

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

Name of State Program: Rhode Island

Reporting Period: 18 November 2002 to 22 October 2007

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer if appropriate.

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.



Recommendation 1

The review team recommends that the Office use a fully documented interim qualification program for inspectors. — Documentation of qualifications provided in original response has been followed and updated accordingly in assigning respective inspection and licensing tasks to staff.

Recommendation 2

The review team recommends that the Office implement the action plan and perform inspections of core licensees at their appropriate frequencies. — The action plan was implemented to regain control of inspections to meet the frequencies and progress was made to address the backlog. However, due to maternity leave, training requirements in other programs and loss of a chief for the Office the timeline has been adversely affected. The prospect of elimination of the program, that was proposed in October 2006, was also a major interruption due to considerations concerning relocation or loss of staff. This was further compromised with the actual loss of staff in May 2007.

Recommendation 3

The review team recommends that the Office inspect core licensees granted reciprocity in accordance with the criteria in IMC 1220. — Inspection of Core reciprocity licensees has been maintained at greater than or equal to 20 %. The current 2007 statistics reflect 4 inspections of the 11 Core licensees on record 1/07 to 8/27/07.

Recommendation 4

The review team recommends that the State adopt overdue regulations required for compatibility. — Regulations since the last IMPEP have been amended on September 2004 and September 2006. It is felt that for the most part we are up-to-date concerning compatibility issues.

¹ Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Recommendation 5

The review team recommends that the office train and qualify a sufficient number of reviewers to conduct and sign safety evaluations of SS&D applications in accordance with NRC/OAS Training Working Group Recommendations. — SS&D reviews were returned to the NRC in May 2006.

B. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Please provide the following organization charts, including names and positions:

(a) A chart showing positions from Governor down to Radiation Control Program Director;

▲ See Attached –Organization Chart 1-State Hierarchy

(b) A chart showing positions of current radiation control program including management; and

▲ See Attached – Organization Chart 2-Management

▲ See Attached – Organization Chart 3-Radiation Control Program

(c) Equivalent charts for sealed source and device, low level radioactive waste and uranium recovery programs, if applicable

▲ Not Applicable

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) of effort applied to the 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, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

▲

Name	Position	Area of Effort	FTE% Feb 07	FTE% Proposed
Dennis Klaczynski	Radiological Health Spec.	Licensing & Inspection	50/50	50/50
Vacant Position as of May 2007 [Charma Waring]	Industrial Hygienist	Licensing & Inspection	15/15	50/50
Shelley Regan	Industrial Hygienist	Emergency response, Equipment maintenance; GL-4 database	15/5/5	15/5/5
Bill Dundulis	Risk Assessment Toxicologist	Specialized licensing; Limited inspections; Emergency response; Regulations & policy	15/5/2.5/3	20/10/5/5
Jack Ferruolo	Supervising Radiological Health Specialist	Administration, Licensing, Inspection,(Training) , Emergency response	30/15/10/5	30/15/10/5

NOTE:

FTE's < 100% are utilized in X-Ray, Tanning, Mammography or other programs.

Proposal with reorganization in program is to add 1 FTE (replacement of vacant Position at 100%) and increase FTE's in other areas by a total of 15%/RAM program.

4. 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, as appropriate.

▲ Not applicable – No new professional staff since last IMPEP.

5. Please list all professional staff who have not yet met the qualification requirements for a license reviewer or materials inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

▲ Not Applicable – per staffing effective August 2007-Table provided for perspective re: program status prior to changes in 2006 and finalized in May 2007. Prior to May 2007 C. Waring was performing limited licensing and inspection actions related to gauge licenses and selective medical licenses.

Employee	Qualifications for License Reviewer/ Inspector	Courses or Training Needed
Dennis Klaczynski License Review & Insp.	Applied Health Physics; Licensing & Inspection Procedures; Industrial Radiography; Transportation	Further experience in inspection procedures
Charma Clay Inspection, Limited. Vacant Since May 2007	Basic Rad Safety & Health Physics; Inspection & Licensing Procedures; Nuclear. Medicine; Transportation; Industrial Radiography	Industrial Radiography and Transportation. Further development of inspection skills as related to radioactive materials.

6. Identify any changes to your qualification and training procedure that occurred during the review period.

▲ None — Excluding IC training for two staff.

The inspection procedures have not changed appreciably during this reporting period. NRC-RI state inspection manuals are utilized to set the stage for the inspection process. RI RCA inspections have routinely been, in essence, performance based. However the flow of an inspection may require in-depth review of specific actions, as dictated by individual records identified during an overall review and/or their level of completeness.

Inspection forms remain unchanged. Implementation of newly generated inspection forms was planned with the changes in RCA regulations. It was felt that utilization of the "old" forms would be helpful during the instructional phases of the inspection process. Changes have not been implemented due to the uncertainty in staffing of the program. It was intended that the inspector could refer to previous inspection entries for direction/assistance in the inspection process instead of having to learn a new mechanism that the instructor also needs to become familiar with. It was a goal to develop new inspection forms once the backlogs in other major areas were properly addressed.

7. Please identify the technical staff that left your program during the review period.

▲ Charma Waring (Industrial Hygienist). Utilized for limited inspections and license review.

8. 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.

▲ Position of Industrial Hygienist has been vacant (officially) since 5 May 2007. Since October 2006 the program was under review for elimination with return of Agreement to the NRC. Official notification to NRC of possible return was made in a letter dated 20 February 2007. Effective 1 July 2007a reorganization, tied to the implementation of new licensing fees, has been under way. Proposed new fees have just completed a mandated public review period and are in the process of being filed with the Secretary of State. Estimated effective date is early October 2007. It is anticipated that a re-staffing of the program will be initiated after implementation of the new fees. Proposal is for development of a Radiological Health Position to replace one of the Industrial Hygienist Positions. This individual (1 FTE) will be responsible for licensing and inspection activities.

9. For Agreement States, does your program have an oversight board or committee, which provides direction to the program and is composed of licensees and other members of the public? If so, please describe the procedures used to avoid a conflict of interest.

▲ § 23-1.3-13 Radiation advisory commission. – There is created an advisory commission to be known as the state radiation advisory commission, which shall consist of eleven (11) members.

The make-up of the committee, the term of appointment and the voting requirements all have a controlling interest in addressing potential conflicts. In addition, in the past, members who had a potential for a conflict would remove themselves from voting on the matter. The Commission functions as an “advisory” group with the Agency having the discretion to accept or reject direction from the commission.

II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC’s Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: licensee name, license number, your inspection interval, and rationale for the difference.

Licensee Name	Licensee Number	RI Inspection Interval	Rationale
Rhode Island Hospital-gamma knife	7A-051-02	3*	Based on past findings and involvement with other licensing/inspection actions.

*It should be noted that if there were other licensees in this category, they would be designated as inspection priority 2 until an inspection history has been acquired and evaluated.

11. Please provide the number of Priority 1, 2, and licensees, as identified in IMC 2800; the number of initial inspections; and the number of increased controls inspections that were completed during the review period.

Priority	1	2	3	5	TOTAL
Total Licensees/priority	6	6	13	36	61
Routine Insp.	19	15	22	44	100
Initial Insp.	0	1	1	6	8
IC Insp.	6	4	2	2	14

NOTE: Current Licensee base is 59 as of 7 September 2007

12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees, increased controls, and initial inspections that are were **conducted overdue** per the applicable guidance. Priority 1, 2, and 3 licensees and initial inspections must be conducted at least as frequently as the inspection intervals established in IMC 2800. Increased controls inspections should be conducted at the intervals established in the Staff Requirements Memorandum for COMSECY-05-0028.

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

▲ Refer to Appendices 1A-1F: Conducted Overdue Routine Inspections – year

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees, increased controls, and initial inspections that are **currently overdue**, per the applicable guidance. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection.

▲ Refer to Appendix 2: Overdue Inspections as of 7 September 2007

14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and the number of candidate reciprocity inspections that were completed each year during the review period.

▲ Refer to Appendix 3: Reciprocity Inspections – 2002 to 2007.

In general, any Category A or Category B approvals would be a candidate for inspection, if they actually entered the state (i.e., some companies maintain a reciprocity approval “just in case” they need to provide short notice services for existing clients). Category C approvals are generally not candidates for inspection. However, they are reviewed on an individual basis (e.g., scope of work, client, past compliance history, etc.) to determine if they should be scheduled for a reciprocity inspection.

III. Technical Quality of Inspections

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

▲ No significant changes to Inspection Procedures Manual or inspection forms. However, inspection frequencies were adjusted in January 2006 to be consistent with revised (2005) NRC inspection frequencies.

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

▲ Refer to Appendix 4: Accompaniments – 2002 to 2007

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

▲ Instrument calibration is provided by equipment mfg. and/or outside vendors. All field instruments are calibrated on an annual frequency and rotated such that sufficient quantities of instruments will be available for use during calibration periods. Laboratory capabilities are limited-the state laboratory no longer has the capabilities to provide assistance with evaluating wipes or other field samples. The Memorandum of agreement with the Nuclear Science Center was terminated by the Science Center on 18 July 2003. Since that time an understanding with two broad scope licensees, that have lab capabilities, was arranged on an as-needed basis to provide limited laboratory assistance.

IV. Technical Quality of Licensing Actions

18. How many specific radioactive material licenses does the Program regulate at this time?

▲ Refer to Appendix 5: Current Licensees [59 specific licensees].

19. 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.

▲ Rhode Island Hospital is our most complex licensee and had requested a number of significant license amendments during the period of this review. While other licenses have been issued, renewed, terminated or decommissioned during the period of this review, none of them would be considered complex or unusual licensing actions that required a disproportionate amount of staff effort for review. However, it should be noted that licensing certain new technologies (e.g., PET and PET/CT), where regulatory jurisdiction is shared with other Health Department agencies, does require a high degree of coordination (and some additional meetings) to ensure that no regulatory approvals are granted until all agencies are ready to proceed with licensing. There were no bankruptcy notifications submitted during the period of this review.

▲ Additional details are provided in Appendix 6: License Terminations – 2002 to 2007

20. Identify any licensees or groups of licensees that were issued increased controls during the review period. Those licensees that were initially identified during the initial implementation of increased controls need not be listed.

▲ No additional increased controls have been imposed on new licensees. However, Rhode Island Hospital has added additional use location that requires implementation of increased controls.

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

▲ No significant variances or exemptions were issued during the period of this review.

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

▲ Revised licensing checklists have been prepared for reviewer use, particularly with regard to medical licensing. In addition, RI-specific regulatory guides (comparable to NUREG 1556 series) have been issued for human-use licenses and academic, research and development, and other licenses of limited scope. RI-specific forms comparable to the latest (2007) NRC forms utilized to document training, experience and preceptor attestation for medical use licensees are in final draft form and will be available for use before the IMPEP site visit.

23. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

▲ Refer to Appendix 7A: Overdue Renewals – 2002 to 2007 and Appendix 7B: Licensing Actions – 2002 to 2007.

Renewal reviews were delayed for a number of reasons, primarily staffing and other actions in the program. During this period 2002 – 2007 attempts were initiated to decrease this backlog by Administrative means. In 2005-2006 attempts were made to extend the expiration date such that licenses are issued for a 10-year term. However, due to program issues with the licensing database this was not accomplished until October 2006. In addition, also during this period 2002-2007 C.

Waring was on maternity leave in “2002-2003” and “2004-2005”. Attempts were made to secure approval for license reviews to be performed while on maternity leave at home. However, Health Department senior management was not willing to approve this request.

V. Technical Quality of Incident and Allegation Activities

24. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See STP Procedure SA-300, *Reporting Material Events* for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:



<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>
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All reportable events have been previously submitted to NMED

25. 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? For Regions, was an appropriate and timely PN generated? For Agreement States, 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.

▲ All reportable incidents/events involved human error and/or failure to follow established procedures. None of the incidents/events involved equipment or source failure or approved operating procedures that were deficient.

26. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

▲ No changes to our protocols for handling incidents or allegations were implemented during the period of this review.

C. **NON-COMMON PERFORMANCE INDICATORS**

I. Compatibility Requirements

27. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

▲ All specific enabling authority for the radiation control program is pursuant to *RIGL 23-1.3 - Radiation Control*. [<http://www.rilin.state.ri.us/Statutes/TITLE23/23-1.3/INDEX.HTM>]. Although several clarifying amendments to this enabling authority were proposed during the 2007 legislative session, none of them were enacted into law. There have been no other changes to our enabling legislation during the period of this review.

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

▲ The *Rules and Regulations for the Control of Radiation* are not subject to a specific “sunset” law per se. However, RIGL 42-35-4.1 requires that all regulations promulgated by state agencies be administratively refiled every five years to remain in effect. The radiation control regulations were last administratively refiled in January 2007 and will not be due for refile again until January 2012. [<http://www.rilin.state.ri.us/Statutes/TITLE42/42-35/42-35-4.1.HTM>]

29. Please review and verify that the information in the enclosed State Regulation Status sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them.

▲ The last major amendments to *Rules and Regulations for the Control of Radiation* were in September 2006 and included the remaining 10 CFR 35 compatibility items. [i.e., through RATS 2005-3]. The June 2007 and October 2007 amendments only implemented fee schedule revisions and did not address any other technical issues. Certain aspects of RATS 2004-1 (Compatibility with IAEA) have been deferred pending approval of the revised SSR CR Part T. This matter has previously been discussed with NRC. RATS 2006-1 is not due for implementation until March 2009. We have opted to delay adopting regulatory amendments consistent with RATS 2006-2 & 2006-3 until such time as the NRC has set a definite date for full implementation of the National Source Tracking System. It did not appear that any of our current licensees would be subject to the requirements under RATS 2006-2 (6 Feb 2007). We have also reviewed our current licensee database to determine if any amendments will be necessary to implement the RATS 2006-3 (15 & 30 November 2007) requirements. No licensees are currently authorized to possess Category 1 sources. A total of twelve licensees were identified as authorized to possess one or more Category 2 sources. We understand that the NRC will issue additional guidance prior to the 15 November 2007 deadline to modify the specified reporting dates. Therefore, we do not intend to issue these license amendments until such time as the NRC has issued more definitive guidance on this issue.

If legally binding requirements were used in lieu of regulations, please describe their use.

▲ As noted above, license amendments have been considered with regards to RATS 2006-3 requirements. We had previously (October 2005) issued appropriate license amendments with regard to implementation of increased controls [RATS 2005-3].

30. 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.

▲ The protocols currently used to maintain compatibility with NRC regulations are essentially identical to those which have been utilized by the Radiation Control Program since receipt of the Agreement in 1980:

1. Applicable NRC regulations (and any applicable SSR CRs) are reviewed by senior staff who generate proposed amendments that are compiled in accordance with our existing regulation format. The length of time for this step is highly variable and depends on the number and complexity of regulations to be reviewed.
2. Once the proposed regulatory changes have been compiled into a "Draft Regulations" document, it is presented to our Radiation Advisory Commission for their review and comments. This is typically accomplished within a month of document completion.
3. At this stage the "Draft" document is typically assigned to the Regulations Subcommittee for further review and modification to produce a "Final" document. This document then comes back to the Commission for additional review before going to public hearing. Although the Commission is only advisory in nature (i.e., does not have any statutory oversight authority), the Radiation Control Program will generally attempt to address any of their concerns before bringing proposed amendments to public hearing. As with step 1, the length of time for this step is highly variable and depends on the number and complexity of regulations to be reviewed.
4. After the public hearing and comment period the "Final" document is adopted as regulation. The public hearing/comment process is governed by our State Administrative Procedures Act, which establishes certain minimum time periods for the various steps in the process. It typically takes approximately 8-10 weeks from the time that a set of proposed amendments is initially

posted for public hearing and the time that they are actually in effect. Regulations which receive multiple or highly technical comments may require additional time for proper review.

II. Sealed Source and Device Program ***NOT APPLICABLE FOR RHODE ISLAND***

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of devices issued during the review period. The table heading should be:

SS&D Registry Number	Manufacturer, Distributor or Custom User	Product Type or Use	Date Issued	Type of Action
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32. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

Technical Staffing and Training - Questions 2-9

Technical Quality of Licensing Actions - Questions 18-23

Technical Quality of Incident and Allegation Activities - Questions 24-26

III. Low-Level Radioactive Waste Disposal Program ***NOT APPLICABLE FOR RHODE ISLAND***

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

Technical Staffing and Training - Questions 2-9

Status of Materials Inspection Program - Questions 10-14

Technical Quality of Inspections - Questions 15-17

Technical Quality of Licensing Actions - Questions 18-23

Technical Quality of Incident and Allegation Activities - Questions 24-26

IV. Uranium Recovery Program ***NOT APPLICABLE FOR RHODE ISLAND***

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

Technical Staffing and Training - Questions 2-9

Status of Materials Inspection Program - Questions 10-14

Technical Quality of Inspections - Questions 15-17

Technical Quality of Licensing Actions - Questions 18-23

Technical Quality of Incident and Allegation Activities - Questions 24-26