

UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555-0001

February 6, 2008

David R. Gifford, M.D. Director Department of Health 3 Capitol Hill, Room 206 Providence, RI 02908

Dear Dr. Gifford:

On January 15, 2008, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Rhode Island Agreement State Program. The MRB found the Rhode Island Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 10, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review of the Rhode Island Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for October 2009.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/**RA**/

Martin J. Virgilio Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs Office of the Executive Director for Operations

Enclosure: Rhode Island Final IMPEP Report

cc w/enclosure: John Ferruolo, Supervisor Rhode Island Radioactive Materials and X-Ray Programs

Thomas Conley, Kansas Organization of Agreement States Liaison to the MRB



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE RHODE ISLAND AGREEMENT STATE PROGRAM

October 22-25, 2007

FINAL REPORT

ENCLOSURE

1.0 INTRODUCTION

This report presents the results of the review of the Rhode Island Agreement State Program. The review was conducted during the period of October 22-25, 2007, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of California. 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 Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of November 18, 2003, to October 25, 2007, for the performance indicator, Status of Materials Inspection Program, and period of November 23, 2002, to October 25, 2007, for the other performance indicators were discussed with Rhode Island's Department of Health managers on the last day of the review.

A draft of this report was issued to Rhode Island for factual comment on November 28, 2007. The State responded by e-mail on December 5, 2007, from John Ferruolo, Supervisor, Radioactive Materials and X-ray Program (the Program). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on January 15, 2008, to consider the proposed final report. The MRB found the Rhode Island Agreement State Program to be adequate to protect public health and safety and compatible with NRC's program.

The Rhode Island Agreement State Program is administered by the Program, within the Division of Environmental and Health Regulation Services (the Division). The Division is part of the Department of Health (the Department). The Director of Health, who heads the Department, is appointed by and reports directly to the Governor. Organization charts for the Department, the Division, and the Program are included as Appendix B.

At the time of the IMPEP review, the Rhode Island Agreement State Program regulated approximately 60 specific licenses authorizing Agreement materials. The review focused on the radioactive 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 Rhode Island and Providence Plantations.

In preparation for the review, a questionnaire addressing the common and applicable noncommon performance indicators was sent to the Program on August 3, 2007. The Program provided its response to the questionnaire on September 20, 2007. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML073180728.

The review team's general approach for conduct of this review consisted of: (1) examination of the Program's response to the questionnaire; (2) review of applicable Rhode Island statutes and regulations; (3) analysis of quantitative information from the Program's database; (4) technical review of selected regulatory actions; (5) one field accompaniment of one Rhode Island inspector; and (6) interviews with staff and managers to answer questions or clarify issues. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Agreement State program's performance.

The review team also evaluated the State's budgetary and associated staffing issues surrounding Rhode Island's proposed return of its Agreement State program. Due to budget issues in October 2006, the State placed the Program under review for possible return to the NRC. Specifically, by letter dated April 1, 2007, Governor Donald Carcieri advised the NRC of Rhode Island's proposed decision to return the "Section 274b Agreement," to the NRC. On July 19, 2007, after the State legislation vetoed the Governor's proposal, Rhode Island informed the NRC that they would retain their Agreement State program. Section 3.1 contains more information on the budget and staffing issues surrounding Rhode Island's proposed return of its Agreement State program.

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews. Results of the current review for the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable noncommon performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. 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.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on November 18, 2002, five recommendations were made and the results were transmitted to Patricia A. Nolan, M.D., former Director of the Department on February 28, 2003. During the followup IMPEP review which concluded on November 18, 2003, four recommendations were closed. The final followup report was transmitted to Dr. Nolan on March 2, 2004. The review team's evaluation of the current status of the open recommendation from previous reviews is as follows:

The review team recommends that the State adopt overdue regulations required for compatibility. (Section 4.1.2 of the 2003 IMPEP report)

Current Status: Since the 2003 IMPEP followup review, the Program has consistently adopted regulations required for compatibility in a timely manner. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Program's 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 Program's questionnaire response relative to this indicator; interviewed managers and staff; and reviewed job descriptions, training plans, and

training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Program consists of five technical staff positions and a supervising radiological health specialist (the Supervisor). The Program's responsibilities include mammography, X-ray, radioactive materials and emergency preparedness/response. One staff member is dedicated to X-ray and mammography, one to the radioactive materials program, and the remaining three staff members, along with the Supervisor, provide partial support to the radioactive materials program. One of the supporting staff positions has been vacant since May 2007. Efforts to fill the vacancy are still ongoing. Based on discussions and information provided in response to the questionnaire, 1.75 full-time equivalents are allocated to the radioactive materials program, including the contribution from the vacant position. With a total of 60 licenses, the level of staffing appeared adequate to perform the Program's licensing and inspections and did not present any performance issues affecting implementation of the Agreement State program.

Since the last IMPEP review, Rhode Island considered returning its Agreement State program to the NRC. The Rhode Island Fiscal Year 2008 Budget Act, which became effective July 1, 2007, created a restricted receipts account for deposit of the Program's licensing fees. The creation of a dedicated fund for the Program allows the radioactive materials program to be financially self-sufficient, recovering associated costs through licensing fees.

The review team determined the qualifications of Program staff from the Program's response to the questionnaire, training records, and discussions with staff. Staff training and qualifications are maintained in a training matrix that documents staff training history and personnel file memoranda. The personnel file memoranda, which are generated on an annual basis, identify the inspection categories for which a staff member is qualified. The training matrix is used to monitor the status of core, supplemental, and other training. The qualified staff attended the core training courses as prescribed by the NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members that had not completed the core training courses but had established competency in some inspection categories. Staff was familiar with Rhode Island regulations, procedures, and policies. At the time of the review, the Program had two staff members that had attended the NRC's Security Systems and Principles Course. Managers were supportive of staff training within the budget constraints of the Program.

Rhode Island statute Title 23, Chapter 23, Section 23-1.3-13 provided for the creation of an 11-member State Radiation Advisory Commission (the Commission), whose members have expertise in radiation protection and radiation health. The Commission provides advice on radiation protection issues and regulations to the Program and meets on an as needed basis. The review team identified no potential conflicts of interest.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

3.2 <u>Status of Materials Inspection Program</u>

The review team focused on five factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Program's questionnaire response relative to this indicator, the data gathered from the Program's inspection data tracking system, the examination of completed inspection casework, and the interviews with managers and staff.

The review team verified that the Program's inspection frequencies for various license types were at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program."

In analyzing the Program's inspection tracking data, the review team observed that routine inspections of Priority 1, 2, and 3 (1, 2 and 3-year inspection interval, respectively) licenses and initial inspections of new licenses were often being conducted at frequencies exceeding those prescribed in IMC 2800. The 2002 IMPEP review team identified previous issues in the Program with the timeliness of inspections, which led to the State being put on Heightened Oversight. During that review period, the Program failed to perform routine inspections for a period of 22 months. The 2003 followup IMPEP review team found that the Program had scheduled all routine Priority 1, 2, and 3 inspections and initial inspections at the appropriate frequency, and the State was taken off of Heightened Oversight. Based on the evaluation of current inspection tracking data, the review team determined that 19 out of 56 Priority 1, 2, and 3 initial inspections were completed overdue during the review period. The review team attributed the root cause of the overdue inspections to the Program's performance of the 2000-2003 backlog inspections, wherein overdue inspections are carried over to the next year; maternity leave of inspection staff; competing training requirements in other program areas; and the loss of the previous Program Chief within this review period. Additionally, the prospect of elimination of the program, proposed in October 2006, may have disrupted the Program's completing inspections due to considerations concerning loss of staff. The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority schedule in IMC 2800.

The review team sampled a cross-section of inspections reports to supplement its analysis of the Program's timeliness of inspections. The review team determined that all but one inspection, an inspection of a Priority 5 (5-year interval) licensee, was performed in a timely manner. Through the evaluation of casework, the review also determined that inspection findings were consistently communicated to licensees less than 30 days after the respective inspection.

To further evaluate Rhode Island's performance under this indicator, the review team evaluated the Program's efforts in reducing its inspection backlog. The review team noted the Program's continued success in reducing its backlog since the November 2003 followup IMPEP review. The review team determined that in 2004, the Program had 11 overdue Priority 1, 2, and 3 and initial inspections. During the review period, the Program reduced its backlog to 6 overdue inspections at the time of the review.

Reciprocity, which permits licensees from other regulatory jurisdictions to work in Rhode Island, was granted to 15 licensees in 2004; 18 licensees in 2005; 22 licensees in 2006; and 21 licensees to date in 2007. During the review period, the Program performed 20 reciprocity inspections. The review team determined that the Program met or exceeded the goal of annually inspecting 20 percent of all candidate licensees operating under reciprocity, as established by IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," during the review period.

The review team determined that the Program adequately planned for the initial set of Increased Controls inspections of affected licensees. The review team evaluated the Program's prioritization methodology and found it acceptable. At the time of the review, the Program had 16 licensees subject to the Increased Controls. The Program had completed all initial Increased Controls inspections of the 16 affected licensees prior to the review.

Based on the IMPEP evaluation in Management Directive 5.6, Rhode Island's performance for this indicator met the criteria for a finding of unsatisfactory. In reviewing this indicator, the review team was cognizant of the guidance in the All-Agreement States letter, "Prioritization Methodology for Increased Controls," dated November 4, 2005. This letter documented an allowance to defer routine health and safety inspections to ensure that Increased Controls inspections are performed in a timely manner. The review team took into account the Program's progress in reducing the backlog of overdue inspections from the previous IMPEP review, as well as the Program's performance of risk-significant reciprocity inspections. Considering the Program's efforts to reduce its inspection backlog, improve its performance of reciprocity inspections, and perform its Increased Controls inspections in a timely manner, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Status of Materials Inspection Program, was satisfactory, but needs improvement, instead of unsatisfactory.

3.3 <u>Technical Quality of Inspections</u>

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 13 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by two Program inspectors and the Supervisor and covered a variety of license types, including: gamma knife, medical private practice, high dose-rate remote afterloader (HDR), teletherapy, industrial radiography, and manufacturing and distribution. Appendix C lists the inspection casework files reviewed, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensees' radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. The documentation supported violations and recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

For the casework reviewed, inspection findings were appropriate and prompt regulatory actions were taken, as appropriate. The Program issues timely compliance letters to licensees

explaining inspection findings and violations. The Program does not have the authority to levy civil penalties. The Supervisor stated that escalated enforcement action is achieved through non-routine inspections which, according to Section I.3.7 of Rhode Island's regulations, require an inspection fee of one-half the annual licensing fee established in Appendix A to Part I of the regulations.

The inspection procedures utilized by the Program are consistent with the inspection guidance found in IMC 2800. Findings were clearly stated and documented. All inspection reports and correspondence are reviewed by the Supervisor prior to issuance. The review team noted that inspection correspondence involving the Increased Controls was appropriately labeled as sensitive information and withheld from public disclosure.

The review team noted that supervisor accompaniments of the inspection staff were completed and consistently performed over the review period.

The review team confirmed that the Rhode Island program maintains an adequate supply of portable radiation detection instruments for use during routine inspections and response to incidents. Instrument calibrations are performed annually by the University of Rhode Island's Nuclear Science Center or other vendors appropriately licensed to provide calibration services using sources that are traceable to the National Institute of Standards and Technology. The State also utilized the Nuclear Science Center for analysis of wipes and environmental samples taken during inspections.

On October 16-17, 2007, a review team member accompanied one of the Program's inspectors on a routine health and safety inspection of a medical facility. The accompaniment is identified in Appendix C. During the accompaniment, the inspector demonstrated appropriate inspection techniques and knowledge of the regulations. The inspector was trained, prepared, and thorough in his audit of the licensee's radiation safety program. The inspector utilized good health physics practices and interviewed licensee personnel in an effective manner. The inspection was adequate to assess radiological health and safety at the licensed facility.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

3.4 <u>Technical Quality of Licensing Actions</u>

The review team examined completed licensing casework and interviewed the staff and discussed 14 licensing actions related to 12 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, operating and emergency procedures, appropriateness of the license conditions, Increased Controls, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures. The casework was checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 2 new licenses, 1 renewal, 8 amendments, and 3 terminations. The sampling included the following license types: industrial radiography; broadscope medical; veterinary non-human; stereostatic radiosurgery; broadscope academic; broadscope manufacturing and distribution; teletherapy; portable and fixed gauges; medical private practice; and research and development. A listing of the licensing casework evaluated can be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality, with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and auditable. Licensees' compliance histories were taken into account when reviewing all renewal applications and major amendments.

Each licensing action is given a technical review by a license evaluator. The Supervisor performs the majority of the licensing actions and additionally performs a technical and supervisory review on licensing actions performed by other reviewers before issuance. Effective August 2006, the Program extended its license expiration dates from a 5-year period to a 10-year period in an effort to reduce the licensing backlog. The Program currently has 60 specific licensees. At the time of the review, there were 16 overdue renewals (a 27 percent backlog). All overdue licenses are under timely renewal and will remain in timely renewal until such time as a technical review can be performed. Although the expiration periods ranged from the year 2000 through 2006, the review team identified no apparent impact on public health and safety due to either ongoing and/or relatively recent licensing actions (amendments).

The review team observed a thorough and complete documentation of the termination process, which included records of an on-site inspection and observance of material transfer. The review team found that terminated licensing actions were well documented, showing appropriate material transfer and survey records. The review team noted that confirmatory surveys were conducted, when appropriate.

The review team observed the Program's implementation of the pre-licensing guidance in the issuance of two new licenses. Although the Program appeared to have implemented the pre-licensing guidance, discussions with Program staff and managers revealed that staff was not fully aware that the pre-licensing guidance is also applicable to other licensing actions (renewals and amendments). Additionally, although staff routinely used the appropriate NRC guidance documents for license reviews, the Program has no formal documentation of the radioactive materials licensing program, and thus, no formal documentation as to how the pre-licensing guidance will be integrated into the radioactive materials licensing program.

The review team examined the list of licensees that the Program determined to meet the criteria for the Increased Controls, per COMSECY-05-0028, "Staff Response to Staff Requirements Memorandum for COMSECY-05-0015: Initiatives for Increasing Agreement State Participation in the Control of Sources," dated July 25, 2005. The review team determined that the Program had correctly identified the licensees that require the Increased Controls based on the criteria. Each licensee was issued a license amendment, requiring the Increased Controls, in accordance with the time lines established by the NRC in the Staff Requirements Memorandum for COMSECY-05-0028. Although the Program appeared to have identified all licensees that meet the criteria for Increased Controls, at the time of the review, the Program had not

The review team noted the depth of experience of the current staff, but had concerns with the Program's ability to transfer historical knowledge and maintain program consistency without a fully-documented radioactive materials licensing program to include the Increased Controls criteria and the pre-licensing guidance. The review team recommends that the State develop a written documentation of its radioactive materials licensing program to ensure that a memorialized program exists to train and transfer knowledge to future, as well as current, staff.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

3.5 <u>Technical Quality of Incident and Allegation Activities</u>

To evaluate the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Rhode Island in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for six radioactive materials incidents. A listing of the incident casework examined can be found in Appendix E. The review team also evaluated the Program's response to four allegations.

The incidents selected for review included medical events, lost/stolen radioactive material, and overexposure. Upon receipt, the Supervisor reviews the report, decides on the appropriate response, assigns the report a specific identification number, and then logs it into the Program's incident tracking system. Written documentation related to each incident is placed in an incident file. The review team determined that the Program's response to incidents was complete and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Program dispatched inspectors for on-site investigations in appropriate situations and took suitable enforcement and followup actions when necessary.

The Supervisor provides information electronically to the NRC's contractor responsible for maintaining NMED. The NMED information is updated as needed. The review team found that incident information in NMED provided by the Program was up to date and complete.

During the review period, the Program received four allegations involving radioactive material. All were reported directly to the Program. The review team evaluated the casework for all four allegations. The review team noted that the Program promptly responded to all allegations with appropriate investigations and followup and close-out actions. All of the allegations were appropriately closed, and appropriate parties were notified of the actions taken.

The Program has complete written guidance for handling incidents and allegations in their inspection procedures. The review team noted that Rhode Island law requires that public documents be made available upon request. The State makes every effort to protect an alleger's identity, but protection cannot be guaranteed.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Only the non-common performance indicators, Compatibility Requirements and Low-Level Radioactive Waste Disposal Program, were applicable to this review.

4.1 <u>Compatibility Requirements</u>

4.1.1 Legislation

Rhode Island became an Agreement State on January 1, 1980. The currently effective statutory authority for the Program is contained in the State of Rhode Island's enabling statute Title 23, Chapter 1.3 (Radiation Control) of the Rhode Island General Laws [RIGL]. as amended. The current implementing regulations are titled Rules and Regulations for the Control of Radiation [R-23-1.3-RAD] and are dated September 2007. In addition to their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affect the radiation control program. The review team noted that no legislation affecting the Program was passed during the review period. Rhode Island Regulations are subject to RIGL-42-35-4.1, requiring all regulations promulgated by State agencies to be refiled every 5 years to remain effective. The radiation control regulations were last filed in January 2007.

4.1.2 Program Elements Required for Compatibility

The Rhode Island Rules and Regulations for the Control of Radiation (R23-1.3-RAD) apply to all sources of ionizing radiation. Rhode Island requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. Rhode Island also requires registration of all equipment designed to produce x-rays or other ionizing radiation, as well as non-ionizing radiation from tanning equipment.

The review team examined the State's administrative rulemaking process and found that the process takes approximately 4 to 6 months after the Program prepares a proposed regulation and submits it to the NRC. The proposed regulation is sent to the Department's legal counsel concurrently with (or slightly before) submission to the NRC, the public, other agencies, and all potentially impacted licensees and registrants for comment. There is a required formal public hearing as part of the public comment process. The Director of Health gives final approval and signs the final regulations. The regulations are then filed with the Secretary of State and become effective 21 days later. The State can adopt other agency regulations by reference and has the authority to issue legally-binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team evaluated the Program's response to the questionnaire, reviewed the status of regulations required to be adopted by the State under the NRC's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the NRC's Office of Federal and State Materials and Environmental Management Programs' State Regulation Status Sheet.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they become effective. The review team identified the following amendment as overdue at the time of the review:

• "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697, 58038), that became effective October 1, 2004, and was due for Agreement State adoption by October 1, 2007.

The review team identified the following NRC amendment that needs to be addressed:

• "Minor Amendments," 10 CFR Part 20, 30, 32, 35, 40 and 70 amendments (71 FR 15005) that became effective March 27, 2006, and is due for Agreement State adoption by March 27, 2009.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Compatibility Requirements, was satisfactory.

4.2 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Rhode Island Agreement State Program has LLRW disposal authority, NRC does not require States to have a program for licensing a LLRW disposal facility until the State is designated as a host State for a LLRW disposal facility. When an Agreement State is notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Rhode Island. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Rhode Island's performance was found satisfactory, but needs improvement, for the performance indicator, Status of Materials Inspection Program, and satisfactory for all other performance indicators reviewed. The review team made two recommendations regarding program performance. Accordingly, the review team recommended, and the MRB agreed, that the Rhode Island Agreement State Program was adequate to protect public health and safety and compatible with NRC's program. Based on the

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results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State.

- 1. The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority schedule in IMC 2800. (Section 3.2)
- 2. The review team recommends that the State develop a written documentation of its radioactive materials licensing program to ensure that a memorialized program exists to train and transfer knowledge to future, as well as current, staff. (Section 3.4)

LIST OF APPENDIXES AND ATTACHMENT

- Appendix A IMPEP Review Team Members
- Appendix B Rhode Island Organization Charts
- Appendix C Inspection Casework Reviews
- Appendix D License Casework Reviews
- Appendix E Incident Casework Reviews
- Attachment December 5, 2007, Letter from John L. Ferruolo Rhode Island's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

| Name | Area of Responsibility |
|---------------------------|---|
| Andrea Jones, FSME | Team Leader Status of Materials Inspection Program Technical Quality of Inspections Technical Quality of Incident and Allegation Activities |
| James Kottan, Region I | Technical Staffing and Training |
| Frieda Taylor, California | Technical Quality of Licensing Actions |
| Monica Orendi, FSME | Compatibility Requirements |
| Donna Janda, Region I | Inspector Accompaniment |

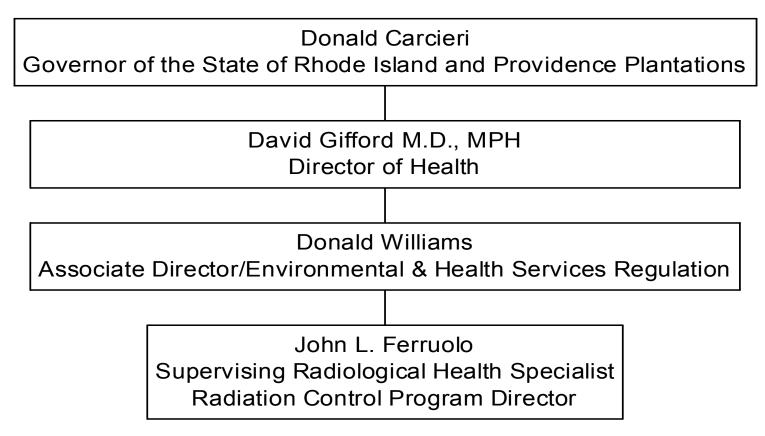
APPENDIX B

RHODE ISLAND ORGANIZATION CHART

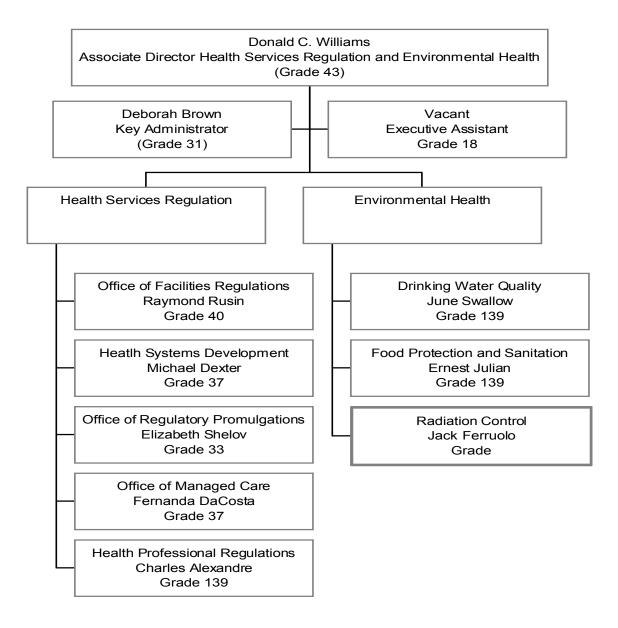
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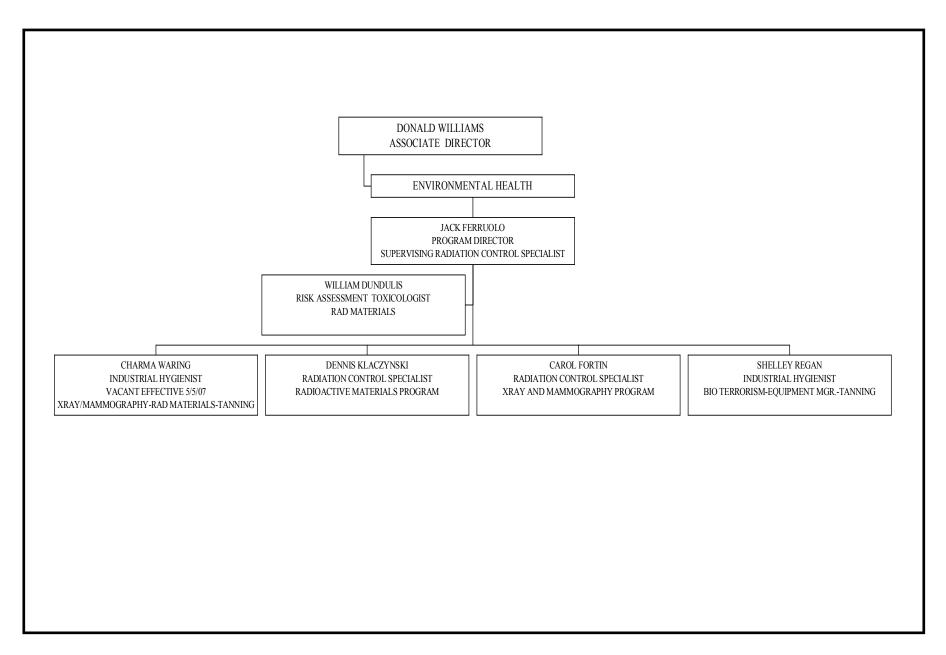
PAGES 1-3

ORG CHART 1 STATE HIERARCHY



ORG CHART -2 HEALTH SERVICES REGULATION AND ENVIRONMENTAL HEALTH MANAGEMENT





APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: Rhode Island Hospital Inspection Type: Routine, Unannounced Inspection Date: 9/4/07

File No.: 2 Licensee: Paul D. Aldinger Inspection Type: Routine, Unannounced Inspection Date: 3/31/04

File No.: 3 Licensee: Kent County Hospital Inspection Type: Routine, Unannounced Inspection Date: 6/27/03

File No.: 4 Licensee: GZA Geotechnical Inc. Inspection Type: Routine, Unannounced Inspection Date: 9/15/05

File No.: 5 Licensee: Jaworski Geotech Inspection Type: Routine, Unannounced Inspection Date: 9/11/02

File No.: 6 Licensee: Cardiology Specialist Inspection Type: Initial, Unannounced Inspection Date: 12/27/05

File No.: 7 Licensee: Digirad Inspection Type: Initial, Announced Inspection Date: 9/6/05

File No.: 8 Licensee: Enviroscience Consultants, Inc. Inspection Type: Initial, Unannounced Inspection Date: 4/30/04 License No.: 7D-051-02 Priority: 3 Inspector: DK

License No.: 3L-107-01 Priority: 5 Inspector: CW

License No.: 7B-020-01 Priority: 3 Inspector: JF

License No.: 3L-079-01 Priority: 5 Inspector: CW

License No.: 3L-119-01 Priority: 5 Inspector: DK

License No.: 7B-134-01 Priority: 5 Inspector: DW

License No.: 7B-133-01 Priority: 5 Inspector: JF

License No.: 3L-118-01 Priority: 5 Inspector: CW Rhode Island Final Report Inspection Casework Reviews

File No.: 9 Licensee: Geisser Engineering Inspection Type: Routine, Unannounced Inspection Date: 6/13/05

File No.: 10 Licensee: South County Cardiology Associates Inspection Type: Initial, Unannounced Inspection Date: 6/24/04

File No.: 11 Licensee: Cardinal Health Inspection Type: Routine, Unannounced Inspection Date: 10/7/02

File No.: 12 Licensee: Niton Corporation Inspection Type: Routine, Unannounced Inspection Date: 12/4/03

File No.: 13 Licensee: Brown University Inspection Type: Routine/Special, Unannounced Inspection Date: 10/27/03

License No.: 3L-050-01 Priority: 5 Inspector: CW

License No.: 7B-129-01 Priority: 3 Inspector: DK

License No.: 3B-114-01 Priority: 1 Inspector: DK

License No.: 3G-105-02 Priority: 5 Inspector: DK

License No.: 3K-036-01 Priority: 3 Inspector: DK

INSPECTOR ACCOMPANIMENT

The following inspector accompaniment was performed prior to the on-site IMPEP review:

Licensee: Rhode Island Hospital Inspection Type: Routine, Unannounced Inspection Dates: 10/16-17/07 License No.: 7D-051-01 Priority: 2 Inspector: DK

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APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: ANVIL International, Inc. Type of Action: Termination Date Issued: 11/3/06

File No.: 2 Licensee: ANVIL International, Inc. Type of Action: Amendment Date Issued: 10/14/05

File No.: 3 Licensee: Rhode Island Hospital Type of Action: Amendment Date Issued: 10/14/05

File No.: 4 Licensee: Ocean State Veterinary Specialists Type of Action: Renewal Date Issued: 4/17/07

File No.: 5 Licensee: Rhode Island Hospital Type of Action: Amendment Date Issued: 10/24/05

File No.: 6 Licensee: Brown University Type of Action: Amendment Date Issued: 10/14/05

File No.: 7 Licensee: Thermo Niton Analyzers LLC Type of Action: Amendment Date Issued: 1/19/06

File No.: 8 Licensee: Rhode Island Hospital Type of Action: Amendment Date Issued: 6/8/07 License No.: 3D-064-01 Amendment No.: 15 License Reviewer: JF

License No.: 3D-064-01 Amendment No.: 13 License Reviewer: JF

License No.: 7D-051-01 Amendment No.: 31 License Reviewer: JF

License No.: 3K-126-01 Amendment No.: 1 License Reviewer: CW

License No.: 7A-051-02 Amendment No.: 21 License Reviewer: JF

License No.: 3K-036-01 Amendment No.: 30 License Reviewer: JF

License No.: 3A-105-01 Amendment No.: 15 License Reviewers: DK, WD

> License No.: 7D-051-01 Amendment No.: 37 License Reviewer: JF

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File No.: 9 Licensee: Radiation Oncology Services of Rhode Island Type of Action: Termination Date Issued: 5/21/07

File No.: 10 Licensee: Northeast Engineers & Consultants, Inc. Type of Action: Amendment Date Issued: 2/3/05

File No.: 11 Licensee: Rhode Island Cardiovascular Group, Inc. Type of Action: New Date Issued: 2/2/07

File No.: 12 Licensee: Rhode Island Psychiatric Research Center Type of Action: Termination Date Issued: 10/30/03

File No.: 13 Licensee: VeroScience, LLC Type of Action: New Date Issued: 4/27/07

File No.: 14 Licensee: Electric Boat Corporation Type of Action: Amendment Date Issued: 12/4/06 License No.: 7A-053-01 Amendment No.: 15 License Reviewer: JF

License No.: 3L-115-01 Amendment No.: 4 License Reviewer: JF

License No.: 7B-137-01 Amendment No.: N/A License Reviewer: JF

License No.: 3K-023-01 Amendment No.: 10 License Reviewer: JF

License No.: 3K-136-01 Amendment No.: 1 License Reviewer: JF

License No.: 3D-005-01 Amendment No.: 17 License Reviewer: JF

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: Rhode Island Hospital (Miriam Campus) Date of Incident: 2/16/05 Investigation Date: 4/11/05

File No.: 2 Licensee: Rhode Island Hospital Date of Incident: 5/9/07 Investigation Date: 5/25/07

File No.: 3 Licensee: Cardinal Health Date of Incident: 3/8/07 Investigation Date: 3/9/07

File No.: 4 Licensee: Rhode Island Hospital Date of Incident: 5/9/07 Investigation Dates: 5/25/07

File No.: 5 Licensee: Rhode Island Hospital Date of Incident: 7/18/05 Investigation Date: 8/19/05

File No.: 6 Licensee: Anvil International Date of Incident: 3/3/06 Investigation Dates: 3/3/06, 3/8/06, 3/16/06 No.: 7D-051-01 NMED No.: 050195 Type of Incident: Lost/stolen RAM Type of Investigation: Telephone

License No.: 7A-051-02 NMED No.: 050529 Type of Incident: Medical Event Type of Investigation: Site

License No.: 3B-114-01 NMED No.: 050139 Type of Incident: Lost/stolen RAM Type of Investigation: Telephone

License No.: 7A-051-02 NMED No.: 070309 Type of Incident: Medical Event Type of Investigation: Telephone

License No.: 7A-051-02 NMED No.: 050529 Type of Incident: Medical Event Type of Investigation: Telephone

License No.: 3D-064-01 NMED No.: 060163 Type of Incident: Overexposure Type of Investigation: Site

ATTACHMENT

December 5, 2007, Letter from John L. Ferruolo Rhode Island's Response to Draft IMPEP Report

ADAMS: ML073400218

Department of Health

Three Capitol Hill Providence, RI 02908-5097

TTY: 711 www.health.ri.gov



5 December 2007

Andrea R. Jones, Health Physicist Division of Intergovernmental Liaison and Rulemaking Office of Federal and State Materials and Environmental Management Programs

Dear Ms. Jones:

As discussed, I have completed a preliminary review of the "Draft" IMPEP report received by this office on 29 November 2007.

Although I am in agreement with the findings, there are few clarifying points and adjustments in the letter and report that I want to apprise you of. In addition to the following bulleted directions to specific pages, paragraphs etcetera, I have also included a printed "Track Changes" version of your letter and report, which identifies the strikethrough and corrected wording.

The following corrected wording is suggested:

- Cover Letter: -inside address-
 - Add MPH after M.D.
- Report
 - Page 1 (Section 1.0) 3rd Paragraph –adjustment in wording to better reflect structure.
 - <u>Insert -Office of Radiological Health after "the" –in first sentence</u>
 - Insert- and Health Services Regulation in 2nd and 3rd sentence
 - Remove- of Health in 3rd sentence
 - <u>Remove- the Office of Health Services Regulation and Environmental Health</u> (the Office) in 3rd and 4th sentence
 - Page 1 (Section 1.0) 3rd Paragraph-1st sentence-at the time of your IMPEP the total number of licensees was 60.
 - Change 61 to 60 in 1st sentence
 - Page 2 (Section 2.0) 1st Paragraph- 1st sentence-I believe the date –year should be 2003.
 Change 2004 to 2003
 - Page 3 (Section 3.1) 2^{nd} Paragraph-9th sentence-total should be 60.
 - Change 61 to 60 in 9th sentence
 - Page 5 (Section 3.2) 1st Paragraph-4th sentence adjustment in wording to better reflect structure-it was the loss of the Chief during the period in question.
 - <u>Change Supervisor to Program Chief in 4th^t sentence</u>
 - Page 6 (Section 3.3) 3rd Paragraph-4th sentence adjustment in wording to better reflect how RI addresses escalated enforcement (PART I, Section I.3.7 of Regs).
 - <u>Remove-limited to issuance of orders</u>
 - Add-in the form of non-routine inspections which, according to Section I.3.7 of the regulations, would require an inspection fee of one-half the

- *annual licensing fee established in Appendix A to Part I of the regulations.*
- Page 6 (Section 3.3) 6th Paragraph-4th sentence adjustment in wording to better reflect practices during review period- (use of other appropriately licensed vendors for calibration services).
 - Insert –or other vendors appropriately licensed to provide calibration services
- Page 9 (Section 4.1.1) 1st Paragraph-2nd sentence adjustment in wording for clarification.
 - Insert after "Island"-'s enabling statute Title 23, Chapter 1.2 (Radiation Control) of the Rhode Island General Laws, as amended [RIGL].
 - Remove and
 - Insert-The current implementing regulations are titled Rules and Regulations for the Control of Radiation [R-23-1-1.3-RAD] and are dated September 2007.
 - <u>Remove-Providence Plantations Department of Health Rules and Regulations</u> for the Control of Radiation, Title 23, chapter 1.3.
- Page 10 (Section 4.1.2) 2nd Paragraph-3rd-4th sentence adjustment in wording to better reflect actual process.
 - <u>Insert after "to"-legal counsel concurrently with (or slightly before)</u> submission to the NRC,
 - Remove after "public", the NRC.
 - <u>Insert after "comment". There is a required formal hearing as part of the</u> <u>public comment process.</u>
- APPENDIX C Page C.2-File No: 9-spelling correction
 - Change to- Geisser.

Sincerely,

J Fernilo

John L. Ferruolo Supervising Radiological Health Specialist Office of Radiological Health