

March 2, 2004

Patricia A. Nolan, M.D.
Director
Rhode Island Department of Health
Three Capitol Hill
Cannon Building, Room 401
Providence, RI 02908

Dear Dr. Nolan:

Enclosed is the final report of the follow-up Integrated Materials Performance Evaluation Program (IMPEP) review of the Rhode Island radiation control program. The review was conducted by a review team consisting of technical staff members from the U. S. Nuclear Regulatory Commission (NRC) on November 17-18, 2003. The team reviewed, in detail, the performance indicator of concern identified during the 2002 IMPEP review, Status of Materials Inspection Program. Ms. Patricia Larkins, NRC Office of State and Tribal Programs, was the team leader for the follow-up review.

The team noted that significant program improvements have been implemented by Rhode Island, which include reducing the inspection backlog and recruiting and training of two new technical staff. The review team recommended closure of four of the five recommendations from the 2002 IMPEP review. These actions have demonstrated a high level of management support for the Agreement State program and a commitment to operating and maintaining a fully satisfactory program in the future.

We appreciate receiving Ms. Marie Stoeckel's e-mail, dated January 16, 2004, supporting the review team's findings and draft follow-up report.

Based on the follow-up IMPEP review, the Management Review Board (MRB) agreed that Rhode Island's performance with respect to the common performance indicator, Status of Materials Inspection Program, be changed from the November 2002 IMPEP review finding of unsatisfactory to satisfactory. The review team recommended and the MRB agreed on discontinuance of the heightened oversight process; however, the NRC will continue to monitor State activities through quarterly teleconferences between the Regional State Agreements Officer and Rhode Island management. The quarterly teleconferences are designed to assess the progress of the State to maintain program improvements, and to address areas that require additional progress.

Section 3.0, on page 4 of the enclosed final report, presents the one open recommendation from the 2002 IMPEP review. We request your response to the open recommendation within 30 days from receipt of this letter.

Based on the results of the follow-up IMPEP review, the next full IMPEP review will be scheduled approximately four years from the 2002 IMPEP review, with a periodic meeting approximately 18 months from the date of the follow-up IMPEP review. This periodic meeting will consider and address removing the program from monitoring if the State maintains satisfactory performance over the 18-month period.

Patricia A. Nolan, M.D.

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I appreciate the courtesy and cooperation extended to the IMPEP team during the follow-up review and your support of the radiation control program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and
State Programs

Enclosure:
As stated

cc: Walter S. Combs, Jr., Ph.D.
Executive Director
Environmental Health

Marie Stoeckel, Chief
Occupational and Radiological Health

Peter Todd, State Liaison Officer
Rhode Island Emergency Management Agency

Mike Broderick, OK
OAS Liaison to the MRB

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bcc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF RHODE ISLAND AGREEMENT STATE PROGRAM

NOVEMBER 17-18, 2003

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the follow-up review of the Rhode Island Agreement State program conducted November 17-18, 2003. This follow-up review was directed by the Management Review Board (MRB) based on results of the November 18-22, 2002 IMPEP review. The MRB directed that a follow-up review of the common performance indicator, Status of Materials Inspection Program, be conducted approximately one year from the last review due to a finding of unsatisfactory for this performance indicator. The follow-up review also included evaluation of the actions taken by the State to address the five recommendations made during the 2002 review. Other aspects of the program, not fully evaluated as part of the follow-up review, were discussed at a periodic meeting held in conjunction with the review. The periodic meeting summary can be found in Appendix D.

The follow-up review was conducted by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC). Review team members are identified in Appendix A. The follow-up review was conducted in accordance with the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the follow-up review, which covered the period of November 23, 2002 to November 17, 2003, were discussed with Rhode Island management on November 18, 2003.

The Rhode Island Agreement State program is administered by the Office of Occupational and Radiological Health (the Office). The Office Chief reports directly to the Executive Director of Environmental Health located in the Department of Health (the Department). Organization charts for the Office and the Rhode Island Department of Health are included as Appendix B. At the time of the follow-up review, the Rhode Island Agreement State Program regulated approximately 53 specific licenses authorizing Agreement materials. The review focused on the regulatory 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 Rhode Island.

Prior to the follow-up review, the NRC conducted a period of heightened oversight of the Rhode Island program, which included the State's development and implementation of a Program Improvement Plan (the Plan) in response to the 2002 IMPEP review. Bimonthly conference calls were conducted between the NRC and Rhode Island to discuss the State's progress in implementing the Plan. Conference calls were held April 7, 2003; June 11, 2003; August 13, 2003; and October 1, 2003. The Plan and minutes from the bimonthly calls can be found in Appendix C.

The review team's general approach for conduct of this follow-up review consisted of: (1) examination of the heightened oversight information; (2) analysis of quantitative information from the Office's inspection databases; (3) review of the status of applicable Rhode Island statutes and regulations; (4) interviews with staff and management to answer questions or clarify issues; and (5) summary review of the Office's inspection files. The review team evaluated the information gathered against the IMPEP performance criteria for the single common performance indicator and made a preliminary assessment of the State's performance.

Section 2 below discusses the results of the follow-up review of the Rhode Island program for the single common performance indicator, including two recommendations from the previous

review. Section 3 summarizes the follow-up review team's findings and one open recommendation. A response is requested from the Program to this one open recommendation. The general status of the other aspects of the Rhode Island program addressed during periodic meeting discussions can be found in Appendix D.

2.0 COMMON PERFORMANCE INDICATORS

The follow-up review addressed one of the five common performance indicators used in reviewing both NRC Regional and Agreement State programs. The team reviewed the one indicator, Status of Materials Inspection Program.

2.1 Status of Materials Inspection Program

During the follow-up review, the review team evaluated actions taken by the Office in response to the finding of unsatisfactory made during the 2002 IMPEP review, the status of the inspections performed since the 2002 review, and the current status of due and overdue inspections.

The team focused on the timeliness of core and initial inspections performed since the last review period, the current and projected backlog of overdue inspections, reciprocity inspections, and the timeliness in communication of inspection results to licensees. The evaluation is based on data provided by the Office from their inspection tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

Two of the five recommendations from the 2002 IMPEP review primarily relate to the materials inspection program. The review team's evaluation of the Office's actions to these recommendations is discussed below. Actions in response to the remaining three recommendations are presented in the periodic meeting summary.

Recommendation 2

The review team recommends that the Office implement the action plan and perform inspections of core licenses at their appropriate frequencies.

Current Status

At the time of the 2002 review, the Office had 14 overdue core inspections. Over the last year, the Office completed 13 of these inspections. The one remaining overdue inspection was not completed due to the renewal of the license and change in the Radiation Safety Officer. The renewed license was issued in early November 2003 and the inspection has been scheduled for January 2004.

Since the last review, two core inspections became due and were conducted within the appropriate frequency. One new license was issued in September 2002 and the initial inspection was conducted in January 2003. A second new license was issued in September 2003 and has been scheduled for inspection in February 2004.

The team determined that the Office has scheduled all core and non-core licensees at the appropriate frequency in accordance with Inspection Manual Chapter (IMC) 2800. The review team recommends that this recommendation be closed.

Recommendation 3

The review team recommends that the Office inspect core licensees granted reciprocity in accordance with the criteria in IMC 1220.

Current Status

Since the 2002 review, the Office has received and approved reciprocity requests for 11 core licensees to conduct licensed activities in the State. The Office inspected four of these licensees. The performance criterion for conducting inspections is 20 percent of core licensees granted reciprocity as indicated in IMC 1220. The Office's performance exceeds the criteria in IMC 1220. The review team recommends that this recommendation be closed.

In addition to the recommendations above, the timeliness of issuance of inspection results was also reviewed by the review team for this indicator. The review team reviewed 19 inspection reports and found that 14 were issued within 30 days. The remaining five reports were issued between 32 and 57 days after the conclusion of the inspection. Three of the five reports were issued during the first half of the review period when the Section Supervisor was working with new inspectors to complete the inspection documents and related correspondence.

Inspection reports, enforcement documentation, and inspection field notes for 10 materials inspections conducted during the review period were evaluated by the review team. The casework included all three of the Office's materials inspectors, and covered inspections of various types as follows: portable gauge, medical broad scope, manufacturing and distribution, service (source exchange), industrial radiography, and medical institution. Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation adequately supported the cited violations. Exit interviews were held with appropriate licensee personnel. Team inspections were performed when appropriate and for training purposes. The review team found that violations are categorized into severity levels which can later be used for escalated enforcement, if necessary. All inspections are reviewed and approved by the Section Supervisor.

In summary, since the last review, the Office completed 13 overdue core inspections, two core and one initial inspection that became due during the review period, four reciprocity inspections, and nine non-core inspections. Future inspections have been scheduled in accordance with IMC 2800. The completion of these inspections and the training of new staff to conduct inspections independently demonstrates that the Office has improved its performance for this indicator during the review period.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Rhode Island's performance with respect to the indicator, Status of Materials Inspection Program, be changed from unsatisfactory to satisfactory.

3.0 SUMMARY

The team noted that significant program improvements have been implemented by the Office, which include reducing the inspection backlog and recruiting and training of two new technical staff. The Office is also working towards transferring responsibility for Sealed Source and

Device Evaluation Program reviews for the State's sole manufacturing and distribution licensee to the Commonwealth of Massachusetts. The review team recommends closure of four of the five recommendations from the 2002 IMPEP review. These actions have demonstrated a high level of Department management support for the Agreement State program and a commitment to operating and maintaining a fully satisfactory program in the future.

The Office has completed the majority of the Plan activities and has almost eliminated the inspection backlog. Therefore, the follow-up review team recommends that Rhode Island's performance for the indicator, Status of the Materials Inspection Program, be changed to satisfactory. The team found that although the status of Legislation and Program Elements Required for Compatibility was found satisfactory during the 2002 IMPEP review, based on an anticipated adoption date of the first half of 2003, little progress has occurred since the 2002 IMPEP review. The amendments remain under review by the State's Radiation Advisory Commission.

Based on the overall findings, the review team recommended and the MRB agreed on discontinuance of heightened oversight. The team recommended and the MRB agreed that the NRC will continue to monitor State activities through quarterly teleconferences between the Regional State Agreements Officer and Rhode Island management. The quarterly teleconferences are designed to assess the progress of the State to maintain program improvements, and to address areas that require additional progress, such as the adoption of overdue regulations, identified in the Plan, which addressed the recommendations in the final 2002 IMPEP report. Finally, the review team recommended and the MRB agreed that the NRC conduct a periodic meeting approximately 18 months from the follow-up review, in April 2005. This periodic meeting will consider and address removing the program from monitoring if the State maintains satisfactory performance over the 18-month period. The next full review should be conducted approximately four years from the November 2002 IMPEP review.

Below is the one open recommendation from the 2002 IMPEP report. No new recommendations were identified during the current review.

1. The review team recommends that the Office adopt overdue regulations required for compatibility. (Section 4.1.2) (Recommendation 4 from the 2002 report)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Rhode Island Organization Charts
Appendix C	Heightened Oversight Program Correspondence
Appendix D	Periodic Meeting Summary
Attachment	January 16, 2004, E-mail from Marie Stoeckel, Chief, Office of Occupational and Radiological Health

APPENDIX A
IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Patricia M. Larkins, NRC/STP	Team Leader Periodic Meeting
Duncan White, NRC Region I	Status of Materials Inspection Program Periodic Meeting

APPENDIX B

RHODE ISLAND
DEPARTMENT OF HEALTH

ORGANIZATION CHARTS
ML040290369

APPENDIX C

HEIGHTENED OVERSIGHT PROGRAM CORRESPONDENCE

Minutes of Bimonthly Conference Calls:

1. April 7, 2003 Minutes (ML031190582)
2. June 11, 2003 Minutes (ML031700324)
3. August 13, 2003 Minutes (ML032471541)
4. October 1, 2003 Minutes and Rhode Island October 2003 Bimonthly Report as of September 17, 2003 (ML032890108); ML032800882)

Letters from/to Rhode Island:

1. March 31, 2002 Letter from P. A. Nolan to C. J. Paperiello submitting Program Improvement Plan (ML031000330)

APPENDIX D

PERIODIC MEETING SUMMARY INCLUDING STATUS OF OTHER RECOMMENDATIONS FROM THE PREVIOUS REVIEW

A periodic meeting was held with Rhode Island management by Patricia Larkins, Team Leader, and Duncan White, Regional State Agreements Officer (RSAO), during the follow-up review pursuant to STP Procedure SA-116, "Periodic Meeting with Agreement States Between IMPEP Reviews." Those topics normally documented during the periodic meeting that received full evaluation as part of the follow-up review will not be discussed in this Appendix. The following topics were discussed:

Status of Recommendations from 2002 Report

See Sections 2.1 for details on recommendation numbers 2 and 3. The status of the remaining recommendations from the 2002 IMPEP report are described below.

1. The review team recommends that the Office use a fully documented interim qualification program for inspectors. (Section 3.1 of 2002 report)

Current Status: The Office developed and implemented an interim qualification program form for inspectors through a Personnel File Memo and a Matrix Training History Form, which were reviewed by the team. The Personnel File Memo identifies the specific inspection categories for which the staff member has been deemed qualified with references to general training categories and accomplishments, i.e. selective NRC training courses, on-the-job-training, mentored accompaniments, and previous experience. The Matrix Training History Form is used to monitor the status of training and is similar to the training form included in the NRC/OAS Training Working Group Report. This form includes the year for completion of core, supplemental, and other training courses, as well as courses waived and courses needed but not completed. Due to the significant staff effort directed towards reducing the inspection backlog and training new staff, the Office was unable to develop training qualification criteria, which has been defined as a long-term goal for the program. The review team recommends that this recommendation be closed.

4. The review team recommends that the State adopt overdue regulations required for compatibility. (Section 4.1.2)

Current Status: As of the 2002 IMPEP review, all due and overdue amendments had been drafted and were under review by the State's Radiation Advisory Commission. Little progress has occurred since the 2002 IMPEP. The amendments are currently under review by a subcommittee of the State's Radiation Advisory Commission. This recommendation remains open.

5. The review team recommends that the Office train and qualify a sufficient number of reviewers to conduct and sign safety evaluations of sealed source and device (SS&D) application in accordance with NRC/OAS Training Working Group Recommendations. (Section 4.2.2)

Current Status: The Office determined that it could not justify the amount of resources necessary to maintain at least two qualified individuals to review SS&D applications for the State's one manufacturer and distributor licensee with two registration sheets. The Office discussed this matter with the licensee and they agreed to formally request transference of the Rhode Island registration sheets to the Commonwealth of Massachusetts. The licensee has a research and development facility in the Commonwealth and has an active registration sheet issued by the Commonwealth for a similar device. The Massachusetts Radiological Health Program maintains several qualified SS&D reviewers due to the significant number of manufacturers and distributors in their jurisdiction. A written request has not been received by the Office from the licensee to transfer the sheets due to a change in the licensee's Radiation Safety Officer. At this time, the Office maintains the registration sheets.

The Office indicated that if an application for an SS&D review was received in the near future, the Office would solicit assistance from the New England Radiological Health Compact to review these sheets. The SS&D sheets would be issued and maintained by the State of Rhode Island. In the long term, Office management would like to train at least two staff members to complete SS&D reviews. At this time, however, core training is of higher priority. The review team recommends that this recommendation be closed.

Current Program Status

A detailed discussion of the Office's inspection program can be found in Section 2.1.

The Office indicated that they plan to revise their inspection field notes next year due to the revision of Part 35 and the State's anticipated adoption of this revision.

The Office currently has 53 specific licenses. The staff discussed the current status of the licensing program. There are currently 19 licensees in timely renewal. All of these actions have been reviewed by Office staff at least once and are currently in various stages of the review process. The Office is currently reviewing two amendments that present some challenges. One action involves the approval of Zevalin at a medical Broad scope and the second involves possession limit increases of xenon and iodine-131 at the State's only nuclear pharmacy. Office staff expects all issues to be satisfactorily resolved and the amendments issued in a timely manner.

The status of the Office's proposed changes to their regulations is discussed in detail under the recommendations status of this appendix.

Program Strengths and/or Weaknesses

In general, the Office Chief related that the program has adequate administrative support, good legal support, stable funding levels and satisfactory laboratory support. The Office has access to the services of a staff member, from another office, to support rulemaking efforts. The Department has hired a new bioterrorism staff member who will provide emergency operations support. The new staff member will also provide support to the Office through management of technical equipment, including maintaining calibration schedules for radiation survey instruments.

The Office experienced significant staffing turnovers that notably impacted the program. The staffing issues impacted the Offices ability to satisfactorily conduct timely inspections, which

resulted in an inspection backlog. As a result of the inspection backlog the Office was placed under heightened oversight during the 2002 IMPEP review. The Office implemented a Program Improvement Plan and has made progress with most of the programmatic issues identified during the 2002 IMPEP review.

The Office has made improvements through the hiring and training of two new staff. The Office is working towards transferring the Sealed Sources and Device Evaluation Program (SS&D) reviews to the Commonwealth of Massachusetts. Considerable efforts were expended in meeting with staff of the Commonwealth to cooperatively find a solution to staffing concerns for SS&D reviews for the one licensee that manufactures devices and distributes under a general license. Although the Office hired two new staff, unforeseen absences occurred that resulted in delays in planned training efforts to fully qualify new staff. The two new staff members have been successfully interim qualified to conduct inspections. While continuing to train new staff, the Office redirected primary staff efforts towards reducing the inspection backlog. The major effort put forth by the inspection supervisor and his staff to reduce the inspection backlog has resulted in only one remaining overdue inspection.

The Office has experienced little progress in the adoption of regulations since the 2002 IMPEP review. Although the Office has significantly reduced the inspection backlog, seven of the ten regulations identified during the 2002 IMPEP review are overdue for adoption and under continued review by the Radiation Advisory Commission. The program will need additional time to maintain operation at a satisfactory level; therefore, the 2003 follow-up IMPEP review team is recommending that NRC monitor program activities through quarterly teleconferences.

Feedback on NRC's Program

The Office Chief and program staff expressed their appreciation for NRC staff's assistance with regard to a number of issues raised over the past year.

Status of Program and/or Policy Changes

There have been no changes to the Office's enabling legislation, its responsibilities, or staff since the last review. Funding levels are anticipated to remain unchanged.

Impact of NRC Program Changes

The NRC staff discussed recent developments regarding the nominations for the two vacant Commission positions. Also discussed was the consolidation of the Region I and Region II materials programs, the status of National Materials Program pilot projects, and the potential impact of NRC's aging workforce (i.e., succession planning). NRC staff also highlighted the proposed changes to two documents that directly affect the IMPEP process: Management Directive 5.6 and STP Procedure SA-116. There was also a discussion on materials licensee security and the proposed 274i Agreements. The Office staff inquired about the status of the final 274i Agreement. The NRC staff indicated that a final 274i Agreement is undergoing staff review. NRC staff also clarified that the proposed Agreement currently covers large irradiators and will encompass additional license types in the future, as necessary.

Office staff inquired about the status of the revisions to the training and education requirements to Part 35. NRC staff indicated that a proposed rule was currently out for comment. The Office indicated that they plan to use the current Subpart J of Part 35 in their proposed changes to their regulations.

The Office also asked about the status of the revised NRC Inspection Manual 2800. NRC staff stated that a revision to IMC 2800 incorporating the Temporary Instruction and experience gained during its implementation had been adopted on October 21, 2003 and would be posted

on the NRC web site shortly. The final version was published November 25, 2003, and is available at the NRC web site at: <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/mc2800.pdf>

Internal Program Audits and Self-Assessments

With the exception of the bimonthly status reports to the NRC in preparation for the conference calls, the Office managers reported that no self-assessments were being performed.

Status of Allegations Previously Referred

No allegations were referred to the Office by Region I since the last review.

Event Reporting and the Nuclear Material Events Database (NMED)

Since the 2002 review, the Office had no reportable materials events. A general discussion was held with Office representatives concerning the NMED database program, including recent modifications. The review team indicated that a new field was recently added to the software program to indicate if an event has been closed by the State.

ATTACHMENT

January 16, 2004, E-mail from Marie Stoeckel, Chief,
Office of Occupational and Radiological Health
Rhode Island's Response to Draft Follow-up IMPEP Report

ML040290379