inspector that is still in training. All other inspectors (including the supervisors) were previously determined to be adequately trained to evaluate health and safety problems, and determine compliance with the regulations in accordance with State procedures.

25. Responses to Incidents and Alleged Incidents (Category I)

NRC Guidelines

Inquiries should be promptly made to evaluate the need for onsite investigations.

Onsite investigations should be promptly made of incidents requiring reporting to the agency in less than 30 days (10 CFR 20.403 types).

For those incidents not requiring reporting to the agency in less than 30 days, investigations should be made during the next scheduled inspection.

Onsite investigations should be promptly made of non-reportable incidents, which may be of significant public interest and concern, e.g., transportation accidents.

Investigations should include in-depth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). 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 (e.g., equipment failure, improper operating procedures).

Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency.

The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

<u>Assessment</u>

All of the incident reports for the calendar years 1993 and 1994 have been previously provided to the Office of State Programs (OSP), and all of these events were reviewed prior to transmittal to OSP. Documentation shows that all incidents are entered into a written log book, and summarized. The detailed report when completed is filed in the respective license file and also in a separated incident file. Only four (4) reportable incidents have occurred during the first 6 months of 1995 that meet NRC's reporting criteria.

In addition, the State related that eight (8) misadministrations were reported to the State in 1993, nine (9) reported in 1994, and nine (9) have been reported to the State through June 6, 1995. All of the misadministration reports have been diagnostic, and do not meet the misadministration reporting criteria currently in effect at NRC. The Compliance Branch Director (a certified health physicist) related that he evaluated each event and misadministration upon receipt, to determine the significance of the event and the actions to be taken. This action (assessment) was verified to be documented in the event reports.

26. <u>Enforcement Procedures (Category I)</u>

NRC Guidelines

Enforcement procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended.

Enforcement letters should be issued within 30 days following inspections and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated.

Enforcement letters should specify the time period for the licensee to respond, indicating corrective actions and actions taken to prevent recurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses.

Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items.

Written procedures should exist for handling escalated enforcement cases of varying degrees.

Impounding of material should be in accordance with State administrative procedures.

Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

<u>Assessment</u>

A review of the State's regulations (Chapter 420-3-26, Radiation Control) confirmed that the regulations contain provisions in Rule 420-3-26-.13 (Administrative Procedures) for enforcement actions. They contain provisions on Organization and Method of Conducting Business, Hearings, Guidance Documents of Division of Radiation Control, the Routing of Radioactive Material Shipments, Criteria for Determining Enforcement Actions, and Appendix A, General Statement of Policy and Procedures for Enforcement Actions.

A review of the casework confirmed that the enforcement actions were appropriate and in accordance with the published procedures in the regulations. The enforcement correspondence was timely, contained clear regulatory language on the items of non-compliance and specific references, specified the time period for response, and requested corrective actions to be detailed in the response. All responses are reviewed by the inspector and his supervisor prior to acknowledgement of the licensee response.

Under Alabama rules, the Department can assess civil penalties for up to \$10,000 per violation per day. The State reported issuing four civil penalties during the reporting period.

27. <u>Inspection Procedures (Category II)</u>

NRC Guidelines

Inspection 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. NRC guides may be used if properly supplemented by policy memoranda, agency interpretations, etc.

Written inspection policies should be issued to establish a policy for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, interviewing workers and observing operations, assuring exit interviews with management, and issuing appropriate notification of violations of health and safety problems.

Procedures should be established for maintaining licensees' compliance histories.

Oral briefing of supervision or the senior inspector should be performed upon return from nonroutine inspections.

For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

<u>Assessment</u>

The DRC utilizes the Inspection Guidance and Procedures provided by NRC Inspection Manual, Inspection Procedure 87100 and Manual Chapter 2800. Updated copies were provided on diskette to the Compliance Branch Director during the review. The DRC procedures, guides, and casework review verify that the inspection procedures are consistent with NRC guidance, and are adequate to provide complete and uniform technical guidance to the staff inspectors. The casework review verified that the procedures are being followed.

28. <u>Inspection Reports (Category II)</u>

NRC Guidelines

Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of licensees' programs, and indicating the substance of discussions with licensee management and licensee's response.

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

<u>Assessment</u>

Twelve compliance files were selected for the casework review. The inspection casework was selected from those license casework files having current inspections (including pre-license inspections) to verify continuity between the licensing program and the inspection program. The compliance casework sample contained inspections performed by each inspector. The casework sample consisted of 3 nuclear pharmacies, 1 broad medical, 1 broad academic, 1 GL distribution, 1 decontamination facility, 1 industrial radiography, 1 institutional medical, 2 private medical, and 1 mobile nuclear medicine file. The reports uniformly documented the scope of the inspections, scope of the licensee's program, substantiated all items of non-compliance and health and safety matters, confirmatory measurements and indicated the substance of discussions with licensee management.

All inspection data are collected in the field and then placed in the computer format in the office.

29. <u>Confirmatory Measurements (Category II)</u>

NRC Guidelines

Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensees' measurements. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, access to testing should be available on an "as needed" basis for confirming licensees' and applicants' programs for measurements related to nonradiological aspects of facility operations, such as soils and materials testing and environmental sampling and analysis, to demonstrate compliance with 10 CFR Part 61 or compatible Agreement State regulations and ensure facility performance. Conditions for nonradiological testing should be prescribed in plans or procedures.

RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samplers, lab counting equipment for smears, identification of isotopes, etc.).

RCP instrumentation should include the following types: GM Survey Meter, 0-50 mR/hr; Ion Chamber Survey Meter, several R/hr; micro-R-Survey meter; Neutron Survey Meter, Fast & Thermal; Alpha Survey Meter, 0-1,000,000 c/m; Air Samplers, Hi and Low Volume; Lab Counters, Detect 0.001 μ Ci/wipe; Velometers; Smoke Tubes; Lapel Air Samplers.

Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities

should not be used unless under a service contract. Exceptions for other State agencies, e.g., a State University, may be made.

Agency instruments used for surveys and confirmatory measurements should be calibrated within the same time interval as required of the licensee being inspected.

<u>Assessment</u>

The inspection reports were reviewed for documentation concerning confirmatory measurements and independent measurements and were found to be consistent with NRC practices and sufficient to document licensee performance. The reports documented the instrumentation used during the inspection and the calibration date of the instrument. The State utilizes a DRC cesium-137 calibration source for the calibration of portable survey instruments. The staff provided a listing of portable equipment for use during inspections and incident evaluations. The listing documents numerous ion chambers, sodium-iodide detectors, GM tubes, micro-R meters, a neutron ball, pancake detectors, single channel analyzers, and velometers. It was determined that the State had sufficient instrumentation capabilities for routine inspections, and for the evaluation of events.