Dora A. Mills, M.D., M.P.H.
Director
Bureau of Health
State House, Station #10
Augusta, ME 04333

Dear Dr. Mills:

On December 1, 1998, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Maine Agreement State Program. The MRB found the Maine program adequate to assure public health and safety and compatible with NRC's program.

Section 5.0, page 15, of the enclosed final report presents the IMPEP team's recommendations and suggestions. We received Mr. Jay Hyland's November 15, 1998 letter which described the actions taken in response to the team's recommendations. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

Frank J. Miraglia, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: W. Clough Toppan, Director
Division of Health Engineering

Jay Hyland, Program Manager
Radiation Control Program

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Jay Hyland, Program Manager
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bcc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MAINE AGREEMENT STATE PROGRAM

September 15-18, 1998

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Maine radiation control program. The review was conducted during the period September 15-18, 1998 by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Mississippi. Review team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 25, 1997, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period June 3, 1995 to September 14, 1998, were discussed with Maine management on September 18, 1998.

A draft of this report was issued to Maine for factual comment on October 21, 1998. The State responded in a letter dated November 15, 1998 (Attachment 1). Maine's factual comments were considered by the team and accommodated in the report. The Management Review Board (MRB) met on December 1, 1998 to consider the proposed final report. The MRB found the Maine radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Maine Agreement State program is administered by the Radiation Control Program (RCP). The RCP Manager reports directly to the Director, Division of Health Engineering located in the Bureau of Health. The RCP presently has a Program Manager and two Environmental Specialist III (ES III) positions assigned to radioactive materials under the Agreement. One ES III position was vacant at the time of the review. This position was filled in October 1998. The Maine program regulates approximately 134 specific licenses authorizing agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maine. Organization charts for the Bureau of Health and the RCP are included as Appendix B.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on June 29, 1998. The State provided a response to the questionnaire on September 3, 1998. A copy of their final response is included in Appendix F to the draft report.

The review team's general approach for conduct of this review consisted of: (1) examination of Maine's response to the questionnaire; (2) review of applicable Maine statutes and regulations; (3) analysis of quantitative information from the RCP licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two Maine inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the RCP's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance

indicators, and Section 5 summarizes the review team's findings, recommendations, and suggestions . Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report. Suggestions are comments that the review team believes could enhance the State's RCP. The State is requested to consider suggestions, but no response is requested.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

At the effective date of the Agreement, April 1, 1992, Maine's program was adequate and compatible. During the orientation visit conducted on August 7, 1992, several weaknesses associated with licensing and inspection backlogs were identified by NRC. The first program review was conducted in April 1993 and the findings for adequacy and compatibility were withheld at that time. The State had performed only 6 inspections during the first year and had 25 overdue inspections. It was noted at that time that the staffing levels were below the expected. (Note, the State disagreed with NRC's findings because of the impact on the Maine program from the licensing workload transferred from the Region.) During the February 1994 follow-up review, the program was found adequate and compatible with only one inspection overdue and an additional staff member hired. During the second review, conducted in June 1995, the State was again found adequate and compatible.

During the previous routine review, which concluded on June 2, 1995, six recommendations were made and the results transmitted to Lani Graham, Director, Department of Human Services, on March 21, 1996. The team's review of the current status of these recommendations is as follows:

1. We recommend that:

   A review of Maine licenses should be performed based upon the requirements of the emergency planning rule;

   The results of the review should be documented and provided to the NRC.

   If the results of the review indicate that Maine has no licenses subject to the provisions of the emergency preparedness (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.

   Maine should take measures to adopt the other regulations which are a matter of compatibility for the RCP.

   Current Status: Maine responded to the recommendation in a July 23, 1996 letter to the NRC, signed by Philip Haines, Acting Director, Bureau of Health. The response indicated that the EP rule would be incorporated through license conditions until rulemaking could be enacted. A review of licensee programs identified that only one, Binax, Inc., met the possession limits specified in the EP rule, thus requiring an emergency plan. Binax

elected to decrease their possession limits below the rule limits and thereby avoided the need for an emergency plan.

At this time, no Maine licenses have possession limits necessitating an emergency plan. Rulemaking for the EP rule is targeted for March 1999. This regulation is included in those identified in Section 4.1.2 for completion. This recommendation is closed.

2. 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.

   Current Status: Since the last review, appointments were made to the Maine Advisory Committee on Radiation representing the industrial, research, academic and medical license communities. The Committee advises the RCP on rulemakings, allegations and other radiation safety issues. This recommendation is closed.

3. 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.

   Current Status: A training program, with a qualification journal, was developed for new staff members which is comparable to NRC's Inspection Manual Chapter (IMC) 1246. The ES III has attended all necessary courses with the exception of the Teletherapy and Brachytherapy course and the RCP manager committed to assign qualification journals to new staff members. This recommendation is closed.

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

   Current Status: The nuclear laundry inspection frequency was changed to priority 2, although Maine does not have any nuclear laundries. All Maine inspection frequencies are at least as frequent as NRC's. This recommendation is closed.

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

   Current Status: Field evaluations of inspectors are performed by the Program Manager at least annually. Since the Program Manager also performs inspections, the ES III inspector performs annual audits of the Program Manager, using the same criteria. This recommendation is closed.

6. 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 violations; point of emphasis; and area of concern.

Current Status: A review of inspection documentation identified that the program uses consistent regulatory language in letters to licensees. Similar to NRC, the terms “violation” and “non-cited violation” are the preferred terms in use. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licensees, and timely dispatch of inspection findings to licensees. The review team’s evaluation is based on Maine’s questionnaire responses relative to this indicator, data gathered independently from the State’s licensing and inspection data tracking system, the examination of completed inspection casework, and interviews with the staff.

The team's review of the State's inspection priorities showed that the State's inspection frequencies for the various types or groups of licenses are at least as frequent as similar license types or groups listed in the NRC Inspection Manual Chapter (IMC) 2800. The State's inspection frequencies for some licensees such as teletherapy, medical institution/no quality management program (QMP) required, medical private practice/no QMP required, and portable gauges are more frequent than required by NRC.

The staff uses Lotus Approach software for the tracking system. This allows them to project the next inspection due date and to sort inspection data by license type, code, name, priority, and inspection date. The tracking system also provides other important information such as licensee contact and telephone numbers. The system allows the RCP to maintain inspection histories such as types and number of violations from previous inspections. Their system maintains the dates that notices of violations were issued, licensee responses were received, and response acknowledgment letters were sent. The system provides the capabilities needed to track inspection and compliance data.

All inspection data are entered in the tracking system by the ES III. He prints a list of licenses with inspections due in the next six months. Due to locations of some licensees, several inspections in an area might be done during a trip. After the inspection is completed, the ES III updates the tracking system. The Program Manager monitors the tracking system to ensure inspections have been performed.

In their response to the questionnaire, Maine indicated that they had 12 inspections (2 core licenses) overdue by more than 25% of the NRC frequency, and stated that the inspections would be completed by September 4, 1998. During the week of the review, the team verified that all overdue inspections (core and non-core) had been completed and all inspections were current. The team looked at the State's experience with overdue inspections during the entire review

period and noted that several inspections were conducted later than the inspection frequency policy. Of the 19 inspection files that were evaluated for timeliness by the team, five (all core licenses) were inspected past the frequency. The overdue inspections included an Academic Type A Broad license (two year inspection frequency) inspected 18 months late and a Research and Development Type A Broad license (two year inspection frequency) inspected 13 months late. Of the 134 licenses regulated by the Maine program, 35 are core licenses, as defined by IMC 2800. The review team recommends that the State perform routine inspections at required frequencies.

With respect to initial inspections of new licensees, 13 new license files were evaluated by the team. Interviews with the Program Manager and ES III indicated that frequent conversations are initiated with license applicants to inform them of RCP regulations and policies. New licenses are sometimes hand-delivered. The State's policy is to inspect all new licenses within six months of license issuance or receipt of radioactive material. Eight of the 13 new license files evaluated were not inspected within the required inspection frequency, but performed from 6 to 18 months past the six-month window. All new licenses issued since the start of the review period were inspected with the exception of two licenses issued in the last six months. Interviews with staff indicated that contacts are made with new licensees to determine if radioactive material has been received, but these telephone conversations are not documented. Therefore, the State believes some of the initial inspections which appear to be late inspections were actually completed within six months of the receipt of radioactive materials. The review team recommends that initial inspections of licensees be performed within 6 months of license issuance or within 6 months of the licensee’s receipt of material and commencement of operations, consistent with IMC 2800.

In their response to the draft IMPEP report (Attachment 1), the State commented that they had documentation to justify not conducting six out of 13 overdue initial inspections during the review period, and that only three of 13 were not conducted within the first year of materials possession. The 3 licensees were inspected at 13 - 21 months of possession of material. According to the State, health and safety issues were not compromised.

The timeliness of issuance of inspection findings was evaluated during the inspection file review. With one exception, inspection correspondence was sent to the licensee within 30 days after the inspection. Licensee responses to inspection findings were received in a timely manner. The Program Manager sends out the acknowledgment to the licensee response and determines if more enforcement action is needed. It was noted during the review that civil penalties may be assessed if the licensee does not take appropriate corrective actions. During an interview with the Program Manager, it was determined that one licensee had to be called in for an enforcement conference and they agreed to take corrective actions. No civil penalties were assessed during the review period.

In their response to the questionnaire, Maine reported that, from 1995 to 1998, they inspected all reciprocity licensees (two) that performed source installations or exchanges as well as over 50% of industrial radiography licenses that filed requests for reciprocity. The team's evaluation of the reciprocity files verified that inspections were performed. Only one Priority 2 licensee was granted reciprocity during the review period, and it was inspected by the RCP.

Although preference is given to the inspection of higher priority reciprocity licensees, approximately 10% of Priority 3-7 licensees that apply for reciprocity are also inspected. Maine's Priority 3 licenses include portable gauges (Priority 5 in IMC 2800). The review team found the State's frequency for Priority 3 licenses acceptable with this variation from IMC 1220.

Late inspections of core licenses (IMC 2800 Priority 1 to 3 and initials) resulted in inspection backlogs at various times during the review period. File evaluations performed by the team identified 13 of 48 (27%) core licenses (35 Priority 1 to 3 and 13 new licenses) were inspected late. At the time of this review, however, no inspections were overdue, core or non-core. The Program Manager is now placing a higher priority on initial inspections and other core licenses. The recent hiring of another ES III will help with that goal. The delay of the initial inspection did not result in any health and safety issues that would have been prevented by performing the initial inspection on time. Based on the management's awareness of the initial inspections backlog and the actions take by the State to eliminate overdue inspections, and the team's observation of the State's inspection methodology during the accompaniments (as discussed in Section 3.2), the team believes that a satisfactory with recommendations finding for improvement is appropriate for the Maine program. Maintaining the current staffing level should lead to improve performance in this indicator.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory with recommendations for improvement.

3.2 Technical Quality of Inspections

The team evaluated the inspection reports and enforcement documentation, and interviewed inspectors for 19 radioactive materials inspections conducted during the review period. Both the Program Manager and the ES III conduct inspections. The casework included both inspectors and covered inspections of various types including medical institution/QMP required, medical institution/no QMP required, academic Type A Broad, teletherapy, industrial radiography, nuclear pharmacy, manufacturing and distribution, mobile nuclear medicine, fixed gauges and portable gauges. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Maine's inspection procedures are consistent with NRC procedures. Inspections are routinely unannounced. Announced inspections usually involve initial inspections, inspections at distant locations, or, rarely, to ensure the presence of knowledgeable licensee staff. The review team noted that for the 19 inspections evaluated, only one inspection was announced.

Maine's enforcement procedures include routine and escalated enforcement mechanisms. Routine enforcement examples include enforcement conferences, Notices of Violation, follow-up inspections, and restrictive license conditions. Escalated enforcement includes civil penalties, temporary suspension of operations, temporary suspension of license, confiscation of radioactive material, and criminal penalty. An interview with the Program Manager revealed that, during the review period, the RCP had only one escalated enforcement action, an enforcement meeting with a licensee which achieved the desired corrective actions by the licensee.

Based on casework, the review team noted that the routine inspections covered all aspects of the licensees' radiation safety programs. Some deficiencies were noted and are documented in Appendix C. The team noted that inspections are performance-based. Inspectors observed licensed operations and had operations demonstrated whenever possible. Team inspections were performed when appropriate.

Maine's inspection field notes are comparable to NRC's Inspection Procedure 87100. The inspection field notes provide documentation of the scope of the licensees' program including receipt, transfer, use and storage of material, leak tests, personnel monitoring, training, disposal of radioactive materials, inventory, surveys and wipes for contamination, posting, labeling, audits, interviews with workers, contacts, independent surveys by the inspector, previous violations, and inspection findings. Field notes were developed to cover all the different types of inspections that are conducted by the State.

The review team noted that the field notes did not document the items discussed in the exit meeting. The inspection reports list the names of individuals interviewed and contacted during the inspection, however, the reports could be strengthened by including a summary of the discussion. The review team also noted that six inspection reports had no supervisory review of the inspection report. The review team suggests that the RCP management continue supervisory review of inspection reports.

The license casework that was evaluated contained complete inspection findings and enforcement correspondence. Telephone conversations with licensees were documented on an agency form that was maintained in each license file folder. The files allowed the reviewer to see that inspectors had conducted the inspections, discussed inspection findings with the Program Manager, and followed up on enforcement action after the licensee response was received.

The inspection findings are issued by the Program Manager. Inspection findings are routinely sent to licensees within 30 days with licensee responses returned in a timely manner. The response is reviewed by the inspector and the Program Manager prior to the State issuing an acknowledgment letter. Agency letters to the licensee outlining inspection findings and enforcement actions are written in a formal form using appropriate style, detail, and regulatory language. One of the findings from the previous program review was that inspection findings language was confusing due to the use of various terminology for violations and items of concern. This issue has been corrected.

As noted in the questionnaire, the State has available a variety of portable instruments for routine confirmatory surveys and use during incidents and emergency conditions. The instruments include high and low range GM detectors, micro-R meters, alpha detectors, ion chambers, rate meters, multi-channel analyzer, single-channel analyzer, and sodium iodide detectors. The inspectors have calibrated alarming ratemeters for use during industrial radiography inspections. They are also issued pocket dosimeters and TLDs. The instruments are calibrated on an annual basis by calibration facilities that use sources traceable to the National Institute of Standards and Technology. The instruments used during the inspector accompaniments with the review team member were operational and calibrated. The State uses the Bureau of Health's Health and Environmental Testing Laboratory to analyze wipes for contamination and for analysis of water and soil samples.

The ES III has been accompanied by the Program Manager annually during the review period. The Program Manager has also been accompanied by the ES III during 1998. The Program Manager stated that annual inspector accompaniments will continue to be done using this approach to ensure inspection procedures are followed and to assess the inspector's ability to conduct inspections of specific types of licensees.

During the week of August 3, 1998, a review team member performed accompaniments of the Program Manager and ES III on separate inspections of licensed facilities (See Appendix C). The inspections included an academic institution and an industrial radiography licensee. During the accompaniments, inspectors demonstrated appropriate inspection skills and knowledge of regulations. The inspectors were well prepared and thorough in the review of licensee programs. Inspection techniques were observed to be performance-oriented and the technical performance of both inspectors was excellent. The inspections were adequate to assess radiological health and safety at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed RCP management and staff, and considered any possible workload backlogs.

At the time of the review, Maine’s radioactive materials program was staffed by the Program Manager and one full time ES III. In August 1997, the former Program Manager left the program and an ES III was named Acting Manager. In July 1998, the acting Program Manager was named Program Manager. For a period of one year, the RCP was short staffed. As discussed in Section 3.1 above, the vacancy contributed to inspection backlogs and late inspections during the review period. The lack of staffing has also affected the promulgation of regulations required for compatibility. Rulemakings have been delayed and are considerably overdue, as described in Section 4.1.2 below. The review team noted that minimal staff time was devoted to rulemaking efforts due to licensing and inspection needs. The State also identified this area as a weakness in the IMPEP questionnaire. The review team suggests that the State evaluate staffing needs to ensure its long-term ability to address regulations and timely completion of inspections.

Additionally, the Low-Level Waste Inspector position in the program has been vacant since May 1998. This staff position relates primarily to the decommissioning of the Maine Yankee reactor, but provides support and depth to the radioactive materials program. The position is currently posted.

In October 1998, shortly after this review, the vacant ES III position was filled. The new hire has commenced the Program’s qualification and training process.

The RCP has a training and qualification program in place for the staff which is taken directly from the NRC's IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Both the Program Manager and ES III are well trained and are qualified from an education and experience standpoint. Both have Bachelor's degrees in the sciences and the Program Manager is also a professional engineer. They have attended most of the training courses prescribed by IMC 1246 and are very familiar with Maine regulations, policies, and procedures. Neither individual has taken the Teletherapy and Brachytherapy course (H-313), but the ES III is enrolled in the March 1999 course. The new hire ES III has been issued a qualification journal.

During a 1997 rulemaking, the State raised licensee fees to cover anticipated travel and training costs. The ability to pay all training costs for NRC-sponsored courses allows priority acceptance and helps staff members maintain training levels required by IMC 1246.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 19 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that had been completed in the review period. The cross-section sampling included the following types: academic broad scope; industrial radiography; medical institutions; nuclear pharmacy; fixed and portable gauges; teletherapy; self-shielded irradiator; and manufacturing. Licensing actions completed during the review period included 24 new licenses, 35 renewals, and 151 amendments (including 15 terminations), for a total of 210 licensing actions. The review team noted that staff is currently reviewing the decommissioning results for the Philips Elmet facility with regard to agreement material in Maine. A list of licenses evaluated with case-specific comments for license reviews may be found in Appendix D.

Types of licensing actions selected for review included two new licenses, eleven amendments to existing licenses, four license renewals, and two terminations. License reviews were generally well done and complete. The review team noted that some licenses included license conditions that were obsolete; however, the presence of these older license conditions did not compromise the safe use of licensed material. Also, the review team noted that one action included privacy

information provided by the licensee in the docket file. This issue is discussed in more detail in Section 3.5.

The licensing process was discussed with the ES III, who is also the primary license reviewer, and with the Program Manager. All licensing actions receive supervisory review, and are signed by management. Deficiencies are addressed by correspondence utilizing appropriate regulatory language. The review team noted that RCP staff did not always document telephone conversations with the licensee that requested specific information in support of completing a licensing action.

The State uses detailed licensing checklists for renewals and new licenses. The review team noted that the program did not develop a checklist for industrial radiography reviews and utilized an NRC checklist for industrial radiography license actions performed during the review period. In discussions with the primary license reviewer, a radiography checklist was not developed due to the small number of radiography licenses in the State, but with addition of new licenses, the RCP has already recognized the need to develop an industrial radiography checklist.

The State utilizes a commercial database system for tracking licensing actions. The ES III also maintains a written log of all licensing actions received and their status. Maine's goal is to complete actions on license amendments within 90 days. However, the RCP's reliance on one primary reviewer to handle all licensing actions (typically six to 10 per month) did result in some amendment actions taking more than 90 days to complete. With one exception, the review team found that renewals were completed within one year of receipt.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents, the review team examined the State's response to the questionnaire regarding this indicator, evaluated selected incidents reported for Maine in the "Nuclear Material Events Database" (NMED) against those contained in the Maine files, and evaluated the casework and supporting documentation for five material incidents. The team also reviewed the State's response to four allegations including one allegation referred to the State by NRC during the review period. A list of incident files examined along with case specific comments is contained in Appendix E.

The five incidents selected for review included abandoned material, procedural failure, contamination event, damage to equipment, and a transportation event.

When notification of an incident or an allegation is received, the Program Manager and staff normally meet to discuss the initial response and the need for an on-site investigation. The safety significance of the incident/allegation is evaluated to determine the type of response that Maine

will take. The small size of the Maine program allows for the prompt dissemination of information regarding the event to all personnel in the program. Radiological incidents can be reported 24 hours a day through the Department's emergency line. The RCP has general written guidance for handling both incidents and allegations in their inspection procedures.

The review team found that the State's responses to incidents and allegations were within the performance criteria. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the State took suitable action.

The review team found the documentation of the incidents to be inconsistent. Although three of the five incidents evaluated had documentation in the incident files, the other two incidents had not been documented nor received supervisory review. The review team also found that the documentation of the incidents involving specific licensees were not placed in the license files. Finally, the review team noted that incidents were not followed up at the next inspection or in a timely fashion. The review team recommends that the program consistently document and perform appropriate follow-up of all incidents.

The review team concluded, after a review of the incidents and discussions with staff, that one of the incidents required reporting to the NRC Operations Center. The Program Manager was familiar with the guidance contained in the "Handbook on Nuclear Event Reporting in the Agreement States." The review team queried the incident information reported to the NMED system for Maine for the review period which identified three events. All three incidents reported to NMED corresponded to events related to activities at Maine Yankee Nuclear Generating Station.

During the review period, there was one allegation referred to the State by the NRC and three allegations reported directly to the program. The review of the State's allegation file indicates that the State took prompt and appropriate action in response to the concerns raised. The review team noted that all documentation related to the investigation of allegations was maintained in a separate file with no cross reference to the license file. Although the review team recognized the program's decision to keep any documentation related to the allegation separated, the review team noted that some privacy information was inadvertently placed in the license files as part of licensing action (see Section 3.4). The review team recommends that the program's procedures be reviewed and updated for handling allegations and other privacy information to reflect Department of Health policy or State laws specific to Maine.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Maine's Agreement does not include a low-level waste disposal

program or a uranium recovery program, so only the first two non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

Along with their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affects the RCP. The currently effective statutory authority for the RCP is contained in the Maine Radiation Protection Statutes in 22 MRSA § 661-690. The Radiation Control Program is designated as the State's radiation control agency. The review team noted that no legislation affecting the RCP was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Maine Regulations for Control of Radiation, found in Maine Administrative Rules 10-144A CMR 220, apply to all ionizing radiation, whether emitted from radionuclides or devices. Maine requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the State’s administrative rulemaking process and found that the process takes approximately four months after filing the draft administrative rule with the Secretary of State. Prior to filing with the Secretary of State, the draft administrative rule is reviewed by management and the Attorney General’s office as well as the Maine Advisory Committee on Radiation. When an acceptable draft proposed revision to a rule has been prepared, it is sent to the Secretary of State, all potentially impacted licensees and registrants, and the NRC, for comment. The Secretary of State announces a public comment/hearing period for the proposed revision to the rule. After responding to comments, the RCP forwards the proposed revision to the rule with the addressed comments to the Commissioner, Department of Human Services for final approval. Comments are considered and incorporated as appropriate before the regulations are finalized. The Commissioner and the Attorney General sign final regulations. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The team evaluated Maine’s responses to the questionnaire and reviewed the status of regulations required to be adopted by the State during the review period. No compatibility-related regulations were adopted by the State during the review period. The review team noted that Maine prepared initial drafts for several of the NRC regulation amendments required to be adopted, however, they have not been finalized and, therefore, they have not been adopted. As stated in Section 3.3, the State identified this area as a weakness. The diminished staffing in the program has limited the time devoted to rulemaking issues, in favor of the inspection and licensing programs.

The State has not yet adopted the following regulations, but intends to address them in rulemakings or by adopting alternate generic legally binding requirements:

- “Emergency Planning Rule,” 10 CFR Parts 30, 40 and 70 amendments (54 FR 14051) that became effective on April 7, 1990. Note, at this time, no Maine licenses have possession limits necessitating an emergency plan.

- “Notification of Incidents,” 10 CFR Parts 20, 30, 31, 34, 39, 40 and 70 amendments (56 FR 64980) that became effective on October 15, 1991.

- “Licensing and Radiation Safety Requirements for Irradiators,” 10 CFR Part 36 amendment (58 FR 7715) that became effective July 1, 1993. At this time, Maine has no pool irradiators.

- "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993.

- “Self-Guarantee as an Additional Financial Mechanism,” 10 CFR Parts 30, 40, and 70 amendments (59 FR 1618) that became effective January 28, 1994.

- “Timeliness in Decommissioning of Materials Facilities,” 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994.

- “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use,” 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767 and 65243) that became effective January 1, 1995.

- “Frequency of Medical Examinations for Use of Respiratory Protection Equipment,” 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995.

- “Low-Level Waste Shipment Manifest Information and Reporting,” 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The Agreement States were expected to promulgate their regulations no later than March 1, 1998 so that NRC and the State would require this national system to be effective at the same time. At this time, Maine licensees are implementing the requirements of these regulations through transfer of material requirements to the low-level waste disposal facilities.

- “Performance Requirements for Radiography Equipment,” 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995.

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.

- “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.

- “Termination or Transfer of Licensed Activities: Record Keeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1996.

- “Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act,” 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.

- “Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997.

- “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.

- “Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947) that became effective June 27, 1997.

- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.

- “Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea,” 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.

- “Deliberate Misconduct by Unlicensed Persons,” 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.

The State indicated they anticipate adoption of the overdue regulations and the regulations which require adoption through 2000, by April 1999. As discussed during the December 1, 1998 MRB, the additional staff hired has enabled the State to put additional effort forth on regulations to achieve promulgation by April 1999. A recommendation that Maine adopt compatible regulations within the 3 year time frame was made during the 1995 review. The review team recommends that the State expedite promulgation of the compatibility-related regulations.

It is noted that Management Directive 5.9, Handbook, Part V, (1)(C)(III) provides that the above regulations should be adopted by the State as expeditiously as possible, but not later than 3 years after the September 3, 1997 effective date of the Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on the IMPEP evaluation criteria, the review team recommends that Maine’s performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory with recommendations for improvement.

4.2 Sealed Source and Device (SS&D) Evaluation Program

At the time of the review, Maine had no sealed source or device manufacturers nor were any applicants anticipated in the near future. The State, however, does not wish to relinquish the authority to regulate SS&D manufacturers in the future. The State committed to have a program in place prior to performing evaluations. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Maine's performance to be satisfactory for the indicators, Technical Quality of Inspections, Technical Staffing and Training, Technical Quality of Licensing Actions, and Response to Incidents and Allegations. The review team found Maine's performance to be satisfactory with recommendations for improvement for the indicators, Status of Materials Inspection Program, and Legislation and Program Elements Required for Compatibility. Accordingly, the review team recommended and the MRB concurred in finding the Maine Agreement State Program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for implementation and evaluation, as appropriate, by the State.

RECOMMENDATIONS:

1. The review team recommends that the State perform routine inspections at required frequencies. (Section 3.1).

2. The review team recommends that initial inspections of licensees be performed within 6 months of license issuance or within 6 months of the licensee's receipt of material and commencement of operations, consistent with IMC 2800. (Section 3.1).

3. The review team recommends that the program consistently document and perform appropriate follow-up of all incidents. (Section 3.5).

4. The review team recommends that the program's procedures be reviewed and updated for handling allegations and other privacy information to reflect Department of Health policy or State laws specific to Maine. (Section 3.5).

5. The review team recommends that the State expedite promulgation of the compatibility-related regulations. (Section 4.1.2).

SUGGESTIONS:

1. The review team suggests that the RCP management continue supervisory review of inspection reports. (Section 3.2).

2. The review team suggests that the State evaluate staffing needs to ensure its long-term ability to address regulations and timely completion of inspections. (Section 3.3).

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Maine Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Attachment 1	State's Response to Draft Report Dated November 15, 1998

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
B. J. Smith, Mississippi	Status of Materials Inspection Program Technical Quality of Inspections
Duncan White, Region I	Technical Quality of Licensing Actions Response to Incidents and Allegations

APPENDIX B

STATE OF MAINE

BUREAU OF HEALTH
DIVISION OF HEALTH ENGINEERING
RADIATION CONTROL PROGRAM

ORGANIZATION CHARTS

Bureau of Health Organizational Chart

Dora A. Mills, MD, MPH
Director
Bureau of Health

Philip W. Haines
Deputy Director
Bureau of Health

- *Environmental Toxicology*

N. Warren Bartlett
Director
Office of Health Data and Program Management

- *Vital Records*
- *School Health Infrastructure*
- *Survey Operations*
- *Data and Research*
- *Office of Primary Health Care*
- *Maine Office of Rural Health*

Jack Kreuger
Chief, Lab On
Health and Environmental Testing Laboratory

- *Chemistry*
- *Clinical Microbiology*
- *Environmental*
- *Clinical Certification*
- *Organics*
- *Inorganics, Nutrients, Microbiology Agents*

Clough Toppan
Director
Division of Health Engineering

- *Plumbing Control*
- *Radiological Health*
- *Eating and Lodging*
- *Drinking Water*

Randy Schwartz
Director
Community and Family Health

Partnership for a Tobacco-Free Maine

Community Health Programs

- *Cancer Prevention Unit*
- *Breast and Cervical Health Program*
- *Community Health/ Chronic Disease Prevention Unit*
- *Oral Health Program*
- *Diabetes Control Project*
- *Injury Prevention and Control Program*
- *Teen and Young Adult Health Program*
- *Cancer Registry*
- *Occupational Health Program*

Family Health Programs

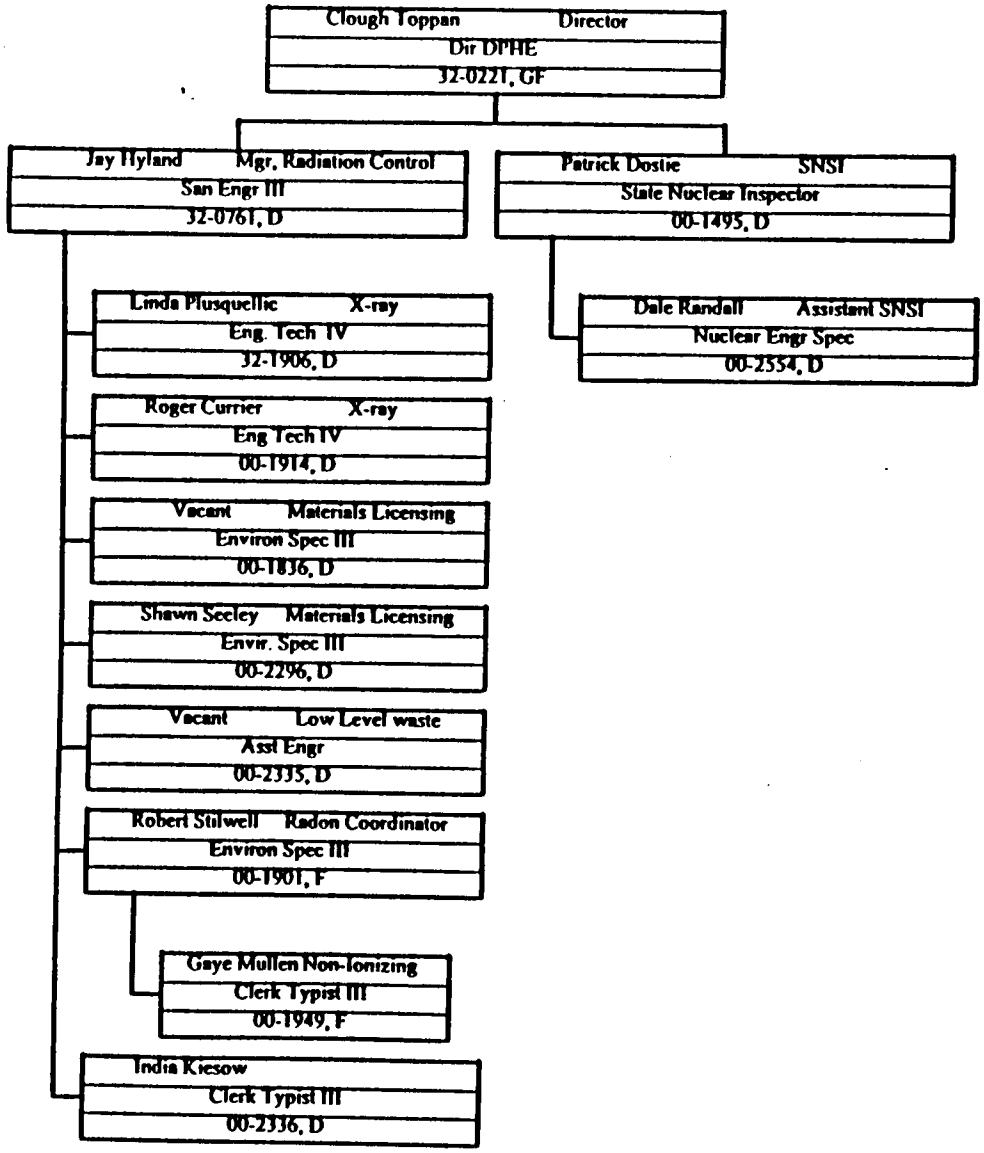
- *Healthy Families Program*
- *Public Health Nursing*
- *Women and Children's Preventive Health Services Program*
- *Lead Poisoning Prevention Program*
- *Coordinated Care Services for Children with Special Needs*
- *Genetics Program*
- *WIC Program*
- *State System Development Initiative*
- *Nutrition Program*

Division of Disease Control
Director (Vacant)

- *HIV/STD Program*
- *Tuberculosis Control Program*
- *Refugee Health Assessment Program*
- *Epidemiology Program*
- *Immunization Program*
- *EPSDT*
- *Immpact*

8/98

RADIATION CONTROL PROGRAM, SION OF HEALTH ENGINEERING
BUREAU HEALTH
Line List and Funding Source
5/11/98



APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: ALL INSPECTIONS LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Bath Iron Works License No.: 23209
Location: Bath, ME Inspection Type: Routine, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 8/24/98 Inspector: SS

Comments:
a) Transportation requirements, such as blocking/bracing package, placarding vehicle were not verified.
b) Inspection 3 months overdue.

File No.: 2
Licensee : Elite Inspection Service License No.: 05703
Location: Portland, ME Inspection Type: Initial, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 9/3/97 Inspector: SS

Comments:
a) Initial inspection 11 months overdue.
b) Licensee did not take appropriate corrective action. Regulations require daily checks of visible signals/audible alarms in exposure room. Licensee stated they would check quarterly.

File No.: 3
Licensee: Quality Assurance Labs License No.: 05139
Location: South Portland, ME Inspection Type: Routine, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 8/6/98 Inspector: JH

Comment:
a) No supervisory review of inspection report at time of review.

File No.: 4
Licensee: Aroostook Medical Center License No.: 03803-01
Location: Presque Isle, ME Inspection Type: Routine, Unannounced
License Type: Teletherapy Priority: 1
Inspection Date: 6/11/98 Inspectors: SS/JH

File No.: 5
Licensee: Aroostook Medical Center License No.: 03803-02
Location: Presque Isle, ME Inspection Type: Routine, Unannounced
License Type: Medical Priority: 3
Inspection Date: 6/11/98 Inspector: SS

Comment:
a) Inspection letter sent 3 months after inspection was completed.

File No.: 6
Licensee: University of Maine License No.: 19827-01
Location: Orono, ME Inspection Type: Routine, Unannounced
License Type: Academic Type A Broad Priority: 2
Inspection Date: 8/20/98 Inspector: SS

Comments:
a) Inspection 18 months overdue.
b) No supervisory review of inspection report.

File No.: 7
Licensee: Pharm-Corp of Maine License No.: 01713-01
Location: Augusta, ME Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 9/14/98 Inspector: SS

Comment:
a) No supervisory review of inspection report.

File No.: 8
Licensee: Jackson Labs License No.: 09507-01
Location: Bar Harbor, ME Inspection Type: Routine, Unannounced
License Type: R&D, Type A Broad Priority: 2
Inspection Date: 3/18/98 Inspector: SS

Comments:
a) Licensee was previously cited for not doing contamination surveys. Inspector should have checked for contamination in labs using wipes.
b) Inspection 13 months overdue.

File No.: 9
Licensee: Diamed, Inc. License No.: 05349
Location: South Windham, ME Inspection Type: Routine, Unannounced
License Type: Manufacturing. & Distribution-Other Priority: 2
Inspection Date: 9/19/97 Inspector: SS

Comment:
a) Contamination wipes should have been taken by inspector to verify surveys were performed.

File No.: 10
Licensee: Eastern Maine Medical Center License No.: 19301-01
Location: Bangor, ME Inspection Type: Routine, Unannounced
License Type: Medical/QMP required Priority: 3
Inspection Date: 9/8/98 Inspector: SS

Comments:
a) Inspection 3 months overdue.
b) Dosimetry records not reviewed.
c) Special inspection performed in 2/96 in response to brachytherapy allegation.

File No.: 11
Licensee: St. Mary's Regional Hospital License No.: 01709
Location: Lewiston, ME Inspection Type: Routine, Unannounced
License Type: Medical/QMP required Priority: 3
Inspection Date: 5/11/98 Inspector: SS

Comment:
a) No supervisory review of inspection report.

File No.: 12
Licensee: St. Joseph's Hospital License No.: 19705
Location: Bangor, ME Inspection Type: Routine, Unannounced
License Type: Medical, QMP required Priority: 3
Inspection Date: 9/11/98 Inspector: SS

Comments:
a) No supervisory review of inspection report.
b) Licensee operations not evaluated, records review only.

File No.: 13
Licensee: Houlton Regional Hospital License No.: 03409
Location: Houlton, ME Inspection Type: Routine, Unannounced
License Type: Medical/QMP required Priority: 3
Inspection Date: 6/11/98 Inspector: SS

File No.: 14
Licensee: Northern Diagnostic Labs License No.: 05615-02
Location: Scarborough, ME Inspection Type: Routine, Unannounced
License Type: Self-Shielded Irradiator Priority: 3
Inspection Date: 9/2/98 Inspector: SS

File No.: 15
Licensee: S.W. Cole Engineering License No.: 19709
Location: Bangor, ME Inspection Type: Routine, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 6/5/97 Inspector: JH

Comment:
a) Enforcement letter sent about revoking license if response was not sent in to Notice of Violation. Licensee sent response in immediately.

File No.: 16
Licensee: James River Corporation License No.: 19521
Location: Old Town, ME Inspection Type: Routine, Unannounced
License Type: Fixed Gauge Priority: 3
Inspection Date: 1/4/96 Inspector: SS

File No.: 17
Licensee: Maine Cardiology License No.: 05627
Location: Portland, ME Inspection Type: Routine, Unannounced
License Type: Medical Private Clinic Priority: 3
Inspection Date: 1/31/96 Inspector: SS

File No.: 18
Licensee: Inland Hospital License No.: 11921
Location: Waterville, ME Inspection Type: Routine, Unannounced
License Type: Medical/QMP required Priority: 3
Inspection Date: 1/16/97 Inspector: JH

File No.: 19
Licensee: Maine DOT License No.: 19603
Location: Bangor, ME Inspection Type: Special, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 7/14/98 Inspector: SS

Comment:
a) State has done 2 field inspections after an inspection in 10/96 discovered numerous violations. Enforcement meeting held with licensee in 11/96 and licensee agreed to correct violations. No other escalated enforcement action required. Inspectors also did unannounced field inspections in 8/97 and 7/98. No violations were cited during last 2 inspections.

NEW LICENSES EVALUATED FOR ISSUE AND INITIAL INSPECTION DATE

File No.: 1
Licensee: Mobile Spect Imaging, LLC License No.: 05701
Location: Portland, ME Inspection Type: Initial, Unannounced
License Type: Mobile Nuclear Medicine Priority: 2
Inspection Date: 4/11/97 Inspector: SS

Comments:
a) Initial inspection not performed in 6 month frequency, license issued 8/9/95.
b) Inspector should verify requirements for mobile nuclear medicine are fulfilled as required by Section G of the regulations.

File No.: 2
Licensee: Weavexx License No.: 25901
Location: Waterville, ME Inspection Type: Initial, Announced
License Type: Portable Gauge Priority: 3
Inspection Date: 6/12/97 Inspector: JH

Comments:
a) Initial inspection not performed in 6 month frequency, license issued 3/1/96.
b) No supervisory review of inspection report.

File No.: 3
Licensee: CV Diagnostic Services License No.: 11203
Location: Waterville, ME Inspection Type: Initial, Unannounced
License Type: Medical Private Practice Priority: 3
Inspection Date: 9/7/98 Inspector: SS

Comment:
a) Initial inspection not performed in 6 month frequency, license issued 9/11/97

File No.: 4
Licensee: M&H Logging & Construction License No.: 07401
Location: Rangeley, ME Inspection Type: Initial, Announced
License Type: Portable Gauge Priority: 3
Inspection Date: 6/30/98 Inspector: SS

Comment:
a) Initial inspection not performed in 6 month frequency, license issued 6/19/96.

File No.: 5
Licensee: R.W. Gillespie License No.: 31703
Location: Saco, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 12/28/95 Inspector: JH

File No.: 6
Licensee: Marriners, Inc. License No.: 13601
Location: Rockport, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 6/10/96 Inspector: SS

Comment:
a) Initial inspection not performed in 6 month frequency, license issued 6/20/95.

File No.: 7
Licensee: J. T. Langille, Inc. License No.: 03501
Location: Presque Isle, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 1/22/97 Inspector: SS

File No.: 8
Licensee: Dayton Sand & Gravel License No.: 31303
Location: Hollis Center, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 1/14/98 Inspector: SS

Comment:
a) Initial inspection not performed in 6 month frequency, license issued 10/25/96.

File No.: 9
Licensee: GZA GeoEnvironmental License No.: 05403
Location: Portland, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 8/5/97 Inspector: SS

File No.: 10
Licensee: Thomas Dicenzo License No.: 29801
Location: Calais, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 8/28/98 Inspector: SS

Comment:
a) Initial inspection not performed in 6 month frequency, license issued 3/10/97.

File No.: 11
Licensee: ATC Construction Corporation License No.: 05207
Location: Westbrook, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 1/15/98 Inspector: SS

File No.: 12
Licensee: Construction Materials License No.: 19203
Location: Bangor, ME Inspection Type: Initial, Unannounced
License Type: Portable Gauge Priority: 3
Inspection Date: 9/8/98 Inspector: SS

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were made as part of the on-site IMPEP review.

Accompaniment No.: 1
Licensee: Quality Assurance Labs License No.: 05139
Location: South Portland, ME Inspection Type: Routine, Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 8/6/98 Inspector: JH

Accompaniment No.: 2
Licensee: Colby College License No.: 11219
Location: Waterville, ME Inspection Type: Routine, Announced
License Type: Academic Type C Broad Priority: 5
Inspection Date: 8/7/98 Inspector: SS

Comment:
a) Missed opportunities to interview radiation workers in laboratories.

APPENDIX D
LICENSE CASEWORK REVIEWS

NOTE: ALL LICENSES LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Bishop Testing Services, Inc. License No.: 23207
Location: Topsham, ME Amendment No.: 1
License Type: Portable Gauge Type of Action: Termination
Date Issued: 12/20/96 License Reviewer: SS

Comment:
a) Termination action complicated by the seizure of licensed material by the Internal Revenue Service.

File No.: 2
Licensee: Immunotech License No.: 05255-01
Location: Bar Mills, ME Amendment No.: none
License Type: Manufacturing and Distribution Type of Action: Termination
Date Issued: 2/19/98 License Reviewer: SS

File No.: 3
Licensee: Longview Inspection License No.: 17501
Location: Mexico, ME Amendment No.: 0
License Type: Industrial Radiography Type of Action: New
Date Issued: 8/25/98 License Reviewer: SS

Comment:
a) Application did not include field forms referenced in licensee's procedures.

File No.: 4
Licensee: Mobile Spect Imaging, LLC License No.: 05701
Location: Portland, ME Amendment No.: 2
License Type: Mobile Nuclear Medicine Type of Action: Amendment
Date Issued: 8/7/97 License Reviewer: JH

File No.: 5
Licensee: Penobscot Bay Medical Center License No.: 13701-01
Location: Rockport, ME Amendment No.: 0
License Type: Medical Institution Type of Action: Renewal
Date Issued: 12/16/96 License Reviewer: SS

Comment:
a) License did not incorporate correspondence in tie-down condition referenced in application.

File No.: 6
Licensee: Maine Cardiology Associates License No.: 05627-01
Location: Portland, ME Amendment No.: 3
License Type: Limited Medical Type of Action: Renewal
Date Issued: 2/11/97 License Reviewer: SS

File No.: 7
Licensee: Binax, Inc. License No.: 05243-01
Location: Portland, ME Amendment No.: 6
License Type: Manufacturing and Distribution Type of Action: Amendment
Date Issued: 10/9/96 License Reviewer: JH

File No.: 8
Licensee: Bridge Corporation License No.: 11209
Location: Augusta, ME Amendment No.: 0
License Type: Portable Gauge Type of Action: Renewal
Date Issued: 8/8/96 License Reviewer: SS

Comments:
a) Reviewer did not address requirements for survey instrument, annual audit or facility diagram.
b) No documentation of deficiency telephone call in the file.

File No.: 9
Licensee: Weavexx License No.: 25901
Location: Norridgework, ME Amendment No.: 0
License Type: Portable Gauge Type of Action: New
Date Issued: 4/9/96 License Reviewer: SS

File No.: 10
Licensee: University of Maine License No.: 19827-01
Location: Orono, ME Amendment No.: 2
License Type: Academic Broad Type A Type of Action: Amendment
Date Issued: 7/30/97 License Reviewer: SS

File No.: 11
Licensee: Pharm-Corp of Maine License No.: 11713-01MD
Location: Augusta, ME Amendment No.: 0
License Type: Nuclear Pharmacy Type of Action: Renewal
Date Issued: 8/26/96 License Reviewer: SS

Comments:
a) Correspondence dating back to June 1988 incorporated into license.
b) Renewal took 33 months to issue.

File No.: 12
Licensee: City of Lewiston License No.: 01501
Location: Lewiston, ME Amendment No.: 1
License Type: Portable Gauge Type of Action: Amendment
Date Issued: 6/4/96 License Reviewer: SS

Comment:
a) Application in license file included privacy information that was not redacted or identified as such.

File No.: 13
Licensee: Bates College License No.: 01205-01
Location: Lewiston, ME Amendment No.: 0
License Type: Research and Development Type of Action: Amendment
Date Issued: 7/22/97 License Reviewer: SS

File No.: 14
Licensee: Diamed, Inc. License No.: 05349
Location: South Windham, ME Amendment No.: 1
License Type: Manufacturing Type of Action: Amendment
Date Issued: 8/25/95 License Reviewers: SS, JH

Comment:
a) Use of nonstandard language in license condition.

File No.: 15
Licensee: Fraser Papers Inc. License No.: 03311
Location: Madawaska, ME Amendment No.: 1
License Type: Fixed Gauge Type of Action: Amendment
Date Issued: 8/26/98 License Reviewer: SS

Comment:
a) Authorized user added to license without documentation of training or experience.

File No.: 16
Licensee: Maine Medical Center License No.: 05615-01
Location: Portland, ME Amendment No.: 2
License Type: Medical Institution Type of Action: Amendment
Date Issued: 5/28/97 License Reviewers: SS, JH

File No.: 17
Licensee: National Semiconductor Corp. License No.: 05637-02
Location: South Portland, ME Amendment No.: 2
License Type: Self-Shielded Irradiator Type of Action: Amendment
Date Issued: 7/17/98 License Reviewer: SS

Comment:
a) No documentation of deficiency telephone call in the file.

File No.: 18
Licensee: Aroostook Medical Center
Location: Presque Isle, ME
License Type: Teletherapy
Date Issued: 8/29/95
License No.: 03803-01
Amendment No.: 18
Type of Action: Amendment
License Reviewer: SS

File No.: 19
Licensee: CV Diagnostics, Inc.
Location: Waterville, ME
License Type: Limited Medical
Date Issued: 8/27/98
License No.: 11203
Amendment No.: 1
Type of Action: Amendment
License Reviewer: SS

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: ALL INCIDENTS LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Pharm-Corp of Maine
Licensee No.: 11713-01MD
Incident Log No.: None
Site of Incident: Lewiston, ME
Date of Incident: 3/21/96
Type of Incident: Transportation
Type of Investigation: None
Investigation Date: N/A
Summary of Incident and Final Disposition: Nuclear pharmacy delivery vehicle involved in a traffic accident during delivery of radiopharmaceuticals to local hospitals. Police officer at the scene had hazardous material training and determined that packages were not damaged. Packages were subsequently delivered to hospitals without incident.

Comments:
a) No follow-up to incident during next inspection of licensee.
b) Incident not cross-referenced in license file.

File No.: 2
Licensee: Turner School District
Licensee No.: Non-licensee
Incident Log No.: None
Site of Incident: Turner, ME
Date of Incident: Unknown
Type of Incident: Abandoned material
Type of Investigation: Site
Investigation Date: 9/24/96
Summary of Incident and Final Disposition: General licensed quantities of uranyl acetate and nitrate found in unoccupied school building. State personnel removed containers and transported back to office for disposal.

File No.: 3
Licensee: Penobscott Bay Medical Center
Licensee No.: 13701
Incident Log No.: None
Investigation Date: 9/10/97
Date of Incident: 4/10/97
Type of Incident: Procedural Failure
Type of Investigation: Site
Site of Incident: Rockland, ME
Summary of Incident and Final Disposition: A nuclear medicine technician failed to follow physician's instructions and administered Tc-99m hepatolite to patient when the result of a previous diagnostic test did not require administration of the radiopharmaceutical. Licensee classified incident as a reportable event. State personnel identified the incident during routine inspection and concurred with licensee's findings.

File No.: 4
Licensee: Industrial Metals
Licensee No.: Non-licensee
Incident Log No.: None
Site of Incident: Arundel, ME
Date of Incident: 7/3/98
Type of Incident: Contamination Event
Type of Investigation: Site
Investigation Date: 7/6/98
Summary of Incident and Final Disposition: Shipment of metal cans returned to facility from Bethlehem Steel in Bethlehem, PA after load tripped the radiation monitor at the Bethlehem facility. Radiation monitors were set at 10% above local background. Truck returned to Maine under DOT exemption. State personnel surveyed truck and did not identify any radiation levels above background. Truck and its contents were subsequently released.

Comments:
a) No documentation of event.
b) No supervisory review.

File No.: 5
Licensee: Worcester Energy Co.
Licensee No.: 29901
Incident Log No.: None
Site of Incident: Cherryfield, ME
Date of Incident: 6/20/98
Type of Incident: Damage to Equipment
Type of Investigation: Site
Investigation Date: 6/23/98
Summary of Incident and Final Disposition: Fire in plant area involved a fixed gauge. State personnel responded to scene and surveyed gauge. Recommended that licensee have the manufacturer inspect gauge to determine if fire damaged the shielding to the source.

Comments:
a) No documentation of event.
b) No supervisory review.
c) No follow-up performed to determine if shielding was evaluated.
d) Event should have been reported to NRC for inclusion in NMED.

STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
DIVISION OF HEALTH ENGINEERING
10 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0010

ANGUS S. KING, JR.
GOVERNOR

KEVIN W. CONCANNON
COMMISSIONER

November 15, 1998

Richard L. Bangart, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Bangart;

This letter is in response to the IMPEP review of the Maine Agreement State Program and the subsequent Draft Report conveyed with your letter dated October 21, 1998.

First I would like to relay my own feelings regarding the first IMPEP that Maine has been evaluated under. It is an excellent program with numerous opportunities for constructive feedback to the evaluated program. The review team was professional and thorough in their evaluations and fair in their recommendations and assessments.

My comments on the draft report are as follows:

1. Status of the Materials License inspection program. (Page 5 paragraph 2) We now have documentation on the new licensees and feel we can justify 6 of 13 not conducted in 6 months, instead of the 8 of 13 referenced, and only 3 of 13 not conducted within the first year of materials possession. Those 3 licensees were inspected at 13, 14, and 21 months of possession of materials. We can make reference to the specific licensees at the MRB or before if you wish. Our emphasis was mistakenly placed on inspecting the new licensees within one year, this has now been corrected. Health and safety was not compromised and consideration should also be given to the fact that 10 of the 13 new licensees were portable gauge licenses.

2. Recommendation 1: Since Maine's inspection priorities are more restrictive than the NRC's we will be undertaking a supervisory review to determine if we need to relax some of our priorities to manage the workload in a timely fashion.

3. Recommendation 2: We concur. This policy change has now been made, see #1.

4. Recommendation 3: We have documented what information is still available for the referenced allegations and incidents, one of which is still ongoing. All allegation and incident records must now receive supervisory review and do not expect this issue to happen again.

5. Recommendation 4: We have determined the State laws and Departmental policies regarding privacy information and are in the process of incorporating this into our own policies. This issue should be resolved before the end of the year.

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ATTACHMENT 1

6. Recommendation 5: We still expect the March 1999 date to be accurate for promulgation of all compatibility regulations required through the year 2000.

I have set aside the week of November 30 to December 4 for the MRB. I would also like to plan a meeting of our Advisory Committee on Radiation to review the new proposed rule changes for that week. If you could get back to me on a date for the MRB soon I would greatly appreciate it.

Thank you for your staff's time and for managing the IMPEP program. It is a very unique State and Federal partnership that is fostering growth for all of us.

Sincerely,

Jay Hyland, P.E., Manager
Maine Radiation Control Program
Division of Health Engineering