

DATED: MAY 18, 1995

SIGNED BY: PAUL H. LOHAUS FOR
RICHARD L. BANGART

Richard G. Hunter, Ph.D.
Deputy State Health Officer
Department of Health and
Rehabilitative Services
1317 Winewood Boulevard
Tallahassee, FL 32301

Dear Dr. Hunter:

This is to transmit the results of the NRC review and evaluation of the Florida radiation control program. This review, which concluded on March 3, 1995, was conducted by Mr. Richard L. Woodruff, Regional State Agreements Officer, Region II. The results of this review were discussed with Mr. Paul Boisvert, Acting Deputy State Health Officer; Dr. Lyle E. Jerrett, Chief, Office of Radiation Control; Mr. William A. Passetti, Manager, Radioactive Materials; and Ms. Cindy Becker, Manager, Field Operations, on March 3, 1995.

As a result of our review of the State's program and the routine exchange of information between the NRC and the State, the staff has determined that the State's program for regulating agreement materials is, at this time, adequate to protect the public health and safety and is compatible with the regulatory programs of the NRC.

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 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 summarizes our review findings for program indicators where we have identified recommendations for improvement. 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 indicator. 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, State regulations have been updated and implemented, and staff continuity has improved. Also, we are pleased that the State is participating in our pilot program on reporting of significant incidents and the exchange of incident information through a common electronic data base.

Richard G. Hunter

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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 Florida Radiation Control Program, February 26, 1993, to March 3, 1995
3. Summary of Assessment of Indicators Adequately Satisfied by the Florida Radiation Control Program, February 26, 1993 to March 3, 1995

cc w/encl: Lyle E. Jerrett, Chief
Office of Radiation Control and
State Liaison Officer

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cc w/encl: Lyle E. Jerrett, Chief
Office of Radiation Control and
State Liaison Officer

bcc w/encl:
The Chairman
Commissioner Rogers
Commissioner de Planque
Commissioner Jackson

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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. 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.

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.

ENCLOSURE 1

STATUS OF PREVIOUS FINDINGS AND
SUMMARY OF REVIEW FINDINGS AND RECOMMENDATIONS
FOR THE FLORIDA RADIATION CONTROL PROGRAM
FEBRUARY 26, 1993 TO MARCH 3, 1995

SCOPE OF REVIEW

The twenty-seventh regulatory program review with Florida representatives was held during the period of February 14-16 and February 27 - March 3, 1995 in Tallahassee, Florida. 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 one inspector accompaniment, 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. Paul Boisvert, Acting Deputy State Health Officer; Dr. Lyle E. Jerrett, Chief, Office of Radiation Control; Mr. William A. Passetti, Manager, Radioactive Materials; Ms. Cindy Becker, Manager, Field Operations; Mr. Harlan Keaton, Manager, Environmental Laboratory; and Mr. Ray Deilman, Manager, Tampa Field Office.

Selected license and compliance files were reviewed by Mr. Richard L. Woodruff, Regional State Agreements Officer, Region II. Mr. Woodruff visited the Environmental Laboratory in Orlando, Florida on February 14, 1995, and the Tampa Field Office on February 15-16, 1995. Field accompaniments of one inspector was made by Mr. Woodruff also on February 15-16, 1995.

CONCLUSION

The program for control of agreement materials is, at this time, adequate to protect the public health and safety and is compatible with the regulatory programs of the NRC.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in letter to Dr. Charles S. Mahan, State Health Officer, dated April 13, 1993. All comments made at that time were satisfactorily resolved as documented during our visit on March 10-11, 1994.

CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 28 of these indicators. Recommendations were made on the two Category II indicators discussed below. The remaining 28 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.

The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, review of the State's written procedures and policies, discussions with program managers and staff members, reviewer observations, and licensing and inspection casework file reviews. Specific assessments and recommendations are as follows:

1. Inspection Reports (Category II)

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 the licensees' programs, and indicating the substance of discussions with licensee management and licensee's response.

Reports should uniformly and adequately document the result 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 results of confirmatory measurements made by the inspector.

Assessment

Eighteen compliance files, and four pre-license inspection reports were selected for the casework review. This sample included casework from each compliance Field Office and the senior inspectors. The inspection casework was selected from those license casework files having current inspections to verify continuity between the licensing program and the inspection program, and to provide a more complete evaluation of the regulatory program. The compliance casework included work from each Field Office and each materials inspector. The casework sample consisted of three nuclear pharmacies, one manufacturing, one distribution, three industrial radiography, one broad medical, six institutional medical, one teletherapy, one portable gauge, and one follow-up teletherapy 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, and indicated the substance of the discussions with licensee management. One area of improvement was identified relating to documentation of confirmatory measurements (see discussion below).

The State's pre-license inspection report forms require a determination to be made of the adequacy of air flows and areas having negative pressure characteristics, such as patient injection areas and fume hoods in nuclear medicine facilities and nuclear pharmacies. The report forms for the selected casework documented that the required determinations were made; however, information was not detailed in the report as to how this determination was made. Discussions with the license reviewer/inspector revealed that velometers and smoke tubes are always

utilized to make the determinations of adequate air flows in new facilities; however, additional information needs to be documented on the standard report form that identifies how determinations and confirmatory measurements were made. Also, three routine inspection reports needed additional information on how negative pressure in the patient injection rooms was determined and the results of the determination.

Recommendation

We recommend that the pre-license inspection reports and the routine inspection reports include documentation on the method(s) used for verifying that rooms in licensee facilities are under negative pressure (when required), and the results of any measurements performed by the inspector.

2. 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. 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 samples, 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 and Thermal; Alpha Survey Meter, 0-1,000,000 c/m; Air Samplers, Hi and Lo Volume; Lab Counters, Detect 0.001 μ C/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.

Assessment

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 with the exception of one item as noted under the "Inspection Reports" indicator. The program utilizes an Orlando, Florida based commercial calibration facility for the routine calibration of portable instrumentation. An updated listing of portable instrumentation was not reviewed; however, discussions were held with the Program Managers, Field Office Manager, Laboratory Manager, and two inspectors concerning the availability of instrumentation. The operability and calibration was checked on a sampling of instruments from the Tampa Field Office. One comment was developed under this indicator during the review of the licensing casework.

One terminated license file (OPTO Mechanik, Inc., Melbourne, Florida) contained information that thorium and tritium materials were being used under a specific license until 1993, at which time the specific license was terminated and the licensee continued to use the thorium material under general license provisions. The reviewer's follow-up check in the general license file revealed that the licensee later filed for bankruptcy. Although confirmatory surveys for tritium were performed under the previous specific license prior to license termination, information in the file indicated that no confirmatory survey was performed for thorium since thorium continued to be used under the general license. The file contained no information that a confirmatory survey had been performed after the licensee filed for bankruptcy.

Recommendation

We recommend that a confirmatory survey be performed on the OPTO Mechanik, Inc. facility in Melbourne, Florida to determine if the former licensed facility can be released for unrestricted use.

SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

A summary meeting regarding the results of the review was held with Mr. Paul Boisvert, Acting Deputy State Health Officer; Dr. Lyle E. Jerrett, Chief, Office of Radiation Control; Mr. William A. Passetti, Manager, Radioactive Materials; and Ms. Cindy Becker, Manager, Field Operations on March 3, 1995.

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, and that a written reply would be requested. The State was informed that since no Category 1 comments were identified, this indicates that the State's program is adequate to protect public health and safety, and compatible with the NRC's program. The State was informed that there were no licensing or inspection backlogs, the regulations needed for compatibility had been adopted within the 3 year time frame, and that the previous recommendations had been resolved.

In reply, Mr. Boisvert related that he would pass the information along to Dr. Hunter, that he was pleased to receive a good report, and the State would respond to our written comments.

SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED
BY THE FLORIDA RADIATION CONTROL PROGRAM
FEBRUARY 26, 1993 TO MARCH 3, 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. 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.

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

Assessment

The State's response to the questionnaire was reviewed and discussions were held with the Program manager concerning changes to the State's statutory authority for the regulation of agreement materials. The Florida Radiation Protection Act (Chapter 404) was last amended in 1984 and designates the Department of Health and Rehabilitative Services (HRS) as the agency to administer a statewide radiation protection program. The Act provides for promulgation of regulations, licensing, fees, inspections, financial sureties, and enforcement. Copies of the statutory authority are on file in the Region II Office. This document has been reviewed during previous reviews and since no changes have taken place since the last review, it was determined that the Program meets the requirements of this indicator.

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

2. Status and Compatibility of Regulations (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 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 Florida Control of Radiation Hazard Regulations, Florida Administrative Code, Chapter 10D-91 was reviewed for uniformity and compatibility. The State adopts and maintains regulations that are compatible with the NRC regulations. The State adopts regulations in accordance with the Florida administrative code that provides for public comment, and proposed regulations are also provided to the NRC for comment prior to adoption. The State has adopted all regulations needed for compatibility up to the "Licensing and Radiation Safety Requirements for Irradiators" (58 FR 7715) that will be needed prior to July 1, 1996. These regulations were implemented as licensing requirements during the licensure of the "Vindicator" food irradiator, and the Program Manager related that the irradiator regulations would be codified prior to the required three year adoption date.

The following regulations will need to be adopted to maintain compatibility with the NRC regulations:

- "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, and 70 (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.

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.

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 organization chart was provided by the State and reviewed. There have been no changes in the Office of Radiation Control (ORC) organizational relationship within the Department of Health and Rehabilitative Services (HRS) or the Governor's Office since the previous review. The Secretary, HRS, reports to the Governor and his Cabinet. The Secretary has a State Health Officer (currently a vacant position) and a Deputy Health Officer, Richard G. Hunter. The ORC reports directly to the Deputy Health Officer. All Agreement State regulatory responsibilities remain within ORC.

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.

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 were received and reviewed. There have been no major changes in the ORC organization since the previous review relative to Atomic Energy Act (AEA) materials. The Program has five technical groups (Field Operations, Environmental Radiation, Radioactive Materials, Radiologic Technology, and X-Ray Machines) in addition to the Administrative functions. All Materials licensing, enforcement coordination, and coordination of Field Offices functions are performed out of the Tallahassee Office. All inspections are performed out of six Florida Field Offices located in Miami, Lantana, Ft. Myers, Tampa, Orlando, and Jacksonville. The Lantana and Ft. Myers offices were upgraded to "full" Field Offices during the past year which provided for more career opportunities for advancement and better communication with the Tallahassee Office. Clear lines of communication and administrative control between the field offices and the Program office have been established. This was confirmed through discussion with the program manager.

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

The response to the questionnaire was reviewed and discussions relative to legal assistance were held with the Program managers. Legal assistance is available as needed from HRS; and the Program managers related that the legal support has been excellent. Records indicate that legal assistance was obtained on eighteen civil penalty cases, and also to clarify certain bonding requirements.

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.

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.

Assessment

Based upon the information provided in the questionnaire and discussions with the Program managers, the Program uses a fifteen member Advisory Council on Radiation Protection to provide support to the Program from the public, medical specialties, industrial radiography, education, and environmental concerns. The committee has had three formal meetings during this reporting period, and the meeting minutes were reviewed. The Program also contracted with a medical consultant on two occasions for the evaluation of two therapy misadministration cases. The results of these cases have been reported separately to NRC.

7. Contractual Assistance (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.

Assessment

The State does not have a Low Level Radioactive Waste site and is not a host State for a site; therefore, this indicator is not currently applicable to the Program review.

8. 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.

Assessment

Based upon discussions with managers and emergency response personnel located in the Orlando Environmental Laboratory, the Program has a comprehensive emergency plan for all types of radiological emergencies. The ORC has a Standard Operating Procedure for Radiation Incidents (SOPRI) which was revised in July of 1994 to update and incorporate changes required by 10 CFR Part 20. The plan's communication list is reviewed and revised on a quarterly basis as needed. The SOPRI and the revised communication list were reviewed. The Program conducts from six to eight emergency drills each year. The Program participates in the exercises for the Crystal River, Turkey Point, St. Lucie, and Farley Nuclear Plants. These exercises include a practice drill and the official drill for each site on an annual basis. The practice drill training materials for the latest exercise were reviewed during the reviewer's visit to the Orlando Environmental Program Office on February 14, 1995 and was found to be appropriate and acceptable.

9. Budget (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 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. 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.

Assessment

A review of the questionnaire response and discussions with the Program managers indicated that the Program has sufficient monetary resources (\$6,197,357.00) for carrying out the regulatory program. In October of 1994, the Program increased the licensing and inspection fees by 15% to meet all program expenditures. The Materials Program is 100% funded by fees which are deposited into a special fund, and the fee schedule is published in the regulations. The Program satisfies all criteria of this indicator.

10. Laboratory Support (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

A review of the questionnaire response and discussions with the Tampa Field Office manager indicate that the State's Laboratory provides timely and accurate results on confirmatory measurement samples. A visit to the Environmental Laboratory was conducted on February 14, 1995. The Laboratory has technical procedures and equipment to analyze all types of media and capabilities for alpha, beta, and gamma quantifications. The laboratory maintains state-of-the-art equipment and a modern emergency response mobile laboratory, and storage facilities for confiscated radiation sources. The Laboratory is centrally located in the State with access to all of the Nuclear Power plants for emergency response. The Program contracts directly with the Utilities to conduct the "off-site" environmental program. Samples are also split with the NRC, and the EPA as appropriate. The Region II manager of the Confirmatory Measurements Branch related that NRC has never experienced any problems with the analysis and accuracy of environmental samples provided by the State laboratory.

11. Administrative Procedures (Category II)

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.

Assessment

The internal procedures updated by the program since the last review were reviewed and discussed with the supervisors and the technical staff. The Program's procedure book was reviewed and the book contained procedures for: receipt, assignment, and tracking of licensing actions; processing fees; policy statements, information notices, media inquiries, weigh station procedures (radiation monitoring), inspection procedures, enforcement policy, and an index of reference materials. The Orlando Environmental Laboratory maintains the incident tracking system for all misadministrations and events, and these procedures were discussed with the incident response coordinator while in the Orlando laboratory. A review of the casework and the reviewer's discussions with the staff indicated that the level of the program's uniformity and continuity in regulatory practices is adequate.

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).

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, 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.

Assessment

The Materials Section Supervisor prepares monthly reports on the status of licensing and enforcement actions, and misadministrations. The current monthly report was reviewed. Discussions with program staff

revealed that staff meetings are held at least weekly with the Materials Section supervisor and also as needed. File documentation indicates that all licensing actions, inspection reports and enforcement cases receive supervisory review. Documentation reviewed also shows that all inspectors are accompanied at least annually, and all Field Offices are audited on a quarterly basis by Program managers.

13. 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 (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 staff should not be used for fee collection and other clerical duties.

Assessment

The Program's computer system has been upgraded to a local area network (LAN) for the HRS Department and the system has modem capability to link with the Internet System. During the review, the computers in the Field Offices were being upgraded to support the LAN. The system will contain a "cc" computer mail capability. Licenses are generated and stored via the computer, and enforcement letters are also computerized. Each Section has an administrative person (Secretary) for administrative support and the program has it's own facsimile machine and copy machines for daily use. Assistance on large reproduction jobs and tasks are available from other divisions in HRS as needed.

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.

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.

Assessment

The State operates under an "open records" law which requires files to be available to the public. However, personal or medical information can be withheld as appropriate. The HRS has a public information office in which all requests for information are coordinated, and administrative procedures have been developed for the coordination of this type of information.

15. Qualifications of Technical Staff (Category II)

NRC Guidelines

Professional staff should have 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 materials licensing and inspection activities have at least a Bachelor of Science degree in the physical and/or life sciences. The materials personnel are attending the NRC sponsored training courses as the courses become available. A separate listing of training courses needed by personnel was obtained and is being provided to OSP under separate cover. All of the materials technical staff meet the requirements of the guideline. Program managers related that no changes had been made in the job descriptions; therefore, the descriptions were not reviewed during this review. The Field Operations managers have been provided copies of NRC's Qualification Journals for materials license reviewers and materials inspectors. The managers related that the Program was moving towards adopting similar qualifications for their technical personnel.

16. Staffing Level (Category II)

NRC Guidelines

Professional staffing level should be approximately 1-1.5 person-years 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.

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).

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.

Assessment

Based upon the data provided in the questionnaire, interviews with staff, and observations made during the review, we believe that the staffing is adequate to maintain a fully adequate and compatible program. Currently the materials program has 20 full time equivalents (FTE) of technical staff persons including the first line supervisors for the regulation of 1142 specific licenses (including 53 major licenses). This staffing was calculated to be equivalent to 1.75 person-years per 100 licenses. The Program also has two additional vacant positions they plan to fill for use in the training program.

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 personnel. Discussions with staff and the review of casework indicates that the supervisors review the work of all personnel, and all projects and tasks are assigned to the staff and are adequately managed. All inspection reports and correspondence are reviewed by management for all inspectors. In licensing, all licenses are reviewed and signed by management.

18. 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 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

A listing of all personnel by training courses was received and evaluated.

All of the senior personnel and some of the junior personnel have attended the NRC core courses as the courses become available. The Program utilizes short courses and workshops sponsored by other agencies to the extent possible. Program management related that a basic Health Physics course on tape is provided to all new employees, and that they plan to add two additional persons for the purpose of providing in house training to technical personnel. The Program sponsored "Part 20" type training to personnel (with the help of Dennis Sollenberger, OSP) during the previous year, and training in use of the Program 's inspection procedures.

19. 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.

Assessment

Discussions with Program managers and the review of the response to the questionnaire verifies that all State employees received a three percent (3%) increase in salaries on October of 1993. A reclassification package for the radiation control positions has not yet been approved, and the reclassification would place the technical personnel in an

Environmental Specialist classification series which receive a higher pay range. Seven persons left the Program in 1993 (one retired); only two persons left the Program in 1994. The Program Director attributed this low rate of turnover to the establishment of two additional Field Offices (Lantana, Florida and Ft. Myers, Florida), which provided for additional supervisory positions and a better career path for personnel.

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 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.

Prelicensing 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.

Assessment

Twenty license files were selected for casework review. The program currently has fifty-three major licenses and the review sample included major licenses that have never been reviewed, to the extent that time would allow. The sample contained nine of the fifty-three major licenses (two manufacturing, one distribution, four nuclear pharmacies, one broad academic, and one broad medical). The remainder of the sample contained two industrial radiography (with portable gauges), five institutional medical, one private medical, one teletherapy, one private medical HDR, and one service license. The technical quality of the licensing actions was determined to meet the criteria listed in the above guideline and documentation in program files was adequate to support issuance of the licenses. The program does not have a licensing backlog, and pre-licensing visits are made to all major licenses prior

to issuance of the license. All new licenses are hand delivered when issued.

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.

The RCP should review manufacturer's information in 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 State has not issued any sealed source and device (SS&D) certificates during this review period; therefore, no source or device files were reviewed. Discussions were held with the SS&D reviewer concerning five reviews that are pending. The reviews are on hold, pending additional information being submitted by the applicant. The SS&D reviewer related that all reference materials and checklists provided by NRC for SS&D reviews were available and followed during the application reviews.

22. Licensing Procedures (Category II)

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 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.

Assessment

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 applicants use. Standard license conditions are also utilized for uniformity, and they were determined to be equivalent to the standard conditions utilized by NRC. Copies of NRC's standard licensing conditions, and license review checklists were provided to the program on diskettes for their information, and in return, the State provided electronic copies of the licensing guides and checklist used by Florida. The casework was reviewed for technical adequacy of application review, significant errors and omissions, utilization of licensing procedures and standard conditions, and documentation. The Information Notices (INs) and Regulatory Guides (RGs) issued by NRC are re-issued under the Florida system and sent to licensees as applicable. These INs and RGs issued since the last review were determined to be equivalent to those issued by NRC.

23. Status of Inspection Program (Category I)

NRC Guidelines

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 pre-operational, 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 LLW 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 vs. 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 computerized inspection tracking system was reviewed. The program does not have an inspection backlog as determined from the review of the data system and the casework files. All inspections are performed during the calendar year in which they are due for inspection. The status of the inspection program is assessed monthly, and on a quarterly basis. The inspection due listing is generated on a quarterly basis, and the listing can be reviewed at any time. A review of the casework and the system verified that licenses and inspections are coded properly and the information is properly and promptly entered into the tracking system. The Program reported receiving 528 reciprocity requests from 74 licensees during the reporting period, and the State performed eight reciprocity inspections of which six were industrial radiographers. In addition, the State reported that eleven radiographers were inspected in the field.

24. 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 and industrial radiographers should be inspected approximately annually. Smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency, including 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. The State utilizes the inspection frequencies that are as frequent as those used by NRC. All inspections are performed on 0.5, 1, 2, 3, or 4 year frequencies. Low-level waste brokers are on a 0.5 year frequency, institutional medical are on a 2 year frequency, and the HDR units were verified to be on a 1 year frequency.

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 reenactment 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 and 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.

Assessment

All of the incident files for the 1993 and 1994 calendar years have been distributed to the Office of State Programs and all of these incidents were reviewed prior to transmittal to OSP. The incident data systems utilized by the State, and the regulations related to incident reporting requirements were reviewed and the State's incident reporting system was discussed in detail with the incident coordinator (Phil Thoma) located in the Orlando Environmental Laboratory. Florida has an event reporting and tracking system very similar to the NRC system being developed by INEL, and the State is participating in the pilot program for testing the INEL system. The program has been very responsive in responding and evaluating incidents and alleged incidents as they occur. Medical consultants have been used on two occasions for independent evaluation of two abnormal occurrences and the documentation has been provided to NRC. The two abnormal occurrences incident files were reviewed in the Tallahassee, Florida office; no other files were reviewed in this office due to time limitations.

27. Enforcement Procedures (Category I)

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.

Assessment

The State's regulations (Florida Administrative Code 10D-91.323-.325) contain provisions for Routine, Periodic Inspections; Performance of Inspections; and Enforcement. The State can assess administrative fines for violations of State regulations, not to exceed \$1,000 per violation per day. The General Statement of Policy and Procedure for Radioactive Material Enforcement Actions September 1992 has been incorporated into the regulations by reference. Copies of this policy has previously been provided to NRC and reviewed. No changes have occurred in the policy; therefore, the policy was not reviewed during this review. The program has issued eighteen fines since the last review. The enforcement procedures and practices were reviewed during the casework reviews and the results indicate that the procedures and the routine inspections provide a substantial deterrent to licensee noncompliance. Program managers also related that pre-license visits and the hand delivery of new licenses are believed to be effective as preventative tools in achieving compliance.

28. Inspection Procedures (Category II)

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 supervisors or the senior inspector should be performed upon return from non-routine inspections.

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

Assessment

The program utilizes the Inspection Guidance and Procedures provided by NRC Inspection Manual, Inspection Procedure 87100 and Manual Chapter 2800. Updated copies of the these documents were provided on diskette to the program managers during the review for implementation. Most of the materials inspectors have attended the NRC Inspection Procedures Course, and all inspectors have attended inspection training provided by the State. The State procedures, guides, State inspector accompaniment, and the casework reviews verify that the inspection procedures are consistent with NRC guidance, and are adequate to provide complete and uniform technical guidance to the staff inspectors.