

DATED: MARCH 21, 1996

SIGNED BY: RICHARD L. BANGART

Lani Graham, M.D., M.P.H.
Director
State of Maine
Department of Human Services
Augusta, Maine 04333

Dear Dr. Graham:

This is to transmit the results of the Nuclear Regulatory Commission's (NRC) review and evaluation of the Maine radiation control program. This review, which concluded on June 2, 1995, was conducted by Mr. Craig Z. Gordon, State Agreements Officer, Region I. At the conclusion of the review, the results were discussed with you and members of the Maine staff: Mr. Clough Toppan, Director, Division of Health Engineering; and Mr. Robert Schell, Manager, Radiation Control Program (RCP).

As a result of our review of the State's program and the routine exchange of information between the NRC and the State, the staff determined that, at this time, the Maine program for the regulation of certain Atomic Energy Act radioactive materials is adequate to protect public health and safety and is compatible with NRC's program.

However, one compatibility regulation has not been adopted by the State within the three-year period provided by the NRC, as follows:

- "Emergency Planning Rule (EP)," 10 CFR 30, 40, and 70 amendments, which were needed by April 7, 1993.

The absence of the EP rule as a part of the Maine RCP will not affect a finding of compatibility at this time. During our review, RCP staff indicated there were no Maine licensees identified which possess radioactive materials in sufficient quantities to meet the requirements of the EP rule provisions. We request that a review of Maine licenses based upon the rule requirements be performed; and the results of the review should be documented and provided to the NRC to confirm that no licensees meet the requirements of this rule. The State may defer rule adoption provided action is taken to adopt the applicable portions of the EP rule if a license application subject to the provisions of the rule is received. Until the

Maine rule becomes effective, the applicable provisions of the EP rule should be incorporated through license conditions.

As discussed in our summary meeting, a concern was raised in the area of "Inspector's Performance and Capability," a Category I indicator. NRC review guidelines state that the compliance supervisor should conduct annual evaluations of inspectors to assess performance in the field. During the review we found that such supervisory accompaniments were not performed. We believe it is necessary that field inspector accompaniments be made to assure application of appropriate and consistent RCP inspection policies.

Please note there has been a change in the format of this letter from our previous review letters. This letter summarizes the findings regarding all 30 program indicators. Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 summarizes our review findings for program indicators where we have identified recommendations for improvements. We request specific responses from the State on the findings and recommendations in Enclosure 2 within 30 days of this letter. We recognize the delay in our issuance of this letter, and if you require more than 30 days to respond, please let us know.

Enclosure 3 presents a summary of the review findings where the State has fully satisfied the indicator. A response to the items in Enclosure 3 is not required.

I appreciate the courtesy and cooperation extended the NRC staff during the review.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:

1. Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"
2. Status of Previous Findings and Summary of Review Findings and Recommendations for the Maine Radiation Control Program April 30, 1993 to June 1, 1995
3. Summary Assessment of Indicators Fully Satisfied by the Maine Radiation Control Program April 30, 1993 to June 1, 1995

cc w/encl:

R. Schell, Manager, RCP
C. Toppan, State Liaison Officer

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3. Summary Assessment of Indicators Fully Satisfied by the Maine Radiation Control Program April 30, 1993 to June 2, 1995

cc w/encl:

- R. Schell, Manager, RCP
- C. Toppan, State Liaison Officer

bcc w/encl:

- Chairman Jackson
- Commissioner Rogers
- Commissioner Dicus

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*See previous concurrence.

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** Memo from D. Cool dated October 16, 1995

OSP FILE CODE: SP-AG-13

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. 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. Comments on Category I indicators that are not significant will not be used as a basis for withholding of findings of adequacy or compatibility.

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. Pursuant to Section 274j of the Act, the Commission may terminate or suspend all or part of its agreement with a State if the Commission finds such termination or suspension is required to protect the public health and safety, or the State has not complied with one or more requirements of Section 274 of the Act.

ENCLOSURE 1

STATUS OF PREVIOUS FINDINGS AND
SUMMARY OF REVIEW FINDINGS AND RECOMMENDATIONS
FOR THE MAINE RADIATION CONTROL PROGRAM
APRIL 30, 1993 TO JUNE 2, 1995

SCOPE OF REVIEW

The second regulatory program review with Maine representatives was held during the period May 30 - June 2, 1995, in Augusta, Maine. 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 policy statement. The review included discussions with program management and staff, technical evaluation of selected license and compliance files, review of the State's policies and procedures, and the evaluation of the State's responses to an NRC questionnaire that was sent to the State in preparation for the review. There were no regional office or field accompaniments of State inspectors performed during this review.

The State was represented by Mr. Robert Schell, Manager, Radiation Control Program (RCP).

Selected license and compliance files were reviewed by Mr. Craig Z. Gordon, Regional State Agreements Officer, NRC Region I; assisted by Mr. Thomas Thompson, Sr. Health Physicist, NRC Region I.

CONCLUSION

The State's program for the regulation of certain Atomic Energy Act radioactive materials is, at this time, adequate to protect the public health and safety and is compatible with the regulatory program of the NRC.

However, one compatibility regulation has not been adopted by the State within the three-year period provided by the NRC, as follows:

- "Emergency Planning Rule (EP)," 10 CFR 30, 40, and 70 amendments, which were needed by April 7, 1993.

The absence of the EP rule as a part of the Maine RCP will not affect a finding of compatibility at this time. During our review, RCP staff indicated there were no Maine licensees identified which possess radioactive materials in sufficient quantities to meet the requirements of the EP rule provisions.

We request that a review of Maine licenses based upon the rule requirements be performed; and the results of the review should be documented and provided to the NRC to confirm that no licensees meet the requirements of this rule. The State may defer rule adoption provided action is taken to adopt the applicable portions of the EP rule if a license application subject to the provisions of the rule is received. Until the Maine rule becomes effective, the applicable provisions of the EP rule should be incorporated through license conditions.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the 1994 follow-up review were reported to the State in a letter to Dr. L. Graham, Director, Department of Human Services, dated October 7, 1994. All comments and recommendations made at that time were satisfactorily addressed and resolved, except for the items identified below. The current status of unresolved comments is as follows:

1. Staff Supervision (Category II)

The issue addressed in the following comment has been satisfactorily resolved and is considered closed.

Comment from the April 1993 Review

During the on-site 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.

Recommendation from the April 1993 Review

We recommend that a selected sample of all license and compliance actions be reviewed in depth by the program manager. We further recommend that every action receive at least a cursory review by the program manager and be initialed off on.

Maine's Response to April 1993 Review

Apparently, the thrust of this comment is that there be a reasonable number of license and compliance reviews by the Radiation Control Program Manager. I have spoken to Mr. C. Toppan, State Liaison Officer, and he has stated that most of the license and compliance actions were reviewed by him, and some were even signed by him. Our goal will be to assure that Mr. Toppan will review all license and compliance actions. The Radiation Control Program will establish a checklist similar to the checklist utilized by the NRC Region I personnel. This will be affixed on the inside of each respective file folder.

NRC'S Evaluation of State's Response

Open Issue. We recommend that the State establish management review procedures to assure the goal of reviewing selected samples of all licensing and compliance actions. This will be examined during the next review.

Status from the 1994 Follow-up Review

From discussions with RCP staff, steps have been taken to improve supervisory review of reports and correspondence prior to issuance. A formal procedure was not drafted, but the staff indicated that they would consider developing a checklist or other mechanism to ensure supervisory reviews. In August 1994, the RCP informed NRC staff that quality control measures for handling licensing and inspection casework (including supervisory reviews) were initiated through periodic RCP staff meetings. This item is open pending NRC evaluation of license and compliance files during the next scheduled review.

June 1995 Status

Copies of new licenses and inspection reports issued by the RCP were submitted throughout the period to the NRC Region I office for review. During the program review, license and compliance files were also reviewed by NRC. From review of these documents and discussions with RCP staff, it was found that the program manager was involved in almost all evaluations of license applications, and routinely reviewed inspection reports prior to licensee transmittal. Reviewed correspondence sent to licensees had either program manager or division director signature. We found staff supervision to be adequate and this item is closed.

2. Technical Advisory Committees (Category II)

The issue addressed in the following comment has not been satisfactorily resolved and remains open.

Comment from the April 1993 Review

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 from the April 1993 Review

The State should take steps to establish a Technical Advisory Committee and also name a Medical Subcommittee. These committees

will prove themselves to be invaluable in their input on draft regulations and a backup in handling radiation incidents.

Maine's Response to April 1993 Review

The Radiation Advisory Committee was eliminated two years ago by an act of the Maine Legislature in an effort to reduce the number of committees and advisory boards. At that time, Mr. Toppan did not believe it was a vital requirement to retain the committee in Legislation. We are currently researching the process needed to re-activate such a committee. Legislation may not be necessary.

NRC'S Evaluation of State's Response

Open Issue. We will continue to evaluate this issue until the Advisory Committee is established.

Status from the 1994 Follow-up Review

By letter dated December 22, 1993, NRC provided membership categories for Maine to consider while forming a new Technical Advisory Committee (TAC). The Manager of the Radiation Control Program has taken action to reestablish the TAC, which included NRC recommendations provided in December 1993. A proposal for a five member committee with staggered terms was introduced into legislation on July 1, 1994. This item will remain open until selection of TAC members is completed.

June 1995 Status

Under legislation passed in 1994, the Technical Advisory Committee was reauthorized but, at the time of the review, members were not appointed. This item will remain open until committee membership is completed or until the RCP establishes an adequate alternate to an established TAC.

3. Administrative Procedures (Category II)

The issue addressed in the following comment has been satisfactorily resolved and is closed.

Comment from the April 1993 Review

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 from the April 1993 Review

Even though the previous review visit recommended the establishment of administrative and office procedures; we recommend that the staff utilize NRC procedures, where possible, and postpone procedure writing until the inspection overdue list is substantially reduced. We believe that since the program is small and there is good communication between staff and management, and most importantly, there is an impending inspection backlog, 1 full time effort (FTE) can be used more effectively in the inspection area.

Maine's Response to April 1993 Review

This is an area that is very important for a number of reasons. As mentioned in item #2 above, a large number of procedures have been obtained from the Conference of Radiation Control Program Directors, Inc. (CRCPD). The Maine Radiation Control Program is currently reviewing and rewriting those procedures that deal with basic day to day activities so as to free Mr. Hyland from some of the less technical, more routine administrative tasks (requests for material licenses, reciprocity applications, and general questions about reciprocity). Their second goal is to rewrite those procedures that deal with common licensing actions and compliance actions.

As you have suggested, the Radiation Control Program is going to attempt to secure through a contract, the services of a legal intern to assist in the writing of these procedures.

NRC'S Evaluation of State's Response

Open Issue. This response appears to be acceptable and its progress will be reviewed at the next review.

Status from the 1994 Follow-up Review

Administrative procedures to assist RCP staff in program implementation were under review and development. In August 1994, during discussions between NRC and RCP staff, RCP staff members indicated that their work on completing the administrative procedures was still in progress and that a customized list of fundamental administrative procedures will be made available prior to the next program review.

June 1995 Status

During the review, it was noted that the RCP was placing its emphasis primarily on inspection of high priority licensees and

in licensing activities as opposed to administrative procedures as recommended during the 1993 review. In addition, during the review, the program manager provided a list of completed administrative procedures which the RCP believed to be essential in addressing internal program functions. The program manager indicated that additional administrative procedures continued to be under development. The manager indicated that they will continue to supplement their procedures with NRC procedures until drafting of all of their administrative procedures is complete.

The NRC reviewer determined that a small number of administrative procedures had been completed and were being used to carry out basic internal program functions. From observation of internal RCP operations and staff interviews, the reviewers determined that the fundamental program operations were being adequately carried out with the RCP's current administrative procedures and that the RCP had adequately addressed our recommendation. Thus, this item is closed.

CURRENT REVIEW FINDINGS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 24 of these indicators. Recommendations were made regarding six indicators discussed below. None of the Category I indicator recommendations are considered significant. The remaining 24 indicators are discussed in Enclosure 3. A questionnaire containing the 30 indicators, with specific questions pertaining to each indicator, was sent to the State prior to the review.

The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, review of the State's written procedures and policies, discussions with program managers and staff members, review team observations, and licensing and inspection casework file reviews. Specific assessments and recommendations are as follows:

1. 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, and 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 than 3 years.

The radiation control program (RCP) has 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.

Assessment

Title 10-144A CMR 220, State of Maine Rules Relating to Radiation Protection, amended October 1, 1994, were compared to the latest chronology of NRC amendments needed for compatibility. The reviewers found that revised rules incorporated compatible 10 CFR Part 20 amendments, "Standards for Protection Against Radiation" and "Quality Management Program and Misadministrations," 10 CFR Part 35 amendments, and were compatible with NRC rules except for one regulation as follows:

- "Emergency Planning Rule (EP)," 10 CFR 30, 40, and 70 amendments, which were needed by April 7, 1993.

The absence of the EP rule as a part of the Maine RCP will not affect a finding of compatibility at this time. During our review, RCP staff indicated there were no Maine licensees identified which possess radioactive materials in sufficient quantities to meet the requirements of the EP rule provisions. We request that a review of Maine licenses based upon the rule requirements be performed; and the results of the review should be documented and provided to the NRC to confirm that no licensees meet the requirements of this rule. The State may defer rule adoption provided action is taken to adopt the applicable portions of the EP rule if a license application subject to the provisions of the rule is received. Until the Maine rule becomes effective, the applicable provisions of the EP rule should be incorporated through license conditions.

Additionally, the State should note the following rules, some of which it may need to adopt:

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) that became effective on July 1, 1993, and may need to be adopted by July 1, 1996. If there are no licensees in the State that would be subject to this rule, it is acceptable to the NRC that the State defer adoption of the rule. To defer adoption, the State is requested to confirm to NRC that there are no facilities subject to the rule and that if an application for an irradiator subject to the rule were to be received, the State would take action to adopt a compatible Part 36 rule, and until such rule becomes effective, to incorporate the provisions of Part 36 through license conditions.
- "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, and 70 amendments (58 FR 39628) that became effective on October 25, 1993, and will need to be adopted by October 25, 1996.
- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose not to adopt self-guarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provisions for financial assurance that include at least a subset of those provided in NRC's regulations, e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee).
- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994, and will need to be adopted by August 15, 1997.
- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 65243, and 60 FR 322) that became effective on January 1, 1995, and will need to be adopted by January 1, 1998.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20, amendment (60 FR 7900)

that became effective on March 13, 1995. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649) that will become effective on March 1, 1998, and will need to be adopted by March 1, 1998.

Recommendation

We recommend that:

- (1) A review of Maine licenses should be performed based upon the requirements of the emergency planning rule;
- (2) The results of the review should be documented and provided to the NRC.
- (3) If the results of the review indicate that Maine has no licenses subject to the provisions of the EP rule, adoption of the rule may be deferred until a license application subject to the provisions of the rule is received. When a license application subject to the EP rule is received, the provisions of the rule should be incorporated through license condition and the State should take measures to adopt the EP requirements as a regulation.
- (4) Maine should take measures to adopt the other regulations which are a matter of compatibility for the RCP.

2. 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.

Assessment

During the previous review, it was found that Maine did not have technical advisory committees and identified this as an open item. As noted above, under legislation passed in 1994, a technical advisory committee of seven members was reauthorized, but at the time of the review members were not appointed. The program manager indicated that expert advice on complex issues related to use of radioactive materials could not be easily obtained from current sources within the State.

Recommendation

We recommend that the membership appointments to the technical advisory committee with individuals who are recognized experts in the use of radioactive material in a wide spectrum of disciplines be completed as soon as possible.

3. 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 an appropriate level of staff technical competence in areas of changing technology.

The RCP staff should be afforded opportunities for training that are consistent with the needs of the program.

Assessment

In the RCP's response to the questionnaire, the State provided information on attendance at NRC core courses, short courses, and workshops. According to the information provided, one of the new staff members has attended all of the NRC core courses and one of the new staff members currently needs NRC core course training. The RCP manager and the senior staff member have previously attended NRC core courses and based upon their previous training

and experience, no core course needs were identified for the senior staff.

Although a concern was identified during the previous review with regard to the State's policy for restricting out-of-State travel to no more than 14 days annually, from our review, it was clear that this policy has not impeded the training of new staff because of support at the Department Director level to authorize this training for staff. In 1994, the newly hired personnel attended three NRC core courses, licensing orientation, inspection procedures and medical practices. Thus, the 1994 recommendation in this area has been adequately addressed and is considered closed.

During the review, it was noted that the RCP did not have a staff training plan, which would include a list of NRC core courses, or equivalent training; a list of specialized training courses; and a schedule for staff training. The RCP manager provided a general training program outline for new employees and indicated that specific training goals and a proposed schedule for new staff members would be considered.

Recommendation

We recommend that the RCP develop and implement a training plan for new staff members, which includes NRC core courses, or their equivalent; specialized training courses; and a schedule for implementation in order to maintain an adequate level of staff technical competence.

4. 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, and industrial radiographers should be inspected approximately annually. Smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency, including initial inspections, should be no less than the NRC system.

Assessment

From review of the RCP list of inspection priorities, the State's inspection priority system for category 1, 2, and 3 inspections are no less than the NRC system, except for one license category. Nuclear laundries, a priority 2 frequency under the NRC

inspection program, was found to be category 3 under Maine's RCP.

Recommendation

We recommend that the RCP change its inspection frequency for nuclear laundries from a priority 3 to a priority 2.

5. 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.

Assessment

NRC accompaniments of inspectors were not performed during this review because new staff were undergoing training to complete inspector qualification. The senior inspector was accompanied by NRC during the previous review and determined to be competent to evaluate licensee health and safety issues. A concern was identified with the ability of the RCP to meet the guidelines under this indicator. From interviews with the Director, Division of Health Engineering (DHE), and program manager it was found that supervisors did not perform individual inspection accompaniments to assess inspector capability in the field. As a result, the reviewer was unable to determine how management evaluated performance of inspection staff regarding implementation of RCP policies while at licensed facilities. This issue was discussed with senior Maine staff and highlighted at the exit meeting with the Department Director. The RCP manager indicated that a plan would be developed to initiate supervisory evaluations of inspectors in the field.

Recommendation

We recommend that field evaluations of inspectors be performed to assess performance and assure consistent application of appropriate RCP rules and policies.

6. 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.

Assessment

The NRC reviewer noted that Part B of the Maine Rules Relating to Radiation Protection covers enforcement actions, procedures, and civil penalties. From an interview with the program manager, it was reported that those rules and enforcement procedures remained unchanged since Maine entered into the Agreement with NRC in 1992. Since the last review the RCP held an enforcement conference resulting from violations identified during

inspections at the University of Maine. Results of the conference were successful in bringing the licensee into compliance.

NRC review found that enforcement procedures appeared effective to ensure licensee compliance. Issued letters were timely, requesting licensee response within 20 days. However, from review of inspection files and correspondence to licensees, a concern was raised with regard to regulatory language used in letters documenting results of inspections. It was found that the following terminology was not well-defined and was used interchangeably in compliance and enforcement letters: non-compliance; notice of violation; non-cited violation; point of emphasis; and area of concern. Examples noted by the reviewer were discussed with the RCP staff, who indicated revisions would be made to more clearly define specific terms used in letters to licensees following inspections.

Recommendation

We recommend that the program develop consistent and clear regulatory language for compliance and enforcement letters. The regulatory language should include clearly defined terminology to describe findings and problem areas identified during inspections, such as the definitions of non-compliance; notice of violation; non-cited violation; point of emphasis; and area of concern.

SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

A summary meeting regarding the results of the review was held with Dr. Lani Graham, Director, State of Maine Department of Human Services, Mr. Clough Toppan, Director, Division of Health Engineering, and Mr. Robert Schell, Manager, Radiation Control Program on June 2, 1995.

The scope and findings of the review were presented. The reviewer discussed changes found in the RCP since the 1994 follow-up review, and noted the progress made in the inspection program, which was an area previously identified by NRC in need of improvement. Findings made from the review that were brought to Dr. Graham's attention included the requirement to adopt compatible rules (EP rule not in State regulations), the need to perform supervisory accompaniments in the field, and concerns identified with regulatory language used in compliance letters following inspections.

In the presentation to Maine's representatives, the reviewer concluded that preliminary indications were that the RCP was adequate to protect public health and safety, but a finding of compatibility would be withheld due to the State's failure to maintain compatible regulations. It was emphasized that the final determination of adequacy and compatibility of the RCP review will be made following evaluation by NRC management.

Dr. Graham stated she had a better understanding of the Agreement State program following the 1994 All Agreements States meeting held in Portland, and was concerned about proposals to reduce NRC training and environmental program support. She expressed her appreciation to NRC for the close program examination over the past two years which resulted in improved effectiveness of the RCP. The NRC reviewer noted that review findings would be transmitted by letter to the Department and a response to findings and recommendations requested.

SUMMARY OF ASSESSMENT OF INDICATORS FULLY SATISFIED
BY THE MAINE RADIATION CONTROL PROGRAM
APRIL 30, 1993 TO JUNE 2, 1995

The assessments below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the program managers and staff members, review team observations, review of the State's policies and procedures, and licensing and inspection casework file reviews. The State fully satisfies the following indicators:

1. 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

Assessment

The State reported there were no changes in statutory authority under which the Maine Department of Human Services (DHS) administers the radiation control program since Maine entered into an Agreement with the NRC in 1992, and the State continues to meet the guidelines under this indicator.

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

A significant change to the Maine legislation occurred in April 1994 when Public Law 1994, Chapter 664 was enacted to consolidate Maine law regarding authorization of radioactive waste regulation. The Act provides:

"Section 8. 22 MRSA § 676, sub-§4,...4. Radioactive waste. The Department of Human Services shall coordinate management of and shall serve as point of contact with the United States Nuclear Regulatory Commission for high-level and low-level radioactive wastes, in consultation with the Department of Environmental Protection, the State Nuclear Safety Advisor ..., and the State Nuclear Safety Inspector..."

"Section 9. 22 MRSA § 679,...§679. Low-level radioactive waste disposal.

State regulation of low-level radioactive waste disposal is subject to the primary jurisdiction of the Department of Human Services, as specified in section 676, except that disposal of low-level radioactive waste in the State is also subject to regulation by the Department of Environmental Protection."

However, the reviewer notes that the State of Maine's Agreement under Section 274b of the Atomic Energy Act (AEA) does not include authority for the regulation of AEA low-level radioactive waste (byproduct, source, and special nuclear materials) disposal. If an application for a low-level radioactive waste disposal facility which includes AEA materials is received by the State or if the State decides it would like to assume authority in this area from the NRC, the State must amend its Agreement with the NRC.

The act also designates the DHS as the agency to fulfill the State regulatory and enforcement requirements for the Texas Low-Level Radioactive Waste Disposal Compact (TLLRWDC); this Compact will include Texas, Maine and Vermont.

These duties include the development of rules to fulfill the State's responsibilities and requirements for the Compact pursuant to the contract requirements; provide for the disbursement of funds from the Radioactive Waste Fund; and to report annually to the Advisory Commission on Radioactive Waste.

2. 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.

Assessment

As shown in the Division of Health Engineering (DHE) organization chart, dated January 19, 1995, the Radiation Control Program along with the Drinking Water and Eating and Lodging programs, reports directly to the Director, DHE. The location of the RCP is comparable with other health and safety programs in the State's organization. The Director, DHE, was readily accessible to RCP staff and as the former program manager, he is very familiar with RCP operations. During the period he was designated as the governor-appointed State Liaison Officer to the NRC.

The Director, Department of Human Services, is at the cabinet level of Maine government. The Director, DHE, stated he was able to meet regularly with the Department Director to discuss DHE activities.

A change in organizational responsibility was made since the last review. As noted above, the DHS now coordinates management of and serves as point of contact for high-level and low-level radioactive waste generated within the State. This responsibility was designated previously to the Department of Environmental Protection. From discussion with the program manager, transfer of this function into the DHS will allow closer coordination with other RCP responsibilities.

3. 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.

Assessment

The internal organization of the RCP was reviewed and the organizational structure was discussed with the program manager. At the time of the review, a concern was identified under this indicator in that the program manager position was vacant, with a governor-mandated restriction on permanent hiring in effect. The current program manager was acting in that position. Subsequently, the restriction was lifted and Mr. Schell was appointed permanently as the Manager, RCP, supervising all sections within the program. On occasion he assists the agreement material staff in licensing casework and field compliance activities.

As a small program with no regional offices, lines of supervision from the program manager to licensing and compliance staff were appropriate to allow program policy to be effectively executed.

4. 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.

Assessment

During the review period, the RCP sought legal advice from the Attorney General's office for review and comment on draft regulations and obtained assistance in enforcement cases. The program manager indicated that the Attorney General's office had personnel knowledgeable on issues relating to the RCP and the RCP had contacted the Attorney General's Office on several occasions for interpretations on issues relating to regulations and escalated enforcement actions. Based upon the State's response to the questionnaire and discussion with the program manager, legal assistance was adequate.

5. 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.

Assessment

As noted under the Legal Authority guideline above, the State has not developed a low-level waste disposal regulatory program and has not assumed this authority through an Agreement with the NRC. Therefore, this indicator was not applicable to the State, at this time, and was not evaluated.

6. Quality of Emergency Planning (Category I)

NRC Guidelines

The State RCP should have a written plan in response to incidents at licensee facilities which takes into account such incidents as spills, overexposure, 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.

Assessment

The reviewers examined Annex H to the State of Maine's Emergency Operations Plan dated April 1987. The Plan, originally developed for incident response activities at the Maine Yankee nuclear power reactor facility in Wiscasset, Maine, also is used by State agencies to assist in coordinating responses to transportation events and related situations requiring immediate State response. An appendix to Annex H, which covers response activities primarily for radiological transportation accidents, identifies organization and assignment of responsibilities for the Maine Emergency Management Agency (MEMA) and the DHE. The Plan provides for MEMA to accept notifications 24-hours a day, respond to incidents when requested by DHE, and coordinate response activities with local governments and communities.

Draft Procedure 2.01, Radiological Monitoring Team Notification (revised August 1994), is a procedure and call list to notify DHE personnel in the event of a radiological accident involving either the Maine Yankee plant or radioactive material. The program manager indicated that DHE staff participated in communications drills during Maine Yankee exercises and tested the draft transportation plan in a table-top exercise at the Portland Jetport.

7. Budget (Category II)

NRC Guidelines

Operating funds should be sufficient to support program needs, such as staff travel necessary to the conduct of 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.

Assessment

Based upon the State's response to the questionnaire and interviews with the program manager, the reviewers determined that the total reported funding of \$724,000 was an adequate operating budget for the Maine radiation control program. For radioactive materials, the program was 100% supported by fees. The materials program support was approximately \$455,000 of the total RCP budget. This amount was sufficient to support program needs. The fee schedule, which has not changed since 1992, was being reviewed by RCP staff for possible change to reflect current program costs.

8. Laboratory Support (Category, II)

NRC Guidelines

The RCP should have 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 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.

Assessment

The reviewers toured the State's Health and Environmental Testing Laboratory in Augusta, Maine and interviewed laboratory personnel responsible for processing samples taken by inspectors. Laboratory capability included operable gamma spectroscopy, alpha spectroscopy, and liquid scintillation counting systems adequate to support RCP needs. At the time of the review, the laboratory

was authorized and was in the process of upgrading capability of counting equipment. Access by inspection staff to counting equipment was coordinated by laboratory radiochemistry personnel.

The methodology to collect and analyze samples taken by inspectors was discussed with the program manager and found to be effective in allowing samples to be analyzed promptly. The laboratory had the capability to complete processing and report results of emergency samples on a priority basis. No changes in laboratory support was made since the last review and the State continues to meet the guidelines under this indicator.

9. Administrative Procedures (Category II)

NRC Guidelines

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, 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.

Assessment

During the review, it was noted that the RCP was placing its emphasis primarily on inspection of high priority licensees and in licensing activities as opposed to administrative procedures as recommended during the 1993 review. In addition, during the review, the program manager provided a list of completed administrative procedures which the RCP believed to be essential in addressing internal program functions. The program manager indicated that additional administrative procedures continued to be under development. The manager indicated that they will continue to supplement their procedures with NRC procedures until drafting of all of their administrative procedures is complete.

The NRC reviewer determined that a small number of administrative procedures had been completed and were being used to carry out basic internal program functions. From observation of internal RCP operations and staff interviews, the reviewers determined that the fundamental program operations were being adequately carried out with the RCP's current administrative procedures and

that the RCP had adequately addressed our recommendation. Thus, this item is closed.

10. 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 funding.

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.

Assessment

Management demonstrated by the program director was adequate to implement the materials program effectively. From staff discussions the reviewer found that since the last review, regular "work sessions" (staff meetings) were held by the program manager to allow staff to stay apprised of licensing and associated events affecting the program. From observations made

during the review, the reviewer noted the program manager was directly involved in decisionmaking for most aspects of administrative and safety operations.

Inspection schedules were maintained on computer database. The reviewer observed a demonstration of the database operation, and noted that it provided a good tool for maintaining inspection schedules. From interviews, it was noted that licensing actions taken by staff are discussed with the program manager and submitted for his review. In response to a previously identified NRC finding regarding management review of licenses, the program manager now signs all licenses.

11. 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 (greater than 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 licensing, inspection, and enforcement staff should not be used for fee collection and other clerical duties.

Assessment

The response to the questionnaire indicated the State added a dedicated clerical position for the radioactive materials and low-level waste program. Materials technical staff had assigned computers which included wordprocessing, database, and spreadsheet software programs. Program staff generate licensing documents and inspection letters from computer systems. Examination of computer hardware found it to be sufficient to produce licenses and other correspondence efficiently. RCP licenses file cabinets were noted to be kept orderly.

Other office equipment such as copying and facsimile machines, and office supplies were available for technical and administrative staff use. Recently, the staff began to use electronic mail for communication with the NRC. The program meets the guidelines under this indicator.

12. 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.

Assessment

From review of Chapter 13, Section 401 of the State Administrative Procedures Act, provisions provide that records be made available for public disclosure. However, there are provisions for protecting information from public disclosure. These provisions include cases where it is necessary to protect records such as evidence recognized by courts, materials used in bargaining proposals, records of designated State boards or commissions, and medical records. From interviews it was found that public inquiries and requests for information were coordinated with the public affairs section within the department.

13. 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

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).

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.

Assessment

From information shown in the questionnaire, the five personnel (3.4 FTEs divided among two supervisors and three licensing/compliance staff) involved in regulation of the radioactive materials program had degrees in the sciences. The RCP manager recently received professional engineering certification satisfying a State requirement for that position and was permanently appointed in July 1995. Since the last review, two of the five staff members were new to the program, and had previous experience in health physics. The new hires began attending NRC training courses and were assisting the program manager and senior staff member in licensing and field inspection activities. The NRC reviewer was given copies of job descriptions for technical positions prepared for use in vacancy announcements and recruitment efforts.

In addition, Public Law 1994, Chapter 664, authorized a new position to carry out the requirements of the Texas Low-Level Radioactive Waste Compact. At the time of the review, a position description request was developed by the RCP and the vacancy was filled.

14. Staffing Level (Category II)

NRC Guidelines

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.

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.

Assessment

From data reported in the questionnaire, the reviewer calculated the amount of time spent by the professional staff on the radioactive materials program to be 2.6 FTEs per 100 licenses (3.4 FTEs for 128 licenses), exceeding the NRC guideline. This figure includes the new hire authorized for the low-level waste program, currently assigned full-time to the program to learn about radioactive materials regulation and to assist qualified staff in licensing and inspection activities.

15. 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.

Assessment

Copies of new licenses and inspection reports issued by the RCP were submitted throughout the period to the NRC Region I office

for review. During the program review, license and compliance files were also reviewed by NRC. From review of these documents and discussions with RCP staff, it was found that the program manager was involved in almost all evaluations of license applications, and routinely reviewed inspection reports prior to licensee transmittal. Reviewed correspondence sent to licensees had either program manager or division director signature. In addition, the senior staff member maintained scheduling of inspection activities, and was designated to provide guidance and on-the-job training to new members in handling licensing actions and performing field inspections. Observations made during the review showed close coordination between all Maine staff members on licensing and compliance regulatory activities.

16. 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.

Assessment

From staff interviews, the reviewers noted that the Director, DHE (former program manager) and senior staff member have been involved in the program prior to Maine's becoming an Agreement State in 1992. The program manager's appointment reflected a promotion within the Division and an increase in salary level. Since the last review two vacancies occurred, and the State actively recruited and hired two entry-level staff, one in the materials program, and the other for low-level waste regulation (currently assigned to the RCP).

17. 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 that these elements 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.

Assessment

At the time of the review the State reported 128 specific licenses in effect, including 16 new licenses. Since the 1994 NRC follow-up review, a noteworthy effort was identified in reissue of NRC licenses transferred under the Agreement as Maine licenses. Action was taken on 46 renewals and 20 amendments during the review period. Twenty-three reissued license files were reviewed including 10 new files and 11 renewals as follows: hospital/broad medical (8), academic (1), teletherapy (1), nuclear medicine facilities (3), research and development facility (1), and fixed or portable gauges (9).

The State commits to following NRC licensing guidance, and file reviews showed that licenses are issued consistent with the NRC program. Licenses had overall good quality with respect to meeting guideline criteria, and contained appropriate information necessary for industrial, medical, and research and development evaluations. Individual license file comments were discussed with program staff. These will be documented and transmitted separately to the State in conjunction with issuance of this report. No significant comments from the file review were identified, and the technical quality of licensing actions was determined to be adequate.

18. 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 in 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.

Assessment

This indicator was not evaluated for this review period. From discussions with the RCP director, the State did not receive any applications for an evaluation of sealed sources and devices. If an application for an evaluation is received, the Maine staff would initiate review of the application using NRC guidance, and should determine whether NRC technical assistance is needed.

19. 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 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.

Assessment

Based upon a review of the program's procedures and discussions with staff, the reviewer verified that the Maine RCP continued to use licensing guides consistent with those of the NRC for evaluation of license applications. Standard license conditions were available on database, and were determined to be consistent with NRC standard license conditions, and contained adequate regulatory language. All program staff performed both licensing and inspection functions, and coordinated closely with each other to ensure compliance status was considered in licensing actions. Files were found to be generally well maintained allowing information to be readily retrievable for access and audit.

20. Status of Inspection Program (Category I)

NRC Guidelines

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.

At least semiannual inspection planning should be done for the number of inspections to be performed, assignments to senior vs. 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.

Assessment

During the 1994 follow-up review, NRC found the State had made substantial progress in eliminating the backlog of priority 1, 2, and 3 inspections identified during the 1993 review. From interviews it was noted that improvements resulted from a revised policy to perform inspections within 25 percent of their scheduled frequency. From current database records maintained for program inspection schedules, the reviewers found there was only one RCP radioactive materials inspection overdue by more than 25 percent of the scheduled inspection frequency. According to the questionnaire, one facility (Pharm Corp.) close-out inspection was performed, one facility

(Phillips-Elmet) close-out inspection was pending, and three reciprocity inspections were performed.

The inspection database is available to all staff, and from interviews, the senior RCP staff member stated the schedule file which lists all Maine licensees is reviewed at least weekly to determine inspections coming due. The reviewers observed a demonstration of the inspection database capability and noted that the program provided dates when last inspections were conducted at each licensed facility.

21. Responses to Incidents and Alleged Incidents (Category I)

NRC Guidelines

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 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.

Assessment

From discussions with the program director and information provided in the questionnaire, there was only one event which required an investigation by RCP staff. Responding promptly to a report of a lost portable gauge, the staff coordinated their response with local authorities until the gauge was retrieved. Although information about the event was provided, the reviewer found that a tracking system for documenting response investigations, allegations, and events was not maintained in office files. This was discussed with the RCP manager, who indicated that a system which better documents event results would be considered. Procedures for handling incidents and events requiring immediate response were available.

22. 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 supervisors or the senior inspector should be performed upon return from non-routine inspections.

For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Assessment

The reviewers evaluated questionnaire responses, examined copies of inspection procedures, and interviewed inspection staff. Inspection guides, checklists, and procedures were available and used by RCP inspectors. File reviews showed that inspection checklists consistent with those of the NRC were used in field evaluations of licensee operations. From staff discussions the reviewers found policies were clear regarding preparation, conduct, follow-up, debriefing of RCP and licensee management, and criteria to follow-up open items. RCP staff also indicated that inspections were performed on an unannounced basis whenever possible. The RCP satisfies this indicator.

23. 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 the licensees' programs, and indicating the substance of discussions with licensee management and licensee's response.

Reports should uniformly and adequately document the result of inspections, including confirmatory measurements, status of previous noncompliance, 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 results of confirmatory measurements made by the inspector.

Assessment

According to information supplied by the program, the compliance staff completed 69 of 71 (97%) of assigned materials inspections from April 1993 through March 1995. Eleven compliance files were reviewed, all performed by the two program inspectors. Included were one academic, four hospitals, one research laboratory, two gauges, one radiography installation, and two nuclear medicine facilities. Reports were generally complete and well documented to meet guideline criteria, and no generic concerns were found. Reports identified how previous items of non-compliance were followed-up and resolved, and documented independent measurements taken by inspectors. Isolated comments pertaining to each file were discussed with the senior inspector at the conclusion of the review, and will be transmitted separately to the State after issuance of this report.

24. 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 licensee's 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, 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 be adequate for surveying license operations (e.g., survey meters, air samples, lab counting equipment for smears, identification of isotopes, etc).

RCP instrumentation should include the following types: GM Survey Meter, 0-50 mR/hr; Ion Chamber Survey Meter, several R/hr; micro-R-Survey meter; Neutron Survey Meter, Fast and Thermal; Alpha Survey Meter, 0-1,000,000 c/m; Air Samplers, Hi and Lo Volume; Lab Counters, Detect 0.001 uC/wipe; Velometers; Smoke Tubes; and 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 used for surveys and confirmatory measurements should be calibrated within the same time interval as required of the licensee being inspected.

Assessment

Inspection of the program's equipment storage area and review of the equipment inventory list dated August 29, 1994, showed that the required survey instruments needed to take confirmatory measurements were available. Instruments included high range (0-1 R/hr, 0-2 R/hr, and 0-5 R/hr) and low range (0-5 mR/hr) survey meters; Geiger-Mueller (G-M) counters; air samplers; and dosimeters. It was found that the RCP had sufficiently

calibrated its instruments to ensure radiation measurements of various types could be taken during inspections and investigations. A section of the field inspection form was designated for inspector confirmatory measurements. Inspector interviews indicated that confirmatory measurements are taken during inspections when deemed necessary.