

DATED: APR 6, 1994; SIGNED BY RICHARD BANGART

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 transmit the results of the NRC review and evaluation of the North Carolina radiation control program conducted by Mr. Richard L. Woodruff, NRC Region II State Agreements Officer, and Ms. Patricia Larkins, Technical Analyst, Office of State Programs which was concluded on December 10, 1993. The results of this review were discussed with Ms. Linda Bray Rimer, Assistant Secretary, Environmental Protection, and Mr. Richard M. Fry, Deputy Director, Division of Radiation Protection.

As a result of our review of the State's program and the routine exchange of information between the NRC and the State of North Carolina, we have determined that 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. The program managers and staff have done an excellent job in filling vacancies in the Materials Section and in training new employees. The program has also done an excellent job in performing complex regulatory actions with a relatively small staff.

Given the number of major complex licensing actions faced by the program and historical turnover of fully trained technical personnel, it appears that additional staff may be needed in the materials program. The level of staffing is currently 1.0 person-years per 100 licenses and we recommend that the staffing level for the materials program be increased to offset the technical efforts that will be needed to support the low-level radioactive waste (LLRW) project. Staffing level is a Category II Indicator.

The State's regulations are compatible with NRC's regulations in all respects with the exception of an amendment to 10 CFR Part 34, "Safety Requirements for Radiographic Equipment," (55 FR 843) which was due for adoption by January 10, 1994. Therefore, a finding of compatibility is being withheld. We recommend that the State continue with plans for adoption of this regulation and inform us when this action is completed. Status and Compatibility of Regulations is a Category I Indicator.

We commend the State for the timely adoption of the amendments equivalent to the revised 10 CFR Part 20. We note that the State adopted the amendments in February 1993.

Finally, although not pertaining to the compatibility finding above for this review, I would like to bring to your attention five rules which will need to be adopted by the State in the future. These regulations are:

1. "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) which need to be adopted by October 15, 1994.
2. "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) which need to be adopted by January 27, 1995.
3. "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) which need to be adopted by July 1, 1996.
4. "Licensing Requirements for Land Disposal of Radioactive Wastes," 10 CFR Part 61 (58 FR 33886) which need to be adopted by July 22, 1996.
5. "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 (58 FR 39628) which need to be adopted by October 25, 1996.

An explanation of our policies and practices for reviewing Agreement State programs is attached as Enclosure 1. Enclosure 2 contains our summary regarding the technical aspects of our review of the materials and LLRW programs that were discussed with Mr. Fry and Ms. Robin Haden, Chief, Radioactive Materials Section. We request specific responses from the State with regard to this letter and the Enclosure 2 comments within 30 days of this letter.

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 to be made available for public examination.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
Ms. Linda Bray Rimer, Assistant Secretary
Environmental Protection
Dept. of Environment, Health and
Natural Resources
Mr. Dayne H. Brown, Director
Division of Radiation Protection
Dept. of Environment, Health and
Natural Resources
NRC Public Document Room
State Public Document Room

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NRC Public Document Room
State Public Document Room

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

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North Carolina File

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

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

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

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

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

ENCLOSURE 1

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

SCOPE OF REVIEW

The 19th 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. This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs. The review included discussions with program management and staff, accompaniments of four State inspectors, technical evaluation of selected license 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 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, Technical Analyst, Office of State Programs during the period of December 6-10, 1993 in Raleigh. Field accompaniments of two inspectors were made by Mr. 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. The results of the review were discussed 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. The State's regulations are compatible with NRC's regulations in all respects with the exception of an amendment to 10 CFR Part 34, "Safety Requirements for Radiographic Equipment" (55 FR 843) that became effective on January 10, 1994. Therefore, a finding of compatibility is being withheld.

ENCLOSURE 2

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 30 indicators were reviewed and the State fully satisfies 28 of these indicators. Specific comments on the remaining two indicators are as follows:

1. Status and Compatibility of Regulations (Category I Indicator)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" which were due by January 10, 1994.

In addition, not pertaining to the finding of compatibility for this review, we would like to bring to the State's attention other regulations needed for compatibility. These rules are:

- "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 need to be adopted 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 need to be adopted by January 27, 1995.
- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) which will need to be adopted July 1, 1996.
- "Licensing Requirements for Land Disposal of Radioactive Wastes," 10 CFR Part 61 (58 FR 33886) which will need to be adopted by July 22, 1996.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 (58 FR 39628) which will need to be adopted by October 25, 1996.

Two of the above rule changes ("Notification of Incidents" and "Quality Management Program and Misadministrations") have been drafted by the State. The State plans to adopt these two regulations by July 1994.

Recommendation

We recommend that the State continue with their plans for adoption of the "Safety Requirements for Industrial Radiographic Equipment."

2. Staffing Level (Category II Indicator)

Comment

The program managers and staff have done an excellent job in filling the vacancies in the Materials Section and in training new employees. The program has also done an excellent job in performing complex regulatory actions with a relatively small staff. It appears, however, that additional staff may be 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 1.0 person-years per 100 licenses. (The LLRW program currently has four Environmental Engineers, a Health Physicist, and an Environmental Radiation Specialist.) The level of staffing for the materials program is marginal for the following reasons: the number of major and complex license applications continues to increase which requires additional work by the fully trained technical staff; the materials program currently loses an average of one senior 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. Finally, additional trained technical materials staff and senior personnel will also likely be needed for support of the LLRW project.

Recommendation

We recommend that the staffing level for the materials program be increased to offset the technical efforts that will be needed to support the LLRW project.

LOW-LEVEL WASTE RADIATION CONTROL PROGRAM

A summary regarding the technical aspects of our review of the low-level waste programs is presented below.

I. LEGISLATION AND REGULATIONS

North Carolina has statutes that provide authority for the issuance of regulations for low-level waste (LLRW) management and disposal. There have been no changes in the State's statutory authority to regulate low level waste disposal during this reporting period. In addition, North Carolina has low-level waste regulations compatible with 10 CFR Part 61.

Comment

No comments or recommendations were offered in this area.

II. ORGANIZATION

The North Carolina Low-Level Radioactive Waste Section is located in a position parallel with comparable health and safety programs. The Section Leader has access to the appropriate levels of State management. With regard to a Technical Committee to extend staff capabilities for unique or technically complex problems, North Carolina uses an eight member Low-Level Radioactive Waste Management Committee. This committee consists of representatives from academia, industry and legal.

Comment

No comments or recommendations were offered in this area.

III. MANAGEMENT AND ADMINISTRATION

The North Carolina LLRW program is currently allocated \$1,387,000 per year of the North Carolina budget. The program has 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.

Comment

No comments or recommendations were offered in this area.

IV. PERSONNEL

The North Carolina LLRW program currently is made up of a Section Chief, four Environmental Engineers, a Health Physicist, and an Environmental Radiation Specialist. In the Low-Level Radioactive Waste Management Section, one person is assigned to monitor all personnel; one person monitors the license review process; one person monitors engineering design/construction review; and one person monitors Quality Assurance activities.

Comment

No comments or recommendations were offered in this area.

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.

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 radiography regulations needed for compatibility on January 10, 1994 had been adopted. The reviewer also discussed the staffing level of the Materials Section, 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 the 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 stated that a letter by the end of January 1994 would be appreciated.