

DATED: OCT 29, 1993

Jon R. Rice, M.D.
State Health Officer
North Dakota State Department
of Health and Consolidated
Laboratories
State Capitol Building
Bismarck, ND 58501

Dear Dr. Rice:

This is to confirm the discussion Mr. Robert Doda and Ms. Teresa Darden had with you, and Messrs. Dana Mount and Ken Wangler on June 25, 1993, in Bismarck, North Dakota, as a result of the review and evaluation of the North Dakota radiation control program conducted June 22-25, 1993.

As a result of our review of the State's program and the routine exchange of information between the Nuclear Regulatory Commission (NRC) and the State of North Dakota, the staff determined that the North Dakota radiation control program for the regulation of agreement materials is adequate, at this time, to protect the public health and safety. However, a finding that the program is compatible with the Commission's program is being withheld due to two regulations which have not been adopted within the three-year period allowed by the NRC: (1) emergency plans for certain licensees, and (2) decommissioning requirements.

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.

We are concerned with the State's demonstration of a pattern of lateness in adopting regulations. During the past review in 1991, regulations were noted to be overdue and deficiencies in this area were also noted during this review. For example, the decommissioning rule was due July 27, 1991 and the emergency planning rule was due April 7, 1993 but are scheduled for adoption in January 1994. In addition, four rules will be due by the time of the next review. These regulations are:

(1) "Standards for Protection Against Radiation," 10 CFR Part 20 amendment (56 FR 61352) needed by January 1, 1994; (2) "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) needed by January 10, 1994; (3) "Notification of Incidents," 10 CFR Parts 20, 31, 34, 39, 40, and 70 amendments (55 FR 40757) needed by October 15, 1994; and (4) "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. We are particularly concerned with the State's adoption of the new 10 CFR Part 20. Although the State's equivalent of these rules have been drafted and are scheduled for adoption by January 19, 1994, the NRC has established January 1, 1994, as the date by which NRC licensees shall implement and Agreement States should have the new 10 CFR Part 20 regulations, or its equivalent, established as a final regulation. The State's equivalent to 10 CFR Part 20 regulations is especially important because it includes the basic radiation protection standards, which are used by the NRC and all of the Agreement State radiation control programs. Therefore, we strongly encourage that a concerted effort be made to promulgate the State's equivalent to 10 CFR Part 20 by January 1, 1994, if possible, and in no case later than your currently scheduled January 19, 1994 date.

Uniformity among regulatory agencies is an important part of the Agreement State Program and we urge your staff to make every effort to expedite the final adoption of these rules and the others identified in Enclosure 2. Please inform me within 30-days of this letter of your schedule, including interim milestones, for completing all actions necessary to implement the revisions to your regulations, especially the new Part 20 equivalent.

Overall, there has been improvement in the North Dakota radiation control program. The Division has an adequate number of staff members performing agreement materials work, and there was a timely replacement of two staff members who left the program early during the review period. The Division has also availed itself of a number of training courses for its staff during the review period, with the result that the radiation control staff is becoming well trained in the general requirements of an agreement materials program.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the review findings that were discussed with you and the agreement materials staff on June 25, 1993. As indicated, we request specific responses from the State on the comments in Enclosure 2.

Jon R. Rice, M.D.

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I appreciate the responsiveness of the State of North Dakota and the courtesy and cooperation you and your staff extended to Mr. Doda and Ms. Darden during the review meeting. Also, I am enclosing a copy of this letter for placement in the State Public Document Room or to otherwise be made available for public review.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/enclosures:
see next page

cc w/enclosures:

J. M. Taylor, Executive Director
for Operations, NRC

J. L. Milhoan, Regional Administrator
NRC Region IV

D. K. Rathbun, Director, Office of
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D. Mount, Director
Division of Environmental Engineering
North Dakota Dept. of Health

F. Schwindt, Chief
Environmental Health Section
North Dakota Dept. of Health
State Public Document Room
NRC Public Document Room

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see next page

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*See previous concurrence.

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APPLICATION OF "GUIDELINES FOR NRC REVIEW
OF AGREEMENT STATES 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 one or more 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 the 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 Category I comments are noted as significant, 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 for improvement in particular program areas is critical. The NRC would request an immediate response. 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.

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. 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.

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE NORTH DAKOTA RADIATION CONTROL PROGRAM
JUNE 7, 1991 TO JUNE 25, 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 Office of State Programs. The State's program was reviewed against the 30 program indicators provided in the guidelines. The review included discussions with program management and staff, technical evaluation of selected license and compliance files, and the evaluation of the State's responses to an NRC questionnaire that was sent to the State in preparation for the review.

The 20th Regulatory Program Review meeting with North Dakota representatives was held during the period of June 22, 1993 through June 25, 1993, in Bismarck, North Dakota. The State was represented by Mr. Dana Mount, Director, Division of Environmental Engineering, and Mr. Ken Wangler, Manager, Radiation Control Program, North Dakota Department of Health. The NRC was represented by Mr. Robert J. Doda, State Agreements Officer, NRC Region IV, and Ms. Teresa Darden, State Agreements Officer, NRC Region I.

A review of selected license and compliance files was conducted during June 22-23, 1993. A review of legislation and regulations, organization, management and administration, and personnel was conducted on June 22, 1993. A summary meeting regarding the results of the regulatory program review was held with Dr. Jon R. Rice, State Health Officer, North Dakota Department of Health, on June 25, 1993, in Bismarck, North Dakota.

In addition to the routine office review, accompaniments of State inspectors were made during State inspections of a broad academic licensee and an industrial radiography licensee. These were performed during September 8-11, 1992, and on June 24, 1993, respectively.

CONCLUSION

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 Dakota, the staff determined that the North Dakota program for the regulation of agreement materials is adequate to protect public health and safety. However, a finding that the program is compatible with the NRC's program for the regulation of similar materials is being withheld due to the fact that two regulations, which are matters of compatibility, have not been adopted as final regulations within the three-year period allowed by NRC.

ENCLOSURE 2

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The previous NRC program review was concluded on June 7, 1991, and comments and recommendations were sent to the State in a letter dated September 27, 1991. At the time, the program was found to be adequate to protect the public health and safety; however, a finding that the program was compatible with the NRC's program for the regulation of similar materials was withheld due to several overdue regulations. These regulations were included in a revision to the State's regulations that was sent to us in July 1992, and we were able to make a finding that the North Dakota agreement materials program was adequate and fully compatible with the NRC's program for radiation control.

Other comments and recommendations from the previous program review were followed up and the State's responses were evaluated for adequacy. All previous comments and recommendations have been closed out, except for two different regulations that are now overdue for compatibility purposes. Also, the State has requested and is receiving technical assistance from the NRC regarding license authorizations for two broad academic licensees to dispose of certain radioactive wastes at county landfills.

CURRENT REVIEW COMMENTS AND RECOMMENDATIONS

The North Dakota radiation control program satisfies the guidelines in 26 of 30 indicators. The State did not meet the guidelines in three Category I indicators and one Category II indicator. Our comment and recommendation concerning the Status and Compatibility of Regulations is significant and has precluded a finding of compatibility for the State's program until such time that the necessary regulations are promulgated in the North Dakota radiation control regulations.

1. Status and Compatibility of Regulations (Category I Indicator)Comment

The review of the State's radiation control regulations disclosed that two regulations, which are matters of compatibility, have not been adopted by the State within a three-year period after adoption by the NRC. These amendments deal with equivalents to:

1. "Emergency Preparedness for Fuel Cycle and other Radioactive Materials Licensees" (10 CFR Parts 30, 40, and 70) adoption date for States was April 7, 1993.
2. "Decommissioning" (10 CFR Parts 30, 40, and 70) adoption date for States was July 27, 1991.

Other compatibility regulations coming due by the time of the next review are:

- "Standards for Protection Against Radiation," 10 CFR Part 20 amendment (56 FR 61352) needed by January 1, 1994.
- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) needed by January 10, 1994.
- "Notification of Incidents," 10 CFR Parts 20, 31, 34, 39, 40, and 70 amendments (55 FR 40757) 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.

The overdue rules and the rules due by the time of the next review have been drafted and are scheduled for adoption by January 19, 1994. As noted earlier, the NRC has established January 1, 1994, as the date by which Agreement States and NRC licensees shall implement and should have the new 10 CFR Part 20 regulations, or its equivalent, established as a final regulation. The State's equivalent to 10 CFR Part 20 regulations is especially important because it includes the basic radiation protection standards, which are used by the NRC and all of the Agreement State radiation control programs.

Recommendation

We recommend that a concerted effort be made to promulgate the State's equivalent to 10 CFR Part 20 by January 1, 1994, if possible, and in no case later than the currently scheduled January 19, 1994 date. We also recommend that considerations be made for promulgation of the regulations as an emergency measure. In addition, we recommend that other regulations needed for compatibility be promulgated as effective State radiation control regulations as soon as possible.

2. Technical Quality of Licensing Actions (Category I Indicator)

Comment

During the previous program review, we found the State had issued amendments to two licensees, the University of North Dakota and North Dakota State University, that authorized the disposal of tritium and carbon-14 waste in forms which exceeded those authorized by the biomedical waste rule in the regulations (Section 33-10-04-04.6. of the North Dakota radiation control regulations). The State responded to an NRC recommendation in 1991 on this subject by placing specific limits on these authorizations.

The State has the authority to make such authorizations on a case-by-case basis. However, to review these authorizations, North Dakota has requested NRC technical assistance to produce appropriate pathway exposure analyses consistent with current NRC waste disposal practices. This request is presently being reviewed by NRC.

Recommendation

We recommend that the State utilize the technical assistance findings to reevaluate the tritium and carbon-14 disposal authorizations.

The findings should also be used to identify the established specific descriptions of the waste characteristics permitted for disposal.

3. Status of Inspection Program (Category I Indicator)

Comment

The program review disclosed that six of the 75 licenses, 8% of the licenses, were overdue for inspection by greater than 50 percent of the inspection frequency. We consider this to be a minor comment since all these licensees are scheduled for inspection at a frequency greater than that of the NRC and would not be considered overdue under NRC inspection policy. For example, five medical institutional (hospitals & clinics) were listed as overdue. These licenses are inspected at a frequency of every two years under the State's inspection policy; whereas, these licenses are inspected every three years under NRC's regulatory program.

Recommendation

We recommend that the Division complete these six inspections as currently scheduled in the Division's inspection plan.

4. Administrative Procedures (Category II Indicator)

Comment

The Division's Administrative Procedures Manual is in need of updating.

Recommendation

We recommend that the Administrative Procedures Manual be updated so that it contains only current information and that it be made available for all staff members.

SUMMARY DISCUSSIONS WITH STATE REPRESENTATIVES

A meeting was held on June 25, 1993, with Dr. Jon R. Rice, State Health Officer, Mr. Dana Mount, Director, Division of Environmental Engineering, and Mr. Ken Wangler, Manager, Radiation Control Program, to discuss the preliminary findings of the program review. The scope and findings of the review were discussed. They were informed of the significant Category I finding regarding the compatibility of the State's radiation control regulations. Dr. Rice said the State would continue with the revision of the State's regulations and that the State plans already include the Part 20 amendments that are necessary for compatibility. During this discussion, he also became more familiar with Agreement State Programs for radiation control and with the difficulty that smaller Agreement State Programs have in maintaining compatible regulations with the NRC program. Mr. F. Schwindt, Chief, Environmental Health Section, attended a portion of this meeting and asked a number of questions concerning the NRC's responsibility for agreement programs that are returned to Federal control.

Dr. Rice expressed the State's appreciation for past NRC assistance and for training for the Division's staff. He said the Department will continue to support the radiation control program, any NRC-sponsored training courses, and cooperative efforts with the NRC and other Agreement State Programs.

A closeout discussion with the radiation control program technical staff was conducted on June 23, 1993. The State was represented by Mr. Dana Mount and his radiation control staff. Several general and specific questions were raised by the State representatives. The review guideline questions and the State's responses were discussed in detail. In addition, the results of the license and compliance casework reviews were provided to the staff for discussion. An instructional phase was included to reinforce the proper methods to be used by State personnel when notifying NRC of incidents, abnormal occurrences, and misadministrations. The misadministration data supplied annually by Agreement States were discussed at some length. The importance of accurate reporting was emphasized.