October 29, 1998

Patricia A. Nolan, M.D., M.P.H.
Director
Department of Health
3 Capitol Hill, Room 401
Providence, RI 02908-5097

Dear Dr. Nolan:

On October 19, 1998, 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 program adequate to assure protection of public health and safety and compatible with NRC's program.

NRC recognizes the efforts of Rhode Island and the other Agreement States to maintain adequate and compatible programs. During the MRB meeting, the importance of each Agreement State maintaining funds for necessary training and travel was discussed. Your consideration of methods to help ensure State funding for training and travel could result in further strengthening of the Rhode Island program.

Section 5.0, page 15, of the enclosed final report presents the IMPEP team's recommendations and suggestions. We have received your letter dated September 29, 1998 which described the actions taken in response to the team's recommendations and suggestions. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely, ***/RA/***

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: See next page

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

Marie Stoeckel, Chief
Division of Occupational & Radiological Health

Peter Todd
Rhode Island State Liaison Officer

Patricia A. Nolan, M.D., M.P.H.
Director
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cc: Walter S. Combs, Jr., Ph.D.
Executive Director, Environmental Health

Marie Stoeckel, Chief
Division of Occupational & Radiological Health

Peter Todd
Rhode Island State Liaison Officer

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

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF RHODE ISLAND AGREEMENT STATE PROGRAM

July 27 - 30, 1998

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 July 27-30, 1998, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of New York. 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 a Final General Statement of Policy," published in the Federal Register on October 16, 1997 and the November 25, 1997, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period January 14, 1994 to July 30, 1998, were discussed with Rhode Island management on July 30, 1998.

A draft of this report was issued to Rhode Island for factual comment on September 4, 1998. The State responded in a letter dated September 29, 1998 (Attachment 1). The Rhode Island's factual comments were considered by the team and accommodated in the report. The Management Review Board (MRB) met on October 19, 1998 to consider the proposed final report. The MRB found the Rhode Island radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Rhode Island Agreement State program is administered by the Office of Occupational and Radiological Health (ORH). The ORH Chief reports directly to the Executive Director of Environmental Health located in the Department of Health. The ORH has five employees including the chief assigned to radioactive materials regulation under the Agreement. The Radiation Control Program within ORH is responsible for the Agreement Program and the Supervising Radiation Control Specialist (SRCS) reports to the ORH Chief. An organization chart for the ORH is included as Appendix B.

At the time of the review, the Rhode Island program regulated 77 specific licenses, including limited scope medical, broad scope, industrial radiography, and nuclear pharmacy licenses.

The review focused on the material's program as it is carried out under the Section 274b. (of the Atomic Energy Act (AEA) 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 indicators was sent to the State on June 19, 1998. The State provided a response to the questionnaire on July 13, 1998. During the review, discussions with the State staff resulted in the responses being further developed. A copy of the final response is included in Appendix G to the draft report.

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; and (5) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each

common and non-common indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous 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 indicators, and Section 5 summarizes the review team's findings, recommendations and suggestions.

Recommendations relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report. Suggestions made by the review team are comments that the review team believes could enhance the State's program. The State is requested to consider suggestions, but no response is requested.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous routine review, which concluded on March 3, 1995, comments and recommendations were made and the results transmitted to Dr. Barbara DeBuono, Director, Rhode Island Department of Health on May 13, 1994. The review resulted in six recommendations. The team's review of the current status of these recommendations is as follows:

(1) We recommend that the following rules and any others needed for compatibility, be promulgated expeditiously as effective State radiation control regulations. As a matter separate from the review, it was noted that the State's attention be directed to other regulations that will be needed for compatibility. The rules identified were:

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) needed by October 15, 1994.

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 153) needed by January 27, 1995.

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) which is needed by July 1, 1996.

- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 (58 FR 39628) which is needed by October 25, 1996.

Current Status: The team reviewed the status of Rhode Island's regulations under Section 4.1.1 "Legislation" and found that the above rules required for compatibility have been implemented with the exception of the irradiator rule. The State does not have an irradiator licensee nor do they have an active application for an irradiator and under current compatibility policy an equivalent State regulation is not required. Should an application be received, the State indicated that they will utilize binding legal requirements like license conditions to implement compatible requirements until a rule is promulgated. This recommendation is closed.

(2) We recommend that the ORH management closely monitor the compliance program's statistical reports in order to ensure the timely inspection of licensees.

Current Status: Considerable improvement in the timeliness of inspections was noted by the team. ORH is using a computer data base to plan inspections. The team also notes that this system will be upgraded with a new computer within a short time. The new system will allow for greater flexibility in the management of inspections (see Section 3.1). This recommendation is closed.

(3) It is recommended that the State ensure that each application for a private practice human-use license be signed by the physician/authorized user.

The previous recommendation focused on the acceptance of signatures from individuals who were not “principals” in the company or business.

Current Status: A review of the licensing actions indicates that the State has made changes in their program to ensure that each license application is signed by an individual with the authority to represent the licensee. This recommendation is closed.

(4) a.) It is recommended that the ORH staff document interviews of radiation workers and ancillary workers in each inspection report.

Current Status: The team confirmed that more detail on worker interviews is being provided in the inspection reports. This recommendation is closed.

b.) It is further recommended that each report contain a clear indication of whether the inspection was unannounced or announced.

Current Status: The State’s inspection reports now document the type of inspection conducted. This recommendation is closed.

(5) a.) It is recommended that wipe samples be obtained during each inspection of facilities utilizing Tritium (H-3), Carbon-14 or where loose contamination is suspected and area surveys indicate readings greater than 2-3 times normal background. A more selective sampling approach should be employed for other facilities.

Current Status: The State has taken considerable effort to improve and implement an improved sampling and confirmatory measurements process. This recommendation is closed.

b.) We also recommend that the ORH work with the Health Department Laboratories to insure adequate handling, processing and reporting of results from wipe samples and samples in any other physical form.

Current Status: The wipe test procedures used and contract laboratory support provides assurance that adequate confirmatory measurements are being performed, analyzed and reported. This recommendation is closed.

(6) We recommend that the State more closely monitor licensees where serious violations have occurred. This monitoring should include the inspection of licensees at their scheduled inspection frequency and follow-up field inspections.

Current Status: The State's policy is to perform inspections at the same inspection frequency as that of NRC. Since the last review, the program has made a more conscious effort to conduct routine and follow-up inspections under their policy. Since the last review the State has improved its tracking procedures for following up on serious violations. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency; overdue inspections; initial inspections of new licenses, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on Rhode Island's questionnaire responses relative to this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of completed inspection casework, and interviews with the SRCS, and the inspection staff.

The team's review of the State's inspection priorities found that the inspection frequencies for various types of Rhode Island licenses are based on NRC's Inspection Manual Chapter (IMC) 2800 with inspection intervals of one through seven years. In comparison with NRC guidance, the State's assignment of inspection priorities was determined to be at least as frequent as NRC'S Inspection Manual Chapter (IMC) 2800 with one exception. Rhode Island inspects its only gamma stereotactic radiosurgery facility once every three years compared to an annual inspection frequency in IMC 2800. During discussions with the MRB, the review team noted that the facility is located at a broad scope licensee, which the State inspects more frequently for both radioactive materials and x-ray equipment. In response to the NRC's proposed revision to program code descriptions and inspection priorities in 1997, Rhode Island responded to the NRC in writing on the proposed revision for gamma stereotactic radiosurgery by indicating that their six years of experience with this type of license had shown no significant safety or compliance issues and that an inspection priority of 3 was adequate. The review team found this acceptable.

The State has provisions to extend or shorten the interval between inspections based upon the evaluation of licensee performance. The SRCS routinely indicates if inspection frequency should be extended, shortened or remain the same on the field notes after they are reviewed. Interviews,

review of inspection reports and the inspection data base indicate that extension for good licensee performance is assigned consistent with State and NRC policy. The State uses a reduced inspection interval as a tool to encourage improved licensee performance. The team noted several instances where the State reduced inspection interval based on poor licensee performance. The most notable was that associated with a major medical institution. The review team noted that extending inspection intervals has provided some workload relief and allows its primary materials inspector to pursue naturally occurring and accelerator produced radioactive materials (NARM) programs that the State is also mandated to enforce.

The normal interval between inspection and report issuance was found to be seven to 14 working days, and no report letter was issued more than 30 days post-inspection. Reports and letters are produced by the inspection staff based upon a standard set of letters and notice of violations.

The State possesses a database for inspection scheduling. The SRCS assigns inspections quarterly based on a list of licensees due for inspection from the database. During the review, the team noted that the quarterly inspection planning contributed to some licensees not being inspected within their inspection frequency. Discussions between the review team and the SRCS revealed that the time between the data query and inspection could be a long enough interval to result in some initial and core inspections to be overdue when inspected. For example, a total of eight new licenses were issued during the review period and for seven that have been inspected (one is not yet due), one was done within the six-month interval and the rest were performed at seven and eight months after license issuance. The review team also noted three core inspections were overdue by one to three months when performed. 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.

In response to the questionnaire, the State indicated that one priority 1 inspection was currently overdue. Based on this review, the review team determined that the licensee indicated by the State as currently overdue was not.

The review team noted those State inspections of licensees with authorization to perform licensed activities at temporary job sites (i.e., radiographer and portable gauges) often did not include observations of activities at temporary job sites. Only one field inspection occurred during the review period. Inspections of licensees working under reciprocity at temporary job sites in Rhode Island were not inspected in accordance with the frequency goals of IMC 1220. Twenty-five priority 1 and 2 licensees were granted reciprocity permits during the review period. The State conducted 4 inspections of these licensees. During discussions with the SRCS and the principal materials inspector, the State was aware of the goals in IMC 2800 and IMC 1220 with regard to inspection of licensed activities at temporary job sites. The State inspector would inquire about the location of temporary job sites during inspections or make phone calls to facilities where licensed activities are likely to occur or to the licensees themselves in an effort to identify any activities at temporary job sites. The review team concluded that there were a number of factors that contributed to the low number of temporary job sites inspections compared to the goals of IMC 2800 and IMC 1220. These included 1) the small size of the State's inspection staff; 2) the expenditure of resources in terms of time needed to locate and inspect licensees in the field; and 3) the limited amount of work that some licensees actually perform in Rhode Island. The review

team suggests that Rhode Island continue to make reasonable efforts to conduct inspections at temporary and reciprocity job sites.

Based on the IMPEP evaluation criteria, the review team recommends that Rhode Island's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.2 Technical Quality of Inspections

The review team examined a selected sample of inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 13 materials inspections conducted during the review period. The casework included both State's materials inspectors, and covered inspections of various types including industrial radiography, medical institutions, academic institutions, portable gauging systems, and a nuclear pharmacy.

Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

The inspection procedures and techniques used by Rhode Island were determined by the review team to be consistent with inspection guidance in IMC 2800. The team reviewed the inspection casework and found them to be comparable with the types of information and data collected under NRC Inspection Procedure 87100. Inspections are generally performed on an unannounced basis. The inspection field notes provide consistent documentation of inspection findings. Rhode Island uses field notes for different types of licenses including industrial radiography, medical, fixed and portable gauges and industrial and academic.

Inspection reports were reviewed to determine if the reports adequately documented the scope of the licensed program, licensee organization, personnel protection, posting and labeling, control of materials, equipment, use of materials, transfer, and disposal. The reports were also checked to determine if the reports adequately documented operations observed, interviews of workers, independent measurements, status of previous noncompliance items, substantiation of all items of noncompliance, and the substance of discussion during the exit interviews with management. Routine enforcement and acknowledgment letters are drafted by the inspectors. All inspection reports and correspondence are reviewed by the SRCS prior to being issued to the licensee.

For the casework reviewed, documented inspection findings led to proper regulatory actions and appropriate enforcement. The SRCS stated that escalated enforcement action beyond the issuance of notice of violations (NOVs) was limited to the issuance of orders. The State does and will conduct follow-up inspection(s) of licensees to ensure their licensed operations are conducted safety and in compliance with State regulations. Each State licensee is assessed a fee for inspection of their program. Rhode Island held one enforcement conference during the review period.

On June 22 and 23, 1998, a review team member accompanied the principal State inspector on an inspection of a medical broad scope facility licensed by the State. The inspection accompaniment is listed in Appendix C. The review team member determined that the inspector demonstrated appropriate inspection skills and knowledge of the regulations. The inspector was

well prepared and thorough in the review of licensee's radiation safety program. The inspector was equipped with, and used, appropriate and calibrated survey and safety equipment. Inspection techniques were observed to be performance oriented, and the technical performance of the inspector was at a high level. The inspection was adequate to assess the licensee's radiological and safety performance.

The ORH Chief issued a memorandum this year stating that supervisory accompaniments of inspectors are performed on an annual basis. The State's principal materials inspector was accompanied this year by the ORH Chief, but had not been in previous years during the review period. The team suggests that the State adhere to their policy of performing supervisory accompaniments of all materials inspectors on an annual basis.

The team noted that Rhode Island has an ample number of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. Instrument calibrations are performed two to three times per year by University of Rhode Island's Nuclear Science Center using NIST traceable sources. A sampling of portable instruments maintained were found to be calibrated and operational. The State also utilizes the radiation laboratory at University of Rhode Island's Nuclear Science Center for the analytical evaluation of samples routinely taken during inspections (i.e., wipes and environmental samples) or during incidents and emergencies.

Based on the IMPEP evaluation criteria, the review team recommends that Rhode Island's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory

3.3 Technical Staffing and Training

Items considered for evaluation of this indicator included: the radioactive materials program staffing level, technical qualifications of the staff, training and staff turnover. To evaluate these items, the review team examined the State's questionnaire responses relative to this indicator, interviewed program management and staff, and considered any possible workload backlogs.

Program staffing remained the same, as there were no new hires or staff turnover since the last review. There are no vacancies with respect to the radioactive materials program, however, ORH management indicated that they are attempting to create two (2) additional positions. The minimum educational requirement for a new hire is a baccalaureate degree in physical or biological science. All current staff exceed the qualifications.

The program consists of the ORH Chief, SRCS, Radiological Health Specialist, Senior Industrial Hygienist and an Industrial Hygienist Technician each of whom contribute a portion of their time to the program for a total of 1.2 FTE. The ORH Chief spends approximately 10% of her time on the radioactive materials program, including inspector accompaniments. The SRCS of the Radiation Control Program provides daily management oversight and support in the licensing program. The Radiological Health Specialist is the principal materials inspector and the Senior Industrial Hygienist is the principal license reviewer. In addition, the Industrial Hygienist Technician, who has been working on the regulation of tanning facilities will begin work in the radioactive materials program. The ORH also has access to an individual trained and experienced in radiation control work. This individual supports ORH by drafting and finalizing regulations. He has conducted

inspections and licenses reviews for the ORH when necessary. The review team suggests that the program continue to cross train staff members in various job functions to meet any future contingency. The review team noted that current staffing levels are adequate and no health and safety concerns attributable to staffing were identified.

During the MRB discussion, the ORH Chief noted that the RCP was funded through general appropriation although RCP collected fees. The ORH Chief noted that the State was challenged to find funding for travel and training.

All license reviewers and inspectors have taken the NRC courses deemed appropriate for their tasks, including the five week health physics course. In addition, program staff regularly participates in other training opportunities available through the CRCPD and the New England Radiological Health Committee. In addition, the program conducts regular monthly in-house meetings for its staff to discuss emerging and outstanding issues. However, there is no written training program for the licensing and inspection staff. 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."

Based on the IMPEP evaluation criteria, the review team recommends that Rhode Island's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the reviewers for ten specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authority. 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 that had been completed in the review period. The cross-section sampling included four of the State's major licenses as identified by the State questionnaire, and included the following types: academic broad scope; medical broad scope; nuclear pharmacy; gauge; and medical specific. Licensing actions during the review period included 11 new licenses, 49 renewals, and 120 amendments (including 11 terminations), for a total of 180 licensing actions. In discussions with management, it was noted that there were no major decommissioning efforts underway with regard to agreement material in Rhode Island. A list of licenses reviewed with case-specific comments for license reviews can be found in Appendix D.

The licensing process was discussed with the principal license reviewer and staff. Types of licensing actions selected for review included new licenses, amendments to existing licenses,

renewal licenses, and terminations. License reviews were well done, well documented, detailed, and complete. All telephone conversations with applicants are well documented in the license file. The State uses NRC guides, checklists and model NRC licenses to evaluate applications and issue licenses. The scope of the license review covered the essential elements expected in a comprehensive radiation protection program.

All licensing actions receive supervisory review, and were signed by management. Deficiencies are addressed by detailed, well-written letters utilizing appropriate regulatory language.

Application packages containing guidance (NRC) are sent to license applicants. The applications are reviewed following standard procedures used by the NRC. The licensing guides, as well as other applicable guidance from NRC, are available. Licenses are written in the exact format as those issued by NRC, the same standard possession limits, chemical and physical form and total activity, and standard license conditions (SLCs) for that particular type of license. The same program code for each type of licensee, as used by NRC is also used. Licenses are issued in entirety only as new licenses or during the renewal process. Amendments are issued only with changes as noted in the amendment request (1 or 2-page amendments). License files are several-part documents organized with the license and amendments separate from other documents and grouped in manila folders by a control number issued for each licensing action. Files contain complete information including application, deficiency letters, review check sheet, telephone documents, memoranda, inspection reports, and licensee response letters. Reviewers are conscientious about including all pertinent documents in the license tie-down.

License files have all current inspection data, in addition to incident data, providing license reviewers with incident reports and inspection reports during the renewal period. Incidents are cross-referenced in licensing files. License reviewers have adequate supporting information and documentation readily available in the file to complete license renewal reviews.

The program has a centralized computer system for tracking licensing actions. The SRCS keeps a listing of licensing actions in progress for tracking purposes. While there are only a limited number of licensing actions ongoing, approximately 40 per year, the program could benefit from a more comprehensive tracking mechanism to track licensing actions through to completion. For example, the current system keeps track of when licenses expire and date notice was sent, but it does not clearly track the action after that time. There is a code for completed licensing actions but there are no reminders that a response is overdue. While in most cases staff know (from memory) the status of each licensing action, there should be a listing of the status of each action, a date a response is expected, or tickle date to remind licensees that a response is expected and none received. The review team suggests that the State improve the license tracking system to assure timely processing of actions.

Based on the IMPEP evaluation criteria, the review team recommends that Rhode Island’s performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents, the review team examined the State's response to the questionnaire regarding this indicator, reviewed selected incidents reported for Rhode Island in the "Nuclear Material Events Database" (NMED) against those contained in the Rhode Island files, and reviewed the casework and supporting documentation for six material incidents. The team also reviewed the State's response to two allegations referred to the State by NRC during the review period. A list of selected incident files examined along with case specific comments is contained in Appendix E.

The six incidents selected for review included a misadministration, a loss of control of radioactive materials, two lost radioactive materials, an equipment failure and a transportation event.

When notification of an incident or an allegation is received, the ORH Chief, SRCS and staff normally meet to discuss the initial response and the need for an on-site investigation. The safety significance of the incident/allegation is evaluated to determine the type of response that Rhode Island will take. The small size of the Rhode Island program allows for the prompt dissemination of information regarding the event to all personnel in the program. Radiological incidents can be reported on a 24-hour basis through the Rhode Island State Police or the Rhode Island Emergency Management Agency.

The review team found that the State's actions were within the performance criteria. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the State took suitable corrective and enforcement action. For those incidents not requiring on-site investigations, copies of letters to licensees were in the incident and licensing files. The review team found the State's incident files thorough and well-documented. Detailed information on each event such as telephone conversations and close out memoranda are maintained in the incident file. The review team did note that incidents were followed up at the next inspection.

The review team found that the State consistently reported incidents to the NRC Operations Center for those that require immediate or 24-hour reporting by the State licensee. The SRCS was familiar with the guidance contained in the "Handbook on Nuclear Event Reporting in the Agreement States." The review team queried the incident information reported to the NMED system for Rhode Island for the review period which identified eight reported materials events and one NARM event. The incidents reported to NMED corresponded to incidents maintained in the State's incident files. A review of the information reported to NMED indicates, with the exception of a misadministration reported in June 1998, that all events have been closed out.

During the review period, there were two allegations referred to the State by NRC. One of the allegations was independently received by the State and action was taken by the time the NRC referred the concern to the State for action. The review of the State's allegation file indicates that the State took prompt and appropriate action in response to the concerns raised. The program utilizes NRC written guidance, IMC 1301, 2800 (which references Management Directive 8.8) and SA-300, for handling both incidents and allegations. The review team observed that although ORH performance in this area is very good, their internal procedures are not well coordinated with

the Departmental policy and Rhode Island laws specific to handling incidents and allegations. The review team suggests that written procedures be revised for processing incidents and allegations to reflect specific Department policy or State laws specific to Rhode Island.

Based on the IMPEP evaluation criteria, the review team recommends that Rhode Island's performance with respect to the indicator, Response to Incidents and Allegations, be found 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.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

The team verified that a clear statutory authority for the State's radiation control agency exists. The authority permits the agency to promulgate regulations, license, inspect and enforce. The statutory authority which designates the Rhode Island Division of Occupational and Radiological Health as the State radiation control agency with authority to regulate agreement materials and other sources of radiation is contained in Title 23, Chapter 1.3 of the General Laws of Rhode Island. Since the last review, Chapter 23 has been amended and the agency now has responsibility for tanning facilities under Chapter 68, Tanning Facility Safety Standards Act. The State's "sunset" requirements do not apply to the ORH.

The Rhode Island Radiation Control Program is mandated by law as a unit of Rhode Island Department of Health and is one of four offices in the Division of Environmental Health Services. Additionally, access to appropriate levels of State management is maintained through the Director of the Department of Health.

4.1.2 Program Elements Required for Compatibility

The team verified that the State's present regulatory agenda includes those NRC regulations that are necessary to assure the regulation compatibility criteria are satisfied. ORH regulations are reviewed as necessary to determine if the requirements are still appropriate and necessary. The ORH provides, under State law, opportunity for public comment on proposed regulation changes. Draft regulations are sent to NRC for review and comment and when necessary, changes suggested by NRC are incorporated before final adoption. ORH rules are implemented by Administrative Act and do not require legislative approval before they become effective.

The team evaluated Rhode Island's responses to the questionnaire and reviewed the regulations adopted by the State since the January 14, 1994 review to determine the status of the Rhode Island regulations under the new Commission Policy Statement on Adequacy and Compatibility.

The team also verified that the compatibility table in the States response to the questionnaire was accurate. Under the State's regulatory agenda all regulations required for compatibility have been adopted or are in rulemaking. The following regulations were promulgated in June 1995 or determined to be not applicable to the Rhode Island program as noted:

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 153) that became effective January 28, 1994. The State promulgated this revision in June 1995.

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) that became effective July 1, 1993. As noted in Section 2, the State does not have an irradiator licensee nor do they have an active application for an irradiator and under current compatibility policy an equivalent State regulation is not required.

- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 (58 FR 39628) that became effective October 25, 1993. The State promulgated this revision in June 1995.

- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," (59 FR 28220) that became effective July 1, 1994. The State does not have regulatory authority under the agreement.

- "Low-Level Waste Shipment Manifest Information and Reporting," (60 FR 15649, 60 FR 25983) that was published March 27, 1995 and became effective March 1, 1998. The State promulgated this revision in June 1995.

The current schedule has nine rules that will be completed in the fall of 1998. The ORH uses a strategy of "bundling" rules into a rulemaking package. Using this method the ORH can make all identified changes in a particular regulation at one time. When this current rulemaking package is completed the State will have all rules implemented for compatibility through January 2000. The nine rules presently being revised are as follows:

- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40 and 70 amendment (58 FR 68726; 59 FR 1618) that became effective January 18, 1994.

- "Timeliness in Decommissioning," 10 CFR Part 30, 40 and 70 amendments (59 FR 28220) that became effective August 15, 1994.

- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective January 1, 1995.

- "Frequency of Medical Examination for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995.

- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995.

- “Radiation Protection Requirements: Amended Definitions and Criteria,” 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.

- “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20, and 35 amendment (60 FR 48623) that became effective October 20, 1995.

- “Termination or Transfer of Licensed Activities: Record Keeping Requirements,” 10 CFR Parts 20, 30, 40, 61, 70 amendments (61 FR 24669) that became effective June 17, 1996.

The State plans on sending the above proposed draft regulations to the NRC for review and comment in early Fall. The team note that “Timeliness in Decommissioning,” “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use,” and “Performance Requirements for Radiography Equipment,” are overdue at the time of the review.

Rhode Island is awaiting the publication of the Suggested State Regulations for Transportation before preparing the following regulation revision:

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.

The ORH has identified rules that will be required in the year 2000 and will begin working on them when the current rule making initiative is completed.

- “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.

- “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Part 20.35 amendment (62 FR 4120) that became effective May 29, 1997.

- Fissile Material Shipments and Exemptions,” 10 CFR Part 71 amendment (62 FR 5907) that became effective February 10, 1997.

- “Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, 150 amendments (62 FR 28947) that became effective June 27, 1997.

- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, 70 amendments (62 FR 39057) that became effective August 20, 1997.

The review team suggests that the State evaluate the process of revising their regulations to ensure that the State meets the three-year time frame.

It is noted that Management Directive 5.9, Handbook, Part V, paragraph (1)(c)(iii), provides that the above regulations should be adopted by the State as expeditiously as possible, but not later than 3 years after the effective date of the new Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on IMPEP evaluation criteria, the review team recommends that Rhode Island's performance with respect to this indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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

4.2.1 Technical Quality of the Product Evaluation Program

During the review period, one SS&D certificate was issued by the State. The SS&D certificate is identified in Appendix F. The team notes that the certificate was originally issued for a device containing non-AEA material. Although, the registration was amended to include AEA material the manufacturer has not made a device containing AEA material.

Review of this file and interviews with the staff indicated that Rhode Island follows the recommended guidance from the NRC SS&D training workshop. The registration file contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. In addition, the SS&D review checklist received at the NRC SS&D workshop was used to assure all relevant materials had been submitted and reviewed. The checklist was contained in the registration file. The team determined that the staff will use the guidance in NUREG-1556, V.3, issued September 1997 for any future reviews. All pertinent ANSI Standards and Regulatory Guides are available and are used when performing SS&D reviews.

4.2.2 Technical Staffing and Training

The principal license reviewer conducts the SS&D reviews and has been through the current NRC training. He has been involved in the SS&D reviews in Rhode Island for several years. He has a degree in biological science and is considered fully trained under the common performance indicator, Technical Staffing and Training. He also has had training in conducting SS&D reviews by attendance at an SS&D workshop. The second reviewer is the SRCS. This reviewer provides the required concurrence review. The second reviewer has a degree in physical sciences and has been reviewing SS&D registrations for 18 years. The team found that the two reviewers work together closely when conducting a review and discuss issues and concerns they have identified in an application. The ORH also has indicated that they would draw upon resources outside of their office if necessary. Outside resources could include State engineers or the local University engineering department, the NRC SS&D Section or another Agreement State. ORH is committed to maintaining a high degree of quality in their SS&D reviews and would, if necessary, send their reviewers for additional training.

The team discussed with ORH the possibility of returning the SS&D evaluation program to the NRC considering the technical staffing and training requirements and the very small number of devices that have been reviewed by the State. The State firmly indicated that it wishes to keep the SS&D evaluation program and will do whatever is necessary to assure that the requisite expertise and experience is maintained to conduct SS&D reviews.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&Ds occurred during the review period, nor were there any defects reported.

Based on the IMPEP evaluation criteria, the review team recommends that Rhode Island's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found 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 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 existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Rhode Island 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 found Rhode Island’s performance with respect to each of the performance indicators to be satisfactory. Accordingly, the team recommended and the MRB concurred in finding the Rhode Island program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the State.

RECOMMENDATIONS:

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)

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)

SUGGESTIONS:

1. The review team suggests that Rhode Island continue to make reasonable efforts to conduct inspections at temporary and reciprocity job sites. (Section 3.1)

2. The team suggests that the State adhere to their policy of performing supervisory accompaniments of all materials inspectors on an annual basis. (Section 3.2)

3. The review team suggests that the program continue to cross train staff members in various job functions to meet any future contingency. (Section 3.3)

4. The review team suggests that the State improve the license tracking system to assure timely processing of actions. (Section 3.4)

5. The review team suggests that written procedures be revised for processing incidents and allegations to reflect specific Department policy or State laws specific to Rhode Island. (Section 3.5)

6. The review team suggests that the State evaluate the process of revising their regulations to ensure that the State meets the three-year time frame. (Section 4.1.2)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

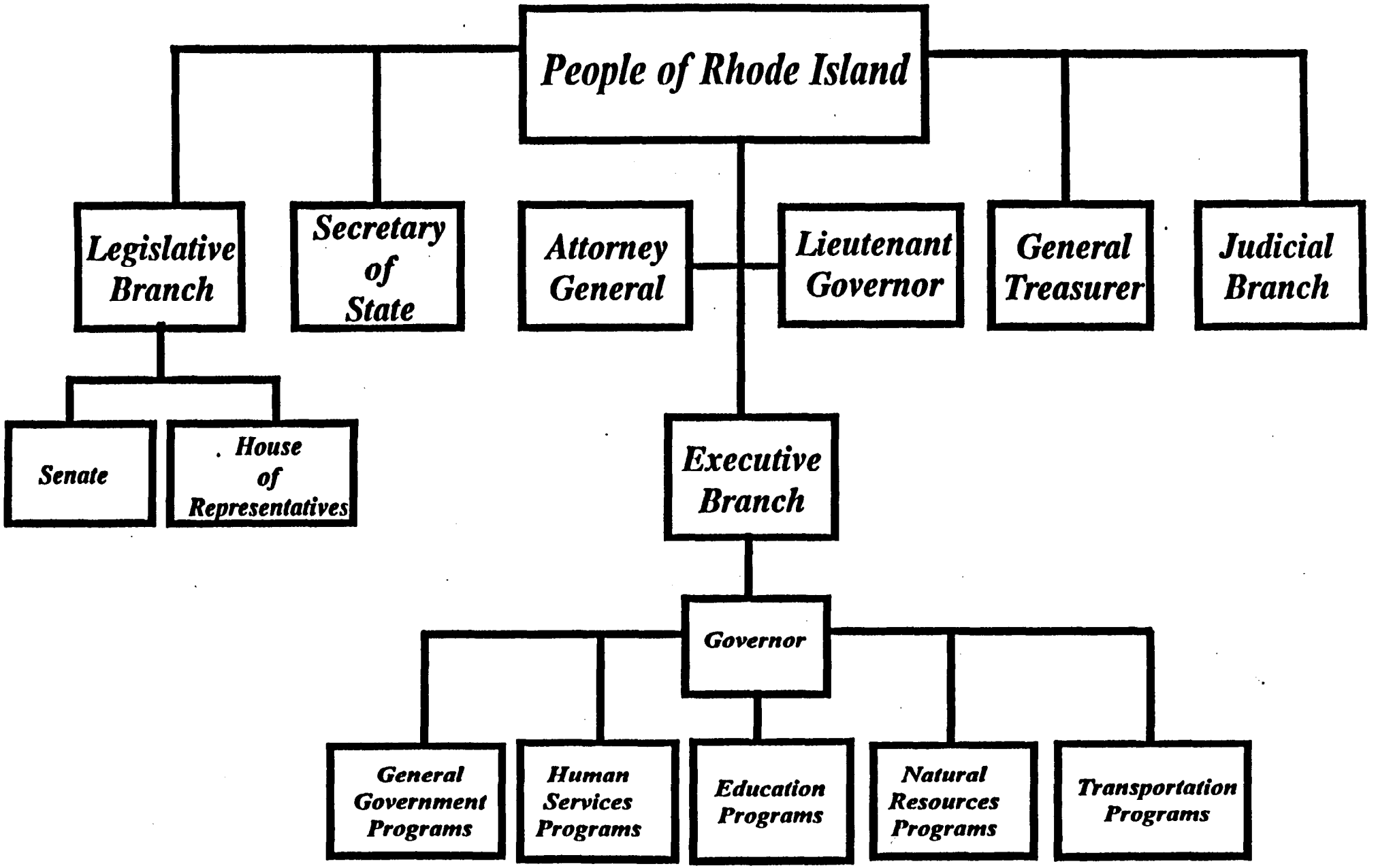
Name	**Area of Responsibility**
James Myers, OSP	Team Leader Status of Materials Inspection Program Technical Staffing and Training Legislation and Program Elements Required for Compatibility Sealed Source and Device Evaluation Program
Steven Gavitt, New York State Department of Health	Technical Quality of Licensing Actions
Duncan White, RSAO, RI	Status of Materials Inspection Program Technical Quality of Inspections Response to Incidents and Allegations

APPENDIX B

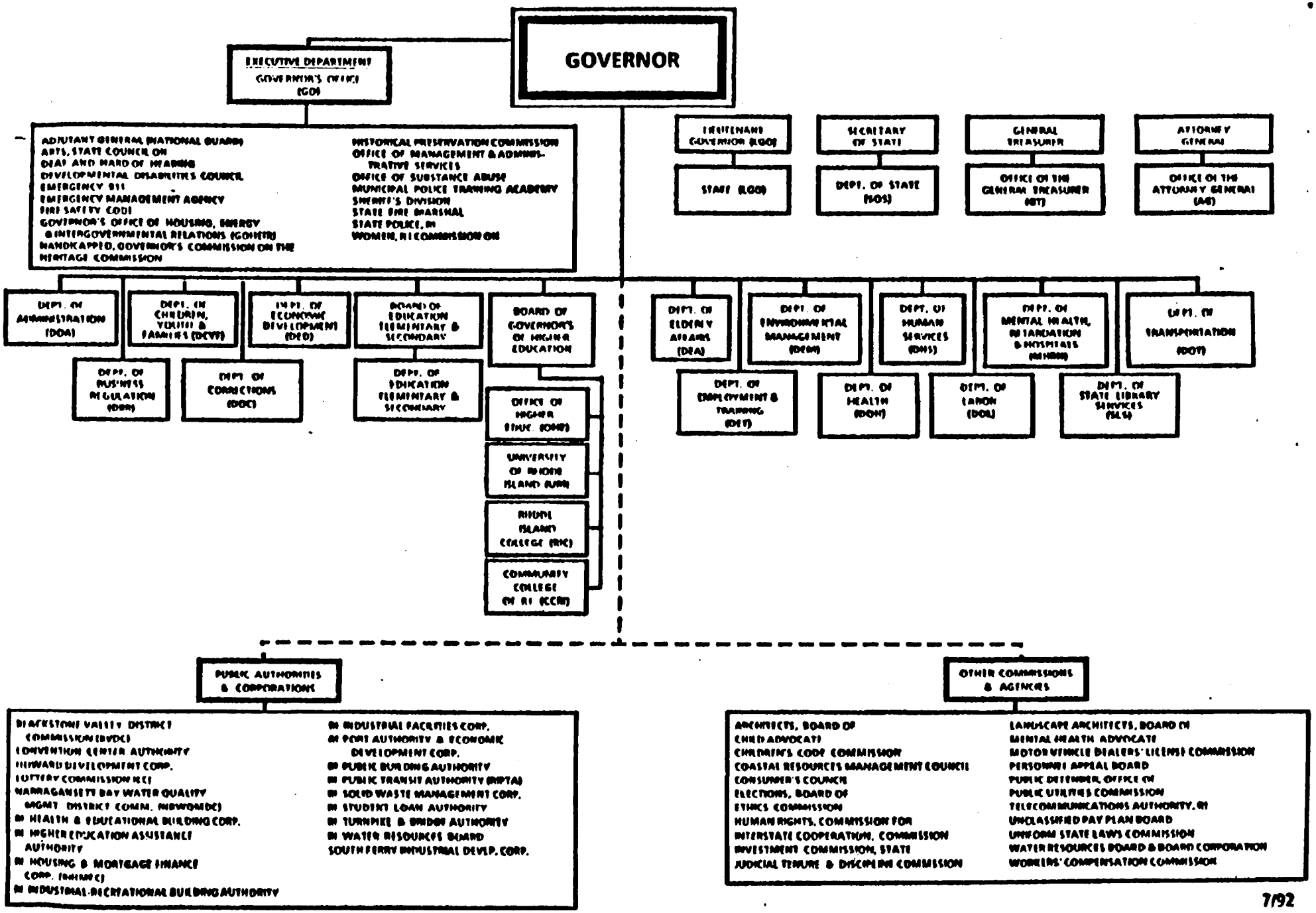
RHODE ISLAND DEPARTMENT OF HEALTH

ORGANIZATIONAL CHART

State of Rhode Island - Organizational Chart



EXECUTIVE BRANCH ORGANIZATION CHART



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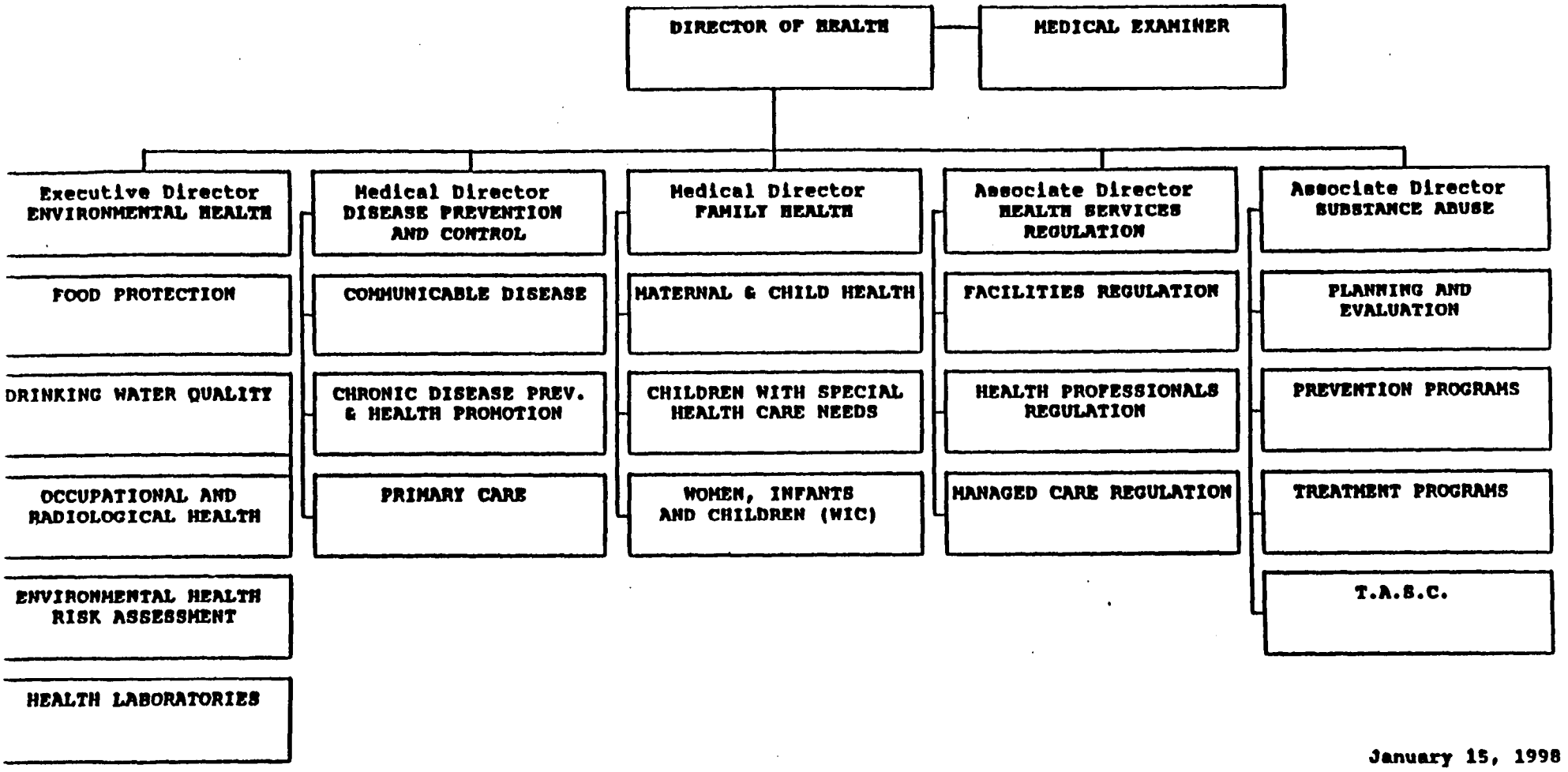
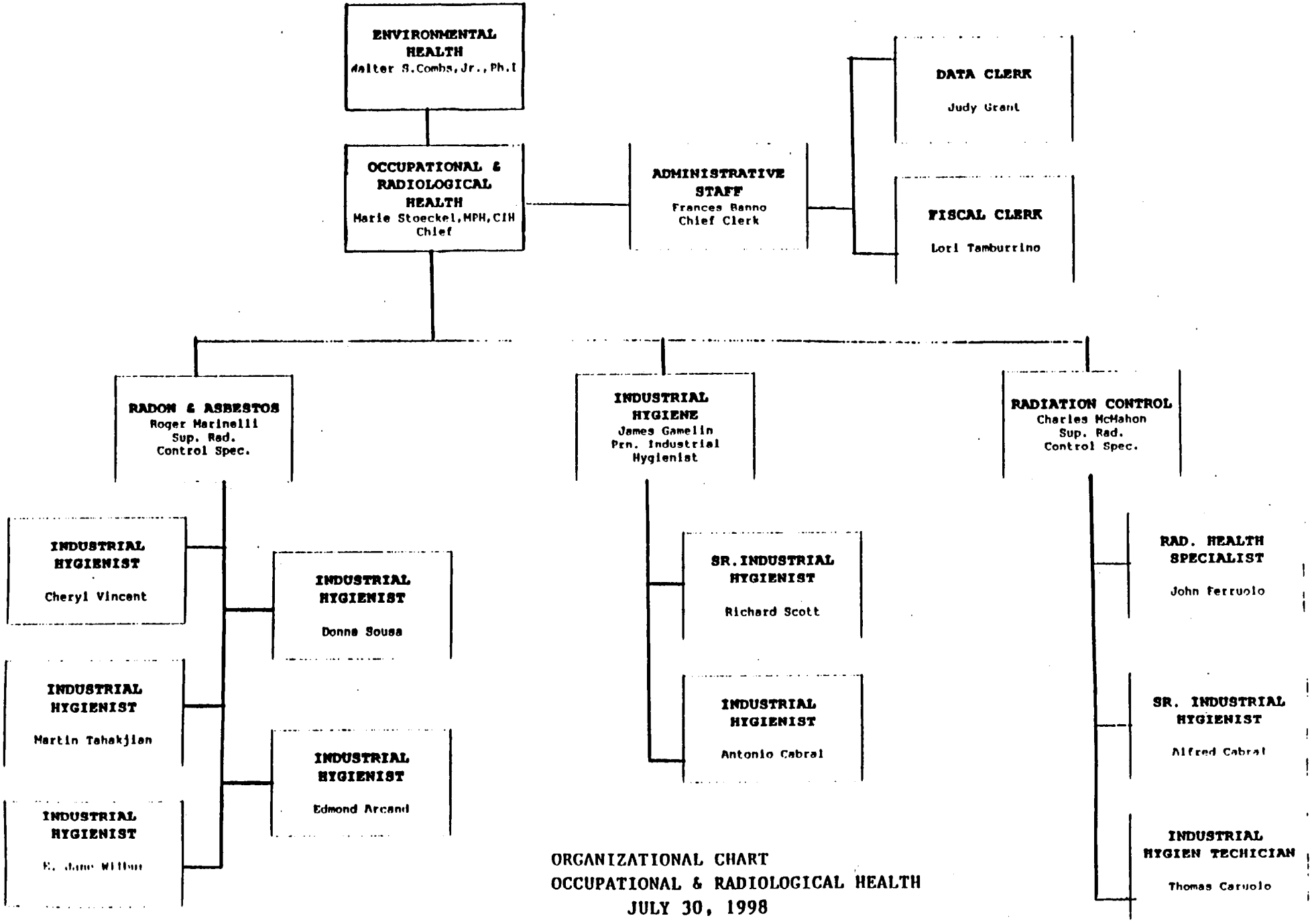
Rhode Island L_ _rtment of Health
Organizational Structure - Fiscal Year 1998



January 15, 1998



ORGANIZATIONAL CHART
OCCUPATIONAL & RADIOLOGICAL HEALTH
JULY 30, 1998

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

September 29, 1998

Richard L. Bangart, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 2055-0001

Dear Mr. Bangart:

We have reviewed the draft Integrated Materials Performance Evaluation Program (IMPEP) report documenting the Agreement State review of the Rhode Island program. Our thanks to Jim Myers, Team Leader, and his colleagues, Duncan White and Steven Gavitt, for their guidance during our first IMPEP review and for their professionalism throughout this process.

I am aware that Marie Stoeckel, Chief of Occupational and Radiological Health, has discussed several corrections and edits with Jim Myers. My understanding is that these comments will be incorporated into the draft IMPEP report.

In anticipation of Marie Stoeckel's meeting with the management review board (MRB) during the second week of October, we are enclosing our response to the two recommendations in the draft report.

We are pleased to be able to continue our long tradition as an Agreement State.

Very truly yours,

Patricia A. Nolan, MD, MPH

Patricia A. Nolan, MD, MPH
Director

Enclosure

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

Marie Stoeckel, MPH, CIH
Chief, Occupational & Radiological Health

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RESPONSE TO RECOMMENDATIONS INCLUDED IN

"INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM:
REVIEW OF RHODE ISLAND AGREEMENT STATE PROGRAM
July 27-30, 1998"

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

Response 1: In the past, licenses have been scheduled for routine inspection by calendar quarters in order to allow flexibility and to make efficient use of staff time. This system allowed the inspector to schedule inspections anytime within the indicated calendar quarter. However, competing RCP requirements have at times led to deferral of radioactive materials inspections towards the end of the quarter, which in turn has led to slippage of some inspections beyond their due dates.

To ensure the performance of inspections in accordance with the priority schedule, inspection due dates will be firmly scheduled within windows around their anniversary dates, as described in NRC Inspection Manual Chapter 2800-05.03. The schedule will be routinely reviewed for adherence to this requirement. In the event of any missed dates, inspections will be rescheduled such that they are still performed within the allowed windows. If it is not possible to perform an inspection before it becomes overdue, it will be rescheduled at the earliest possible time, and a note will be placed in the file indicating the reason(s) for the delay.

New licenses will be issued only when the licensee indicates that they are ready to possess materials or to begin licensed activities. Initial inspections will then be scheduled at the time of license issuance in accordance with the performance requirements specified in MC 2800-04.03(a).

Recommendation 2: The review team recommends that the State document a training and qualifications program equivalent to that in NRC's Inspection Manual 1246, "Formal Qualifications Programs in the Nuclear Materials Safety and Safeguards Program Area." (Section 3.3)

Response 2: The State will develop a training and qualifications program for license reviewers and inspectors. We will utilize the NRC/OAS TRAINING WORKING GROUP RECOMMENDATIONS FOR AGREEMENT STATE TRAINING PROGRAMS as a guide and resource for identifying appropriate program elements and contents.