

February 28, 2003

Patricia A. Nolan, M.D.
Director
Department of Health
3 Capitol Hill
Providence, RI 02908-5097

Dear Dr. Nolan:

On February 3, 2003, 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 IMPEP review was conducted November 18-22, 2002. The MRB received for consideration the comments in your letter dated January 15, 2003. The MRB found the Rhode Island program adequate but needs improvement, and compatible with the Nuclear Regulatory Commission's program. Because of the significance of the concerns, the MRB recommends heightened oversight of the Rhode Island program. I request that bimonthly conference calls take place with the appropriate Rhode Island and NRC staffs to discuss the status of the program. Mr. Duncan White, Regional State Agreements Officer, Region I, will coordinate the bimonthly conference calls. I request that, two weeks prior to the calls, you submit a brief status report on the activities conducted since the last report and the necessary statistical data.

I also request that you prepare and submit a program improvement plan that addresses the recommendations in Section 5 of the enclosed final report. I request that this report be submitted within 30 days of receipt of this letter. Upon review of the program improvement plan, the staff will schedule the first conference call and a more detailed outline for the status reports. I request the initial conference call be scheduled and conducted no later than April 4, 2003.

Based on the results of the current IMPEP review, a follow-up review will be scheduled during the period November 2003 - January 2004. The follow-up review will cover the State's actions on the recommendations from the November 2002 review.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your continuing support of the Office of Occupational and Radiological Health. 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

Roland Fletcher, MD
OAS Liaison to the MRB

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bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

Roland Fletcher, MD
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF RHODE ISLAND AGREEMENT STATE PROGRAM

November 18-22, 2002

FINAL REPORT

U. S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Rhode Island radiation control program. The review was conducted during the period November 18-22, 2002, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. Team members are identified in Appendix A. The team was accompanied by a representative from the General Accounting Office. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC [Management Directive 5.6](#), "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of July 31, 1998 to November 22, 2002, were discussed with Rhode Island management on November 22, 2002.

A draft of this report was issued to Rhode Island for factual comment on December 18, 2002. The State responded in a letter dated January 15, 2002. At the time of the review, the review team found Rhode Island's performance to be satisfactory for six performance indicators and unsatisfactory for the indicator, "Status of Materials Inspection Program." Because of the significance of the concerns, the team recommended that a program of heightened oversight be implemented to assess the progress of the State in implementing corrective actions.

The MRB met on February 3, 2002, to consider the proposed final report. The MRB concurred in the individual findings by the review team for each indicator and concurred in the review team's recommendation for a program of heightened oversight to assess the progress of the State in implementing corrective actions. The MRB found the Rhode Island radiation control program was adequate, but needs improvement, and compatible with NRC's program.

The MRB directed that: (1) a program improvement plan be submitted in addition to the responses to the recommendations found in Section 5; (2) that a follow-up review be conducted during the period November 2003 - January 2004; and (3) that bimonthly conference calls take place with Rhode Island staff, and that written progress reports be submitted two weeks prior to each call.

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. Organization charts for the Office and the Rhode Island Radiation Control Hierarchy are included as Appendix B. At the time of the review, the Rhode Island program regulated 58 specific licenses authorizing Agreement materials.

The review focused on the material 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.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on July 11, 2002. The State provided an electronic response to the questionnaire on October 17, 2002. A copy of the questionnaire

response may be found on NRC's Agencywide Document Access and Management Systems using the Accession Number ML023370670.

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

A Periodic Meeting was held with Rhode Island in July 2001. During that meeting, the NRC learned that staffing problems had resulted in the radiation control program falling behind in licensing and inspections, and in fact, the program had not performed routine inspections in over 18 months. In October 2001, the State was placed under increased monitoring. Monthly teleconferences began between the State and NRC to discuss the status of the Agreement State program and closely track the State's progress in addressing staffing and training issues and the inspection backlog. The teleconferences continued until this IMPEP review.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings. Recommendations made by the review team are comments that relate directly to 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 routine review, which concluded on July 30, 1998, two recommendations were made and the results were transmitted to Dr. Patricia Nolan, Director, Rhode Island Department of Health, on October 29, 1998. The review team's evaluation of the current status of these recommendations is as follows:

1. The review team recommends that the State upgrade their inspection tracking system to assure that all licensees are inspected in accordance with the frequency established by the program. (Section 3.1)

Current Status: The State upgraded their inspection tracking system and now has an accurate tool to plan inspection workload. This recommendation is closed. As noted in Section 3.2, inspections were not performed timely, and a recommendation is made to resolve that issue.

2. The review team recommends that the State document a training and qualifications program equivalent to that contained in the "NRC/OAS Training Working Group Recommendations for Agreement State Training Programs." (Section 3.3)

Current Status: The State developed a table outlining the qualifications and needed training for the technical staff. The requirements are based on NRC Inspection Manual Chapter 1246 and are equivalent to the Working Group recommendations. This recommendation is closed.

During the 1998 review, six suggestions were also made for the State to consider. The team determined that the State considered the suggestions.

3.0 COMMON PERFORMANCE INDICATORS

The IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State 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) Response to Incidents and Allegations.

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 State's questionnaire responses relative to this indicator, interviewed Office management and staff, and considered any possible workload backlogs.

Since the last IMPEP review, the Rhode Island radiation control program experienced significant turnover due to retirements and promotions. In 1999 and 2000, the senior license reviewer, the principal inspector and the radioactive materials program supervisor left the program. The loss of the three key staff members severely impacted the radioactive materials program.

Also during this period, the Department of Health implemented a new Department-wide system (License 2000) to standardize and integrate licensing and inspection. In order to support this effort, the radiation control program invested a significant amount of time reviewing existing licenses to ensure that they were accurate. A new accounting system was also integrated with License 2000. The radiation control program was directed by Department of Health management to revise its fee structure and integrate it into the new licensing system. The implementation of this system involved a significant amount of time and effort from Office management and staff. Direct effects were felt in the inspection program as discussed in Section 3.2.

In March 2001, the former principal inspector returned to the program to fill the Supervising Radiological Health Specialist (the Supervisor) position. The principal inspector position was filled in February 2001. An industrial hygienist was hired in October 2000, primarily for the x-ray program but with limited (5% of her time) in the radioactive materials area. Another industrial hygienist hired in September 2002 provides emergency response and instrumentation assistance to the program.

The addition of new staff from the private sector was done during a time when there was a Department-wide hiring freeze in place. The supervisory position was filled in an expedient manner in part by posting the position prior to it being vacated.

A Department toxicologist, currently working in another Office but formerly with the radiation control program, continues to provide support (approximately 0.25 FTE) to the Agreement State program in the area of regulations and therapeutic radiation modalities (inspection and licensing).

Current staffing in the radioactive materials program is approximately 2.1 FTE, including the contribution from the Department toxicologist. With a total of 58 radioactive materials licenses, the level of staffing appears adequate.

The Office continues to use the NRC/OAS Training Working Group Recommendations as a template to train their new Radiological Health Specialist and Industrial Hygienist for licensing and inspection of radioactive materials licensees.

The Radiological Health Specialist completed a number of training courses including: Applied Health Physics (5 weeks), Inspection Procedures, Licensing and Industrial Radiography. The Industrial Hygienist completed the Introductory Health Physics and Inspection Procedures courses and received basic radiation protection training at the University of Rhode Island Nuclear Science Center. A detailed training schedule has been prepared for each of the staff members who lack full qualification.

During the last periodic meeting with the State, the concept of interim qualification for inspections of various categories of licenses was discussed to allow the newer employees to assist the program with its backlogged inspections, prior to their full qualification as inspectors. Reference was made to the format used in the NRC/OAS Training Working Group Recommendations Report including documentation of interim qualification levels. The review team recommends that the Office use a fully documented interim qualification program for inspectors.

The Radiation Advisory Commission, as constituted under Rhode Island General Law Title 23 - Chapter 1.3.-13 through 15, consists of 11 members appointed by the Director of Health. The Commission acts in a purely advisory role for the Program, primarily for the review of draft regulations. No potential conflicts of interest were identified.

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, is satisfactory.

3.2 Status of Materials Inspection Program

The 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 the performance of reciprocity inspections. The review team's evaluation is based on the Office's questionnaire responses relative to this indicator, data gathered

independently from the Office's inspection data tracking system, the examination of complete licensing and inspection casework, and interviews with managers and staff.

The review team's review of the Office's inspection priorities verified that inspection frequencies for various types of material licenses were at least as frequent as those listed in NRC Inspection Manual Chapter (IMC) 2800. The Office extends inspection intervals for good performance. During the review, the team noted that two licenses were categorized as Priority 3, but based on their authorized material and use, could be categorized as Priority 5. This was brought to the attention of Office staff who indicated that they will make the appropriate changes to their database.

For a period of approximately 22 months starting in early 2000, the Office did not conduct any routine inspections. This was the result of a number of personnel changes, the necessity of hiring new staff and the implementation of the Department of Health's License 2000 system (see Section 3.1 for details). This problem was discussed during Periodic Meetings in July 2001 and April 2002.

In their response to the questionnaire, the Office indicated that there are currently 13 inspections of core licensees overdue by more than 25 percent of the State frequency. This information was verified during the inspection casework reviews and the review of the Office's inspection priority list which was provided to the team.

The Office has 11 Priority 1 licenses, three Priority 2 licenses and 12 Priority 3 licenses for a total of 26 core licenses. With regard to the Priority 1 licenses, nine were overdue at the time of the review and the other two licenses were inspected overdue during the review period. All three Priority 2 licenses and one Priority 3 license were overdue at the time of the review. Three additional Priority 3 licensees were inspected overdue during the review period.

The review team also evaluated the Office's initial inspections. The team noted that the Office issued nine new licenses during the review period. At the time of the review, two of the licenses were not yet due for inspection, one was conducted at four months, four were conducted between six and eight months, and the remaining three were conducted at 17 - 37 months post-license issuance.

The Office provided an action plan with their questionnaire response to conduct overdue inspections and train the two newest staff members to conduct inspections independently. The team reviewed the action plan and discussed some needed plan enhancements with Office management. The enhancements should include specific milestones and assignment of responsibilities. The review team recommends that the Office implement the action plan and perform inspections of core licenses at their appropriate frequencies.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. The Office has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. The Office tries to complete each inspection report and deliver the notice of violation to the licensee within 30 days. The licensee is then instructed to respond within 30 days. Of the eight license files reviewed, the Office generally met the 30-day goal with the longest duration to issue inspection findings being 38 days post inspection.

During the review period, the Office granted 37 core reciprocity licenses. The Office exceeded the 20 percent criteria prescribed in IMC 1220 for 1998 when three of the seven core licensees were inspected. For the remainder of the review period, the Office performed two inspections of the 30 core licensees who filed for reciprocity. The review team recommends that the Office inspect core licensees granted reciprocity in accordance with the criteria in IMC 1220.

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, is unsatisfactory.

3.3 Technical Quality of Inspections

The team evaluated the inspection reports and enforcement documentation, and interviewed inspectors for eight radioactive materials inspections conducted during the review period. The casework included all of the Office's materials inspectors, and covered inspections of various types including: gamma knife, medical private practice, high dose-rate remote afterloader (HDR), teletherapy, industrial radiography, and manufacturing/distribution. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments.

Based on casework, the review team observed that the routine 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 licensee's performance with respect to health and safety was 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. All inspection reports and correspondence are reviewed by the Supervisor prior to issuance.

For the casework reviewed, inspection findings were appropriate and prompt regulatory actions were taken as necessary. The Office issues timely compliance letters to licensees explaining inspection findings and violations. The Supervisor stated that escalated enforcement action was limited to the issuance of orders, as monetary penalties are not authorized.

One inspector was accompanied during inspections by a review team member on October 22, 2002. The inspector, formerly with the Office, works for another program in the Department of Health and is assisting the program in its recovery from loss of technical staff. The accompaniment was at a medical private practice facility with teletherapy and high dose-rate afterloader licenses. 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. He utilized good health physics practices, interviewed licensee personnel in an effective manner, and his inspections were adequate to assess radiological health and safety at the licensed facilities.

The Office has a policy requiring supervisory accompaniments of inspectors on an annual basis. The Supervisor accompanied each of the inspectors several times as part of the training process.

The review team confirmed that the Rhode Island program has an adequate number 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 Nuclear Science Center using NIST-traceable sources. The review team evaluated a sampling of portable instruments and determined that all were calibrated and operational. The State also utilizes the Nuclear Science Center for analysis of wipes and environmental samples taken during inspections. A revised Memorandum of Understanding was executed with the University in January 2002.

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, is satisfactory.

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for nine 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 license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period. The sampling included the following types: academic type A broad scope, medical institution broad scope (with HDR and gamma knife), industrial radiography, portable gauges, medical private practice, teletherapy, veterinary medicine, and nuclear pharmacy. Licensing actions reviewed included two new licenses, four renewals, and three amendments to existing licenses. A listing of the casework licenses evaluated with case-specific comments may be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of very good quality, with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. As discussed in Section 3.1, the casework evaluation identified two medical private practice licensees categorized as Priority 3 which could have been Priority 5.

Licenses are currently being reviewed by three staff members, including the Supervisor. The Supervisor performs a technical and supervisory review on all licensing actions prior to the issuance and signs each license. The State issues licenses for a five-year period. The Office

utilizes NRC licensing guides and policies as appropriate, uses standard licensing conditions, and uses internal check lists as appropriate for each licensing action.

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, is satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the Office 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 Office files, and evaluated the casework and supporting documentation for three material incidents. The team also reviewed the State's response to one allegation. No allegations were referred to the State by NRC during the review period. A listing of the incident casework evaluated with case-specific comments may be found in Appendix E.

The incidents selected for review involved misadministrations and an intentional overexposure. Two of the incident files evaluated were incomplete with very little information available for review. However, one incident file was well documented. The team found that the Office's response to incidents was generally complete and comprehensive. Initial responses to each incident were prompt and the level of effort was commensurate with the health and safety significance. The Office took suitable enforcement and follow-up actions, as appropriate.

Initial response and follow-up actions to materials incidents were assigned to and handled by the Supervisor. 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 incident tracking system. Written documentation related to each incident is placed in an incident file. Management and staff informed the team that missing documentation for the two incomplete incident files was likely misplaced during the transition period between the prior and current supervisors.

The team identified three incidents in NMED for Rhode Island during the review period. The Office adheres to procedures providing that reports of incidents that require immediate notification to the State be provided to the NRC within 24 hours of notification, and that reports of incidents that require notification to the State within 30 days be provided to the NRC monthly. The review team noted that all significant events (requiring 24-hour notification) and routine and/or event updates (requiring 30-day notification) were reported to the NMED in a timely manner. Also, the team noted that the Office was responsive in providing the requested information to the NMED contractor by way of e-mail with attachments. The Office is aware of the NMED web site address for reporting incidents.

In evaluating the effectiveness of Rhode Island's actions responding to allegations, the review team examined the Office's questionnaire response relative to this indicator. No allegations were reported in the questionnaire response, and none were referred by the NRC for review. However, the team discovered that one allegation was reported directly to the State. The Office evaluated the allegation, determined the proper level of response, and took prompt and

appropriate action in response to the alleged complaint. The allegation was appropriately closed. The documentation for the one allegation was discovered in the inspection section of the license file. Separate files are not created for allegation reports, and allegations are not tracked in the database system for incidents and allegations. The team discussed this issue with Office management.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Rhode Island's performance with respect to the indicator, Response to Incidents and Allegations, is satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Rhode Island's Agreement does not authorize regulation of uranium recovery activities, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

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 currently effective statutory authority for the Program is contained in the Rhode Island General Law Title 23 - Chapter 1.3. The Office is designated as the State's radiation control agency. The review team noted that no legislation affecting the Office was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Rhode Island Rules and Regulations for the Control of Radiation (R23-1.3-RAD) applies 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 and non-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 four to six months after the proposed regulation is prepared by the Program and sent to the State's Radiation Advisory Commission. Often, the Commission will form a subcommittee to review the proposed regulation and make recommendations to the full Commission. When the Commission completes its review and recommends its adoption, the Department's legal counsel reviews the proposed regulations. Once the legal counsel has given its preliminary approval, a public hearing is scheduled to take place in approximately four to six weeks. The proposed regulation is sent to the public, the NRC, other agencies, and all potentially impacted licensees and registrants, for comment. After the public hearing and the

collection of written and oral testimony, the Office reviews the comments and prepares an analysis of the comments. The finalized regulations are returned to the Department of Health's legal counsel for approval. 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 Office's responses 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 Office of State and Tribal Program's "State Regulation Status Data Sheet." Since the previous IMPEP review, the Program adopted 17 amendments in a rule package that became effective in July 1999.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. As discussed during the Periodic Meetings, the review team found that the following amendments are currently overdue.

- ! "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.
- ! "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective January 27, 1997.
- ! "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, 70 amendments (62 FR 39057) that became effective August 20, 1997.
- ! "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70 and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.

Due to staffing changes and the need to address higher priority items during parts of the review period, the Office made the decision to prepare one rulemaking package that included the amendment that completely revised NRC's regulations on the Medical Uses of Byproduct Material. All of the above amendments have been drafted and are currently under review by the State's Radiation Advisory Commission. The anticipated adoption date for these amendments is during the first half of 2003. The review team recommends that the State adopt overdue regulations required for compatibility.

The Office will need to address the following six regulations in upcoming rulemakings or by adopting alternate legally binding requirements:

- ! "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000.

- ! “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.
- ! “New Dosimetry Technology,” 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001.
- ! “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. The Program addressed the reporting requirements for generally licensed device distributors which was due by August 16, 2001 by amending the license of the State’s sole manufacturer/distributor of generally licensed devices.
- ! “Revision of the Skin Dose Limit,” 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.
- ! “Medical Use of Byproduct Material,” 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002.

All of the above amendments, including the overdue amendments, have been drafted and are currently under review by the State’s Radiation Advisory Commission. The anticipated adoption date for these amendments is during the first half of 2003.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Rhode Island’s performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, is satisfactory.

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

In conducting this review, three sub-indicators were used to evaluate the State’s performance regarding their SS&D Evaluation Program. These sub-indicators are: (1) Technical Quality of the Product Evaluation Program; (2) Technical Staffing and Training; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Office’s SS&D Evaluation Program, the review team examined information provided by the Office in response to the IMPEP questionnaire on this indicator. A review of the SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff’s use of guidance documents and procedures, and interviewed the staff and the Supervisor involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The State has one licensee that manufactures x-ray fluorescence (XRF) devices and distributes them under a general license. The Office processed one new SS&D application since the last review and performed three amendments to existing SS&D registry sheets. The casework review indicated that Office staff follows NRC guidance during the review process to ensure that licensees submit the information necessary to support the product. The tie-down conditions are stated clearly and are inspectible and enforceable. Deficiency letters clearly stated regulatory positions and were used at the proper time. A concurrent review was

accomplished by a second qualified SS&D reviewer for the new application and amendment completed in 1998 and 2000. Since 2001, the Office has had only one qualified SS&D reviewer. The concurrence review for the amendments completed in 2001 was performed by the Supervisor. This matter is discussed in more detail in Section 4.2.2. A listing of the SS&D casework evaluated with case-specific comments may be found in Appendix F.

The review team interviewed the staff and supervisor responsible for SS&D evaluations, and examined the staff's use of guidance documents and procedures. The Office used NUREG-1556, Volume 3, and pertinent ANSI standards and regulatory guides for their reviews. The team found no health and safety issues relative to the SS&D evaluations which were reviewed.

4.2.2 Technical Staffing and Training

During the first half of the review period, the former Supervisor and the license reviewer conducted SS&D reviews. Both individuals had more than 10 years of experience and were qualified to conduct and sign safety evaluations of SS&D applications in accordance with the NRC/OAS Training Working Group Recommendations. These individuals are no longer with the Office and since 2001, the Office has had only one qualified reviewer whose recent experience with SS&D reviews is limited. The review team interviewed this individual and determined that he was familiar with the SS&D evaluation process, applicable guidance and reference documents. The team also determined that this reviewer meets the technical training required for SS&D reviewers as described in the NRC/OAS Training Working Group Recommendations.

With only one qualified reviewer, the current Supervisor conducted the concurrence review for the two amended SS&D registry sheets issued by the Program in 2001. The Supervisor does not meet the technical training required for SS&D reviewers as described in the NRC/OAS Training Working Group Recommendations. Without a second qualified SS&D reviewer, the Office currently does not have sufficient trained staff to perform SS&D reviews. In the opinion of the team, the two uncomplicated concurrence reviews performed by the Supervisor during this review period were satisfactory. 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.

The review team discussed with Office management the difficulty of maintaining an SS&D evaluation program considering the technical staffing and training requirements and a limited number of device reviews. Office management indicated that, if necessary, they would draw upon resources outside their office including State engineers, a local University engineering department, the NRC, or another Agreement State to maintain the SS&D evaluation program if a complex source or device evaluation is required which surpasses the Office's expertise. The review team also discussed the potential for return of the SS&D portion of the Agreement to the NRC, if so desired by the State.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Two incidents were reported to the Office by other Agreement States caused by the improper assembly or modification of devices during the review period. The team found that the Office

addressed these issues in a comprehensive manner and took appropriate actions. This included conducting an inspection, issuing inspection findings that addressed the root cause, following up on corrective actions taken by the manufacturer, and interacting with other Agreement States. A listing of the SS&D incident casework evaluated with case-specific comments may be found in Appendix E.

The review team conducted a search of the NMED system to determine whether other incidents or defects might have taken place that were not identified by the Office. No additional incidents or defects were identified that could have been related to malfunctioning devices or products considered during the review.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Rhode Island's performance with respect to the indicator, Sealed Source and Device Evaluation Program, is satisfactory.

4.3 Low-Level Radioactive Waste 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 low-level radioactive waste (LLRW) as a separate category. Those States with existing 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 has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which 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 and 4 above, the review team and the MRB found Rhode Island's performance to be satisfactory for six performance indicators, and unsatisfactory for the indicator "Status of Materials Inspection Program." Accordingly, the review team recommended and the MRB concurred in finding the Rhode Island Agreement State program to be adequate, but needs improvement, and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended and the MRB concurred that a period of heightened oversight (including bimonthly teleconferences and progress reports) and a follow-up review be performed in approximately one year.

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

RECOMMENDATIONS:

1. The review team recommends that the Office use a fully documented interim qualification program for inspectors. (Section 3.1)
2. The review team recommends that the Office implement the action plan and perform inspections of core licenses at their appropriate frequencies. (Section 3.2)
3. The review team recommends that the Office inspect core licensees granted reciprocity in accordance with the criteria in IMC 1220. (Section 3.2)
4. The review team recommends that the State adopt overdue regulations required for compatibility. (Section 4.1.2)
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. (Section 4.2.2)

LIST OF APPENDICES AND ATTACHMENTS

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
Appendix F	Sealed Source and Device Casework Reviews
Attachment	January 15, 2003 Letter from Dr. Patricia A. Nolan Rhode Island's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Technical Quality of Inspections Technical Staffing and Training Inspector Accompaniments
Duncan White, Region I	Status of Materials Inspection Program Sealed Source and Device Evaluation Program Legislation and Program Elements Required for Compatibility
Cynthia Sanders, Georgia	Technical Quality of Licensing Actions Response to Incidents and Allegations

APPENDIX B

Rhode Island

Radiation Control Hierarchy

and

Office of Occupational and Radiological Health

ORGANIZATION CHARTS

ML023370673

RI Radiation Control Hierarchy

Lincoln C. Almond
Governor of the State of Rhode Island and Providence Plantations

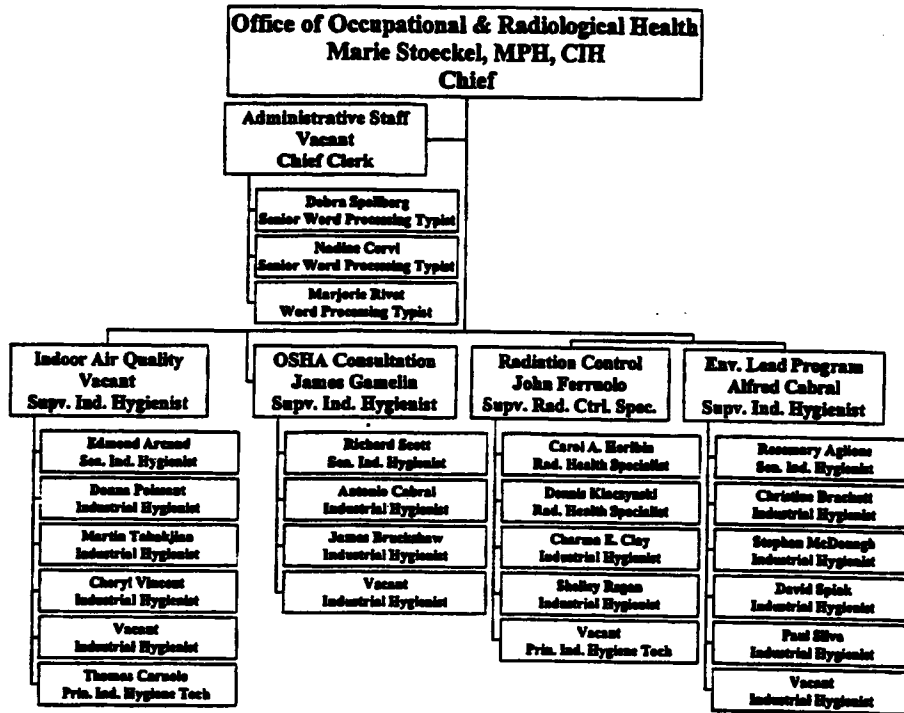
Patricia A. Nolan, M.D., MPH
Director of Health

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

Marie Stoeckel, MPH, CIH
Chief/Occupational and Radiological Health
Radiation Control Program Director

Office of Occupational and Radiological Health

October 2002



ATTACHMENT

January 15, 2003 Letter from Dr. Patricia A. Nolan
Rhode Island's Response to Draft IMPEP Report

ML030240390

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF HEALTH



Safe and Healthy Lives in Safe and Healthy Communities

Patricia A. Nolan, MD, MPH
Director of Health

January 15, 2003

Mr. James L. Lynch
Regional State Agreements Officer
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Mr. Lynch:

In response to your letter dated December 18, 2002, I am writing to confirm that the draft IMPEP report was received and reviewed by the radiation control program staff. While we agree with the content of the report and are in the process of implementing the recommendations, several edits are suggested below for clarification purposes:

1. Page 8, item 4.1.2, 1st paragraph: 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.
2. Page D.2, file no. 7: License Reviewer was "WD."
3. Page E.2, file no. 3: Under "comment," please be aware that the file contained written documentation for Inspection 99-01, an inspection scheduled for the purpose of review and follow-up of the incident.

With respect to the meeting between Rhode Island and the Management Review Board, please be advised that Marie Stoeckel, Chief of the Office of Occupational and Radiological Health, is available to attend the meeting scheduled for Monday, February 3, 2003. Her staff would appreciate the opportunity of participating via a conference call.

My thanks to you and your colleagues on the review team for your professionalism and courtesy throughout the IMPEP process.

Sincerely,

Patricia A. Nolan, MD, MPH

Patricia A. Nolan, MD, MPH
Director of Health

cc: Dr. Walter S. Combs
Marie Stoeckel

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