Document Contral February 17, 1994 Dr. Lyle Jerrett, Chief Office of Radiation Control Dept. of Health & Rehab. Services 1317 Winewood Blvd. Tallahassee, FL 32399-0700 Dear Dr. Jerrett: This will confirm a recent conversation with you and Ms. Becker relating to NRC's visit to review the Florida Radiation Control Program for Agreement Materials. The visit is scheduled for March 8-11, 1994. This will be an informal visit to assess the status of your program and to discuss any topics of mutual concern with you and your staff. The usual questions sent to you in preparation for a full review will not be needed for this visit. Tentative arrangements were made with Ms. Becker to accompany Mr. Pockelwald and Mr. Horowitz out of the Jacksonville Field Office on March 8-9, 1994, and to accompany Mr. Roberts out of the Tallahassee Office on March 10, 1994. would like to come by your office on March 10 prior to the accompaniment and on Friday March 11, 1994 for informal discussions concerning the status of your program and any topics of mutual concern. If you have any questions or suggestions concerning the visit, please let me know. Sincerely, Charlet woo Speel Richard L. Woodruff Regional State Agreements Officer Stewart D. Ebneter Regional Administrator NRC, Region II bcc: R. L. Woodruff, RSAO R. E. Trojanowski, SLO J. P. Stohr, DRSS DCD (SP01) RII: ORA Rhw RWoodruff

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APPENDIX A

EVALUATION OF AGREEMENT STATE RADIATION CONTROL PROGRAM

PART I PROGRAM GUIDELINES AND STATE QUESTIONNAIRE UPDATE

Name of State Program

Reporting Period from: April 17, 1992 to April 29, 1994

I. LEGISLATION AND REGULATIONS

A. <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.

Questions:

- 1. What changes were made to the State's statutory authority to regulate agreement materials, low level waste disposal, or uranium mill operations in the reporting period?
- Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.
- B. 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

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

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 should have 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.

Questions:

- What is the effective date of the last compatibility-related amendment to the State's regulations?
- Referring to the latest NRC chronology of amendments, identify those that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them.
- Identify the person responsible for developing new or amended regulations affecting agreement materials.

II. ORGANIZATION

Under the Appendix B title sheet provided at the end of this document, please enclose copies of your organization charts as follows:

- a) organization chart(s) showing the position of the radiation control program (RCP) within the State organization and its relationship to the Governor, other State and local RCPs (if any), and comparable health and safety programs.
- b) Internal organization charts for the Bureau of Radiological Health and the Bureau of Solid and Hazardous Waste. If applicable, include regional offices and contract agencies.

All charts should be current, dated, and include names and titles for all positions.

A. 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.

Ouestions:

- During the reporting period, did the management, program name, or location of the RCP within the State organization change?
- B. 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.

Questions:

- What changes occurred in the organization of the RCP during the reporting period?
- 2. If changes occurred, how have they affected the RCP and its effectiveness?
- C. <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.

Questions:

- If legal assistance was utilized during the reporting period, briefly describe the circumstances.
- Was the legal assistance satisfactory during this period? If not, what were the problems?
- D. <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.

Questions:

- Please list the names, affiliations, and terms of the technical committee(s) members.
- If an advisory committee or consultant was used during the reporting period, briefly describe each circumstance (i.e., the subject, the need, the result, and the manner obtained – by meeting, phone call, or letter).

E. <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.

- Please describe the procedures that are in place for the acquisition of technical and vendor services or provide a copy for review.
- 2. If the State has utilized outside contractors since the last review, please provide a listing of the contractors, the project under contract, and the status of the project.

III. MANAGEMENT AND ADMINISTRATION

A. Quality of Emergency Planning (Category I)

NRC Guidelines: The State RCP should have a written plan for response to 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.

Questions:

- Other than the communications list, when was the emergency plan last revised?
- 2. If the plan was revised since the last review, what changes were made?
- 3. If the plan was substantially revised during the reporting period, was the NRC provided the opportunity to comment on the revision while it was in draft form?
- 4. When was the emergency communication list last reviewed or revised?
- 5. When and how was the plan last tested?

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

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

Questions:

 Show the amount for funds for the Division of Radiological Health (DRH) for the current fiscal year obtained from:

DRH Funds

State general fund

- a. Fees
- Federal grants and contracts (identify)
- c. Other
- d. Total:
- Show the total amounts in the current DRH budget allocated for the following (if contract costs are incurred, please include):

DRH Budget

- a. Administration
- b. Radioactive materials
- c. X-ray
- d. Environmental surveillance
- e. Emergency planning
- f. Other (radon, non-ionizing, operator credentialing, etc., please identify).
- g. Total:
- 3. What percentage of your radioactive materials program is supported by fees?
- 4. Discuss any changes in program funding that occurred during the reporting period, the reasons for the changes (new programs, change in emphasis, statewide reduction, fee cost recovery percentage, etc.), and how the changes affected the program.
- 5. Overall, is fu in sufficient to support all of the program needs? If not, what are the problem areas?

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

NRC Guidelines: The RCP should have the laboratory support capability in-house, or readily available through established procedures, to conduct bioassays, analyze environmental samples. analyze samples collected by inspectors, etc., on a priority established by the RCP. In addition, States regulating the disposal of low-level radioactive waste facilities 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.

Questions:

- Describe changes in your laboratory support, such as new instruments, cutbacks, etc., in this period.
- 2. Have there been problems in obtaining timely and accurate lab results? If yes, discuss the circumstances and how the problem might be corrected.

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

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

Questions:

1. Briefly list the changes, such as new procedures, updates, policy memoranda, etc., made in your written administrative procedures during the reporting period. Include internal processing of license applications, inspection policies, decommissioning and license termination, fee collection, contacts with media, conflict of interest policies for employees, and

exchange of information procedures.

2. Briefly list any new procedures, policy, etc., that have been implemented with respect to the implementation of the regulatory functions under the current organization.

E. 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 fundings. 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.

Questions:

- 1. How many management reviews of license cases were performed in this period?
- Were all license reviewers included in the cases selected for management review? If not, explain.
- 3. What audits were made of regional and contract offices?

F. 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.

Questions:

- Has the secretarial and clerical support been adequate during this period? If not, explain.
- What word processing, data base, and spread sheet programs are you using?

G. 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.

Questions:

1. Have changes occurred in the manner in which you handle public information?

IV. PERSONNEL

A. 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. 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

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).

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.

Questions:

Please list all new technical personnel in the Radioactive Materials Program and the Division of Radioactive Waste Management, indicate the degree they received, if applicable, and additional training and years of experience in health physics, engineering, geology, hydrology, etc..

B. Staffing Level (Category II)

NRC Guidelines: Professional staffing level should be approximately 1-1.5 person-year 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 builet 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.

Questions:

1. Complete a table listing the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program and the radioactive waste management program. If consultants were used to carry

out the program's RAM responsibilities, include their efforts. The table heading should be:

NAME

POSITION AREA OF EFFORT FTE%

- 2. Is the staffing level adequate to meet normal and special needs and backup? If not, explain.
- 3. Do you currently have vacancies? If so, when do you expect to fill them?

C. 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.

Questions:

 Identify your senior personnel assigned to monitor the work of junior personnel.

D. <u>Training</u> (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.

Questions:

 Prepare a table listing all of the training courses, workshops, seminars, symposia, etc. that your materials personnel and your radioactive waste management personnel have attended since the last review. The table heading should be:

Student Course Sponsor Dates

 If any of your materials radioactive waste management staff currently need NRC training, please identify the employees and the courses needed.

E. 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.

Questions:

 Identify the technical staff who left the Agreement program during this period and, if possible, give the reasons for the turnovers.

V. LICENSING

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

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

Questions:

Update the list of the State's major licensees. In addition

to the name, license number and type, please indicate if the license is new or was terminated (action). Include:

- Broad Licenses
- o LLW Disposal
- o LLW Brokers (All Types)
- o Manufacturers and Distributors
- o Uranium Mills
- o Irradiators (Other than Self-Contained)
- o Nuclear Pharmacies
- Other Licenses With a Potential Significance for Environmental Impact

The table heading should be:

Licensee Name License Number License Type Action

- Identify any major, unusual, or complex licenses issued or renewed in this period.
- 3. Have any new or amended licenses affected the list of licensees requiring contingency plans?
- Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the period.

B. 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.

Questions:

 Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the reporting period. The table heading should be:

SS&D	Manufacturer,	Type of	Indicate	Indicate if
Registry	Distributor or	Device	if	Agreement
Number	Custom User	or Source	NARM	Material

- List the applications for SS&D registrations for which registry documents have not yet been issued.
- 3. Please provide a listing of approval documents for any radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste, that the State has approved since the last review.

C. <u>Licensing Procedures</u> (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 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.

Questions:

What changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period for materials licenses and for the radioactive waste licenses?

VI. COMPLIANCE

A. 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 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. There should be at least semiannual inspection planning 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.

Questions:

1. Prepare a table identifying the Priority 1, 2, and 3 licenses with inspections that are overdue by more than 50% of their scheduled frequency. Include the licensee name, inspection priority, the due date, and the number of months the inspection is overdue. The list should include initial inspections that are overdue. The table heading should be:

Insp. Freq.

Licensee Name (Years) Due Date Months O/D

- Describe your action plan for completing your overdue inspections. If there is a backlog of
 - (1) inspections with an inspection frequency of 3 years or less that are overdue by more than 50% of thier scheduled frequency, or

(2) inspections with lower inspection frequencies that are overdue by more than 100% of thier scheduled frequency,

please include with the questionnaire a written action plan for eliminating the backlog. The written action plan should contain inspection priorities, numerical and time frame goals for reducing the backlog, provide a method to measure the program's progress, and provide for management review of the program's success in meeting the goals.

- 3. How many on-site close-out inspections prior to license termination were made during the reporting period?
- 4. How many on-site close-out inspections are pending at this time?
- 5. How many reciprocity notices were received in the reporting period?
- 6. How many reciprocity inspections were conducted?
- 7. Other than reciprocity licensees, how many field inspections of radiographers were performed?
- 8. What percentage is this of your total number of radiographer licensees?

B. <u>Inspection Frequency</u> (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.

Questions:

 Identify individual licensees or groups of licensees the State is inspecting more frequently than called for in the State's inspection priority system and discuss the reason for the change.

C. Inspector's Performance and Capability (Category I)

NRC Guidelines: Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies

prior to independently conducting inspections. 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 quides.

Ouestions:

 Prepare a table showing the number and types of supervisory accompaniments made during the reporting period. Include:

Supervisor Inspector License Category Date

- Were all inspectors accompanied at least annually by the compliance supervisor during the reporting period? If not, explain.
- D. Responses to Incidents and Alleged Incidents (Category I)

NRC Guidelines: Inquiries should be promptly made to evaluate the need for on-site investigations. On-site 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. On-site 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 timestudy 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.

Ouestions:

 In this reporting period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so,

- a. How and when were other State licensees who might be affected notified?
- b. Was the NRC notified?
- For incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.
- If the RCP utilized medical or technical consultants for an emergency during the reporting period, please describe the circumstances for each case.
- 4. In the reporting period, were there any cases involving possible criminal wrongdoing that were looked into or are presently undergoing review? If so, please describe the circumstances for each case.
- Please provide a copy of your written procedures for reporting events data and misadministrations to NRC.
- 6. Please describe how you inform your licensees about the importance of reporting accurate and timely events information, including misadministration reporting.
- Please have copies of all misadministrations and events available for dicsussion and review.

E. <u>Enforcement Procedures</u> (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.

Questions:

- 1. If during the reporting period the State issued orders, applied civil penalties, sought criminal penalties, impounded sources, or held formal enforcement hearings, identify these cases and give a brief summary of the circumstances and results for each case.
- Discuss changes made in the enforcement procedures during the reporting period.
- 3. Briefly describe the enforcement program used to regulate permittees that transfer radioactive waste to the LLW site.

F. <u>Inspection Procedures</u> (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 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.

Questions:

1. What changes were made to your written inspection procedures during the reporting period?

G. <u>Inspection Reports</u> (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 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 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.

Questions:

- What changes were made in the formats of your reports or inspection forms during this period?
- H. 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 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 include the following types:

GM Survey Meter: 0-50 mr/hr
Ion Chamber Survey Meter: up to several R/hr
Neutron Survey Meter: Fast & Thermal
Alpha Survey Meter: 0-100,000 c/m
Air Samplers: Hi and Low Volume
Lab Counters: Detect 0.001 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 should be calibrated at intervals not greater than that required to licensees being inspected.

(Note: Addition types of instrumentation that are highly desirable are thin window plastic or NaI detectors for low energy gammas and "micro-R" weters with audio signal for searching for lost gamma emitter sources.)

Questions:

 Describe any changes in your instrumentation or methods of calibration in this reporting period.

VII. SPECIAL TOPICS OF CURRENT INTEREST

A. If you like, describe your program's successes, problems or difficulties that occurred during this reporting period.

PART II PROGRAM STATISTICS

For calendar year ending December 31, 1993

(Also, please provide on a seperate chart the following information for 1994 through April)

- *1. How many specific licenses are currently in effect?
- 2. During the last calendar year,
 - a. how many new licenses were issued?
 - b. how many licenses were terminated?
 - c. how many licenses were renewed?
 - d. how many amendments were issued?
 - e. how many SS&D evaluations were completed?
- 3. How many prelicensing visits were made during this past calendar year?
- 4. How many new licenses (or major amendments) were hand delivered to the licensee?
- 5. How many materials incidents, other than unfounded allegations, occurred during the last calendar year?
- 6. How many on-site investigations of incidents were conducted during the last calendar year?
- *7. How many incidents required NRC notification, either by telephone or by written report?
- *8. How many of the incidents required Abnormal Occurrence Reports?
- *9. How many of the incidents involved leaking from sealed sources?
- *10. How many misadministrations occurred during the last calendar year?
- 11. How many civil penalties were imposed during the last calendar year?
- 12. How many orders were issued during the last calendar year?

*13. How many technical FTE's (not including administrative, clerical or unfilled vacancies) are currently assigned to the:

Radioactive materials program?

Low-Level waste program?

Uranium mills program?

- *14. Compute the professional/technical person-year effort of person-years per 100 licenses (excluding management above the direct RAM supervisor, vacancies and personnel assigned to mills and burial site licenses). Count only time dedicated to radioactive materials.
- *15. List the RCP salary schedule as follows:

Position Title

Annual Salary Range

*16. Please complete the following table using the license categories as shown, and including the total number of specific licenses in each category, the priority or inspection frequency, the number of inspections made during the review period, and the number of overdue inspections in each category. (In Priorities 1-3, include those overdue by more than 50% of their scheduled inspection frequency; in lower priorities, include those overdue by more than 100% of their scheduled frequency.)

License Category

No. of Freq. Insps. Overdue Licenses (years) Made Insps.

Academic Type A Broad Academic Type B Broad Academic Type C Broad Academic Other Medical Institution Broad Medical Institution Limited Medical Institution Custom Medical Private Practice Medical Private, Custom Eye Applicators Strontium-90 Mobile Nuclear Medicine Service HDR Remote Afterloader Mobile HDR Remote Afterloader Teletherapy Veterinary Non-Human In-Vitro Testing Laboratories

License Category

Nuclear Pharmacies Medical Product Distribution (Prepared Radiopharmaceuticals) Medical Product Distribution (Generators and Kits) Medical Product Distribution (Sources and Devices) Well Logging, All Sources Well Logging, Sealed Sources Only Well Logging, Unsealed Sources Measuring Systems Fixed Gauges Measuring Systems Portable Gauges Measuring Systems Analytical Measuring Systems Gas Chromatographs Measuring Systems Other Mfg. and Dist., Type A Broad Mfg. and Dist., Type B Broad Mfg. and Dist., Type C Broad Mfg. and Dist., Other Nuclear Laundry Decontamination Services Leak Test Service Only Calibration Service Only (Less Than 100 Curies) Calibration Service Only (Greater Than 100 Curies) Leak Test & Instr. Cal. Service (Less Than 100 Curies) Leak Test & Instr. Cal. Service (Greater Than 100 Curies) Other Services Waste Disposal (Burial) Waste Disposal Service, Prepackaged Waste Disposal Service Incineration Waste Disposal Service Processing General License Distribution Ind. Radiography Fixed/Temp. Site Ind. Radiography Temp. Site only Irradiators Self Shielded (Less Than 10000 Curies) Irradiators Other (Less Than 10000 Curies)

Insp. No. No.*
No. of Freq. Insps. Overdue
Licenses (years) Made Insps.

No. of

Licenses

No. *

Overdue

Insps.

Insp.

Freq.

(years)

No.

Insp.

Made

License Category

Irradiators Self Shielded (Greater Than 10000 Curies) Irradiators Other (Greater Than 10000 Curies) R and D, Type A Broad R and D, Type B Broad R and D, Type C Broad R and D, Other Civil Defense Byproduct Material Possession Only Decommissioning of Facilities Low Level Waste Storage - Other U-Mills Source Material Other (Less Than 150 Kilograms) Source Material Shielding Source Material GL Distribution Source Material Other (Greater Than 150 Kilograms) Heap Leach, Ore Buying Stations, Byproduct Recovery Rare Earth Extraction and Processing Source Material Possession Only Hot Cell Operations SNM - Unsealed, Less Than 200 Grams SNM - Sealed Sources in Devices Pacemaker - Medical Institution Pacemaker - Individual Pacemaker - Mfg. and Dist.

APPENDIX B ORGANIZATION CHARTS

CHRONOLOGY

Amendments to be Considered by Agreement States (from September 1971)

Effective Date	10 CFR Part	Regulations1	Summary
Sept. 24, 1971	20 30	Part C, Sch. B Part D, App. B	*Addition of an exempt quantity for Ba-133.
March 26, 1971	20 30 40 70 71	A.3 C.40 C.100 D.207	*Addition and modification of transport and packaging procedures.
Nov. 2, 1972	20	Part D, App. A	*Changes in values of radionuclides of all concentrations in air and water.
Sept. 17, 1973	19	Part J	*Requirements for notices, instructions and reports by licensees to workers, and options available to workers with regard to inspections.
Oct. 24, 1973	20 30 32	A.2(i) Part C, Sch. A Part D, App. A and App. B	*Change to abbreviations for "curie" and "micro- curie," and addition of definition for "milli- curie."
Jan. 10, 1974	31 32	C.22(i) C.28(h)	Authorization to use C-14 in <u>in vitro</u> clinical or laboratory tests.
March 11, 1974	30 31 40 70 150	C.40	*Requirement that suppliers must verify that customers are authorized to receive the material shipped.
July 29, 1974	20	A.2(i) Part D, App. A	*Special curie definitions and concentration values for U and Th.

^{*}Compatibility Item.

1 Refers to the Suggested State Regulations for Control of Radiation prepared by the Conference of Radiation Control Program Directors, Inc.

Effective Date	10 CFR Part	Regulations ¹	Summary
Aug. 16, 1974	31 32 35	C.22(h) C.26(c) C.28(h) C.28(j)	Addition of H-3 and Fe-59 to <u>in vitro</u> tests and extension of Medical Group licensing.
Jan. 15, 1975	31 32	C.22(d) C.28(d)	*Modification of require- ments for distribution of 31.5 GL devices.
Jan. 19, 1975		A.3(c)	*Clarification of AEC contractors exemption pursuant to Energy Reorganization Act.
June 25, 1975	20	D.206	*Requirements for control of licensed material in unrestricted areas and not in storage.
June 25, 1975	35	Part C, Sch. C	Addition of I-125 seeds for interstitial treatment of cancer to Group VI.
Jan. 19, 1976	20	D.1(a)	*Incorporation of "As Low As Is Reasonably Achievable (ALARA)" wording.
Jan 29, 1976	20	Part D, App. A	*Modification of occupa- tional exposure limit for Rn-222.
Feb. 23, 1976	35	Part C, Sch. C	Addition of Sn-113/In-113m generators to Group III.
April 19, 1976	35	Part C, Sch. C	Addition of Yb-169 DTPA for cisternography to Group II.
June 2, 1976	20 31 32 35 40 70 150	Parts C, D and E	Requirements for preservations of certain records required by the regulations

^{*}Compatibility Item.

Effective Date	10 CFR Part	Regulations ¹	Summary
Aug. 4, 1976	34	E.203	Personnel monitoring requirements for industrial radiographers.
Aug. 16, 1976	35	Part C, Sch. C	Addition of I-125 fibrinogen for detection of deep vein thrombosis to Group II.
Dec. 29, 1976	20	D.103	*Authorizes use of respirators. Bases internal exposure limits on intake into the body.
Jan. 5, 1977	40	C.21(d)	Establishes GL for depleted uranium products.
March 7, 1977	40	C.3(c)	*Exemption for personnel neutron dosimeters containing thorium.
May 31, 1977	31 32	C.22(i) C.28(h)	Addition of Se-75 to <u>in</u> <u>vitro</u> GL.
June 27, 1977	31 32	C.22(i) C.28(h)	Addition of Mock Iodine- 125 calibration sources to <u>in vitro</u> GL.
Aug. 15, 1977	35	C 25(b)	Modification of requirements for individual physician use of radioactive material for human use.
Jan. 6, 1978	40	C.21(a)	Extends small quantity source material GL to Federal, State and local governments for operational purposes.
Jan 16, 1978	35	Part C, Sch. C	Addition of Tc-99m human serum albumin for heart blood pool imaging to Group III.
Feb. 7, 1978	35	Part C, Sch. C	Addition of Tc-99m medronate sodium for bone imaging to group III.

^{*}Compatibility Item.

Effective Date	10 CFR Part	Regulations ¹	Sunary
Feb. 16, 1978	30	C.4(c)	*Exemption for spark gap irradiators containing Co-60.
March 14, 1978	20	D.203(c)	*Additional requirements for controlling areas in which radiation levels in excess of 500 rems/hr exist.
June 16, 1978	35	Part C, Sch. C	Addition of Tc-99m gluceptate sodium for brain and renal perfusion imaging to Group III.
June 23, 1978	20	D.203(f)	*Removal or defacing of radioactive material labels on empty containers.
Sept. 7, 1978	35	Part C, Sch. C	Addition of Tc-99m human serum albumin microspheres for venography to Group III.
Dec. 28, 1978	35	G.3(c)	Requirement to perform survey of patients to confirm that implants have been removed.
March 22, 1979	35	Part C, Sch. C	Deletion of diagnostic procedures from medical groups.
June 5, 1979	30 40 70	C.31(d)	Notice of discontinued licensed operations.
July 9, 1979	35	G.3(d), (e), (f),(g),(h)	Teletherapy calibrations
Aug. 20, 1979	19 20	D.1, D.101, D.102 J.13	*Control of radiation to transient workers.
Sept. 27, 1979	71	C.100	*Modification of transportation requirements.

^{*}Compatibility Item.

Effective Date	10 CFR Part	Regulations ¹	Summary
March 3, 1980	34	Part E C.26(e)	Amendments to industrial radiography requirements.
March 28, 1980	71	A.3(b) C.101	*Correction to reference to Postal Service regulations.
Sept. 2, 1980	35	C.26(c)	Testing of radioisotope generators.
Sept. 19, 1980	40	C.21(a)	Deletion of GL for source material medicinals.
Nov. 10, 1980	35	D.409	Medical misadministration reporting.
Nov. 17, 1980	40	A.2 C.25(e),(f) (g), (h) C.29 Part C, Sch. E	*Requirements to implement the Uranium Mill Tailings Act.
Dec. 1, 1980	20	D.106(g)	*Reference to 40 CFR 190 for uranium fuel cycle operations.
Jan. 28, 1981	20	D.304	*Deletion of waste burial authorization.
March 6, 1981	35	Part C, Sch. C	Addition of Tc-99m oxidronate sodium to Group III.
March 13, 1981	34	E.203(b)	Disposal of dosimeter records.
March 31, 1981	20	D.306	Biomedical waste rule.
May 13, 1981	30	C.4(c)	*Exemption for survey instrument calibration sources.
Sept. 23, 1981	30	C.4(c)	*Addition of Am-241 to exemption for survey instrument calibration sources.

^{*}Compatibility Item.

Effective Date	10 CFR Part	Regulations ¹	Summary
Nov. 30, 1981	20	D.201	*Radiation protection survey requirement.
Dec. 24, 1981	40	C.3(c)(6)	*Clarification of exemption for uranium shielding in shipping containers.
March 26, 1982	35	Part C, Sch. C	Addition of Tc-99m labeled disofenin to Group III.
April 15, 1982	20	D.103	Placement of provisions of Reg. Guide 8.15 in regulations.
June 29, 1982	35	Part C, Sch. C	Addition of Tc-99m labeled succimer to Group III.
July 6, 1982	71	C.104	*Advance notification of transport of waste.
Sept. 13, 1982	35	C.26(a)	Change medical isotope committee to radiation safety committee.
Jan. 26, 1983	61	Part M D.307 D.308 D.309	*Licensing requirements for land disposal of radioactive waste, and waste classification.
Dec. 27, 1983**	20	D.311	*Transfer for disposal and manifests.
March 4, 1983	35	G.4(h),(i)	Teletherapy room monitors and servicing of source exposure mechanisms.
March 7, 1983	35	C.26(c)	Exemption from requirements for use of approved radiopharmaceuticals for unapproved procedures.

^{*}Compatibility Item.

**Published in conjunction with Part 61.

Effective Date	10 CFR Part	Requlations ¹	Summary
June 28, 1983	35	Part C, Sch. C	Addition of I-125 sealed source in portable device to Group VI.
Aug. 15, 1983	30 40 70	C.32	Expiration and termination of licenses.
Sept. 6, 1983	71	Part T	*Transportation regs compatibility with IAEA.
Sept. 28, 1983	30 70 150	W.501	Irretrievable well logging source.
Sept. 11, 1984	40	C.3(c)	*Elimination of exemption for glass enamel and glass enamel frit.
Sept. 10, 1985	35	C.26(c)	Addition of T-99m labeled pharmaceuticals for gastro esophegeal imaging and other clinical procedures.
Nov. 15, 1985	40 Appendi 150	Part U x A	*Uranium Mill Tailings (proposed)EPA Standards
July 16, 1986	34	Part E	*Industrial radiography storage surveys and quarterly audits
Feb. 11, 1987	30 40 61 70	Part C,M,U	*Bankruptcy notification
March 24, 1987	35	Part G, (proposed) Part C	Exemption for use of aerosols.
April 1, 1987	35	Part G, (proposed) Part C	Revision for medical use. *Medical misadministration reporting
July 14, 1987	39	Part W	*Requirements for well logging.
*Compatibility It	em.		

Effective Date	10 CFR Part	Requlations ¹	Summary
Feb. 12, 1988	20	Part D	*NVLAP certification of dosimetry processors.
July 27, 1988	30,40, 70	Part C	*Decommissioning
June 26, 1989	61	Part D	Greater than Class C
July 17, 1989	39	Part W	Exemption-Authorized to use sealed sources in well logging.
October 12, 1989	35	Part G	Addition of Palladium-103 for Interstitial Treatment of cancer.
April 7, 1990	30,40, 70	Part C	*Emergency Plan.
August 23, 1990 August 23, 1993	35	Part G	Use of Radiopharmaceuticals for therapy
January 10, 1991 radiographic equi	34 pment	Part E	*Safety requirements for
April 18, 1991	34	Part E	ASNT Certification of Radiographers
June 20, 1991 Radiation	20	Part D	*Standards for Protection Against
October 15, 1991	20,30,31 34,39,40 70	Part C, D	*Notification of Incidents
January 27, 1992 Misadministration	35 s	Part G	*Quality Management Program and
October 2, 1992 recordkeeping	30 35	Part G	Eliminating the requirements for departures from manufacturer's instructions
July 1, 1993	36	Part C, D	*Licenses and radiation safety requirements for large irradiations

^{*}Compatibility Item.

Effective Date 10 CFR Part	Regulations	Summary
July 22, 1993 61	Part M	*Licensing Requirements for Land Disposal of Radioactive Waste (Definition)
October 25, 1993 30, 40 70, 72	Part C	*Decommissioning and license termination: Documentation additions

^{*}Compatibility Item.