December 21, 1993

MEMORANDUM FOR: John J. Surmeier, Acting Assistant Director
for State Agreements Program
Office of State Programs

FROM: Richard L. Woodruff, RSAO, RII

SUBJECT: NORTH CAROLINA REVIEW REPORT FOR 1993

Enclosed is the subject review report and review references. The package contains the documents as outlined below.

1. Control sheet

2. Summary Letter Report:
   - o Comment Letter
   - o Enclosure 1, "Application of Guidelines for NRC Review"
   - o Enclosure 2, "Summary of Assessments and Comments"

3. Review References:
   - o Cover Sheet
   - o Appendix A, Questionnaire with State Responses
   - o Appendix B, State Organizational Charts
   - o Appendix C, Reviewer Explanatory Comments and Observations
   - o Appendix D, License File Reviews
   - o Appendix E, Compliance File Reviews
   - o Copy of previous review visit report

Richard L. Woodruff

cc: North Carolina file

NC93REV.RLW

REVIEW CONTROL SHEET

1.	Radiation Control Program:		North Carolina
2.	Type of Review:		Routine
3.	Dates of Review: Year		1993
	a. RCP Office Review		December 6-10, 1993
	b. Field Evaluations		November 16,17, and 23, 1993
	c. Regional or Other Office or Site Visits		NA
	d. Visits to State-Licensed Facilities		November 23, 1993
	e. Exit Meeting		December 10, 1993
4.	Total Field Evaluations 2	Total Licensee Visits	1
5.	Period of Review:	November 22, 1991 to December 10, 1993	
6.	Staff Days in State: Total		14
	a. Regional SAO		9
	b. Other Regional Representatives		0
	c. Other SP Representatives		5
	d. Other NRC Representatives		0
	e. Other Review Participants		0
7.	Review hours devoted to technical assistance or staff training:		6

NC93REV.RLW

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

Mr. Jonathan B. Howes, Secretary
Department of Environment, Health
and Natural Resources
P. O. Box 27687
Raleigh, NC 27611-7687

Dear Mr. Howes:

This is to confirm the discussion Mr. Richard L. Woodruff, NRC Region II State Agreements Officer, and Ms. Patricia Larkins, Office of State Programs, held on December 10, 1993 with Ms. Linda Bray Rimer, Assistant Secretary, Environmental Protection, and Mr. Richard M. Fry, Deputy Director, Division of Radiation Protection following our review and evaluation of the State's Radiation Control Program.

As a result of our review of the State's program and the routine exchange of information between the Nuclear Regulatory Commission and the State of North Carolina, the staff determined that overall the North Carolina program for regulation of agreement materials is adequate to protect the public health and safety. However, a finding of compatibility is being withheld at this time because the State has not adopted regulations equivalent to "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991.

Status and Compatibility of Regulations is a Category I Indicator. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable, but no later than three years after the effective date of the NRC regulation. During the review, your staff related that the above regulations would be presented to the North Carolina Radiation Protection Commission for "emergency rule adoption" during its February 1994 meeting. Technically, this rule is needed by January 10, 1994 for the State to remain compatible with the NRC's regulations in accordance with the three year criteria above. We recommend that the State adopt this rule as soon as possible. Other regulations that will be needed for compatibility are addressed in the Enclosure 2 comments.

Staffing level is a Category II Indicator. The staffing level of the materials program should be approximately 1.0 to 1.5 person-years per 100 licenses in addition to the staffing needed for the Low-Level Radioactive Waste (LLRW) program. Currently, the materials staff level is approximately 1.1 person-years per 100 licenses which is a minimum level for this type of program. Additional support will be needed in the coming months for senior level Health Physics support to the LLRW program, and to handle the increased trend in numbers of materials licenses and major licenses. Other regulations that will be needed for compatibility are addressed under the Enclosure 2 comments.

An explanation of our policies and practices for reviewing Agr. ..ent State programs is included as Enclosure 1. Enclosure 2 contains our summary regarding the technical aspects of our review of the program and that were discussed with Mr. Fry and Ms. Robin Haden during our exit meeting with him and his technical staff. We request specific responses from the State with regard.. to this letter and the Enclosure 2 comments.

We appreciate your support of the Radioactive Materials Program and your regulatory efforts to protect public health and safety. We also appreciate your cooperation with this office and the courtesy and cooperation extended by your staff to Mr. Woodruff and Ms. Larkins during the review.

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

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
1. Application of NRC Guidelines
2. Summary of Assessment and Comments

cc w/encls:
J. Taylor, Executive Director for Operations, NRC
S. Ebneter, Regional Administrator, Region II, NRC
Ms. Linda Bray Rimer, Assistant Secretary
Environmental Protection
Dept. of Environment, Health and Natural Resources
Post Office Box 27687
Raleigh, NC 27611-7687
Mr. Dayne H. Brown, Director
Division of Radiation Protection
Dept. of Environment, Health and Natural Resources
Post Office Box 27687
Raleigh, NC 27611-7687
NRC Public Document Room
State Public Document Room

ENCLOSURE 1

Application of "Guidelines for NRC Review
of Agreement State Radiation Control Programs"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs," were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories.

Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

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

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

ENCLOSURE 2

SUMMARY OF ASSESSMENTS AND COMMENTS
NORTH CAROLINA RADIATION CONTROL PROGRAM
FOR THE PERIOD
NOVEMBER 22, 1991 TO DECEMBER 10, 1993

SCOPE OF REVIEW

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 Agreement State Program, Office of State Programs. The review included discussions with program management and staff, accompaniments of four State inspectors, technical evaluation of selected license files and compliance files and the evaluation of the State's response to an NRC questionnaire that was sent to the State in preparation for the review.

The nineteenth regulatory program review meeting with North Carolina representatives was held during the periods of November 16,17, and 23, and December 6-10, 1993 in Raleigh, North Carolina. The State was represented by Dayne H. Brown, Director, Division of Radiation Protection, and his staff. Selected license and compliance files were reviewed by Richard L. Woodruff, Regional State Agreements Officer and Patricia Larkins, Office on State Programs during the period of December 6-10, 1993 in Raleigh. Field accompaniments of two inspectors were made by R. Woodruff on November 16 and 17, 1993, and two inspectors were accompanied during the initial source loading and licensee safety checks at the Abbott Laboratories Irradiator on November 23, 1993. A summary meeting regarding the results of the review was held with Mr. Richard M. Fry, Deputy Director, Division of Radiation Protection and Ms. Robin Haden, Chief, Radioactive Materials Section on Friday, December 10, 1993.

CONCLUSION

The North Carolina program for control of agreement materials is adequate to protect public health and safety. However, a finding of compatibility is being withheld because of the need to adopt regulations equivalent to the "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in a letter to Mr. William W. Cobey, Secretary, Department of Environment, Health and Natural Resources dated January 15, 1992. All comments and recommendations made at that time were satisfactorily resolved and closed out during our visit held on December 9-11, 1992.

CURRENT REVIEW COMMENTS AND RECOMMENDATIONS

All thirty indicators were reviewed and the State fully satisfies twenty-eight of these indicators. Specific comments on the remaining two indicators are as follows:

1. **Status and Compatibility of Regulations is a Category I indicator. The following comment with our recommendation is made.**

   Comment:

   The State's regulations are compatible with the NRC regulations up to the 10 CFR Part 34 amendments on "Safety Requirements for Industrial Radiographic Equipment" that became effective on January 10, 1991.

   The following regulations were identified during the review as being needed for compatibility and have been drafted by the State:

   - "Safety Requirements for Industrial Radiography Equipment" 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991 and will be needed by January 10, 1994.

   - "Notification of Incidents", 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) that became effective on October 15, 1991 and will be needed by October 15, 1994.

   - "Quality Management Program and Misadministrations", 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992 and will be needed by January 27,1995.

   State regulations equivalent to the regulations identified above are being drafted. The State has plans to present the revised Industrial Radiography regulations to the Radiation Protection Commission for "emergency adoption" during the February 1994 Commission meeting. The State projects that all of the above identified regulations will be fully adopted by July of 1994.

   Recommendation:

   We recommend that the State continue with their plans for adoption of the "Safety Requirements for Industrial Radiographic Equipment" and the other regulations that are needed for compatibility.

2. **Staffing Level is a Category II Indicator. The following comment with our recommendation is made.**

   Comment:

   Although the Program managers and staff have done an excellent job in filling the Materials Section vacancies, training new employees, and performing complex regulatory actions with a relatively small staff, we believe that additional staffing is needed.

The radioactive materials technical staffing level should be approximately 1 to 1.5 person-years per 100 licenses in addition to the technical staffing for the Low Level Radioactive Waste (LLRW) project. The current staffing level for the materials program is about 1.1 persons per 100 licenses. This level of staffing is marginal for the following reasons: additional trained technical materials staff and senior personnel will be needed for support of the LLRW project; the number of major, complex license applications continues to increase which requires additional work by the fully trained technical staff; the materials program currently looses an average of one senior, fully trained technical staff member per year; and replacement of technical personnel requires at least one year for the hiring and training of personnel to perform independent evaluation and inspection of licensee's safety programs.

Recommendation:

We recommend that the staffing level be increased to the 1.5 person-years per 100 licenses level.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review meeting was held on Friday, December 10, 1993 with Ms. Linda Bray Rimer, Assistant Secretary, Environmental Protection, Department of Environment, Health and Natural Resources and Mr. Richard M. Fry, Deputy Director, Division of Radiation Protection.

In general, the reviewer discussed the scope of the review, the excellent support the Program receives from the Department, and expressed the staff view that the program was adequate to protect public health and safety. The State was informed that a finding of compatibility would likely be withheld until the regulations needed for compatibility on January 10, 1994 have been adopted. We also discussed the staffing level, the impact that the LLRW program will have on the Materials Section staff workload, and the importance of recruiting and training additional staff before licensing and inspection backlogs develop.

Ms. Rimer was informed that the details of the review would be discussed with the Radioactive Materials Program, and a letter from Mr. Richard L. Bangart, Director, Office of State Programs, would be sent to Secretary Howes with the results of the review and that a reply would be requested.

In response, Ms. Rimer related that she would convey our comments to the Secretary, that the regulations needed for compatibility would be presented to the Radiation Protection Commission for adoption, and that the staffing level would be considered. Ms. Rimer also related that a letter from Mr. Bangart by January of 1994 would be appreciated.

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

Distribution:
SA RF
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H. Thompson, DEDS
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OFC	RII:SAO	RII:DRSS	RA:RII	OSP:SA	OSP:SA:AD	OSP:DD
NME	RWoodruff	JStohr	SEbneter	CMaupin	JSurmeier	SSchwartz
DTE	12/20/93	12/ 6/93	12/ 9/93	01/ /94	01/ /94	01/ /94

OFC	NMSS:D	OGC	OSP:D	DEDS	EDO		
NME	RBernero	STreby	RBangart	HLThompson	JMTaylor		
DTE	12/ /93	01/ /94	01/ /94	01/ /94	01/ /94		

APPENDIX A

EVALUATION OF AGREEMENT STATE RADIATION CONTROL PROGRAM

PART I
PROGRAM GUIDELINES AND
STATE QUESTIONNAIRE UPDATE

Name of State Program

Reporting Period from: November 22, 1991 to December 10, 1993

I. LEGISLATION AND REGULATIONS

A. 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]

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?

   ANS. No changes were made in the statutory authority.

2. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

   ANS. No.

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 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

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

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:

1. What is the effective date of the last compatibility-related amendment to the State's regulations?

   ANS. The June, 1993 amendment to the North Carolina Regulations for Protection Against Radiation was the last compatibility-related amendment.

2. 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.

   ANS. The "Safety Requirements for radiographic equipment" compatibility rules have not been formally adopted. The Part 20 conforming amendment was given a higher priority. The Agency proposes to undertake an Emergency Rulemaking to ensure that the rule will be effective by the next Radiation Protection Commission meeting scheduled for 2/25/94. The emergency rulemaking mandates that a final rule be in place within 180 days of the date of the emergency rule. The "Quality Management Programs and Misadministrations" conforming rule has been drafted and is anticipated to be in place by July, 1994.

3. Identify the person responsible for developing new or amended regulations affecting agreement materials.

ANS. Currently, the Health Physics Supervisor completes the initial draft of new or amended regulations affecting agreement materials. The drafts are reviewed and commented upon by the Chief and Deputy Chief before actual introduction of the regulation into the rulemaking process.

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.

ANS. See attached.

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.

ANS. See attached.

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.

Questions:

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

ANS. No changes.

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:

1. What changes occurred in the organization of the RCP during the reporting period?

   ANS. No changes.

2. If changes occurred, how have they affected the RCP and its effectiveness?

   ANS. N/A

C. 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.

Questions:

1. If legal assistance was utilized during the reporting period, briefly describe the circumstances.

   ANS. Legal assistance was used several times during the reporting period. The nature of the majority of the requests was the question of how to deal with licensees and registrants that demonstrate gross lack of control of their programs. Legal assistance was used in drafting correspondence with such entities. Additionally, legal assistance was requested for 3 cases where the licensees were not willing to pay fees or properly dispose of their RAM.

2. Was the legal assistance satisfactory during this period? If not, what were the problems?

ANS. Since the Attorney General reps are located in downtown in Raleigh and are responsible for all of the DEHNR issues, there is often difficulty in getting prompt responses. As of January 1, 1994, the Attorney General will assign a full time attorney to serve in the DRP office.

D. 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.

Questions:

1. Please list the names, affiliations, and terms of the technical committee(s) members.

NORTH CAROLINA RADIATION PROTECTION COMMISSION

Charles Welby, Ph.D., Chairman
Charles Barry Burns, Vice Chairman

Ex Officio Members (Effective October 1, 1993)

Current Member	Representing
Dayne H. Brown, Director (C)	Radiation Protection Program
David Mallette, Code Consultant (C)	Department of Insurance
William D. Rippy, M.D. (B)	Commission for Health Services
Gerald R. Fleming, Director (C)	Board of Transportation
John H. Thomas, Commissioner (C)	Utilities Commission
William S. Farabow, M.D. (B)	Environmental Management
Angela Waldorf (A)	Department of Labor
Randolph Ward (A)	Industrial Commission
David E. Crisp, Chief/Plans Branch (C)	Div. of Emergency Management
John M. Syria, Director (A)	Medical Care Commission

A= Commission member/state employee
B= Commission member/private sector
C= Committee member/state employee; Commission member
D= Committee member/private sector; Commission member
E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

Voting Public Members (Effective October 1, 1993)

Commission Position/Current Member	Term Expires
Atomic Energy Other Than Power Generation William F. Walker (B) Raleigh, NC 27614	June 30, 1994
Chiropractor Ronald S. DeMars, D.C. (D) Greensboro, NC 27408	June 30, 1995
Dentist from North Carolina Dental Society Donald A. Tyndall, D.D.S. (C) Dept. of Diagnostic Sciences School of Dentistry, CB# 7450 UNC-Chapel Hill	June 30, 1997
Environmental Protection James E. Watson, Jr., Ph.D., Professor (C) Director, Radiological Hygiene Program Dept. of Environmental Sciences & Engineering UNC-Chapel Hill	June 30, 1994
Expert From The State-At-Large Vicky Caldwell Best (C) Fletcher, NC 28732	June 30, 1995
Faculty of An Institution of Higher Learning Charles Welby, Ph.D. (C) North Carolina State University Earth, Marine, Earth & Atmospheric Sciences	June 30, 1995
Hospital Administrator Wayne R. Thomann, Ph.D. (D) Director of Environmental Safety Duke University Medical Center	June 30, 1997
Nuclear Electric Utility Billy H. Webster (D) Cary, NC 27511	June 30, 1997
Physician From North Carolina Medical Society R. William McConnell, M.D. (D) Department of Radiology East Carolina University School of Medicine	June 30, 1997
Podiatrist C. Jeff Mauney, D.P.M. (D) Shelby, NC 28150	June 30, 1994
Radiologic Technologist Charles Barry Burns, MSPH (C) Division of Radiologic Science UNC-Chapel Hill	June 30, 1995

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B= Commission member/private sector
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D= Committee member/private sector; Commission member
E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

RADIATION PROTECTION COMMISSION: EMERGENCY PREPAREDNESS COMMITTE

	Term Expires
David E. Crisp, Chairman (C) Chief/Plans Branch Division of Emergency Management Dept of Crime Control & Public Safety	
Vicky Caldwell Best (C) Fletcher, NC 28732	June 30, 1995
Dayne H. Brown, Director (C) Division of Radiation Protection Dept. of Environment, Health, & Natural Resources	
Major William S. Ethridge (E) Raleigh, NC 27604	July 1, 1994
Gerald R. Fleming, Director (C) Occupational Safety & Emergency Planning Department of Transportation Division of Highways, Highway Building	
Jay Osborne, DRP Legal Counsel (E) Attorney General's Office	
Johnny D. James, DRP Staff Liaison (E)	

A= Commission member/state employee
B= Commission member/private sector
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D= Committee member/private sector; Commission member
E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

RADIATION PROTECTION COMMISSION
Low-Level Radioactive Waste Management Committee

	Term Expires
James E. Watson, Jr., Chairman (C) Director, Radiological Hygiene Program Dept. of Environmental Sciences & Engineering UNC-Chapel Hill	June 30, 1994
Capt. William H. Briner (F) Associate Professor of Radiology Director, Nuclear Medicine Laboratory Duke Medical Center	July 1, 1994
Dayne H. Brown, Director (C) Division of Radiation Protection Dept. of Environment, Health, & Natural Resources	
David Mallette, Code Consultant (C) Engineering Division Department of Insurance	
Billy H. Webster (D) Cary, NC 27511	June 30, 1997
Charles Welby, Ph.D. (C) North Carolina State University Dept. of Marine, Earth & Atmospheric Sciences	June 30, 1995

Jay Osborne, DRP Legal Counsel (E)
Attorney General's Office

Lee Cox, DRP Staff Liaison (E)

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E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

Effective October 1, 1993

RADIATION PROTECTION COMMISSION: NON-IONIZING COMMITTEE

	Term Expires
Wayne R. Thomann, Ph.D. (D) Director of Environmental Safety Duke University Medical Center	June 30, 1997
Dayne H. Brown, Director (C) Division of Radiation Protection Dept. of Environment, Health, & Natural Resources	
Joe A. Elder, Ph.D. (F) U.S. Environmental Protection Agency Health Effects Research Laboratory (MD-51) Research Triangle Park, NC 27711	July 1, 1994
Tim Hitchcock (F) IBM Corporation Research Triangle Park, NC 27709	July 1, 1994
George J. Oliver, Ph.D. (F) Carolina Power & Light Company	July 1, 1994
Daniel D. Sprau, Dr.P.H. (E) East Carolina University Office of Radiation Safety	July 1, 1994
Myron L. Wolbarsht, Ph.D. (F) Dept. of Psychology Duke University	July 1, 1994

Jay Osborne, DRP Legal Counsel (E)
Attorney General's Office

Ben Midyette, DRP Staff Liaison (E)

A= Commission member/state employee
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E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

Effective October 1, 1993

RADIATION PROTECTION COMMISSION

Radioactive Materials Control Committee

	Term Expires
Dayne H. Brown, Director (C) Division of Radiation Protection Dept. of Environment, Health, & Natural Resources	
Gerald R. Fleming, Director (C) Occupational Safety & Emergency Planning Department of Transportation	July 1, 1994
Scott P. Murray (F) General Electric Company Nuclear Fuel & Components Manufacturing	July 1, 1994
Daniel D. Sprau, Dr.P.H. (E) East Carolina University Office of Radiation Safety	July 1, 1994
Robert E. Uhorchak (F) Research Triangle Institute	July 1, 1994
Billy Webster (D) Cary, NC 27511	June 30, 1997
Bobby M. Wilson (E) Radiation Safety Officer UNC-Chapel Hill	July 1, 1994
Jay Osborne, DRP Legal Counsel (E) Attorney General's Office	
J. Robin Haden, DRP Staff Liaison (E)	

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E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

Effective October 1, 1993

RADIATION PROTECTION COMMISSION: X-RAY SURVEILLANCE COMMITTEE

	Term Expires
Charles Barry Burns, MSPH, Chairman (C) Division of Radiologic Science UNC-Chapel Hill	June 30, 1995
Dayne H. Brown, Director (C) Division of Radiation Protection Dept. of Environment, Health, & Natural Resources	
Ronald S. DeMars, D.C. (D) Greensboro, NC 27408	June 30, 1995
Feargus O'Foghludha, Ph.D. (F) Durham, NC 27705	July 1, 1994

Conrad M. Knight, RSO (F) — July 1, 1994
Duke University Medical Center

R. William McConnell, M.D. (D) — June 30, 1997
Dept. of Radiology
East Carolina University School of Medicine

C. Jeff Mauney, D.P.M. (D) — June 30, 1994
Shelby, NC 28150

H. Wayne Mohorn, D.D.S. (D)
Greensboro, NC 27408

Effective October 1, 1993

RADIATION PROTECTION COMMISSION: X-RAY SURVEILLANCE COMMITTEE

Term Expires

Donald A. Tyndall, D.D.S. (C) — June 30, 1997
Dept. of Oral Diagnostics
UNC-Chapel Hill School of Dentistry

David Washburn, Ph.D. (E) — July 1, 1994
UNC-Chapel Hill

Jay Osborne, DRP Legal Counsel (E)
Attorney General's Office

Beverly O. Hall, DRP Staff Liaison (E)

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D= Committee member/private sector; Commission member
E= Committee member/state employee; non-Commission member
F= Committee member/private sector; non-Commission member

Effective October 1, 1993

2. 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).

ANS. The Commission meets two times per year and the Commission's committees meet two to four times per year to address current regulatory and program needs.

E. 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.

1. Please describe the procedures that are in place for the acquisition of technical and vendor services or provide a copy for review.

   ANS. Vendor assistance is available through the state purchasing system.

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.

   ANS. A contrator, Environmental Resources Management (ERM-Southeast) is utilized for the LLRW 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:

1. Other than the communications list, when was the emergency plan last revised?

   ANS. Brunswick - Change 1, Revision 2, September, 1990
   Catawba - Revision 3, December, 1991
   McGuire - Revision 2, January, 1990
   Harris - Change 5, Revision 2, December, 1992

2. If the plan was revised since the last review, what changes were made?

   ANS. See the above list in No.1 for changes.

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?

   ANS. The nuclear power plant emergency response plans are maintained by the Division of Emergency Management, Department of Crime Control and Public Safety and are reviewed by FEMA.

4. When was the emergency communication list last reviewed or revised?

   ANS. October 1993 (DRP Staff)

5. When and how was the plan last tested?

   ANS. DRP participated in two nuclear power plant exercises in 1993. The Shearon Harris exercise was on July 27, 1993 and the McGuire exercise was on October 20, 1993.

B. Budget (Category II)

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

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

			DRH Funds
State general fund			$2362K
a.	Fees		694K
b.	Federal grants and contracts (identify)	EPA	149K
		NRC	70K
c.	Other	DFS Contract	57K
		Adult Health Cont.	65K
d.	Total:		$3397K

2. Show the total amounts in the current DRH budget allocated for the following (if contract costs are incurred, please include):

		DRH Budget
a.	Administration	$280K
b.	Radioactive materials	$430K
c.	X-ray	$727K
d.	Environmental surveillance	$223K
e.	Emergency planning	$184K

f.	Other (radon,	$149K
	non-ionizing,	$ 17K
	LLRW.	1387K
g.	Total:	$ 3397K

3. What percentage of your radioactive materials program is supported by fees?

   ANS. Approximately one-third.

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.

   ANS. Changes include expanded support for LLRW licensing effort to strengthen the overall program.

5. Overall, is funding sufficient to support all of the program needs? If not, what are the problem areas?

   ANS. Additional money was requested ($275K) for LLRW Contracts.

C. Laboratory Support (Category, II)

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

1. Describe changes in your laboratory support, such as new instruments, cutbacks, etc., in this period.

   ANS. The Division of Laboratory Services performs most of the environmental sample preparation and counting for DRP. DRP staff members perform the majority of the final analyses of results. DRP retains the Mobile Laboratory with its own analytical capabilities.

2. Have there been problems in obtaining timely and accurate lab results? If yes, discuss the circumstances and how the problem might be corrected.

ANS. There continues to be no problems with the accuracy of laboratory results. Earlier in 1993, there was difficulty with the timeliness of the results; however, this appears to be corrected following meetings between DRP and DLS staff.

D. Administrative Procedures (Category II)

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

   ANS. (1) The log system for incidents and misadministrations has been changed. The incidents and misadministrations are now maintained in seperate notebooks to better facilitate information requests. (2) Licenses are now maintained a revisable documents. For medical licenses, this allows us to update the group medical procedures constantly as new products are added.

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.

   ANS. (1) Procedures were added for the use of medical isotopes for purposes other than what was originally intended.

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?

   ANS. The Health Physics Supervisor reviews all licensing actions prior to their departure from DRP. In the situation of a particularly complex license (ie. large pool irradiators, etc.), the application is passed to the Deputy Director for review.

2. Were all license reviewers included in the cases selected for management review? If not, explain.

   ANS. All reviewers receive feedback from management on licensing actions. In the case of the more complex licenses, the applications may be circulated to all reviewers for comment.

3. What audits were made of regional and contract offices?

   ANS. N/A

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:

1. Has the secretarial and clerical support been adequate during this period? If not, explain.

   ANS. (1) Radioactive Materials. The Section lost a good and experienced secretary to private industry in December, 1992. She was replaced by a temporary in December, 1992. Due to the quality of work and "fit" in the work environment, the temp was made permanent on March 1, 1993. Even during the transition,

secretarial and clerical support did not suffer greatly in quantity performed or quality.

2. What word processing, data base, and spread sheet programs are you using?

ANS. (1) Radioactive Materials currently has access to & uses WORDPERFECT 5.1, DBASE IV and LOTUS 123.

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?

ANS. No changes have been made in the way that public information is handled. The volume of PI requests continues to increase as the date for the submission of the LLRW facility application approaches.

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.[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.

Questions:

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[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).

1. 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..

ANS. (1) Radioactive Materials

NAME	DEGREE	OTHER HP EXPERIENCE
Jeff Buaron	BS ENVIRONMENTAL SCIENCE	Rutger's Rad Safety Office, 1yr. State of NJ, BRP, Rad. Physicist III, 4 yrs. State of NJ, BRP, Rad. Physicist, 4 yrs.
Walter Lee Cox, III	BA CHEMISTRY	CP&L, HP RAM shipping tech, procedure writing, regulatory compliance, 3 yrs.
Mark R. Janas	BS Radiologic Science	UNC Hospitals:Quality Control Technologist & Cardiac Cath tech, 3 yrs. UNC Radiation Survey Technician, 1 yrs.
Wendy B. Tingle	BS Radiologic Technology	Arkansas Division of Radiological Control, Health Physicist, 1.5 yrs.

ANS. (1) Low-Level Radioactive Waste Management New Personnel

NAME	DEGREE	OTHER EIPERIENCE
MIKE ROGERS	B.S. AEROSPACE ENGINEERING M.S. AERONAUTICAL ENGINEERING	PROGRAM/ENGINEERING MANAGEMENT, 16 YEARS
JOHN MERCURIO	B.S. MECHANICAL ENGINEERING NAVAL NUCLEAR POWER PLANT TRAINING	CHIEF ENGINEER FOR NAVAL NUCLEAR POWER PLANT, 4 YEARS QUALITY ASSURANCE MANAGER, 1 YEAR
TOM GIROUX	B.S. CIVIL ENGINEERING	CIVIL ENGINEER, 2 YEARS
JAMES ALBRIGHT	B.S. BIOLOGY M.A. GOVERNMENT	RADIOLOGICAL HEALTH & SAFETY TECHNICIAN III, 5 YEARS HEALTH PHYSICIST, 1 YEAR

ANS. (1) Low-Level Radioactive Waste Management Other Technical Personnel

NAME	DEGREE	OTHER EIPERIENCE

ED BURT	B.S., M.S. PH.D. IN GEOLOGY CERTIFIED PUBLIC MANAGER	GEOLOGIST/MANAGER WITH STATE GEOLOGICAL SURVEY, 17 YEARS CHIEF OF LLRW SECTION, 2 1/2 YEARS
DAVID BRYAN	B.S. CIVIL ENGINEERING	NUCLEAR POWER PLANT CONSTRUCTION AND MODIFICATION, 11 YEARS OTHER ENGINEERING IN PRIVATE SECTOR, 2 YEARS ENGINEER LLRW SECTION, 2 YEARS
KATHRYN VELAZAQUEZ	B.S. ENVIRONMENTAL ENGINEERING M.S. RADIOLOGICAL HYGIENE	HEALTH PHYSICIST, 2 YEARS ENVIRONMENTAL RADIATION SPECIALIST, 2 YEARS

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 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.

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%

ANS. (1) Radioactive Materials Section

NAME	POSITION	ADM	LIC	COM	ER	LLW	ENV	FTE
Robin Haden	Chief	50%	20%	15%	5%	5%	5%	1.0
David Howell	HP	20%	15%	55%	5%	----	5%	1.0
Grant Mills	HP	15%	20%	55%	5%	----	5%	1.0
Wendy B. Tingle	HP	20%	40%	25%	5%	----	5%	1.0
Jeff Buaron	HP	40%	30%	20%	5%	----	5%	1.0
Walter Lee Cox, III	HP	15%	10%	10%	5%	60%	----	1.0
Mark R. Janas	HP	15%	20%	55%	5%	----	5%	1.0

ANS. (1) Low-Level Radioactive Waste Management

NAME	POSITION	ADM	LIC	COM	ER	LLW	ENV	FTE
Ed Burt	Chief	---	---	---	---	100%	---	---
Mike Rogers	Envir. Engineer II	---	---	---	---	100%	---	---
David Bryan	Envir. Engineer I	---	---	---	---	100%	---	---
John Mercurio	Envir. Engineer I	---	---	---	---	100%	---	---
Tom Giroux	Envir. Engineer I	---	---	---	---	100%	---	---
James Albright	Health Physicist	---	---	---	---	100%	---	---
Kathryn Velazquez	Envir. Radiation Specialist	---	---	---	---	100%	---	---

2. Is the staffing level adequate to meet normal and special needs and backup? If not, explain.

ANS. (1) Radioactive Materials. Staffing level is currently adequate for our needs;however, the LLRW project will make use of valuable resources.

ANS. (1) Low-Level Radioactive Waste Management. Staffing level is adequate; significant contractor resources are available for unexpected vacancies.

3. Do you currently have vacancies? If so, when do you expect to fill them?

ANS. (1) Low-Level Radioactive Waste Management. LLRW Health Physicist in Administrative Section 1/2 FTE for LLRW Program to be filled first quarter 1994.

ANS. (1) Radioactive Materials. The RAM section is currently fully staffed.

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:

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

ANS. (1) Radioactive Materials.

Robin Haden,	Monitor all personnel
David Howell,	Monitor inspection priorities and participate in the on-the-job training of new personnel.
Grant T. Mills,	Monitor inspection priorities and handling of incidents and participate in the on-th-job training of new personnel.
Wendy B. Tingle,	Monitor licensing priorities, monitor inspection priorities and participate in the on-the-job training of new personnel.

ANS. (1) Low-Level Radioactive Waste Management.

Ed Burt	Monitor all personnel.
Mike Rogers	Monitor license review process.
David Bryan	Monitor engineering design/construction review.
John Mercurio	Monitor Quality Assurance activities.

D. Training (Category II)

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

Questions:

1. 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

ANS. (1) Radioactive Materials

STUDENT	COURSE	SPONSOR	DATES
JANAS, Mark	Medical Uses	NRC	3/8-12/93
"	Indus. Radiography	NRC	5/17-5/21/93
"	5 Week HP Course	NRC	7/19-8/20/93
"	LLW Transport Wkshp	SE Compact States	9/29 - 9/30/93
COX, Walter Lee	Inspection Procedures	NRC	4/19-4/24/93
"	Indus. Radiography	NRC	7/26-7/30/93
"	Medical Uses	NRC	3/8-3/12/93
TINGLE, Wendy	Indus. Radiography	NRC	8/92
"	5 Week HP Course*	NRC	2/92-3/92
"	RERO*	FEMA	4/92
"	LLW Transp. Wksp.	SE Compact States	9/29-9/30/93
MILLS, Grant	Intro. to Licensing	NRC	5/11-5/15/92
"	RERO	FEMA	9/30-10/9/92
"	Rad. Prot. Engineer.	NRC	12/7-12/11/93
"	10 CFR Pt. 20	NRC, Region II	8/3-8/4/93
BUARON, Jeffrey	5 Week HP Course	NRC	2/1-3/5/93
"	Inspection Procedures	NRC	4/19-4/24/93
"	Materials Licensing	NRC	6/14-6/18/93

"	Nuclear Medicine	NRC	8/23-8/27/93
HADEN, J. Robin	10 CFR Part 20 Workshop(s)	NRC Texas	2/92,8/93 12/93
"	Special Topics Wkshp	NRC	9/92
"	All Agreement States Meeting(s)	NRC	10/92 10/93
"	LLRW Workshop	NRC	7/93
"	Manager's Workshop	NRC	8/93
"	14th DOE Conference	DOE	11/92
HOWELL, David	Special Topics Wkshp	NRC	8/23-8/25/93
"	REAC/TS	DOE	9/14-9/18/93

* - Training completed while employed in Arkansas.

ANS. (1) Low-Level Radioactive Waste Management.

STUDENT	COURSE	SPONSOR	DATES
BURT, ED	13TH DOE CONFERENCE	DOE	11/91
"	LICENSE REVIEW TRAINING	DOE	3/92
"	CONTRACT MANAGEMENT	DOE	5/92
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	2/93
ROGERS, MIKE	14TH DOE CONFERENCE	DOE	11/92
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	2/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	11/93
BRYAN, DAVID	13TH DOE CONFERENCE	DOE	11/91
"	LICENSE REVIEW TRAINING	DOE	3/92
"	ENGINEERING/CONCRETE VAULTS, TOUR SRL	DOE	9/92
"	FUNDAMENTALS OF MANAGEMENT	NC PERSONNEL	1/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	2/93
"	ASCE CONFERENCE	ASCE	10/93
"	ENGINEER-IN-TRAINING REVIEW	NCSU	3/93-10/93

"	QUALITY ASSURANCE	DRP CONTRACTOR	10/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	11/93
MERCURIO, JOHN	QA TRAINING	DRP CONTRACTOR	10/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	11/93
GIROUX, TOM	ENGINEERING/CONCRETE VAULTS, TOUR SRL	DOE	9/92
"	14TH DOE CONFERENCE	DOE	11/92
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	2/93
"	ACI SEISMIC DESIGN/CONCRETE	ACI	3/93
"	NRC ANNUAL LLRW WORKSHOP	NRC	7/93

STUDENT	COURSE	SPONSOR	DATES
GIROUX, TOM	CENTER DE'L'AUBE TOUR	DSIN	9/93
"	ASCE CONFERENCE	ASCE	10/93
"	ENGINEER-IN-TRAINING REVIEW	NCSU	3/93 - 10/93
"	QA TRAINING	DRP CONTRACTOR	10/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	11/93
ALBRIGHT, JAMES	MEETING FACILITATION SKILLS TRAINING	DOE	1/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	2/93
"	QA TRAINING	DRP CONTRACTOR	10/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	11/93
VELAZQUEZ, KATHRYN	LICENSE REVIEW TRAINING	DRP CONTRACTOR	2/93
"	RESRAD COURSE	DOE	6/93
"	QA TRAINING	DRP CONTRACTOR	10/93
"	LICENSE REVIEW TRAINING	DRP CONTRACTOR	11/93

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

ANS. Mark Janas needs the Licensing and Inspection Courses. Lee Cox needs the 5 Week course and the Licensing course; however, he will be assigned to the LLRW Project for the next 12-15 months.

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:

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

ANS. (1) Radioactive Materials.
Allen M. Mabry - Private industry position
J. Todd Whitaker - Private industry position

ANS. (1) Low-Level Radioactive Waste
Patrick Watters - Promotion within state government
David Lee - Private industry position

V. LICENSING

A. Technical Quality of Licensing Actions (Category I)

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

1. 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:

   - o 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
   - o Other Licenses With a Potential Significance for Environmental Impact

   The table heading should be:

   Licensee Name License Number License Type Action

ANS. (1) Radioactive Materials

LICENSEE NAME	LICENSE NUMBER	LICENSE TYPE	ACT.
Duke University	032-0247-1	Broad, Academic	N/A
East Carolina University	074-0296-1	Broad, Academic	N/A
NC State University	092-0090-3	Broad, Academic	N/A
UNC-Chapel Hill	068-0214-1	Broad, Academic	N/A
Burroughs Wellcome	032-0368-1	Broad, Academic	N/A
Ciba-Geigy	041-0450-1	Broad, Academic	N/A
General Electric	065-0317-1	Broad, Academic	N/A
Glaxo	032-0779-1	Broad, Academic	N/A
Process Technology	001-0701-1	Pool Irradiator	N/A
Charlotte Meck Hosp Auth	060-0014-3	Broad, Medical	N/A
Duke University Med Ctr	032-0085-3	Broad, Medical	N/A
East Carolina University	074-0296-3	Broad, Medical	N/A
NC Baptist Hospital	034-0358-1	Broad, Medical	N/A
UNC Hospitals	068-0565-1	Broad, Medical	N/A
Security Engineering	034-0358-1	Mfg & Dist	N/A
Yale Security	090-0732-1	Mfg & Dist	N/A
Axiom Research Corp	092-0849-1	Mfg & Dist	TERM

Computec Diagnostics	001-0561-1	Mfg & Dist	N/A
Organon Teknika Corp	032-0808-3	Mfg & Dist	STOR
Strandberg Engr Labs	041-0523-1	Mfg & Dist	N/A
Humboldt Scientific	092-0750-1	Mfg & Dist	N/A
SRB Technologies	034-0534-1,-2,-3	Mfg & Dist	N/A
Troxler Electronic	032-0182-1	Mfg & Dist	N/A
Centurion Systems	041-0897-1	Mfg & Dist	N/A
Law Enforcement Assoc	092-0870-1	Mfg & Dist	TERM
Sirchie Finger Print	092-0862-1	Mfg & Dist	TERM
NC Nuclear Pharmacy	041-0780-1	Nuclear Pharmacy	N/A
Photon Imaging	092-0780-2	Nuclear Pharmacy	N/A
Gamma RX	011-0780-3	Nuclear Pharmacy	N/A
Syncor International	060-0794-1	Nuclear Pharmacy	N/A
Research Triangle Inst	032-0131-1	R & D	N/A
Duke Power	060-0379-4	Utility	N/A
Duke Power	060-0379-7	Utility	N/A
IDIS	001-0944-1	Mobile NM	NEW
CIIT	032-0551-1	R & D	N/A
Abbott Laboratories	064-0969-1	Pool Irradiator	NEW
Charlotte Meck Hosp Auth	060-0014-A2	Cyclotron	NEW
Southeastern Diagnostics	060-0971-1	Mobile NM	NEW

2. Identify any major, unusual, or complex licenses issued or renewed in this period.

   ANS. (1) Carolinas Medical Center - Cyclotron License
   (2) Abbott Labs - Pool Irradiator
   (3) IDIS - Mobile Nuclear Medicine
   (4) Southeastern Diagnostic - Mobile NM

3. Have any new or amended licenses affected the list of licensees requiring contingency plans?

   ANS. We are currently reviewing the licensees that could be required to have contingency plans.

4. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the period.

   ANS. No variances have been issued since the last review.

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:

1. 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 Registry Number	Manufacturer, Distributor or Custom User	Type of Device or Source	Indicate if NARM	Indicate if Agreement Material

SS&D NO.	MFG, DIST OR USER	DEVICE OR SOURCE	NARM?	AGREEMENT MATERIAL?
NC646D135B	TROXLER	MODEL 3242 ASPHALT CONTENT GAUGE	NO	YES Cf-252
NC646D136S	TROXLER	Model 4430 Asphalt/ Water Content Gauge	NO	YES Am-241 Cs-137

2. List the applications for SS&D registrations for which registry documents have not yet been issued.

ANS. We have 2 general license device distributors that are developing their own SS&D registry sheets. They are re-distributing devices mfg by ATI.

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.

ANS. None.

C. 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 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:

1. 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?

   ANS. (1) Radioactive Materials. The Part 20 conforming amendment to the regulations has prompted us to begin revising licensing procedures to assist applicants in preparing their packages and us in their review.

   (2) Low-Level Radioactive Waste. License Application Review Management Plan and associated procedures, Quality Assurance Plan and associated procedures, site access rules.

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:

Licensee Name	Insp. Freq. (Years)	Due Date	Months O/D

ANS. There are no licenses overdue by 50%.

2. 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 their scheduled frequency , or

   (2) inspections with lower inspection frequencies that are overdue by more than 100% of their 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.

   ANS. Due to the low number of overdue inspections, the plan to reduce the backlog remains unchanged. The licenses overdue for inspection are priority one. Some licenses become overdue because of their physical location. Outlying areas of the State are not visited as frequently and a license will often have to wait for other licenses in the area to become due for inspection. This generally still will not result in a delay of 50% of the inspection. The Health Physics Supervisor reviews the list of inspections that are due to assist in prioritizing.

3. How many on-site close-out inspections prior to license termination were made during the reporting period?

   ANS. None.

4. How many on-site close-out inspections are pending at this time?

   ANS. None.

5. How many reciprocity notices were received in the reporting period?

ANS. 26 companies have been granted reciprocity in the state so far in FY 93-94. 41 companies were issued reciprocity for FY 92-93.

6. How many reciprocity inspections were conducted?

ANS. FY 92-93: 10
FY 93-94: 5

7. Other than reciprocity licensees, how many field inspections of radiographers were performed?

ANS. FY 92-93: 14
FY 93-94: 23

8. What percentage is this of your total number of radiographer licensees?

ANS. 100%

B. Inspection Frequency (Category I)

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

Questions:

1. 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.

ANS. Due to the number of field inspections performed on industrial radiography operations, the inspection frequency is higher than the regulations require. Any licensee that has an identified problem (through inspections or other means) can be subjected to more frequent and unannounced inspections.

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 guides.

Questions:

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

Supervisor Inspector License Category Date

ANS.

SUPERVISOR	INSPECTOR	CATEGORY	DATE
Robin Haden	David Howell	ACCELERATOR	08/31/93
Robin Haden	Grant Mills	PORTABLE GAUGE	10/11/93
Robin Haden	Wendy Tingle	MEDICAL FACILITY	11/01/93
Robin Haden	Lee Cox	PORTABLE GAUGE	06/16/93
Robin Haden	Mark Janas	MEDICAL FACILITY	06/25/93

Additional accompaniments were made by the senior staff during the training of the new inspectors.

2. Were all inspectors accompanied at least annually by the compliance supervisor during the reporting period? If not, explain.

ANS. No. All inspectors were not accompanied each year during the last review period. As new HP Supervisor (since May, 1992), the first several months were dedicated to learning my new job. As of January, 1993, all inspectors that are authorized to perform independent inspections have been accompanied. It is my intention to continue this practice even though I interact constantly with staff both personally and through review of inspection reports.

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 time-study measurements (normally within a few days). Investigation (or inspection) results should be documented and enforcement action taken when appropriate. State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures). Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency. The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Questions:

1. 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?

      ANS. Other affected licensees would be notified as soon as the agency noted a problem. They would be notified by telephone and in writing.

   b. Was the NRC notified?

      ANS. The NRC would be notified; however, the incident that we have bee working on came to our attention through the NRC to begin with.

2. 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.

   ANS. The incident involved one of our licensees and we are currently following up on the possibility of generic design deficiency.

3. If the RCP utilized medical or technical consultants for an emergency during the reporting period, please describe the circumstances for each case.

   ANS. The Agency has available volunteers through the TOREV network. In some cases, these volunteers are able to access an incident scene before a DRP staff member. This is particularly useful in cases of scrap metal alarms in that the trained volunteers can initiate the CRCPD exemption form.

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.

   ANS. None

5. 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.

   ANS. Applicants are advised of the requirements during the licensing process. When licenses are delivered or inspected, the licensee is reminded of the importance of reporting of such data.

7. Please have copies of all misadministrations and events available for dicsussion and review.

   ANS. All files will be available.

E. 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.

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.

   ANS. One order has been issued since the last review. The order was against a pair of roofing companies that had loose claims to the same gauge. As a result of the order, DRP took possession of the gauge and is in the process of disposing of it.

2. Discuss changes made in the enforcement procedures during the reporting period.

   ANS. The enforcement procedures for DRP are currently under review. We still retain the Statuatory Authority to levy administrative penalties.

3. Briefly describe the enforcement program used to regulate permittees that transfer radioactive waste to the LLW site.

F. 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 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?

   ANS. The inspection procedures remain essentially the same. The majority of home office inspections are performed on an announced basis. Field radiography and reciprocity inspections are still performed on an unannounced basis. Confirmatory (follow-up) inspections of 'problem' licensees can be performed unannounced.

G. 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 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:

1. What changes were made in the formats of your reports or inspection forms during this period?

   ANS. No major changes have been made to the inspection forms and reports since the last program review. Several of the technical staff have taken advantage of notebook computers to generate inspection reports. The format being used is identical in content, but it appears compressed.

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 μc/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" meters with audio signal for searching for lost gamma emitter sources.)

Questions:

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

   ANS. No changes.

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, 1992

(Also, please provide on a seperate chart the following information for 1993 through November)

*1. How many specific licenses are currently in effect? 600

2. During the last calendar year,

   a. how many new licenses were issued? 33

   b. how many licenses were terminated? 15

   c. how many licenses were renewed? 27

   d. how many amendments were issued? 526

   e. how many SS&D evaluations were completed? 1

3. How many prelicensing visits were made during this past calendar year? 6

4. How many new licenses (or major amendments) were hand delivered to the licensee? 24

5. How many materials incidents, other than unfounded allegations, occurred during the last calendar year? 25

6. How many on-site investigations of incidents were conducted during the last calendar year? 6

*7. How many incidents required NRC notification, either by telephone or by written report? 1

*8. How many of the incidents required Abnormal Occurrence Reports? 0

*9. How many of the incidents involved leaking from sealed sources? 1

*10. How many misadministrations occurred during the last calendar year? 22

11. How many civil penalties were imposed during the last calendar year? 0

12. How many orders were issued during the last calendar year? 1

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

Radioactive materials program?	ANS. 7
Low-Level waste program?	ANS. 8
Uranium mills program?	ANS. 0

*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.

ANS. 6.4 persons per 6.0 hundred licenses = 1.07

*15. List the RCP salary schedule as follows:

Position Title	Annual Salary Range
Division Chief	43,339 to 70,647
Deputy Div. Chief	37,787 to 61,456
H.P. Supervisor	32,986 to 53,462
LLRW Supervisor	31,507 to 51,056
Environmental Engineer II	32,986 to 53,462
Environmental Engineer I	30,125 to 48,726
Environmental Radiation Specialist	28,876 to 46,538
Health Physicist (7)	28,876 to 46,538

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

(Editorial: The State utilizes a different system for assigning license categories, and the reviewer advised the State not to revise the system until the new "National Performance Review Indicators" have been established. Then the State will consider revising the categories. The categories that the State does not utilize are red lined below, and the State reported no inspection backlogs for the calendar years 1992 and 1993.)

Academic Type A Broad
Academic Type B Broad
Academic Type C Broad
Academic Other
Medical Institution Broad
Medical Institution Limited

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

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

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

License Category	No. of Licenses	Insp. Freq. (years)	No. Insp. Made	No.* Overdue Insps.
Ind. Radiography Temp. Site only				
Irradiators Self Shielded (Less Than 10000 Curies)				
Irradiators Other (Less Than 10000 Curies)				
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.

PART IIA
PROGRAM STATISTICS

For calendar year 1993 to date November, 1993

*1. How many specific licenses are currently in effect? 579

2. During the last calendar year,

   a. how many new licenses were issued? 55

   b. how many licenses were terminated? 13

   c. how many licenses were renewed? 18

   d. how many amendments were issued? 395

   e. how many SS&D evaluations were completed? 1

3. How many prelicensing visits were made during this past calendar year? 0

4. How many new licenses (or major amendments) were hand delivered to the licensee? 29

5. How many materials incidents, other than unfounded allegations, occurred during the last calendar year? 22

6. How many on-site investigations of incidents were conducted during the last calendar year? 2

*7. How many incidents required NRC notification, either by telephone or by written report? 0

*8. How many of the incidents required Abnormal Occurrence Reports? 0

*9. How many of the incidents involved leaking from sealed sources? 0

*10. How many misadministrations occurred during the last calendar year? 25

11. How many civil penalties were imposed during the last calendar year? 0

12. How many orders were issued during the last calendar year? 0

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

Radioactive materials program?	ANS. 7
Low-Level waste program?	ANS. 8
Uranium mills program?	ANS. 0

*13. 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.

ANS. 6.4 persons per 6.0 hundred licenses = 1.1

*14. List the RCP salary schedule as follows:

Position Title	Annual Salary Range
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Health Physicist (7)	28,876 to 46,538

*15. 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 TYPE	PROGRAM CODE	NUMBER LICENSES	PRIORITY YEARS	#INSPECT
Medical Inst., In vivo	00	3	04	1
Medical Inst.	01	54	02	26
Medical Inst. & Sealed Sources	02 38	02	19	
Medical Inst., Sealed Only	03	15	02	7
Medical Inst., Teletherapy	04	2	01	2
Medical, Broad	05	5	01	5
Medical Inst., Pacemaker	06	5	02	2
Medical, Private	11	28	02	13
Medical, Private & Sealed	12	8	02	4
Private, Sealed Only	13	12	02	7
Private, Teletherapy	14	1	01	1
Private, Mobile NM	15	2	01	2
Portable Gauges	20	88	03	27
Fixed Gauges	21	81	03	23
Industrial, other	22	30	03	9
Industrial, Broad	23	6	01	6
Industrial, Irradiator	24	2	01	2
Radiography, fixed only	30	4	01	4
Radiography, field only	31	11	01	11
Radiography, fixed & field	32	3	01	3
Manufacturing only	40	3	02	2
Mfg. & Dist.,GL	41	4	02	2
Mfg. & Dist.,Specific	42	4	02	2

LICENSE TYPE	PROGRAM CODE	NUMBER LICENSES	PRIORITY YEARS	#INSPECT
Dist. only, GL	43	3	02	2
Dist. only, Specific	44	4	01	4
Laboratory, In Vitro	50	3	04	1
Laboratory, R&D	51	26	02	11
Laboratory, Analytical	52	14	03	4
Laboratory, Irradiator		53	8	02 4
Laboratory, GC	54	19	03	5
Laboratory, Other	55	4	03	2
Services, Leak Testing	61	8	04	2
Services, Other	62	2	04	1
Services, Calibration	63	4	02	2
Services & Dist. CG Cells	64	2	02	1
Educational, Broad	70	4	01	4
Educational, Instructional	71	15	02	6
Educational, Irradiator	72	7	02	3
Educational, R & D	73	10	02	6
Educational, Other	74	3	03	1

Educational, GC	75	1	02	0
Government, Portable Gauge	80	15	03	4
Government, Ind. Radiography	81	1	01	1
Government, GC	82	8	03	3
Government, Analytical	84	7	03	3
Government, Civil Defense	85	2	03	1
Government, In Vitro	86	2	03	1
Government, Other	87	2	02	1
Demonstrations	90	2	03	1
General Licenses	635	04		

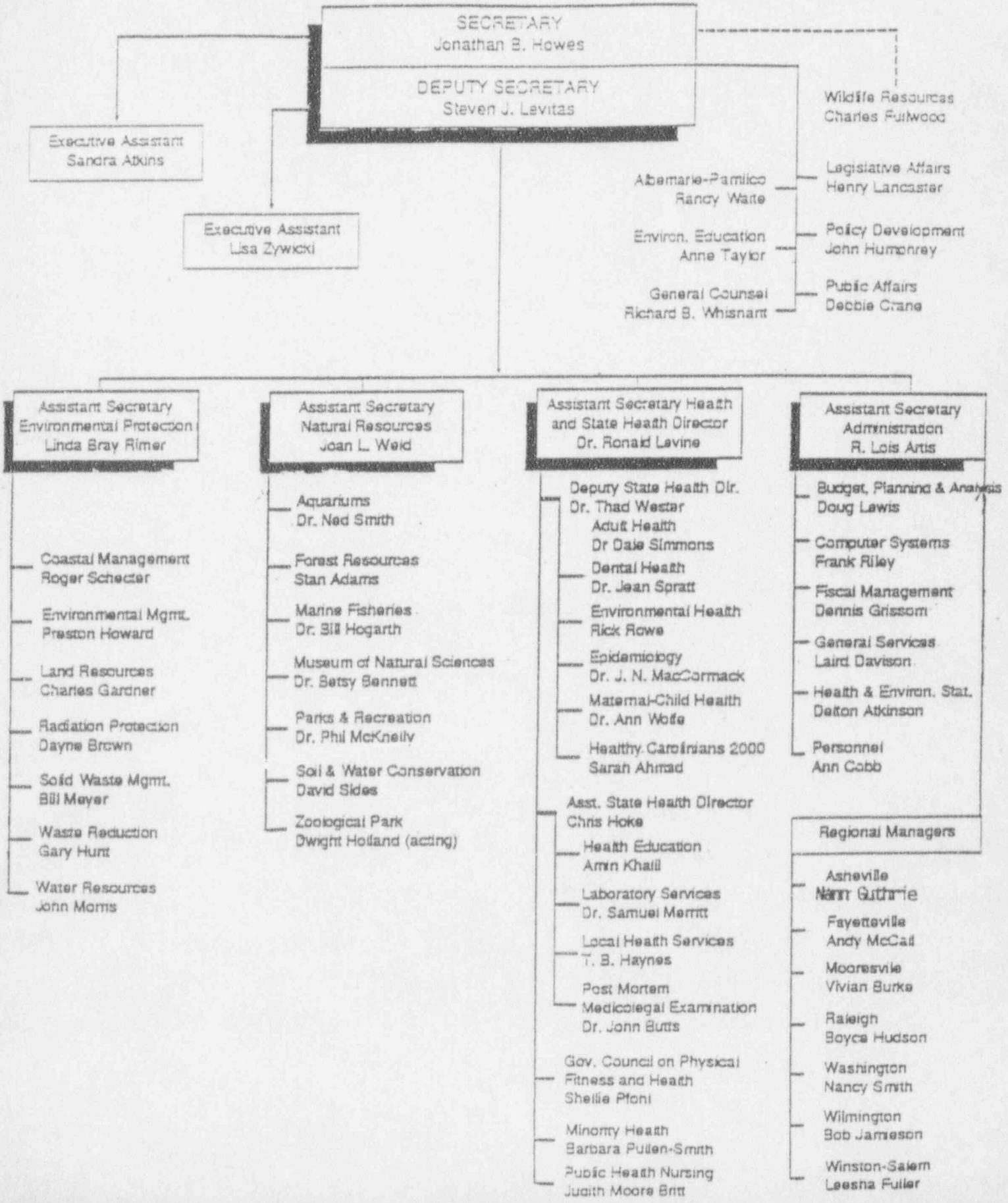
APPENDIX B

ORGANIZATION CHARTS

Secretary Howes reports to the Governor of North Carolina, James B. Hunt, Jr.

Department of Environment, Health, & Natural Resources

Organization Chart



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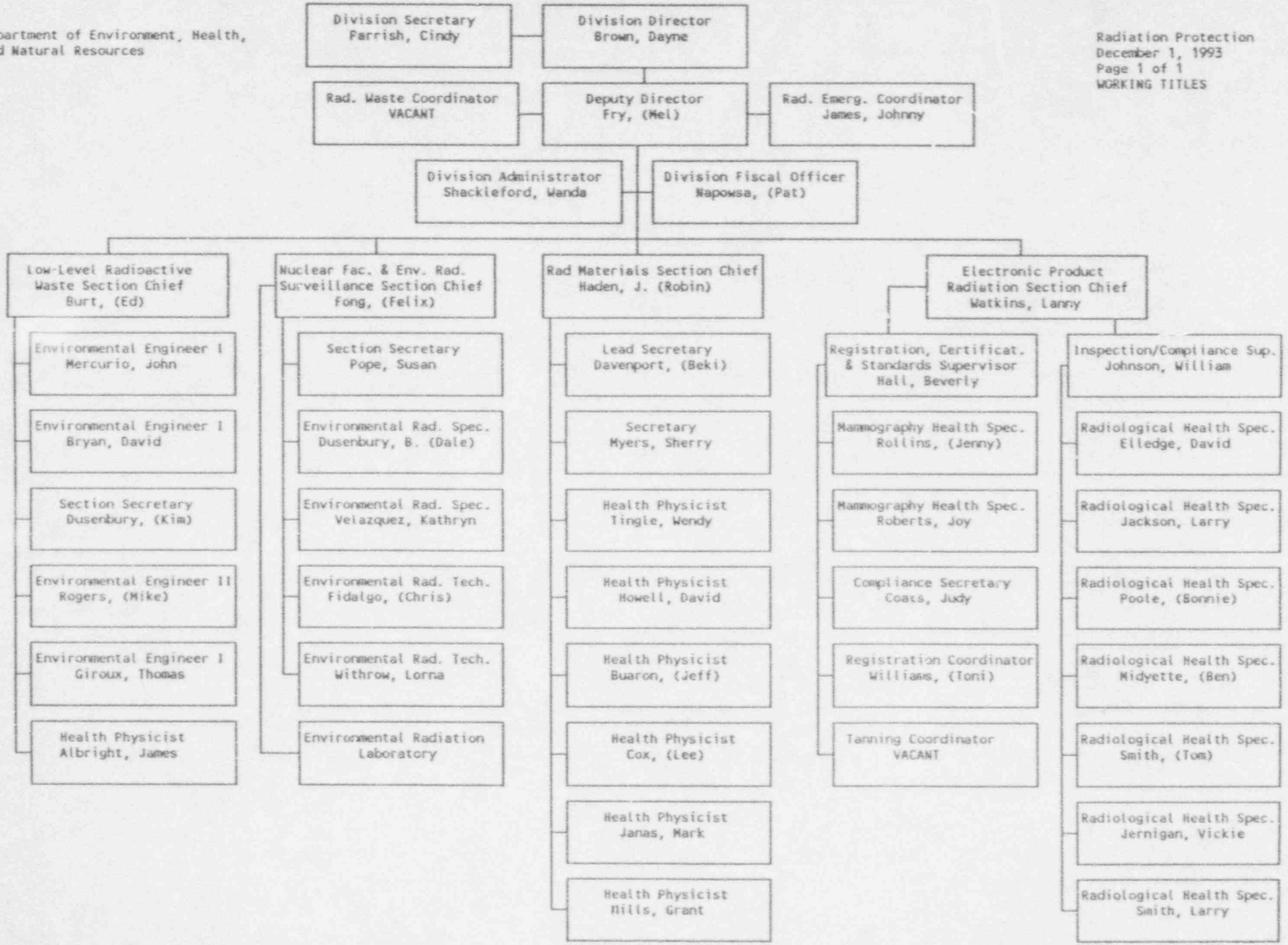

APPENDIX C

REVIEWER EXPLANATORY COMMENTS AND OBSERVATIONS

The following Indicator assessments, comments and recommendations were developed during the review. They are based upon the Appendix A Questionnaire, discussions with the Program staff members, observations, casework file reviews, and inspector accompaniments.

I. LEGISLATION AND REGULATIONS

A. Legal Authority (Category I)

Assessment:

There have been no changes to the State's statutory authority for the regulation of radioactive materials since the last review, and the requirements of this Indicator have been satisfied.

No comments or recommendations were offered under this Indicator.

B. Status and Compatibility of Regulations (Category I)

Assessment:

The State's regulation amendments were reviewed for compatibility as they were processed through the rule adoption administrative process. The July 1993 edition of the State's "Regulations for Protection Against Radiation" was also spot checked for compatibility and uniformity.

The State will not have not have regulations that are compatible with NRC's regulations on January 15, 1994.

Comment:

The State's regulations are compatible with the NRC regulations up to the 10 CFR Part 34 amendments on "Safety Requirements for Industrial Radiographic Equipment" that became effective on January 10, 1991.

The following regulations were identified during the review as being needed for compatibility and have been drafted by the State:

- "Safety Requirements for Industrial Radiography Equipment" 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991 and will be needed by January 10, 1994.
- "Notification of Incidents", 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) that became effective on October 15, 1991 and will be needed by October 15, 1994.
- "Quality Management Program and Misadministrations", 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992 and will be needed by January 27,1995.

State regulations equivalent to the regulations identified above are being drafted. The State has plans to present the revised Industrial Radiography regulations to the Radiation Protection Commission for "emergency adoption" during the February 1994 Commission meeting. The State projects that all of the above identified regulations will be fully adopted by July of 1994.

Recommendation:

We recommend that the State continue with their plans for adoption of the "Safety Requirements for Industrial Radiographic Equipment" and the other regulations that are needed for compatibility.

II. ORGANIZATION

A. Location of the Radiation Control Program Within the State Organization (Category II)

Assessment:

There have been no changes to the location of the RCP within the State Organization as provided in Appendix B. The RCP satisfies the requirements of this Program Indicator.

No comments or recommendations were offered under this Indicator.

B. Internal Organization of the RCP (Category II)

Assessment:

There have been no changes in the internal organization of the RCP as provided in Appendix B. The State satisfies the requirements of this Indicator.

No comments or recommendations were offered under this Indicator.

C. Legal Assistance (Category II)

Assessment:

The RCP has utilized legal assistance as needed, and the Attorney General's Office has assigned a full time attorney to the Department beginning January 1, 1994. The State satisfies the requirements of this Indicator.

No comments or recommendations were offered under this Indicator.

D. Technical Advisory Committees (Category II)

Assessment:

The Radiation Control Program (RCP) has established a Radiation Protection Commission consisting of ten "ex officio members" and eleven "voting public members" that meet two times per year. The minutes of the last two meetings were reviewed. The RCP satisfies the requirements of this Indicator.

No comments or recommendations were offered under this Indicator.

E. Contractual Assistance (Category II)

Assessment:

The contractual assistance procedure was discussed verbally with the Low Level Radioactive Waste (LLRW) Section Chief, and the State appears to meet the requirements of this guideline.

No comments or recommendations were offered under this indicator.

III. MANAGEMENT AND ADMINISTRATION

A. Quality of Emergency Planning (Category I)

Assessment:

The RCP has been involved in numerous Emergency Exercises since the last review and the communication list has been updated. The RCP satisfies the requirements of this Guideline Indicator.

No comment or recommendation was offered under this Indicator.

B. **Budget (Category II)**

Assessment:

The materials program is 33 percent funded by fees and these funds are credited to a special fund. The RCP satisfies the requirements of this guideline indicator. The State has plans for the re-evaluation of the fee schedule.

No comment or recommendation was offered under this indicator.

C. **Laboratory Support (Category II)**

Assessment:

The State has a TLD monitoring contract with the NRC and the performance under the contract is assessed by Region II. There were no problems identified with the States' capabilities for Radiological assessment. The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

D. **Administrative Procedures (Category II)**

Assessment:

The internal procedures were reviewed and discussed with the Section Chief and the technical staff. Special attention was given to the review of the procedures for handling confidential information, anonymous complaints, incident tracking, misadministrations, and enforcement procedures. The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

E. **Management (Category II)**

Assessment:

Based upon the discussions with Program managers and staff, the review of reports, procedures, technical references, and the review of the technical casework (Appendices D and E), the requirements of this guideline indicator are being satisfied.

No comment or recommendation was offered under this indicator.

F. **Office Equipment and Support Services (Category II)**

Assessment:

The RCP appears to have an excellent administrative support staff and the computer system is being upgraded to a local area network. The RCP satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

G. **Public Information (Category II)**

Assessment:

The State operates under an "open records" law whereby "proprietary" information can be withheld as appropriate. The State does not operate under "sunset" provisions. The RCP satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

IV. PERSONNEL

A. Qualifications of Technical Staff (Category II)

Assessment:

The qualifications of the technical staff were reviewed and all meet the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

B. Staffing Level (Category II)

Assessment:

Based upon the projected staffing needs in the radioactive materials program, the State does not fully satisfy the requirements of this guideline indicator.

Comment:

Although the Program managers and staff have done an excellent job in filling the Materials Section vacancies, training new employees, and performing complex regulatory actions with a relatively small staff, we believe that additional staffing is needed.

The radioactive materials technical staffing level should be approximately 1 to 1.5 person-years per 100 licenses in addition to the technical staffing for the Low Level Radioactive Waste project. The current staffing level for the materials program is about 1.1 persons per 100 licenses. This level of staffing is marginal for the following reasons: additional trained technical materials staff and senior personnel will be needed for support of the LLRW project; the number of major, complex license applications continues to increase which requires additional work by the fully trained technical staff; the materials program currently looses an average of one senior, fully trained technical staff member per year; and replacement of technical personnel requires at least one year for the hiring and training of personnel to perform independent evaluation and inspection of licensee's safety programs.

Recommendation:

We recommend that the staffing level be increased to the 1.5 person-years per 100 licenses level.

C. Staff Supervision (Category II)

Assessment:

A review of the training and experience of the senior personnel indicates that the senior personnel are adequate to provide guidance and review the work of junior personnel. The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

D. Training (Category II)

Assessment:

All of the senior personnel have received the required training. The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

E. Staff Continuity (Category II)

Assessment:

A review of the Appendix A questionnaire indicates that the materials program looses about one person per year to private industry. This level of staff turnover does not appear to be excessive. The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

V. LICENSING

A. Technical Quality of Licensing Actions (Category I)

Assessment:

Nineteen license files were selected for casework review. This sample also included file reviews on several of the major licenses and the devices that have been approved since the previous review. The quality of the licensing actions was found to be excellent and only minor comments were developed on the casework. It was noted that license reviewers are also inspectors, and that the quality of work is enhanced by technical management review prior to the documents being issued to the licensee. The casework is listed under Appendix D. The Program does not have a licensing backlog.
The Program satisfies the requirements of this guideline indicator.

No recommendation was offered under this indicator.

B. Adequacy of Product Evaluations (Category I)

Assessment:

Two device registrations were reviewed for this report period and no comments were developed. The RCP satisfies the requirements of this Guideline Indicator.

No comment or recommendation was offered under this indicator.

C. Licensing Procedures (Category II)

Assessment:

The Program essentially utilizes NRC policy guidance and procedures and appears to fully meet the requirements of this guideline indicator. Copies of NRC's standard licensing conditions, and license review checklists were provided to the Program on diskettes during the review.

No comment or recommendation was offered under this indicator.

VI. COMPLIANCE

A. Status of Inspection Program (Category I)

Assessment:

The inspection due listing was reviewed and the Program does not have any inspections that are overdue for inspection. It was noted that all radiography licenses are required to notify the state for each temporary work site, which allows the Program to inspect all radiographer licensees in the field on an unannounced basis, and the licensees are also inspected at their office and isotope storage location during the year. The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

B. **Inspection Frequency (Category I)**

Assessment:

A comparison was made of the inspection frequencies utilized by the State and the Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this indicator.

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

Assessment:

All Inspector accompaniments have been performed by supervision and the RCP satisfies the requirements of this guideline indicator.

All senior inspectors have been accompanied by the reviewer within the past two years. Two Inspector accompaniments and one major licensee visit were performed by the reviewer during this review as follows:

Date:	11-16-93
Inspector:	Mark Janus
Licensee:	Rex Hospital, Inc.
Location:	Raleigh, N.C.
License Number:	092-0160-1
License Type:	Institutional Medical with Brachytherapy

Date:	11-17-93
Inspector:	Windy Tingle
Licensee:	Wake Medical Center
Location:	Raleigh, N.C.
License Number:	092-0297-1
License Type:	Institutional Medical (generator program)

Date:	11-23-92 (visit)
Inspectors:	Robin Haden and Robert Hogg
Licensee:	Abbott Laboratories
Location:	Rocky Mount, N.C.
License Number:	064-0969-1
License Type:	Irradiator, 4.8 mega-curies, cobalt-60, (initial source loading and operational safety checks)

The inspectors were well prepared and conducted the inspection in accordance with State procedures.

No comment or recommendation was offered under this indicator.

D. **Responses to Incidents and Alleged Incidents (Category I)**

Assessments:

All of the incident files for the 1991 and 1992 years have been collected from the State previously for distribution to State Programs and the AEOD. The incidents (to date) for 1993 were reviewed by Ms. Pat Larkins, the file and data systems were reviewed and the back-up information in the license files were reviewed.

The State's incident reporting system with emphasis on medical misadministrations was discussed with the Program Manager and the Program staff.

The RCP maintains logs of misadministrations, complaints, and events along with the summary forms that are used for file documentation. Copies of the procedures for handling complaints misadministrations, and allegations were updated; however, the tracking system is maintained manually and not computerized. The inspectors were observed to make appropriate inquires of licensee staff concerning misadministrations and events during the inspection accompaniments. Also, the inspectors review safety committee minutes, consultant reports, and other records as appropriate to determine if misadministrations have occurred. Records of misadministrations are recorded in the inspection report. The files indicate that 22 events and 25 misadministrations have occurred thus far during the 1993 calendar year.

The reporting requirements for misadministrations went into effect in May of 1991 along with the 1987 version of the SSRCR version of the misadministration rule. In addition, the State has mailed copies of a "Bulletin: Reporting of Misadministrations" (Bulletin Number 93-04) to all Medical licensees dated June 25, 1993.

The Program satisfies the requirements of this guideline indicator.

No comment or recommendation was offered under this Guideline Indicator.

E. **Enforcement Procedures (Category I)**

Assessment:

The enforcement procedures and practices were reviewed, and the RCP satisfies the requirements of this Guideline Indicator.

No comment or recommendation was offered on this Indicator.

F. **Inspection Procedures (Category II)**

Assessment:

The RCP uses essentially the technical inspection guidance utilized by NRC. The RCP satisfies the requirements of this Guideline Indicator.

Twenty compliance files were reviewed as casework during this review and the results are summarized in Appendix E. The inspection procedures contained in MC 2800 and 87100 were provided to the State on diskette for update as appropriate.

No comments or recommendations were offered under this Indicator.

G. **Inspection Reports (Category II)**

Assessment:

Only isolated, minor comments were developed from the re of the inspection reports, and these minor comments were discussed with th chnical staff in a

summary meeting. The RCP satisfies the requirements of this Guideline Indicator.

No comments or recommendations were developed under this Indicator.

H. **Confirmatory Measurements (Category II)**

Assessment:

The inspection reports were reviewed for documentation concerning confirmatory measurements and independent measurements. Also, the Program appears to have sufficient instrumentation for their needs. The RCP satisfies the requirements of this Guideline Indicator.

No comments or recommendations were offered under this Indicator.

APPENDIX D

REVIEW OF SELECTED LICENSE FILES

Nineteen license files were selected for full review. The casework was reviewed in general for: (1) technical adequacy of application review; (2) significant errors and omissions; (3) utilization of licensing procedures; and (4) documentation.

The following licenses were reviewed and for purposes of this report, a numerical casework number was assigned to each license as follows:

Casework No. 01

Licensee:	Gamma Rx
Location:	Arden, NC
License No./Amendment:	011-0780-3, Amendment 6
Date Issued:	09-10-93
Date Expires:	10-31-96
License Type:	Pharmacy

Case Work No.02

Licensee:	Photon Imaging
Location:	Raleigh, NC
License No./Amendment:	092-0780-2, Amendment 6
Date Issued:	10-29-93
Date Expires:	04-30-96
License Type:	Pharmacy

Casework No.03

Licensee:	Syncor International Corporation
Location:	Charlotte, NC
License No./Amendment:	060-0794-1, Amendment 17
Date Issued:	07-16-93
Date Expires:	11-30-96
License Type:	Pharmacy

Casework No.04
Licensee: Charlotte-Mecklenburg Hospital Authority
Location: Charlotte, NC
License No./Amendment: 060-0014-3, Amendment 98
Date Issued: 07-29-93
Date Expires: 12-31-95
License Type: Broad Medical with HDR

Casework No.05
Licensee: N.C. Baptist Hospital (Bowman-Gray)
Location: Winston-Salem, NC
License No./Amendment: 034-0158-1, Amendment 67
Date Issued: 10-01-93
Date Expires: 12-31-95
License Type: Broad Medical

Casework No.06
Licensee: Charlotte Cardiology Associates, Inc.
Location: Charlotte, NC
License No./Amendment: 060-0885-1, Amendment 3
Date Issued: 06-25-93
Date Expires: 09-30-95
License Type: Medical, Private Practice, Cardiology

Casework No. 07
Licensee: Southeastern Diagnostics, Inc.
Location: Charlotte, NC
License No. 060-0971-1
Date issued: 10-18-93
Date expires: 10-31-98
License Type: Medical, Mobile Diagnostic

Casework No. 08
Licensee: Independent Diagnostic Imaging Services, Inc.
Location: Burlington, NC
License No.: 001-0944-1
Date Issued: 05-26-93
Date Expire: 11-30-97
License Type: Medical, mobile diagnostic

Casework No. 09
Licensee: Law Enforcement Associates, Inc.
Location: Raleigh, NC
License No.: 092-0870-1, Amendment 1
Date Issued: 03-09-92
Date Expires: Terminated
License Type: Mfg and Distribution

Casework No. 10
Licensee: Sirchie Finger Print Laboratories
Location: Raleigh, NC
License No.: 092-0862-1, Amendment 1
Date Issued: 03-09-92
Date Expires: Terminated
License Type: Manufacturing and Distribution

Casework No. 11
Licensee: Axiom Research Corporation
Location: Raleigh, NC
License No.: 092-0849-1, Amendment 5
Date Issued: 03-09-92
Date Expires: Terminated
License Type: Manufacturing and Distribution

Casework No. 12
Licensee: Testco, Inc.
Location: Greensboro, NC
License No.: 041-0894-1, Amendment 3
Date Issued: 05-28-93
Date Expires: 01-31-95
License Type: Industrial Radiography, temporary locations

Casework No. 13
Licensee: Atwood & Morrill Co. Inc.
Location: Washington, NC
License No.: 007-0453-1, Amendment 19
Date Issued: 02-05-93
Date Expires: 06-30-95
License Type: Industrial Radiography (Fixed location)

Casework No. 14
Licensee: GAI Consultants, Inc.
Location: Raleigh, NC
License No.: 092-0438-1, Amendment 31
Date Issued: 01-22-92
Date Expires: 01-31-95
License Type: Portable Gauge

Casework No. 15
Licensee: Troxler Electronic Laboratories, Inc.
Location: Research Triangle Park, NC
License No.: 032-0182-1, Amendments 66,67,68,& 69
Date Issued: 03-17-92,06-02-93, 08-06-93. & 08-23-93
Date Expires: 05-31-94
License Type: Manufacturer & Distribution (Device Reviews)

Casework No. 16

Licensee:	Rex Hospital, Inc.
Location:	Raleigh, NC
License No.:	092-160-1, Amendment 60
Date Issued:	11-08-93
Date Expires:	10-31-94
License Type:	Institutional Medical with Brachytherapy

Casework No. 17

License:	Wake Medical Center
Location:	Raleigh, NC
License No.:	092-0297-1, Amendment 67
Date Issued:	06-29-93
Date Expires:	10-31-95
License Type:	Institutional Medical (Generator use)

Casework No. 18

Licensee:	Abbott Laboratories
Location:	Rocky Mount, NC
License No.:	064-0969-1
Date Issued:	09-13-93
Date Expires:	09-30-98
License Type:	4.8 Mega-Curie, Pool Type Irradiator

Casework No. 19

Licensee:	New Hanover Radiation Oncology
Location:	Willmington, NC
License No.:	065-0860-1, Amendment 3
Date Issued:	08-19-92
Date Expires:	01-03-95
License Type:	Private Medical, Brachytherapy

Summary Table

The following table lists the specific comments developed during the review of the numbered casework files above.

	Specific Comments	Casework Number
a.	Additional information is needed to define the licensee's restricted and controlled areas, and the protective measures (clothing, shoes, etc.) that will be utilized inside these areas.	2,
b.	The license distribution condition (14) should be revised to indicate that the authorized distribution is only for the facilities listed in condition 10.	4,
c.	Licensee has not developed a method for counting contamination survey smears.	17,
d.	Licensee was authorized to use CDV-700's and CDV-715 survey meters as the only meters for portable surveys.	17,

APPENDIX E

REVIEW OF SELECTED COMPLIANCE FILES

APPENDIX E

REVIEW OF SELECTED COMPLIANCE FILES

Summary and Conclusion

The State uses a field inspection form to document information obtained during the inspection. In general, the reports were reviewed to determine: (1) if the reports were sufficiently detailed to document that the license's program was sufficient to comply with the rules and regulations, and to protect public health and safety; and (2) if the inspections were complete and substantiated all items of noncompliance and recommendations. The files were reviewed to determine: (1) if appropriate enforcement actions were taken; (2) written in appropriate regulatory language; (3) timeliness of letters; (4) if adequate responses were received from the licensee to close out the enforcement actions.

Twenty license compliance files were selected for review. For purposes of this report, a numerical casework code (1 through 20) was assigned to the following compliance files.

Case No. 01

Licensee:	Gamma Rx
Location:	Arden, NC
License No:	011-0780-3
License Type:	Pharmacy
Inspection Date:	07-21-93
Type of Inspection:	Routine
Inspectors:	Grant T. Mills and David C. Howell
Type of Report:	Form, computer
Enforcement Letter/Date:	Clear, dated 07-21-93
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 02

Licensee:	Photon Imaging
Location:	Raleigh, NC
License No:	092-0780-2
License Type:	Pharmacy
Inspection Date:	01-08-93
Type of Inspection:	Routine, announced
Inspectors:	Grant T. Mills, David C. Howell, Jeffery Buaron
Type of Report:	Form, computer
Enforcement Letter/Date:	NOV dated 01-19-93
Licensee Response Date:	02-19-93
State Acknowledgement Date:	03-09-93

Case No. 03

Licensee:	Syncor International Corporation
Location:	Charlotte, NC
License No:	060-0794-1
License Type:	Pharmacy
Inspection Date:	12-09-92
Type of Inspection:	Routine, announced
Inspectors:	David C. Howell
Type of Report:	Form, narrative
Enforcement Letter/Date:	NOV dated 12-18-92
Licensee Response Date:	01-14-93 and 05-18-93
State Acknowledgement Date:	06-29-93

Case No. 04

Licensee:	Charlotte-Mecklenburg Hospital Authority
Location:	Charlotte, NC
License No:	060-0014-3
License Type:	Broad Medical
Inspection Date:	08-20-92 and 10/7-8/92
Type of Inspection:	Routine, announced
Inspectors:	David C. Howell, Jeffrey J. Buaron
Type of Report:	Form, narrative
Enforcement Letter/Date:	Clear, dated 10-08-92
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 05

Licensee:	N.C. Baptist Hospital (Bowman Gray)
Location:	Winston-Salem, NC
License No:	034-0158-1
License Type:	Broad Medical
Inspection Date:	02/2-5/93
Type of Inspection:	Routine, announced
Inspectors:	Mills, Howell, Tingle, & Cox
Type of Report:	Narrative
Enforcement Letter/Date:	NOV dated 02-15-93
Licensee Response Date:	03-22-93
State Acknowledgement Date:	03-24-93

Case No. 06

Licensee:	Charlotte Cardiology Associates, P.A. Location: Charlotte, NC
License No:	060-0885-1
License Type:	Medical, Private Practice
Inspection Date:	05-18-93
Type of Inspection:	Routine, announced
Inspectors:	Walter Lee Cox, David C. Howell
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 05-26-93
Licensee Response Date:	06-22-93
State Acknowledgement Date:	06-25-93

Case No. 07

Licensee:	Testco, Inc.
Location:	Raleigh, NC
License No:	041-0894-1
License Type:	Industrial Radiography
Inspection Date:	07-08-93
Type of Inspection:	Routine, Announced (Office)
Inspectors:	Mark R. Janus
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 07-14-93 and 09-17-93
Licensee Response Date:	08-14-93 and 09-09-93
State Acknowledgement Date:	09-27-93

Case No. 08

Licensee:	Testco, Inc.
Location:	Raleigh, NC
License No:	041-0894-1
License Type:	Industrial Radiography
Inspection Date:	01-10-92
Type of Inspection:	Routine, Unannounced (Field location)
Inspectors:	David C. Howell
Type of Report:	Form
Enforcement Letter/Date:	Clear, dated 01-10-92
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 09

Licensee:	Atwood & Morrill Co. Inc.
Location:	Washington, NC
License No:	007-0453-1
License Type:	Industrial Radiography (Fixed)
Inspection Date:	12-08-93
Type of Inspection:	Routine, Announced
Inspectors:	Grant T. Mills
Type of Report:	Form, computer
Enforcement Letter/Date:	Pending
Licensee Response Date:	Pending
State Acknowledgement Date:	Pending

Case No. 10

Licensee:	GAI Consultants, Inc.
Location:	Raleigh, NC
License No:	092-0438-1
License Type:	Portable Gauge
Inspection Date:	10-16-92
Type of Inspection:	Routine, announced
Inspectors:	Windy B. Tingle
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 11-09-92
Licensee Response Date:	01-21-93
State Acknowledgement Date:	02-01-93

Case No. 11

Licensee:	Troxler Electronic Laboratories, Inc.
Location:	RTP, NC
License No:	032-0182-1
License Type:	Manufacturing and Distribution
Inspection Date:	06-18-93
Type of Inspection:	Routine, Announced
Inspectors:	Windy B. Tingle & Walter Lee Cox, III
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 06-24-93
Licensee Response Date:	07-13-93
State Acknowledgement Date:	08-06-93

Case No. 12

Licensee:	Rex Hospital, Inc.
Location:	Raleigh, NC
License No:	092-160-1
License Type:	Institutional Medical
Inspection Date:	11-16-93
Type of Inspection:	Routine, announced
Inspectors:	Mark Janus (Woodruff accompaniment)
Type of Report:	Form, computer
Enforcement Letter/Date:	NOV dated
Licensee Response Date:	Pending
State Acknowledgement Date:	Pending

Case No. 13

Licensee:	Rex Hospital, Inc.
Location:	Raleigh, NC
License No:	092-106-1
License Type:	Institutional Medical with Brachytherapy
Inspection Date:	11-05-91
Type of Inspection:	Routine, announced
Inspectors:	Grant T. Mills
Type of Report:	Form, Field
Enforcement Letter/Date:	NOV dated 11-12-91
Licensee Response Date:	12-11-91
State Acknowledgement Date:	12-19-91

Case No. 14

Licensee:	Wake Medical Center
Location:	Raleigh, NC
License No:	092-0297-1
License Type:	Institutional Medical
Inspection Date:	11-17-93
Type of Inspection:	Routine, unannounced
Inspectors:	Windy Tingle (accompanied by Woodruff)
Type of Report:	Computer form
Enforcement Letter/Date:	NOV dated
Licensee Response Date:	Pending
State Acknowledgement Date:	Pending

Case No. 15

Licensee:	Wake Medical Center
Location:	Raleigh, NC
License No:	092-0297-1
License Type:	Institutional Medical
Inspection Date:	11-06-91
Type of Inspection:	Routine, announced
Inspectors:	J. Todd Whittaker
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 11-12-91
Licensee Response Date:	12-12-91
State Acknowledgement Date:	12-19-91

Case No. 16

Licensee:	Abbott Laboratories
Location:	Rocky Mount, NC
License No:	064-0969-1
License Type:	Pool Irradiator
Inspection Date:	11-23-93
Type of Inspection:	Initial source loading
Inspectors:	J.Robin Kaden and Robert Hogg (Woodruff visit)
Type of Report:	Form
Enforcement Letter/Date:	NA
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 17

Licensee:	New Hanover Radiation Oncology
Location:	Wilmington, NC
License No:	065-0860-1
License Type:	Private Medical, Brachytherapy
Inspection Date:	03-01-93
Type of Inspection:	Routine, announced
Inspectors:	Janas, Tingle, & Mills
Type of Report:	Form
Enforcement Letter/Date:	03-17-93
Licensee Response Date:	04-07-93
State Acknowledgement Date:	04-19-93

Case No. 18

Licensee:	Duke University Medical Center
Location:	Durham, NC
License No:	032-0085-3
License Type:	Broad Medical
Inspection Date:	04/12-16/93
Type of Inspection:	Routine, announced
Inspectors:	Tingle, Janus, Cox, Howell, Mills, & Bauron
Type of Report:	Form
Enforcement Letter/Date:	04-27-93
Licensee Response Date:	05-24-93
State Acknowledgement Date:	06-03-93

Case No. 19

Licensee:	Craven Regional Medical Center
Location:	New Bern, NC
License No:	025-0421-3
License Type:	Institutional Hospital
Inspection Date:	02-15-93
Type of Inspection:	Routine, Announced
Inspectors:	Tingle and Janus
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 02-22-93
Licensee Response Date:	04-06-93
State Acknowledgement Date:	04-21-93

Case No. 20

Licensee:	Catawba Memorial Hospital
Location:	Hickory, NC
License No:	018-0292-1
License Type:	Institutional Medical
Inspection Date:	04-05-93
Type of Inspection:	Routine, announced
Inspectors:	Howell and Cox
Type of Report:	Form
Enforcement Letter/Date:	NOV dated 04-21-93
Licensee Response Date:	05-10-90
State Acknowledgement Date:	06-08-93

Summary Table

The following table lists the specific comments developed during the review of the numbered inspection casework files above.

Specific Comments	Case No.
a. Citation was for the wrong regulation (human use license). Also, the contaminated area was in a licensee controlled area, not general public. The licensee and the inspector should take appropriate safety precautions while in potentially contaminated areas.	2,
b. An inadequate response was received from the licensee and a "sticky" note was attached to the response that related "...will send up better response", and dated. The second response was not received until 3 months later, then an acknowledgement letter was sent to licensee. A second letter should have been sent to licensee after the first response documenting the inadequacies, and requesting the additional information.	3,
c. The report was not initialed as having been reviewed by supervision.	3,
d. Citations in letter need to be more specific as to which regulations, conditions, records, etc., were in non-compliance.	3,
e. Inspection report appeared not to have been reviewed by management.	15,