

October 3, 2002

Linda McLean, ASO
Region IV
U. S. Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Dear Ms. McLean;

Enclosed please find the completed IMPEP questionnaire for your (and the team's) review pending the review of the State of Maine's Agreement. If you need any additional information please let me know.

We look forward to seeing you on the 29th of October. If there are any specific needs that you or the review team have, that will make your stay in Maine more comfortable or productive please let Shawn or myself know and we will do what we can.

If there are any questions regarding the answers provided on the enclosed questionnaire that you or any team member would like answered before arrival, please give myself or Shawn a call and we will provide you with whatever additional information you need.

Sincerely,

/RA/

Jay Hyland, P.E.

Radiation Control Program
Maine Bureau of Health

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
QUESTIONNAIRE

Name of State: **Maine**

Reporting Period: **September 18, 1998, to October 25, 2002**

A. COMMON PERFORMANCE INDICATORS

I. Status of Materials Inspection Program

1. Please prepare a table identifying the licenses with inspections that are overdue by more than 25% of the scheduled frequency set out in NRC Inspection Manual Chapter 2800. The list should include initial inspections that are overdue.

Response: Currently there are no overdue inspections.

2. Do you currently have an action plan for completing overdue inspections? If so, please describe the plan or provide a written copy with your response to this questionnaire.

Response: Not applicable.

3. Please identify individual licensees or groups of licensees the State/Region is inspecting more or less frequently than called for in NRC Inspection Manual Chapter 2800 and state the reason for the change.

Response: See attached list

NOTE: Some of the inspection frequencies are the old NRC inspection frequencies, circa 1992. At the time that Maine became an Agreement State we made all of our inspection frequencies part of the rules. This was due to the fact that a fee was associated with the activity. In August of 1997 we went to an annual fee for funding the program that was dependent upon the type of licensed activity and removed the inspection frequencies from the rules. This gave us the option to decrease our frequencies to the present NRC frequencies, though we have chosen to not do that yet, since we believe that a more active inspection program is an asset to the overall program mission. A full listing with all program areas will be provided at the review. This chart incorporates the changes made with Temporary Instruction 2800/033 issued 04/02/02.

4. Please complete the following table for licensees granted reciprocity during the reporting period.

Priority	Number of Licensees Granted Reciprocity Permits Each Year	Number of Licensees Inspected Each Year
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Service Licensees performing teletherapy and irradiator source installations or changes	1998 - 2001 0 2002 1	1998 - 2001 0 2002 1
1	1998 3 1999 5 2000 2 2001 3 2002 1	1998 1 1999 3 2000 1 2001 1 2002
2		
3	1998 8 1999 14 2000 9 2001 12 2002 6	1998 1 1999 4 2000 3 2001 2 2002
4		
All Other	1998 - 1999 0 2000 1 2001 -2002 0	1998 - 2002 0

Please note: All of our category 3's are actually considered category 5's by NRC.

5. **Response: Not applicable.**

II. Technical Quality of Inspections

6. What, if any, changes were made to your written inspection procedures during the reporting period?

Response: Updates to field notes were made in response to changes of NRC Inspection Manual. All our inspection and licensing procedures mirror the NRC procedures to decrease development time on the Maine staff with the exception that a checklist is still utilized during the inspection.

7. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Inspector Supervisor License Cat. Date

Seeley Hyland02110 4/18/02

Malloch Hyland02120 5/17/02
Malloch White(NRC) 02120 5/24/01
Malloch Hyland02120 3/15/01

8. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field.

Response: Supervisory accompaniments have been conducted though no specific procedure exists to dictate how it is conducted, and the only documentation is found in the licensee file, in the inspection notes. Supervisory reviews of inspections are expected to be conducted yearly of all radioactive materials inspectors.

9. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available through the review period?

Response: See attached sheet for a list of instruments. Instruments are sent to a licensed entity who performs the calibrations.

III. Technical Staffing and Training

10. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response:

NAME	POSITION	AREA OF EFFORT	%FTE
Jay Hyland	Program Manager (SE III)	Administration(x-ray, non-ionizing etc.)	50
	Low Level Waste	10	
	Radioactive Materials	40	
Shawn Seeley	Rad Materials Inspector (ES III)	Radioactive Materials	100
Wayne Malloch	Rad Materials Inspector (ES III)	Radioactive Materials	100
Tom Hillman	LLW Inspector (AE)	Low Level Waste	100

11. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

Response: Wayne Malloch and Tom Hillman are both new since the last review. Mr. Malloch has attended the core courses required in IMC 1246 and is authorized to conduct license reviews and inspections in the State. Mr. Hillman is the Low Level Waste Coordinator and is working on becoming cross-trained as a radioactive materials inspector and license reviewer.

12. Please list all professional staff, who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapters 1246; for Agreement States, please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

Response: Tom Hillman will become cross-trained as a materials inspector and license reviewer. He attended the Inspection Procedures course but did not pass the first time in September 2000. The scheduled retake in September 2001 was canceled and he finally attended the course the week of September 16, 2002. Once he has attended the required courses and completed the required training outlined in IMC 1246, then he will be approved as an authorized radioactive materials license reviewer and inspector.

13. Please identify the technical staff, who left the RCP program during this period.

Response: NONE

14. List the vacant positions in each program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

Response: Not Applicable

IV. Technical Quality of Licensing Actions

15. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period. Also identify any new or amended licenses that now require emergency plans.

Response: During the review period, Maine Medical Center's medical license was converted into a broad scope license. We had 2 licensees go through bankruptcy (Brescia Construction and Pine State Environmental) and both ended up in terminated licenses. We also issued the program's first veterinary nuclear medicine license (Hypurrcat).

16. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

Response: The only variances came when dealing with a new medical technology or radiopharmaceutical, as was the case with intravascular brachytherapy (IVB) technology and the use of Zevalin as an approved radiopharmaceutical.

17. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

Response: Updates in any procedures were made in response to changes of NRC regulations and/or requirements. All our licensing procedures mirror the NRC procedures to decrease development time on the Maine staff including a checklist is still utilized during the inspection. We have developed all our checklists to mirror the NUREG 1556 series guidance.

18. For NRC Regions, identify by licensee name, license number and type, any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed.

Response: Not Applicable

V. Responses to Incidents and Allegations

19. For Agreement States, please provide a list of the reportable incidents (i.e., medical misadministration, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc. See Handbook on Nuclear Material Event Reporting in Agreement States for additional guidance.) that occurred during the review period. Information included in previous submittals to NRC need not be repeated (i.e., those submitted under OMB clearance number 3150-0178, Nuclear Material Events Database).

NONE

20. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? **NONE**

21. For Agreement States, for incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

Response: No, please see answer above. In the case of the Aroostook Medical Center, the equipment involved was the collimator of the source head and not the source head itself.

22. Identify any changes to your procedures for handling allegations that occurred during the period of this review. **Response: NONE**

VI. General

23. Please prepare a summary of the status of the State's actions taken in response to the comments and recommendations following the last review. Describe the results of any program audits completed during the review period.

Response: To recommendations:

1: ...that the State perform routine inspections at required frequencies. Response: With the hiring of Mr. Wayne Malloch in October 1998 we have been performing routine inspections at the required frequencies as evidenced in A.I.1 above as we currently have no overdue inspections.

2: ...that initial inspections be performed at 6 month intervals. Response: With the hiring of Mr. Wayne Malloch in October 1998 we have been performing initial inspections at the required 6 month frequencies, or if no material has been possessed or used at 1 year.

3: ...that the program consistently document and perform appropriate follow-up of all incidents. Response: The Program has a policy (unwritten) of "responding" to any complaint or question posed at any time. A file (red) is started and all the pertinent information relating to that case is placed inside for future reference.

4: ...that the program's procedures be reviewed and updated for handling allegations and other privacy information. Response: see response in #3 above.

5: ...that the State expedite promulgation of the compatibility related regulations.

Response: The Program has promulgated rules 3 times since the last review. The Program plans to promulgate rules on at least an annual basis. If the changes are determined to be minor in nature, then discretion can be used where rules may be promulgated every 2 years.

Response: To suggesttions:

1: ...that the RCP management continue supervisory review of inspection records.

Response: Currently all inspection reports are reviewed by the Manager of the RCP or a senior materials inspector.

2: ...that the State evaluate staffing needs to ensure its long-term ability to address regulations and timely completion of inspections. **Response:** The Program currently has no vacancies and we don't anticipate any for some time. However, the Program continues to consider staffing needs with the current economical forecasts and materials events within the State, especially in the wake of our only nuclear power plant decommissioning project.

24. For NRC Regions, briefly describe any recent efforts, or future plans, on your part to: (1) improve the safety performance of licensees operating below acceptable levels for ensuring public health and protection, (2) increase the public confidence in your program, (3) increase your effectiveness, and efficiency, or (4) reduce any unnecessary regulatory burden for your stakeholders. **Response: Not Applicable**

25. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems or difficulties, which occurred during this review period.

Response:

Strengths: We feel our strengths are those of any Agreement State, timeliness, and closeness to the regulated community being the biggest. We also feel that since the former senior materials inspector (Jay Hyland) and is now the program manager that he has a keen sense of the important issues of the NRC Agreement State Program. We have a relatively young staff (mostly late 30's), which could promote long-term stability and ensure consistency for an extended period of time. We currently have 2 individuals who are FEMA and DOE radiological trainers certified to train emergency responders and others in radiological monitoring and emergency preparedness.

Weaknesses: Due primarily to the size of the program the loss of even one trained individual has a significant effect on the program. When a new person is hired we need preferential treatment for training course attendance from the NRC. We intend to pay for our training and travel and have budgeted accordingly. There is one additional weakness related to the staff size and our own desire to meet the NRC training standards. That is with the frequency that the training courses are offered it may, depending on the individual hired, be 10 to 16 months before we have a new person trained to the standard. We are presently hoping for an individual with a significant amount of radiation safety experience. Additionally any large involved licensing actions like the Philips Elmet decommissioning (1997-98), large scale training efforts, and excessive resource needs related to 9/11/01, take a significant amount of time and staff effort.

B. NON-COMMON PERFORMANCE INDICATORS

I. Legislation and Program Elements Required for Compatibility

26. Please list all currently effective legislation that affects the radiation control program (RCP).

Response: Radiation Protection Statutes 22 MRSA § 661-690

27. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations. **Response: NO**

28. Please complete the enclosed table based on NRC chronology of amendments. Identify those that have not been adopted by the State as detailed in the current RATS form, explain why they were not adopted, and discuss any actions being taken to adopt them. Identify the regulations that the State has adopted through legally binding requirements other than regulations.

29. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

Response: Not Applicable

II. Sealed Source and Device Program

30. Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the review period. **Response: Not Applicable**

31. What guides, standards and procedures are used to evaluate registry applications? **Response: NRC License/review guides and procedures.**

32. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

Response: Jay Hyland and Shawn Seeley have attended the NRC's Sealed Source and Device course/workshop and are authorized to perform SS&D reviews, although no reviews have been conducted to date.

III. Low-Level Waste Program

33. Please include information on the following questions in Section A, as they apply to the Low-level Waste Program:

Response: Our low level waste position is primarily related to the legislature of Maine and the rules and regulations of the Texas-Vermont-Maine compact. The person is specifically a staff person to the Advisory Commission on Radioactive Waste, a commission to the

legislature. Though based on the technical nature of the position we hired a person that can be a support person to the Agreement State program as well. Please note that since the last review, the Maine Legislature has passed a law which will remove Maine from the above mentioned compact. Maine will therefore be out of the Texas Compact around May 2004.

IV. Uranium Mill Program

34. Please include information on the following questions in Section A, as they apply to the Uranium Mill Program:

Response: Not Applicable

TABLE FOR QUESTION 28.

10 CFR RULE	DATE DUE	DATE	OR	
		ADOPTED OR EFFECTIVE	CURRENT STATUS	EXPECTED ADOPTION
Any amendment due prior to 1993. Identify each regulation (refer to the Chronology of Amendments)		Up to Date	Up to Date	
Emergency Planning; Parts 30, 40, 70	4/7/93	8/1/01		
Standards for Protection Against Radiation; Part 20	1/1/94	8/1/01		
Safety Requirements for Radiographic Equipment; Part 34	1/10/94	8/1/01		
Notification of Incidents; Parts 20, 30, 31, 34, 39, 40, 70	10/15/94	8/1/01		
Quality Management Program and Misadministrations; Part 35	1/27/95	8/1/01		
Licensing and Radiation Safety Requirements for Irradiators; Part 36	7/1/96	N/A		
Definition of Land Disposal and Waste Site QA Program; Part 61	7/22/96	N/A		
Decommissioning Recordkeeping: Documentation Additions; Parts 30, 40, 70	10/25/96	8/1/02		
Uranium Mill Tailings: Conforming to EPA Standards; Part 40	7/1/97	N/A		
Timeliness in Decommissioning Parts 30, 40, 70	8/15/97	8/1/01		
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use; Parts 30, 32, 35	1/1/98	8/1/01		
Frequency of Medical Examinations for Use of Respiratory Protection Equipment	3/13/98	8/26/99		
Low-Level Waste Shipment Manifest Information and Reporting	3/1/98	8/1/02		
Performance Requirements for Radiography Equipment	6/30/98	8/1/01		

Radiation Protection Requirements: Amended Definitions and Criteria	8/14/98	8/1/01		
Medical Administration of Radiation and Radioactive Materials.10/20/	98	8/1/01		
Clarification of Decommissioning Funding Requirements	11/24/98	8/1/01		
10 CFR Part 71: Compatibility with the International Atomic Energy Agency	4/1/99	8/2/02		
Termination or Transfer of Licensed Activities: Recordkeeping Requirements.6/	16/99	8/26/99		
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act	1/9/2000	8/1/01		
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State	2/27/2000	8/1/01		
Criteria for the Release of Individuals Administered Radioactive Material	5/29/2000	8/1/01		
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations; Final Rule	6/27/2000	8/1/01		
Radiological Criteria for License Termination	8/20/2000	8/26/99		
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea	1/2/2001	8/26/99		
Deliberate Misconduct by Unlicensed Persons	2/12/2001	8/2/02		
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections	7/9/2001	8/1/01		
Minor Corrections, Clarifying Changes, and a Minor Policy Change	10/26/2001	8/1/02		
Transfer for Disposal and Manifest; Minor Technical Conforming Amendments	11/20/2001	8/1/02		
Radiological Criteria for License Termination of Uranium Recovery Facilities	6/11/2002	N/A		
Respiratory Protection and Controls to Restrict Internal Exposures	2/2/2003	8/1/02		
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications	5/17/03	8/1/02		
New Dosimetry Technology	1/8/04	8/1/01		

MATERIALS REQUESTED TO BE AVAILABLE FOR THE ONSITE PORTION OF AN IMPEP REVIEW

ORGANIZATION CHARTS

Clean, sized 8½ X 11" including names and positions

- 9 One showing positions from Governor down to Radiation Control Program Director (RCPD)
- 9 One showing positions of current radiation control program with RCPD as Head
- 9 Equivalent charts for LLRW and mills programs, if applicable

LICENSE LISTS

9 Printouts of current licenses, showing total, as follows:

Name	License #	Location	License Type	Priority	Last Inspection	Due Date
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Sort alphabetically

Also, sort by due date and by priority (if possible)

THE FOLLOWING LISTS

- 9 List of open license cases, with date of original request, and dates of follow up actions
- 9 List of licenses terminated during review period.
- 9 Copy of current log or other document used to track licensing actions
- 9 Copy of current log or other document used to track inspections
- 9 List of Inspection frequency by license type
- 9 List all incidents occurring during the review period. Show whether incident is open or closed and whether it was reported to the NRC
- 9 List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC
- 9 List of all wrongdoings occurring during the review period. Show whether the allegation is open or closed

THE FOLLOWING DOCUMENTS

- 9 All State regulations
- 9 Statutes affecting the regulatory authority of the state program
- 9 Standard license conditions
- 9 Technical procedures for licensing, model licenses, review guides
- 9 SS&D review procedures
- 9 Instrument calibration records
- 9 Inspection procedures and guides
- 9 Inspection report forms
- 9 Records of results of supervisory accompaniments of inspectors
- 9 Emergency plan and communications list
- 9 Procedures for investigating allegations
- 9 Procedures for investigating incidents
- 9 Enforcement procedures, including procedures for escalated enforcement, severity levels, civil penalties (as applicable)
- 9 Copies of job descriptions
- 9 Copies of audits or self audits conducted