

DATED: JUL 28, 1993

Lani Graham, M.D.
Director
Bureau of Health
State House, Station 10
Augusta, ME 04333

Dear Dr. Graham:

This letter is to confirm the discussion Mr. Lloyd Bolling and Mrs. Teresa Darden held with you and Mr. Warren Bartlett, Assistant Director, Bureau of Health, on April 30, 1993, following our review of the State's radiation control program, and follow-up discussions with me.

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 Maine, we are withholding findings of adequacy and compatibility for the State's program for regulating agreement materials with the regulatory program of the NRC. These findings represent a decline in your program that is very disappointing. Only a year ago, the Maine radiation control program was found adequate and compatible to regulate those materials subject to an Agreement.

Stronger management involvement and control must be instituted along with increased staffing in order to regain an adequate and compatible 274b program. We would appreciate meeting with you within about 30 days to discuss your action plan for responding to the recommendations in the enclosure.

The finding of program adequacy to protect the public health and safety and compatibility will be withheld because of a significant finding in the Category I Indicator, Status of Inspection Program.

At the time of this review, the program had been in existence for one year and only six inspections were completed. In our opinion, the backlog relates directly to the failure of the State to maintain a staffing level that meets our minimum staffing criteria. A plan should be developed to address the current backlog of inspections and to monitor the pending inspection cases to prevent future backlogs.

Response to Incidents and Alleged Incidents is a Category I Indicator. Although the State responded to reports of incidents in an acceptable manner, the State has not developed a comprehensive set of written procedures providing staff guidance on responding to reports of incidents and alleged incidents. The reviewers recommended that the Maine staff work with their legal staff to develop a comprehensive set of procedures in this area.

Although Staffing Level is a Category II Indicator, staff shortages have a direct relationship to the inability of the program to conduct inspections. The radiation control program is currently staffed at a level of approximately 0.9 person-year/100 licensees. This level of technical support is below our guidelines for staffing level of 1-1.5 person-years per 100 licenses in effect. The radiation control program (RCP) must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel. We strongly recommend that one additional professional staff person be added to the RCP staff.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs.

Enclosure 2 is a summary of the review findings which were discussed with Mr. W. Clough Toppan, Manager, Radiological Health Program, and Mr. Jay C. Hyland, Radiological Specialist. We request specific responses from the State on the comments in Enclosure 2.

In accordance with NRC practice, I am enclosing a copy of this letter for placement in the State's Public Document Room or otherwise to be made available for public review.

I appreciate the courtesy and cooperation extended to the NRC staff during the review. I am looking forward to our meeting and your comments regarding management involvement, inspection backlog, staffing, training and your staff's responses to the Enclosure 2 recommendations.

Lani Graham, M.D.

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The present status of the Maine radiation control program is of serious concern. The State should expect a follow-up review this fall to review the State's progress toward developing an acceptable program. In addition, Mr. James M. Taylor, Executive Director for Operations, NRC, will be communicating our concerns to the Governor's office under separate cover.

Sincerely,

Carlton Kammerer, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
W. Clough Toppan, Manager
Maine Radiological Health Program
J. M. Taylor, Executive Director for
Operations, NRC
Thomas T. Martin, Regional Administrator
NRC Region I
State Public Document Room
NRC Public Document Room

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J. M. Taylor, Executive Director for
Operations, NRC
Thomas T. Martin, Regional Administrator
NRC Region I
State Public Document Room
NRC Public Document Room

bcc w/encls:

The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner dePlanque

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TDarden, RI Maine File DCD (SP01)

*See previous concurrence

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OFC	OSP:SA	OSP:SA	OSP:SA:AD	OSP:DD
NME	LBolling	CMaupin	JSurmeier	SSchwartz
DTE	06/25 /93*	06/25 /93*	06/25 /93*	06/28/93*
OFC	NMSS:D	OSP:D	DEDS	EDO
NME	RBernero	CKammerer	HLThompson	JMTaylor
DTE	07/15/93*	07/27/93*	07/27/93*	07/ /93

SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE MAINE RADIATION CONTROL PROGRAM
APRIL 1, 1992 TO APRIL 30, 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, State Agreements Program. The State's program was reviewed against the 30 program indicators provided in the Guidelines. The review included inspector accompaniments, 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 first annual regulatory program review meeting with Maine representatives was held during the period April 27-30, 1993 in Augusta, Maine. The State was represented by W. Clough Toppan, Manager, Radiological Health Program and Jay C. Hyland, Radiological Specialist.

Selected license and compliance files were reviewed by Lloyd Bolling, State Agreements Program, NRC Headquarters and Teresa Darden, Acting Regional State Agreements Officer, Region I. One inspector was accompanied during two inspections on April 27 and 28, 1993. A summary meeting regarding the results of the review was held with Dr. Lani Graham, Director, Bureau of Health, and Mr. Warren Bartlett, Assistant Director, Bureau of Health on April 30, 1993.

CONCLUSION

Findings of adequacy to protect the health and safety and compatibility are being withheld, pending the resolution of a significant finding in the Category I Indicator, status of inspection program.

STATUS OF PROGRAM RELATED TO THE INITIAL REVIEW VISIT

The results of the orientation meeting were reported to the State in a letter to W. Clough Toppan, dated September 15, 1992. At that time, the reviewer noted that the program had gotten off to a slow start in both licensing actions and compliance cases completed.

The current finding indicates the need for a more aggressive inspection schedule and the need to keep up to date on licensing amendments, as well as new applications.

CURRENT REVIEW COMMENTS AND RECOMMENDATIONS

All 30 program indicators were reviewed and the State fully satisfies 23 of these indicators. Specific comments and recommendations for the remaining indicators are as follows:

1. Status of Inspection Program is a Category I Indicator

Guideline Statement

The State should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. When backlogs occur, management should develop and implement a plan to reduce the backlog.

Comment

During the onsite review of vital program data, the NRC staff noted that inspection statistical information is handled quite well by computer. Ten licensees were overdue for inspection by greater than 50% of the scheduled inspection interval. In addition, there are another 23 priority 1, 2, and 3 licensees, including medical facilities, which are currently in the 50% overdue area. Based on review findings, you are not conducting inspections of reciprocity licensees.

Recommendation

We strongly recommend that all licensees in inspection priorities 1, 2, and 3 be placed on a schedule which will eliminate the backlog.

We further recommend that an effort be made to inspect reciprocity licensees coming into Maine from other jurisdictions to conduct field work. This effort should include inspections and/or observations of reciprocity servicing of the State's only teletherapy unit and any self-contained irradiators, as these are complex and potentially hazardous operations.

2. Response to Incidents and Alleged Incidents is a Category I IndicatorGUIDELINE STATEMENT

- Inquiries should be promptly made to evaluate the need for onsite investigations.
- Onsite 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.
- Onsite investigations should be promptly made on 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 radiation control program (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.

Comment

The State did not have a comprehensive set of procedures to provide guidance to the staff for handling reports of incidents and alleged incidents.

Recommendation

We recommend that basic procedures to guide staff on handling reports of incidents be drafted with the assistance of the legal staff. We also recommend that the State use its equivalent to Part 20 and the various guidance letters sent to all Agreement States focussing on the QM Rule, Abnormal Occurrences, or procedures already developed by other Agreement States, like Illinois, etc., to develop its procedures for handling incidents.

3. Staffing level is a Category II Indicator

Guideline Statement

Professional staffing level should be approximately 1-1.5 person-years per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel.

Comment

The radioactive materials program is currently staffed at a level of approximately 0.9 person-years/100 licenses. Presently, the State has only one professional staff person other than the program manager. The staff deficiency is contributing to the significant finding in the Category I Indicator, Status of Inspection Program.

Recommendation

We strongly recommend that one additional professional person be added to the Maine staff. The radiation control program (RCP) must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity.

4. Staff Supervision is a Category II Indicator

Guideline Statement

- 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.

Comment

During the onsite review of selected license and compliance files, it was not evident from the review of the files whether or not the action being taken had the benefit of supervisory review in all cases.

Recommendation

We recommend that a selected sample of all license and compliance actions be reviewed in depth by the program manager. We suggest the use of a checklist for consistency and documentation purposes.

5. Training is a Category II Indicator

Guideline Statement

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

Comment

The technical staff is currently restricted from traveling for more than 14 days annually out-of-State. Specialized training in regulatory health physics requires that new personnel have at least 11 weeks of basic courses over a two year period. Beyond this, senior personnel are expected to attend periodic workshops, seminars and National meetings.

Recommendation

We recommend that the out-of-State travel restrictions be lifted for radiation control personnel to permit staff to attend necessary training courses to establish and maintain technical competence and NRC sponsored workshops and meetings.

6. Technical Advisory Committees is a Category II Indicator

Guideline Statement

- 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.

Comment

The radiological health program does not currently have a Technical Advisory Committee for general radiation matters, nor a Medical Advisory Subcommittee for medical radiation matters.

Recommendation

The State should take steps to establish a Technical Advisory Committee and also name a Medical Advisory Subcommittee. These committees will prove themselves to be invaluable in their input on draft regulations and a backup in handling radiation incidents.

7. Administrative Procedures is a Category II Indicator
Guideline Statement

The RCP should establish written internal policy and administrative procedures to assure that program functions are carried out as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies, decommissioning and license termination, fee collection, contact 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, inspection and enforcement.

Comment

During this review meeting it was noted that the program staff was diligently at work drafting administrative procedures. A comment on the need for such procedures was expressed during the initial visit in September 1992.

Recommendation

We recommend the establishment of administrative and office procedures. However, in view of the staff resource problem and the inspection backlog, we recommend that as an interim measure the staff utilize NRC procedures where possible and postpone procedure writing until the inspection backlog is satisfactorily reduced.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review was held on April 30, 1993, with Dr. Graham, Mr. Bartlett and Mr. Toppan. The review team explained the background and obligations of the Agreement State Program, the history of the Maine radiation control program, the scope of the current review.

The details of the findings in the Category I Indicators, as well as those found in the five Category II Indicators identified in this enclosure, were discussed at length. The review team pointed out that the root cause for the inspection backlog is the program management failure to maintain the target inspection schedule of approximately 40 inspections per year. An adequate staffing level is critical to meeting this target.

Mr. Toppan, the Maine program director, stated that the inspection schedule had in fact been allowed to build up. He attributed this to a staffing shortage, both technical and secretarial, and the focus that they placed on writing procedures. The NRC staff stated that while operating procedures are important, we would advise that the Maine staff utilize NRC procedures where possible in order to concentrate on pending casework (licensing and compliance). This comment also extends to the other Category I Indicator regarding procedures for handling allegations.

A Category II Indicator regarding the establishment of technical and medical advisory committees was of interest to Dr. Graham. Dr. Graham agreed that these committees could be of use to the State's radiation control program and indicated that she would review the path needed to activate them.

Regarding the staffing shortfall, Mr. Toppan stated that a replacement for the secretary that they lost was already hired and would start work on June 10, 1993. Additionally, the need for a technical position was anticipated by the State. However, as a result of the findings of this review, Mr. Toppan indicated that he would file the required paperwork to accelerate the hiring process. Dr. Graham was responsive to our comment on the State's restriction (14 days per year) regarding out-of-State travel and she indicated that she would try to get this restriction lifted.

The review team leader expressed appreciation for the cooperation given to the team by the State staff. It was also explained that Mr. Carlton Kammerer, Director, Office of State Programs, will submit the final results of the review in a letter to Dr. Graham, and that the State will be expected to respond to the comments in the letter and this enclosure. Due to the serious nature of the findings, it was explained that the State should expect a follow-up review within the next three to nine months to review program progress.

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