DATED: JULY 6, 1999 SIGNED BY: FRANK J. MIRAGLIA, JR.

Mr. Arthur W. Ray, Deputy Secretary
Maryland Department of Environment
2500 Broening Highway
Baltimore, MD 21224

Dear Mr. Ray:

On June 22, 1999, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Maryland Agreement State Program. The MRB found the Maryland program adequate to protect public health and safety and compatible with NRC's program.

Section 5.0, page 19, of the enclosed final report presents the IMPEP team's recommendations. The June 3, 1999 letter from Merrylin Zaw-Mon, Director, Air and Radiation Management Administration, detailed the actions Maryland was taking in response to the recommendations made by the review team. We request your evaluation and response to Recommendations 4, 6, 7, 8, and 9 within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, a follow-up IMPEP review focusing on the State's licensing and sealed source and device evaluation programs will be completed in one year and 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/***

Frank J. Miraglia, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Merrylin Zaw-Mon, Director
Air and Radiation Management Administration
Maryland Department of the Environment

Roland G. Fletcher, Manager
Air and Radiation Management Administration
Maryland Department of the Environment

Steven Collins, Organization of Agreement
States Representative to MRB

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bcc: Chairman Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

Distribution: See next page.

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MARYLAND AGREEMENT STATE PROGRAM

March 22 - 26, 1999

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Maryland radiation control program. The review was conducted during the period March 22-26, 1999 by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Texas. Review 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, 1998, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period September 27,1996 to March 26, 1999, were discussed with Maryland management on March 26, 1999

A draft of this report was issued to Maryland for factual comment on April 26, 1999. The State responded in a letter dated June 3, 1999. The Management Review Board (MRB) met on June 22, 1999, to consider the proposed final report. The MRB found the Maryland radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Maryland Department of the Environment (MDE) is the agency within the State of Maryland that regulates environmental and radiation hazards. The Secretary, MDE, is appointed by and reports directly to the Governor. The Radiological Health Program (RHP) is organized under the Air and Radiation Management Administration. The RHP consists of a Radiation Machines Division and the Radioactive Materials Licensing and Compliance Division. The Radiation Materials Licensing and Compliance Division includes a supervisor and two Sections, the Inspection and Enforcement Section with four persons, and the Licensing and Environmental Radiation Section with three persons. Organization charts for the MDE, the Air and Radiation Management Administration, and RHP are included as Appendix B. The Maryland program regulates approximately 592 specific licenses. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maryland.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on January 13, 1999. The State provided a response to the questionnaire on March 1, 1999. A copy of the questionnaire 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 Maryland's response to the questionnaire; (2) review of applicable Maryland statutes and regulations; (3) analysis of quantitative information from the RHP licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two Maryland inspectors; 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 criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the RHP'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 performance indicators, and Section 5 summarizes the review team's findings and

recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous IMPEP review of the Maryland radiation control program concluded on September 27, 1996. Following the last review, fifteen recommendations and four suggestions were made in the March 21, 1997 letter and final report to Ms. Merrylin Zaw-Mon, Director, Air and Radiation Management Administration, MDE. The State initially responded to the issues by letter dated February 3, 1997, prior to NRC's issuance of the final report, and also responded to the March 21, 1997 letter and report in a letter dated April 25, 1997. The status of the recommendations were discussed during a periodic meeting with the RHP on May 8, 1998. The team's review of the current status of the open recommendations is as follows:

1. The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review.

   Current Status: The team found that MDE's Waste Management Administration has taken action to revise the definition of "person" in COMAR 26.14.01.02B(28)(e) to clearly exclude the regulation of Federal agencies located in Maryland. The team reviewed the revised definition and found it compatible with NRC regulations, however, the steps outlined in OSP Procedure SA-201, Review of State Regulations, should be completed before any rule is adopted as final. The revised definition was published on April 9, 1999 for comment with final adoption expected by July 1999. This recommendation will remain open until a final rule is adopted.

2. The review team recommends that the State of Maryland inform NRC when the referring physician/patient notification requirements has been completed by Sacred Heart Hospital.

   Current Status: The State received a progress report on July 18, 1997, regarding the 1987-1988 therapeutic misadministrations at Sacred Heart Hospital. The progress report indicated that the hospital had received location confirmation from 14 of the 19 physicians involved in the care of 26 of the 33 misadministered patients. Since that time, the hospital has changed ownership and gone through a consolidation. The new owners continued to pursue information regarding patient notification from the 14 physicians with little success. Interviews were conducted with ten of the 20 physicians, and one physician is deceased. Most physicians did not recall the exact circumstances or notification actions. Based on the efforts put forth by the Maryland program and the hospital, as well as the period of time that has elapsed since the misadministrations, this recommendation is closed.

3. The review team recommends that the State incorporate the April 1995 revisions to NRC Inspection Manual Chapter 2800 into their Inspection Procedures Manual.

   Current Status: The State updated their inspection frequencies. This recommendation is closed.

4. The review team recommends that management provide a corrective action plan to address the issue of qualifying staff. The team also recommends that management provide a training and qualification plan for new staff that includes an appropriate education background, and a requalification plan for staff that do not meet the initial qualifications, and staff who are reassigned from another technical area, and continued training for long-term staff.

   Current Status: The State added a chapter to their Radiological Health Inspection Manual that adequately addressed this recommendation. This recommendation is closed.

5. The review team recommends that the State assess the adequacy of the program staff to ensure the long-term ability of the program to complete the pending rules and amendments for adoption to remain compatible.

   Current Status: The State formed a special team to develop regulations needed for compatibility and to assure that Maryland's regulations remain compatible. This issue was also highlighted at the Division level as a priority task. Additional details are provided under Section 4.1. This recommendation is closed.

6. The review team recommends that the State adhere to the policy of annual supervisory accompaniments of all inspectors.

   Current Status: The State is adhering to the policy of conducting annual accompaniments of inspectors. This recommendation is closed.

7. To ensure consistency in performance among inspection staff, the review team recommends that the State develop a program outlining the necessary steps to be followed by compliance staff for full inspector qualification.

   Current Status: The State created a program outlining the necessary steps for full inspector qualification. This recommendation is closed.

8. The review team recommends that the State begin voluntary reporting of all reportable events to the NRC Operations Center and begin participating in the NMED database system collection of material events by providing event information directly into the NMED system electronically or providing compatible information in written form in accordance with guidance contained in the "Handbook on Nuclear Material Event Reporting in the Agreement States," Draft Report, March 1995.
   Current Status: The State's corrective actions were fully implemented by November 1998, and the State is currently adhering to the recommended policy. This recommendation is closed.

9. The team recommends that the State provide event information for three events identified by the State in response to the Questionnaire, as follows: (1) 1/23/95 Maryland State Highway event, (2) 5/26/95 Soil Safe Inc. event, and (3) 5/30/96 Aerosol Monitoring event.

   Current Status: The information on the named events has been provided to the NMED data system. This recommendation is closed.

10. The review team recommends that the State improve the effectiveness of the Regulation Adoption Management Plan by providing a realistic schedule of milestones for development and adoption of the 10 rules currently identified in the plan for adoption by the end of 1997.

    Current Status: The State completed this task with the formation of the regulation reviews committee and the progress is discussed in Section 4.1. This recommendation is closed.

11. The review team recommends that the State address the process for handling multiple rulemakings to ensure that they are completed within three years of the effective date.

    Current Status: The State's process is currently working as discussed in Section 4.1. This recommendation is closed.

12. The team recommends that the State address the staff's comments relating to Maryland's COMAR final rules that were transmitted to the State.

    Current Status: The State addressed the comments from the 1996 report during subsequent rule revision correspondence. The status of the Maryland regulations is discussed under Section 4.1. This recommendation is closed.

13. The review team recommends that the State implement a plan to review all registration sheets, based on the risk associated with the device, especially detailed QA/QC program information.

    Current Status: The original recommendation was made in 1993 but was never closed. The State did not review all registration certificates for missing information or against existing guidance. The State requested QA/QC programs be submitted for the more significant devices, except for Neutron Products, Inc. (NPI). The State wanted NPI to address other more significant issues. This recommendation is closed and will be carried forth as a repeat recommendation in Section 4.2.

14. The review team recommends that the State adopt regulations compatible with 10 CFR 30.32 (g) and 10 CFR 32.210. (Section 4.2)

    Current: The State has adopted these regulations. This recommendation is closed.

15. The review team recommends that an additional senior staff member should be trained to perform the SS&D evaluations to supplement the program as it matures.

    Current Status: The State is training one of its license reviewers to perform SS&D reviews. He has performed one review and has attended an NRC SS&D workshop. He currently does not meet the qualification guidance in Management Directive 5.6. This recommendation remains open and will be carried forth as a repeat recommendation in Section 4.2.

During the 1996 review, four suggestions were made concerning: (1) the development of a formal training plan; (2) the assessment of certain inspections performed by a previous employee; (3) the development of guidance documents for license terminations; and (4) the

implementation of an allegation tracking system. The team determined that the State considered the suggestions and took appropriate actions. However, with regard to the allegation tracking system, the RHP managers related that they did not plan to establish a tracking system for allegations since no allegations were received during the review period except those referred to Maryland by the NRC.

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 common indicator: inspection frequency, overdue inspections, initial inspections of new licenses, and timely dispatch of inspection findings. The team reviewed Maryland's response to the questionnaire responses relative to this indicator, data gathered from the State's licensing and inspection database and tracking systems, examination of completed inspection casework and interviews with staff members.

Half of Maryland's 52 licensee categories have more aggressive inspection intervals than specified in Inspection Manual Chapter (IMC) 2800. There are no categories with inspection intervals longer than that required by the IMC. Although the inspection manual indicates that inspection intervals can be lengthened or shortened based on the licensee's performance, the present practice is only to shorten intervals when needed.

The State's response to the questionnaire indicated that it had no backlog or overdue inspections. The team confirmed this by reviewing 49 examples of casework. All inspections were performed well within the required frequency due to the tighter inspection intervals and the inspection scheduling system used. The State performs initial inspections within the first six months of license issuance. The State also conducts a site visit prior to issuing a license to discuss aspects of the license and verify the readiness of the future licensee to receive radioactive material.

Reciprocity inspections are performed at the proper frequency in accordance with IMC 1220, except for source exchange licensees. Since the last IMPEP review, one of four licensees was missed in 1998, three of four missed in 1997, and two of two missed in 1996. RHP management agreed that additional effort should be made to inspect all source exchange licenses due to the high potential hazard.

The team noted that inspection correspondence was generally sent within 30 days of inspection to the licensee. Notices of violation are dispatched well within the 30-day requirement, with only occasional longer time periods. Of the 49 casework reviewed, 45 inspection reports were issued within 30 days or less and two reports were issued within 35 days. Two reports were issued at 69 and 82 days.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, inspection field notes, and enforcement documentation, and interviewed inspectors for 22 material inspections conducted during the review period. The casework included inspections by all four material license inspectors. The casework covered inspections of various license types, including: portable gauge, nuclear pharmacy, private nuclear medicine, mobile nuclear medicine, institutional medicine, blood irradiator, teletherapy, academic, broad academic, industrial radiography, well logging, and service companies. Appendix C lists the inspection casework reviewed for completeness and adequacy including the case-specific comments.

The RHP has developed computerized inspection field notes that are based on NRC field notes and inspection guidance. Based upon the inspector accompaniments and the casework reports reviewed, the team verified that the inspection procedures are consistent with NRC procedures and that inspections are being performed unannounced. The RHP has computerized the licensing/inspection data and a print out of inspections due is available on the computer system. The Supervisor, Radioactive Materials Licensing and Compliance Division, makes the inspection assignments. The inspector prepares for the inspection by obtaining the appropriate inspection forms and notes from the computer and reviewing the license/inspection file for open compliance issues, incidents, and allegations.

Based on casework, the review team noted that 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, 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. The casework documentation shows that inspectors are utilizing the appropriate inspection notes and addressing both open items from previous inspections and any incidents that have occurred since the previous inspection. The casework also shows that the inspection forms and notes are used consistently by inspectors to assure uniform and complete inspection practices.

Following an inspection, the inspector debriefs with the Supervisor to discuss the inspection results and appropriate enforcement action as needed. The field notes are then completed along with an inspection report and a draft enforcement letter is prepared as appropriate. The team noted that a narrative inspection report is prepared for all facilities with a one year inspection frequency and for all escalated enforcement cases. According to the State's procedure, the draft report and draft enforcement letter are reviewed by the Supervisor within 10 days, and prior to any enforcement documents being prepared in final form. All final enforcement correspondence is signed by the RHP Manager. Enforcement practices allow for a Maryland Form E-1 to be issued by the inspector on site at the time of the inspection if there are no items or only minor items of noncompliance. RHP also utilizes a Form E-2 which is similar to the NRC Form 592. The team found that approximately two thirds of the casework reviewed resulted in no items of noncompliance. As noted above, the Supervisor is required to review all field notes and inspection reports within 10 days following the inspection. The team found that in 10 cases, the Supervisor had not reviewed the field notes or inspection reports within the 10-day period following the inspection, as required by the inspection procedure, and that the Supervisor's review was often performed after the Notice of Violation had been issued. The review team

recommends that all inspection documentation be reviewed and signed by RHP management before the inspection correspondence is issued to the licensee.

Licensing and inspection information is combined in one file and maintained by both inspection and licensing staff. The review team discussed with RHP the difficulty in locating reports and correspondence in the State's files. However, in all cases, the technical staff were able to locate the missing documents. After consideration, the team considers this to be an administrative issue rather than a performance issue.

During the week of February 1, 1999, a review team member performed accompaniments of the two State inspectors on separate inspections of licensed activities (see Appendix C). The inspections were of a medical institution and field industrial radiography licensee. During the accompaniments, inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were well prepared and thorough in the review of licensee programs. Inspection techniques were observed to be performance-oriented and the technical performance of both inspectors was outstanding. The inspections were adequate to assess radiological health and safety of the licensed activities.

The review team found that Maryland maintains a sufficient number of portable radiation detection instruments for use during routine inspections and response to radiological incidents and emergencies. Included in the inventory are ion chambers, micro R meters, high range detectors, Geiger Mueller tubes, ratemeters, scintillation detectors, high and low range pocket dosimeters, alpha meters, calibration check sources, and air sampling equipment. The review team examined instrumentation and observed that the survey instruments available during the IMPEP review were calibrated and operable. The RHP has an arrangement with Baltimore Gas and Electric Company which assists the RHP by providing a database for the instrument calibration and can provide additional instrumentation for emergencies if needed. The RHP also contracts with a commercial radiological service company to provide calibrations and repairs. The Environmental Laboratory was not visited during the review; however, the RHP managers and technical staff related that the laboratory provides good support in performing quantitative analyses of samples collected during inspections or incidents in a timely manner.

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

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program 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 RHP management and staff, and considered any possible workload backlogs.

At the time of the review, eight staff members were directly involved with the Agreement State radioactive material program, including management. There are currently no unfilled vacancies. The Licensing and Environmental Section has three individuals and the Inspection and Enforcement Section has four individuals currently assigned. During the review period, one inspector left, and an individual was hired within nine months to refill that position. The new staff member possesses a bachelor's degree and several years experience in nuclear medicine.

Although RHP has the ability to hire an individual at an entry level (health physicist trainee), RHP does not have any trainees on the staff. All staff are at least at a Health Physicist II level.

License reviewers and inspectors have all been through the core courses listed in IMC 1246, and the management's commitment to staff training is evident in the quickness that the new staff member has been the given opportunity and funds to complete the core course offered by the NRC. The RHP staff has also had training from other agency training programs, including the Department of Energy and the Federal Emergency Management Agency, commercial vendors and local educational institutes. A 1996 IMPEP recommendation advocated the creation of a corrective action plan for the qualification of staff. The Radiological Health Inspection Manual now contains a chapter on training and qualifications procedures, utilizing previous training, core and specialized training, inspection accompaniments, and evaluation by management to qualify individual staff.

The review team expressed concern that future demands and workload on the present staff may impact the long-term ability of the RHP to maintain a full level of proficiency in all areas of the program. This concern is based upon the projected retirement of the individual responsible for oversight of the RHP's adoption of regulations (Section 4.1), the processing of enforcement actions (Section 3.1), the performance in the licensing area (Section 3.4), and performance in the sealed source and device area (Section 4.2). The staffing level should be closely monitored given the possible retirement and need to improve overall performance of the program, particularly in the licensing and sealed source and device evaluation program areas. The review team recommends that the State evaluate present and future staffing needs of the RHP and develop a strategy that will assure RHP's continued adequacy and compatibility.

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

3.4 Technical Quality of Licensing

The review team examined completed licenses and casework for 25 licensing actions, representing the work of four license reviewers. The license reviewers and RHP management were interviewed to supply additional information regarding licensing decisions or file contents.

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 accuracy, appropriateness of the license and its tie-down conditions, and overall technical quality. Casework was evaluated for adherence to good health physics practices, reference to appropriate regulations, supporting documents, peer or supervisory review, and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

The licensing actions reviewed included the following types of licenses: academic; medical (both broad scope and specific); industrial radiography; radiopharmacy; panoramic and self-shielded irradiator; portable and fixed gauge; High Dose Rate (HDR) afterloader; brachytherapy; manufacturing and distribution; waste broker; incinerator; and service. Licensing actions included 2 new licenses, 13 amendments, 7 renewals, and 3 terminations. A list of these licenses with case-specific comments may be found in Appendix D.

The program processed 1158 licensing actions during the review period, or an average of 460 actions per year. These consisted of 52 terminations, 81 new license applications, 172 renewals, and 853 amendments. Monthly tracking reports are generated and reviewed by RHP management.

All incoming licensing actions are briefly reviewed by the Supervisor and then logged into a computer tracking system by the licensing staff. There are currently two individuals who perform license reviews full time and have signature authority. A third individual recently started performing reviews. A majority of the licensing actions are performed by the most experienced license reviewer. This staff member also assigns each action. If a deficiency letter is required, the license reviewer prepares the letter using standard deficiency paragraphs for the signature of the Supervisor. After the review is completed, each licensing action, including the cover letter, is reviewed by the Supervisor.

The Supervisor's review is initialed on both the license and letter, and then sent to the RHP Manager for signature. The Administrative Assistant confirms the proper review, prints the final copy for signature, and mails the license to the licensee. Boilerplate licenses as well as standard conditions for each type of amendment are used to generate all new and renewed licenses thus ensuring a standard license. If the licensing action is an amendment request, RHP will issue the completed amendment on a supplement sheet indicating only those license conditions that were changed.

The review team found that most of the licensing actions were thorough, complete, consistent and with health and safety issues properly addressed. Tie-down conditions are backed by information contained in the file, and are inspectable. Deficiency letters clearly state regulatory positions, are used when appropriate, and identify deficiencies in the licensees' documents. Terminated licensing actions are well-documented, showing appropriate transfer and survey records. The program uses a combination of NRC and State regulatory guides. In addition, a number of additional guidance documents are used. Checklists for most categories of licenses are used for new or renewal actions and maintained with the license file. The licensing staff conducts a pre-licensing visit to all new applicants prior to issuing the license to review the conditions of the licenses, COMAR regulations, and RHP policies. These visits are documented with a checklist maintained in the appropriate docket file. The review team noted that RHP has initiated the practice within the last year of routinely amending licenses to incorporate licensees' commitments made in response to notices of violations issued from inspection findings.

The review team noted that 8 of the 25 licensing actions reviewed either did not authorize the licensed material requested by the licensee, did not authorize the correct isotope form or possession limit, named the wrong Radiation Safety Officer (RSO), did not address an aspect of the radiation protection program, authorized distribution of licensed material not included on the device's Sealed Source & Device (SS&D) registration's sheet, or did not include tie-down conditions committing the licensee to follow submitted procedures. For example, the team noted that one of the omitted tie-downs included the operational procedures for the use of an HDR source in a coronary afterloader in an Investigative Device Evaluation study. There were also two cases where license amendments were issued out of sequence instead of incorporating the action with the pending renewal or new application. In the case of the new application, the applicant submitted additional information which was issued as an amendment prior to the issuance of the new license. Although there is a potential health and safety consequence as a result of these license deficiencies, none have been observed by RHP or reported by the licensee.

The review team noted that at the time of the review, 50 license renewals have been in timely renewal for one year or more, or approximately 10% of all materials licenses. A majority of the overdue renewals (65%) have been in timely renewal between one and two years, a significant number (27%) have been pending for more than three years. Two of the actions have been in timely renewal for more than 10 years with the oldest action in renewal for over 12 years for one of the State's largest medical broad scope licenses. A number of these actions have been pending for extended periods needing either a written response from the licensee to a deficiency letter, review of the licensee's application, or review of the licensee's response to a deficiency letter by the program.

The review team discussed the licensing backlog and the accuracy and technical quality of licenses with RHP management who indicated their awareness of the situation and discussed with the review team the need to provide additional staffing and oversight of the licensing staff. The review team recommends that RHP management implement an action plan to reduce the number of backlogged licensing actions and set goals to improve the accuracy and overall technical quality of licenses.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Technical Quality of Licensing, be found satisfactory with recommendations for improvement.

3.5 Response to Incidents and Allegations

To evaluate 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, evaluated selected incidents reported for Maryland in the "Nuclear Material Events Database" (NMED) against those contained in the Maryland files, and evaluated the casework and supporting documentation for eight radioactive material incidents. A list of incident casework examined along with case specific comments is contained in Appendix E. The team also evaluated the State's response to six radioactive materials allegations which were referred to the State by NRC during the review period.

The review team discussed the State's incident and allegation processes, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with the program managers and selected staff. In addition, the State's understanding and use of the NMED system was verified by a team member during a demonstration of data entry into the system, and through the generation of specific reports requested during the review.

When notification of an incident is received, the managers and staff discuss the health and safety risk associated with the incident, the information needed, the need for an on-site investigation, and coordination with other Agencies. The actions taken in response to the event are documented in a report, filed, and the data entered into the NMED system. Enforcement actions or other regulatory actions were taken as appropriate. The team confirmed that the State has the most recent NRC guidance for reporting incidents. The key program staff were all aware of the guidance and had general knowledge about the use of the NMED database system.

The State had 18 radioactive materials incidents during the review period. Eight incidents were selected for casework review, including a stolen portable gauge, two misadministrations, one occupational overexposure, two damaged portable gauge incidents, one industrial radiography

accident, a leaking source, and a stuck teletherapy source incident. The review team found that the State's responses to incidents were complete and comprehensive. Initial responses were prompt and well-coordinated. 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 enforcement action including coordination with the license reviewers and follow up, as appropriate. There were no performance issues identified during the incident casework reviews.

During the review period, there were no materials allegations received by the State directly, and six materials allegations were referred to the State by the NRC. All six were examined in detail by the review team. The review of the casework and the State's files indicates that the State took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed and the team noted that allegations were treated and documented internally in the same manner as incidents. There were no performance issues identified from the review of the casework documentation, except for one allegation report that was filed in a non-confidential file that contained the identity of the alleger.

The State has allegation procedures, "Radioactive Materials Procedure for Handling Allegations, Revision 0, dated September 18, 1996, which were assessed in accordance with IMPEP criteria, draft OSP Procedure SA-105, "Response to Incidents and Allegations," and the NRC Management Directive 8.8, "Management of Allegations," revised February 4, 1999. Copies of the NRC documents were provided to the State during the review. The team's assessment shows that the State's procedure does not adequately address the following: (1) the definition of "allegation;" (2) the protection of the allegers identity; (3) allegations received during inspections; (4) the referral of allegations not under RHP jurisdiction (except for criminal cases); and (5) documentation for closing out the concern(s) with the alleger, except for cases where an inspection or investigation is not warranted. The review team recommends that the State revise their allegation procedure to incorporate appropriate elements following NRC guidance documents.

The team also determined during the review that Maryland can protect the identity and confidentially of individuals and related information. The RHP Manger provided specific "excerpts" from a "Public Information Act Manual" prepared by the Attorney General's office. This information was referenced as Public Information Statue, 10-618(f)(2)(iv).

Based on the IMPEP evaluation criteria, the review team recommends that Maryland'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. Maryland's Agreement does not cover a uranium recovery program, 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

Along with 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 is contained in Annotated Code of Maryland, Environmental Article, Title 8, "Radiation," and Title 7, "Hazardous Materials and Hazardous Substances." The RHP, Air and Radiation Management Administration, MDE implements the radiation control program.

4.1.2 Program Elements Required for Compatibility

The statutes are contained in COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation" (1994) that applies to all ionizing radiation. COMAR 26.15 "Disposal of Controlled Hazardous Substances-Radioactive Hazardous Substances" contains statues specific to low-level radioactive waste issues. Maryland requires a license for the possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. Maryland also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The review team examined the State's administrative rulemaking process and found that the process takes six months from the development stage to the final approval by the Secretary of the Environment, after which the rule becomes effective in 10 days. The regulation adoption process is provided in Title 10, "Government Procedures," Subtitle 1, "Administrative Procedures Acts - Regulations." The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated as appropriate before the regulations are finalized and approved by the Secretary of the Environment. The State can adopt other agency regulations by reference which has been done with respect to transportation regulations adopted by the U.S. Department of Transportation and the U.S. Postal Service regulations that were in effect on May 15, 1996. The State also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The team evaluated Maryland's response to the questionnaire and reviewed the status of regulations under the Commission's new adequacy and compatibility policy. The review team noted that regulations were updated on December 6, 1996 (Supplement 1), November 3, 1997 (Supplement 2), June 29, 1998 (Supplement 3) and December 28, 1998 (Supplement 4). The team found that the State addressed the following NRC regulation amendments since the last IMPEP review:

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) that became effective July 1, 1993.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) 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 and 65243) that became effective January 1, 1995.

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

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The Agreement States are to promulgate their regulations no later than March 1,1998 so that NRC and the State would require this national system to be effective at the same time.

The State has not yet adopted the following regulations, but intends to address them in timely rulemaking, or by adopting alternate generic legally binding requirements:

- The definition of "person" in the low-level radioactive waste regulations COMAR 26.14. 01.02B(28)(e) as it relates to Federal agencies. As noted in Section 2, this was identified in both the 1993-94 review, 1995 follow-up review, and the 1996 IMPEP review. The team reviewed the revised definition and found it compatible with NRC regulations, however, the steps outlined in OSP Procedure SA-201, Review of State Regulations, should be completed before any rule is adopted as final. The revised definition was published on April 9, 1999 for comment with final adoption expected by July 1999.

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

- "Radiation Protection Requirement: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 CFR 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 amendments (60 FR 48623) that became effective October 20, 1995.

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

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

- "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 February 27, 1997.

- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.

- "Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28948) that became effective June 27, 1997.

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

- "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.

- "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.

- "License for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 393477 and 63 FR 45393) that became effective October 26, 1998.

- "Transfer for Disposal and Manifest; Minor Technical Conforming Amendments," 10 CFR Parts 20, 35, 36, and 39 amendment (63 FR 50127) that became effective November 20, 1998.

During the review, the State related that seven of the above regulations required for compatibility are combined in two packages (Supplements 5 and 6) and are in the process of being adopted. Both supplements have been reviewed by NRC and the State expects them to be adopted by August 1999. Four additional regulations required for compatibility by September 2000 are currently being developed by RHP staff for incorporation into COMAR (Supplement 7).

The team noted that the RHP staff member responsible for oversight of the adoption of NRC regulations required for compatibility is scheduled to retire by end of this year. In light of this pending retirement, the State's past difficulties in adopting NRC regulations for compatibility, and the need for the State to adopt a number of significant regulations currently under development by the NRC over the next few years, the team discussed the importance of maintaining the level of performance for this indicator with MDE management.

It is noted that Management Directive 5.9, Handbook, Part V, (1)(C)(III) provides that regulations required prior to September 3, 1997, should be adopted by the State as expeditiously as possible, but not later than three years after the September 3, 1997 effective date of the Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

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

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

In assessing the State's Sealed Source & Device (SS&D) evaluation program, the review team examined information provided by the State in response to the IMPEP questionnaire on this indicator. A review of selected new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team observed the RHP's use of guidance documents and procedures, and interviewed the staff, RHP Manager, and Supervisor involved in SS&D evaluations.

Since the last review, the State has instituted a policy that the RHP Manager and Supervisor review and sign all registration certificates prior to issuance in addition to the two reviews conducted by the technical staff. These reviews are not technical in nature, but are to ensure the technical soundness, readability, and understandability of the registration certificates.

4.2.1 Technical Quality of the Product Evaluation Program

Since the last IMPEP review, the State has issued three new SS&D certificates, seven amendments, and three corrections. The review team examined five new or amended SS&D registration certificates and their supporting documentation. The registration certificates reviewed covered the period since the last IMPEP review and represented cases completed by three reviewers. In addition, one registration certificate from the previous IMPEP review was reviewed for resolution of previously identified items. The review team identified additional significant technical issues that need to be addressed in this registration certificate. It was noted that previous comments on all casework reviewed during the 1996 IMPEP were not addressed. The registration certificates issued by the State and evaluated by the review team are listed with case-specific comments in Appendix F.

The review team found that some SS&D evaluations do not fully address important health and safety concerns. For two of the registration certificates reviewed, MD-1003-D-101-G and MD-1003-D-102-G, the review team identified significant deficiencies common to both. These deficiencies include inadequate description of the device and safety features in the description section of the registration certificate; inadequate engineering drawings; inadequate dose estimates; inadequate engineering analyses performed by the applicant; and improper instructions in the device's user's manual.

The review team was unable to make a determination that the above devices could be used safely under the expected conditions of use due to the above deficiencies. These findings are significant since both of these devices are distributed as generally licensed, where it is assumed that the user is able to use the device safely without being trained in radiation safety. The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F for each registration certificate, and amend the registration certificates accordingly.

The review team also identified repeated examples of deficiencies with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing guidance. Adequate engineering drawings were not provided in most cases. The engineering drawings should contain safety critical components, such as the shutter, pneumatics, source holders, shielding, etc., with materials of construction, methods of construction, and dimensions and tolerances. Four of the registration certificates had attachments listed as proprietary or confidential, contrary to the State's policy on proprietary information. Several deficiency letters issued by the State and responses from the applicants could not be located in the supporting

files. Several documents submitted by the applicants should have been referenced in the registration certificates. Finally, there was a lack of documentation (e.g., staff reviewers stated that they had discussed deficiencies and received information from applicants over the telephone and there was no information in the supporting files documenting these calls).

During the 1993 review, NRC recommended that the State and vendors should replace missing information and review outdated registration sheets in accordance with the standard format and content guidance. The 1993 review recommended that the State obtain and maintain sufficient documentation on file to establish a complete health and safety basis for the integrity of the product designs. This item was closed out based on the State's response to the 1993 review. With the assignment of new staff to the program in 1995, the review team requested the documentation of the State's actions to this previous comment. The staff present in 1996 was not aware of this commitment and management was not able to produce documentation of actions taken by Maryland in response to the 1993 review.

Based on the above, the 1996 IMPEP review team recommended that the State implement a plan to review all registration certificates, based on the risk associated with the device, especially detailed quality assurance/quality control (QA/QC) program information. The State requested QA/QC programs be submitted by their registration certificate holders for the more significant devices, except for Neutron Products, Inc. (NPI). The State wanted NPI to address other more significant issues. These QA/QC programs were reviewed and incorporated into the distribution licenses of the registration certificate holders. The State did not review all registration certificates for missing information or against existing guidance. The team is concerned about the magnitude of the issues identified in this review, and the fact that similar issues raised in the 1996 IMPEP review were not fully addressed. The team recommends that the State, using NUREG-1556 guidance and following the description of a “concurrence review” in Management Directive 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device.

The State’s reviewers stated that they currently follow the NRC’s guidance in NUREG-1556, Vol. 3, “Consolidated Guidance on Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration,” when reviewing applications and drafting registration certificates. Prior to this document’s issuance in July 1998, the State’s reviewers followed the NRC’s guidance in NUREG-1550, “Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations,” and Regulatory Guide 10.10, “Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material.” NUREG-1556, Vol. 3, combined and superseded the guidance provided in these documents. Review of the five registration certificates and interviews with the staff indicates that staff is not adequately following the prescribed guidance. Section 4.2.2 contains a recommendation that addresses this issue.

4.2.2 Technical Staffing and Training

During this IMPEP period, all reviews were performed by three staff members. All three staff members are health physicists, two are qualified license reviewers, and the third is a senior inspector. All three have attended at least one of the NRC’s sealed source and device evaluation workshops. Only one reviewer worked with a qualified SS&D reviewer (the former SS&D reviewer who retired in June 1995) prior to independently reviewing and signing registration certificates. The other two staff members had no experience reviewing applications

or drafting registration certificates prior to being assigned cases as the primary reviewer for formal review.

Based on interviews and discussions with the staff and the extensive deficiencies, findings, comments, and issues identified in the registration certificates reviewed, the team determined that the RHP staff do not fully meet the qualification guidance in Management Directive 5.6 and need additional training and experience in the review of applications and drafting of registration certificates. Specifically, the staff needs additional training and experience in the following areas: understanding and interpreting the appropriate prototype tests that ensure the integrity of the products under normal and likely accidental conditions of use; reading and understanding blueprints and drawings (including the types and contents of blueprints and drawings that applicants are required to submit); understanding the conditions of use; and understanding and utilizing basic knowledge of engineering materials and their properties. During the 1996 IMPEP review, an offer was extended to the State for a reviewer to work with the Sealed Source Safety Section at NRC Headquarters. No reviewer from the State of Maryland has worked with staff at NRC Headquarters. This review team has made the same offer to the State. The 1996 IMPEP team recommended that an additional senior staff member be trained to perform the sealed source and device evaluations to supplement the program as it matures. The State had assigned an additional individual to the program who has completed one review to date and would also benefit from additional training and experience. The review team recommends that the State provide the staff additional training and experience in the review of sealed source and device applications and the drafting of registration certificates (including the guidance contained in NUREG 1556, Vol. 3). This should include training and experience which will meet the qualification guidance found in Management Directive 5.6.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team reviewed the State's response to two events requiring the evaluation of defects and incidents regarding sealed sources and devices. The State responded satisfactorily to both events.

4.2.4 Summary

Based on the IMPEP evaluation criteria, the review team recommended that Maryland's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory with recommendations for improvement. During the MRB meeting on June 22, 1999, the MRB requested that the team revise appropriate portions of the SS&D section to reflect meeting discussions. Many of those MRB discussions were directed at understanding the review team's decision to recommend a satisfactory with recommendations for improvement rating as opposed to an unsatisfactory rating for this indicator. The MRB commented that based on the criteria in Management Directive 5.6, an unsatisfactory rating for this indicator appeared to be a possibility and questioned each team member concerning the satisfactory with recommendations for improvement rating. Given the significance of the comments made on the SS&D casework reviewed by the team, the MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report, and the MRB directed that a follow-up review of the State's SS&D program be completed in one year. Due to the findings involving the common performance indicator, Technical Quality of Licensing Actions, the MRB also directed that the follow-up review include the State's licensing program. The MRB accepted the team's recommendation that Maryland's performance with respect to this indicator be found satisfactory with recommendations for improvement.

4.3 Low-level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC 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 Maryland 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 Maryland. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Maryland's performance to be satisfactory in all but two indicators. The indicators, Technical Quality of Licensing Actions and SS&D Evaluation Program were found to be satisfactory with recommendations for improvement. However, in view of the State's performance demonstrated in the Status of Inspection Program and the Technical Quality of Inspections indicators, the review team recommended and the MRB concurred in finding the Maryland Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. A follow-up review focusing on the State's licensing and SS&D programs will be completed in approximately one year.

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

RECOMMENDATIONS:

1. The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review. (Section 2.0)

2. The review team recommends that all inspection documentation be reviewed and signed by RHP management before the inspection correspondence is issued to the licensee. (Section 3.2)

3. The review team recommends that the State evaluate present and future staffing needs of the RHP and develop a strategy that will assure RHP's continued adequacy and compatibility. (Section 3.3)

4. The review team recommends that RHP management implement an action plan to reduce the number of backlogged licensing actions and set goals to improve the accuracy and overall technical quality of licenses. (Section 3.4)

5. The review team recommends that the State revise their allegation procedure to incorporate appropriate elements following NRC guidance documents. (Section 3.5)

6. The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F for each registration certificate, and amend the registration certificates accordingly. (Section 4.2.1)

7. The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrence review" in Management Directive 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.2.1)

8. The 1996 IMPEP team recommended that an additional senior staff member be trained to perform the sealed source and device evaluations to supplement the program as it matures. The State had assigned an additional individual to the program who has completed one review to date and would also benefit from additional training and experience. The review team recommends that the State provide the staff additional training and experience in the review of sealed source and device applications and the drafting of registration certificates (including the guidance contained in NUREG 1556, Vol. 3). This should include training and experience which will meet the qualification guidance found in Management Directive 5.6. (Section 4.2.2)

9. The MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report. (Section 4.2.4)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Maryland's 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	Maryland's Response to Draft IMPEP Report Dated June 3, 1999

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Richard Woodruff, Region II	Team Leader Response to Incidents and Allegations
Duncan White, Region I	Technical Quality of Licensing Actions Legislation and Program Elements Required for Compatibility Inspector Accompaniments
Joseph DeCicco, NMSS	Status of Materials Inspection Program Technical Staffing and Training
William Silva, Texas	Technical Quality of Inspections
Brian Smith, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B

STATE OF MARYLAND
DEPARTMENT OF ENVIRONMENT

AND

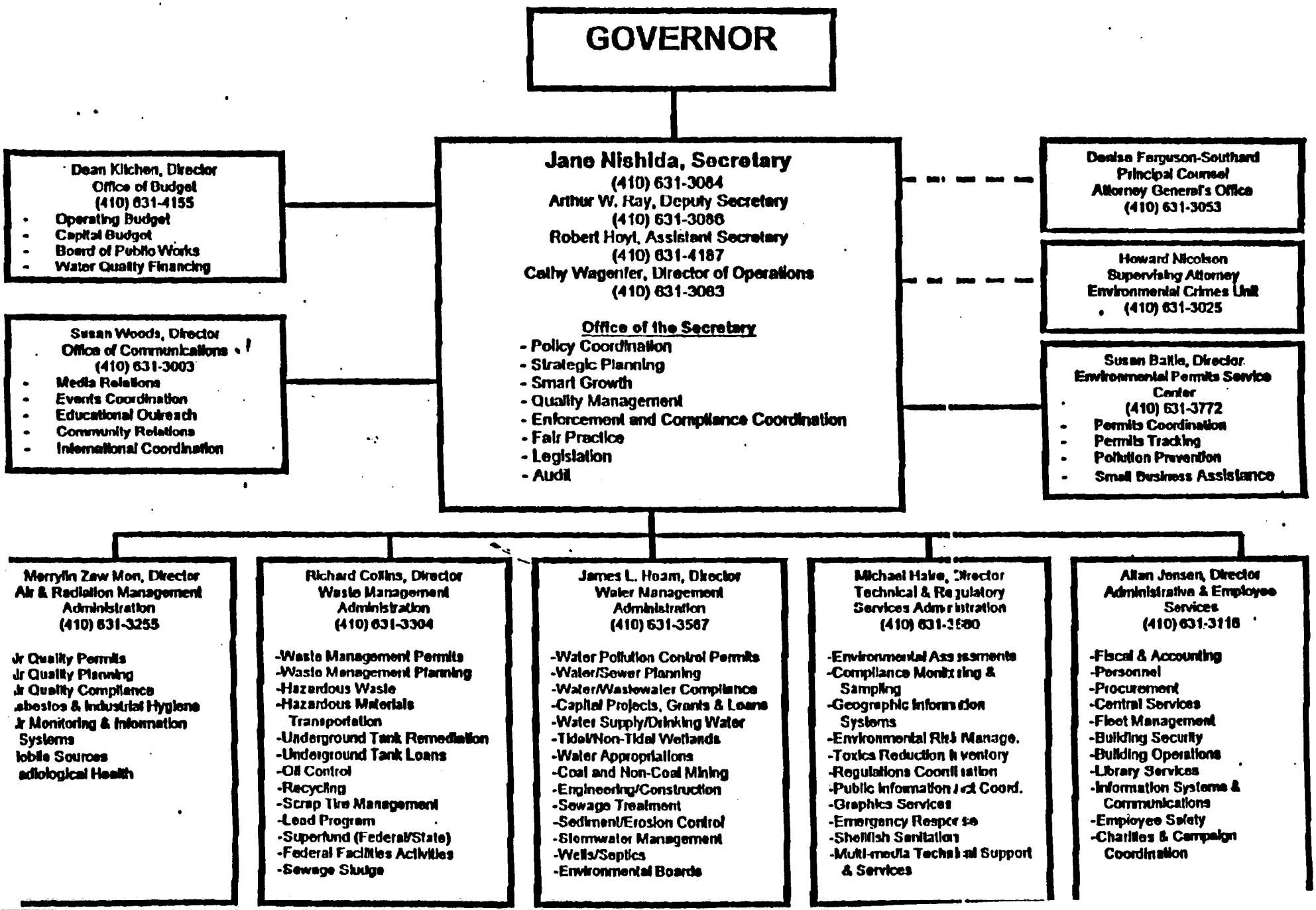
AIR AND RADIATION MANAGEMENT ADMINISTRATION

AND

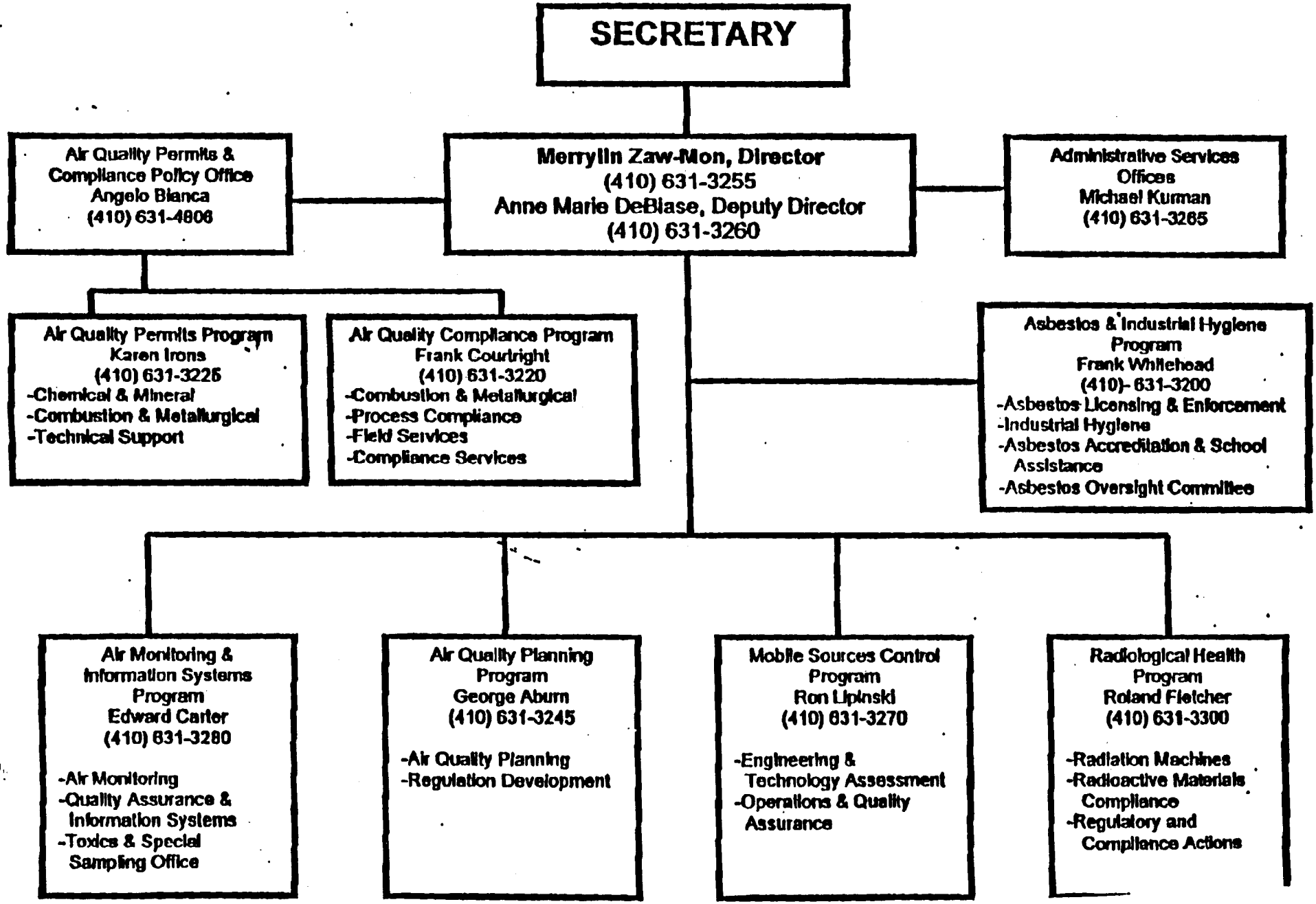
RADIOLOGICAL HEALTH PROGRAM

ORGANIZATION CHARTS

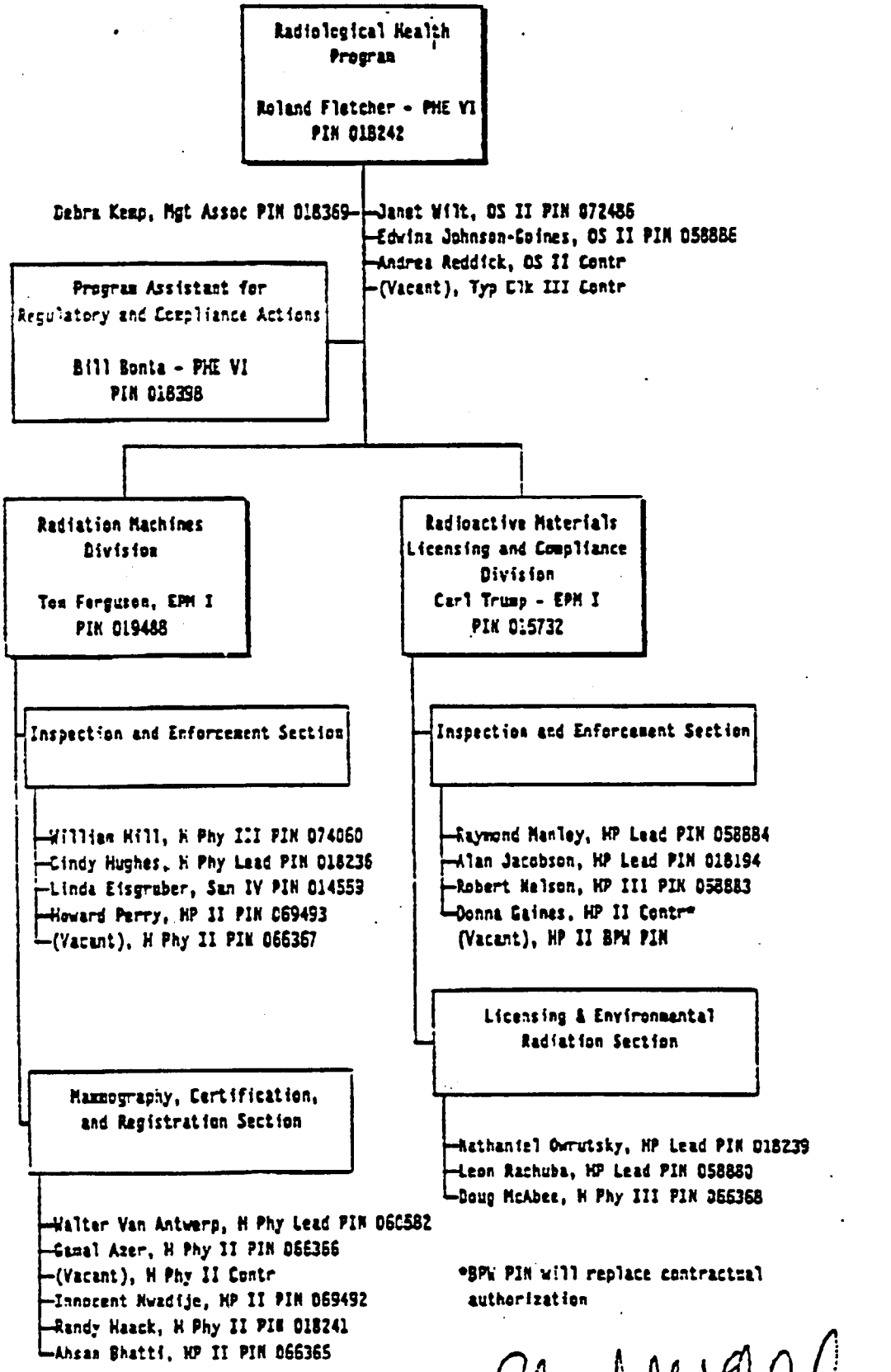
MARYLAND DEPARTMENT OF THE ENVIRONMENT



AIR AND RADIATION MANAGEMENT ADMINISTRATION



RADIOLOGICAL HEALTH PROGRAM



*BPW PIN will replace contractual authorization

Roland Fletcher
Program Manager
October 6, 1998

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OSP

Paul H. Lohaus, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

RE: Draft Integrated Materials Performance Evaluation Program (IMPEP) Review of Maryland Agreement State Program during March 22-26, 1999

Dear Mr. Lohaus:

Your letter of April 26, 1999 to Deputy Secretary Arthur Ray conveying the draft results of the Integrated Materials Performance Evaluation Program (IMPEP) review has been referred to me for response. Preliminarily, I would like to extend our appreciation to you and to the members of the IMPEP team for your comprehensive and thorough review of the Maryland Radioactive Materials Program. We have reviewed the IMPEP team's draft report of the March 22-26, 1999 MDE audit and, generally find the information contained in the draft report to be factually accurate. Our detailed comments are noted below. The section numbers used refer to the corresponding section in the draft report.

Section 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

Maryland's response to specific open items listed is as follows:

ITEM 1. The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B (28) (e) that was identified in both the 1993-1994 review and the 1995 follow-up review.

STATUS: The revised definition of "Person" was published as a Notice of Proposed Action in the Maryland Register on April 9, 1999 for comment with final adoption expected by July 1999. Upon adoption, the NRC will be notified in writing.

ITEM 2. The review team recommends that the State of Maryland inform NRC when the referring physician/patient notification requirement has been completed by the Sacred Heart Hospital.

STATUS: Sacred Heart Hospital is now a part of the Western Maryland Health System which stated in a letter dated October 2, 1998 that all twenty physicians had been notified as of March 24, 1997. Interviews with 10 of the 20 physicians revealed documented responses that at least 21 of the 33 patients were notified of the 1987-88 misadministrations. Of the remaining physicians, one is deceased and at least five have relocated or retired. MDE has been kept informed of all notifications and continues to monitor the Hospital's attempts to confirm evidence of notification of remaining patients/families from all living-attending physicians. Due to the fact that these misadministrations occurred several years ago and record keeping was not computerized, further confirmation of notification is not likely to be achieved. Based on these circumstances, MDE recommended to Ms. Pat Larkins of NRC Headquarters, that this item be closed as of June 30, 1999.

ITEM 13. The review team recommends that the State implement a plan to review all registration sheets, based on the risk associated with the device, especially detailed QA/QC program information.

STATUS: This item is being carried forward as open because the team determined that the State did not review all registration certificates for missing information or against existing guidance. The State, however, in response to the IMPEP recommendation of 1996, did review its registration sheets. During the week of October 15, 1996, Radiation staff sought guidance from Mr. Steve Baggett, who was the Director of the NRC's SS&D review program at that time, regarding how Maryland should implement NRC's 1996 recommended scope of safety review for previously issued Maryland SS&D sheets. Mr. Baggett's recommendation was that Maryland should perform a review of all previous sheets for potential significant safety considerations. A review of the quality assurance and quality control (QA/QC) aspects, using NRC Regulatory Guide 6.9, was for the more complex SS&D sheets. Based on Mr. Baggett's advice, Maryland performed a safety review of all sheets and did not identify any significant safety deficiencies. Maryland even went beyond Mr. Baggett's recommendation by performing a QA/QC review of all sheets, not just the most complex, using the NRC Regulatory Guide 6.9. Based on this review no changes to the QA/QC procedures were deemed necessary for previously issued sheets. Therefore, Maryland believed that we had adequately responded to the 1996 recommendation. The IMPEP team now appears to recommend that all sheets should be reviewed and brought to all current NRC standards. If this is an accurate interpretation, Maryland believes that this should be considered a new recommendation and should not be tied to NRC recommendations in previous reviews.

ITEM 15. The review team recommends that an additional senior staff member should be trained to perform the SS&D evaluations to supplement the program as it matures.

STATUS: MDE concurs with the need for training additional staff to conduct SS&D evaluations and will review the qualification guidance discussed in Management Directive 5.6. As the opportunity permits, additional senior staff members will be trained to perform SS&D evaluations.

All other recommendations from the 1996 IMPEP review are closed.

Section 3.0 COMMON PERFORMANCE INDICATORS

3.1 Status of Materials Inspection Program

The IMPEP review team noted that the inspection frequency of source exchange licensees operating under reciprocity in Maryland was not in accordance with NRC guidelines, that is, at least once per year.

COMMENT:

Maryland acknowledges that current NRC guidelines require an inspection frequency of at least once per year for source exchange licenses. Maryland will implement a procedure to ensure that this frequency is met.

3.2 Technical Quality of Inspections

It was noted by the IMPEP team that inspection reports are not always reviewed by the supervisor prior to the issuance of the compliance letter to the licensee. Additionally, the supervisor had not reviewed the field notes or inspection reports within the 10-day period following the inspection.

COMMENT:

As a result of NRC's recommendation, a goal has been established for inspectors to complete their reports within 10 days of the inspection date for non-complex licenses and to include a draft copy of the compliance letter, if necessary, for review by the supervisor. For complex license inspections, the goal will be a 30-day completion schedule for inspection reports and compliance correspondence.

3.3 Technical Staffing and Training

CORRECTION to this sentence

"During the review period, one inspector left, and an individual was hired within seven months to refill that position." Please change "seven" to "nine" months.

COMMENT:

The State recognizes the importance of adequate staffing and is evaluating present and future staffing needs in order to assure RHP's continued adequacy and compatibility.

3.4 Technical Quality of Licensing

The IMPEP review team found a significant backlog of license renewal applications and raised concerns regarding the technical quality and accuracy of some of the licenses issued.

COMMENT:

RHP recognizes the licensing backlog involving both renewal applications and routine amendment requests. The supervisor is currently working with the licensing section to implement an action plan to reduce the backlogs. The plan will involve the setting of goals to improve the accuracy and technical quality of licenses. We anticipate this plan will be completed by September 30, 1999.

3.5 Response to Incidents and Allegations

The IMPEP review team strongly recommends that RHP revise the current allegation procedure in accordance with OSP Procedure SA-105, "Response to Incidents and Allegations" and NRC Management Directive 8.8, "Management of Allegations."

COMMENT:

Both documents will be reviewed and incorporated into RHP procedures. We anticipate that the new procedure will be completed by September 30, 1999.

Section 4.0 NON-COMMON PERFORMANCE INDICATORS

4.1 Legislation and Program Elements Required for Compatibility

The RHP recognizes that it is vitally important to maintain compatibility by keeping up with the adoption of regulations and addressing them in timely rulemaking. Also, the RHP is fully aware that the current chairperson of the Regulations Committee is scheduled for retirement this year. MDE has addressed this concern by hiring and training an individual to coordinate Radiation Regulations Promulgation. This individual was hired on May 5, 1999.

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

The IMPEP review team found deficiencies in the SS&D registration sheets that it reviewed. They recommended amendment to two specific certificates and the development of a plan to review all registration certificates for missing information and against existing NRC guidance. The team also recommended that RHP staff who perform SS & D reviews should receive additional training.

COMMENTS:

MDE recognizes the importance of the SS&D program. MDE is currently looking at the areas of reviewer qualification and technical content of the reviews with the objective of overall program improvement. Our evaluation will consider all options to address the IMPEP team's recommendations.

With respect to training, one member of the RHP staff participated in the April 7-8, 1999 preliminary SS&D Workgroup meeting held at NRC headquarters. Though not specifically dubbed as training, the knowledge and experience gained from direct interface with NRC and other Agreement State staff members who perform SS&D certifications is extremely useful. The RHP will continue to participate in other training opportunities as they become available.

Finally, regarding the recommendations to amend two specific certificates, RHP has completed one review and the other will be finished by June 30, 1999. The NRC will be informed of amendments that are made following completion of the reviews.

Section 5.0 SUMMARY

The review team recommended that the MRB find the Maryland Agreement State program to be adequate to protect public health and safety and compatible with NRC's program.

The IMPEP Team also made nine recommendations to the Maryland Program. Each recommendation will be reviewed, evaluated and corrective measures will be discussed and implemented. Maryland concurs with both the findings and these recommendations and has already initiated actions to achieve full satisfactory evaluations in all areas.

Again, **MDE** is appreciative of the IMPEP team's technical and professional review of the Maryland program. Should there be any questions concerning this letter, you may contact Mr. Roland Fletcher at (410) 631-3300.

Sincerely,

Gene Marie DeBiase

for Merrylin Zaw-Mon, Director
Air and Radiation Management Administration

MZM/RGF/jw

cc: Arthur Ray
Roland G. Fletcher