DATED: MARCH 21, 1997 SIGNED BY: H. L. THOMPSON, JR.

Ms. Merrylin Zaw-Mon, Director
Air and Radiation Management Administration
Maryland Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

Dear Ms. Zaw-Mon:

On March 6, 1997, 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 considered and concurred with the review team's recommendation that the Maryland program be found adequate to protect public health and safety but needs improvement, and not compatible with NRC's program.

Several compatibility issues were identified by NRC just prior to the MRB meeting. In a letter dated February 28, 1997, to the State of Maryland, NRC identified compatibility issues in the State's final equivalent rules, that became effective October 9, 1995, for Parts 20.1703, 20.1801, 20,2202, 30.50, 39.49, and 39.51, that had not been previously identified by NRC during previous reviews of the regulations in question. The State staff indicated at the MRB meeting that they would revise the Maryland regulations within a reasonable period of time. The MRB stated that NRC will reevaluate the compatibility determination upon final promulgation of the revisions of the specific regulations that were identified by NRC as not compatible, in the February 28, 1997, letter to the State.

Due to less than satisfactory performance of a HP-inspector during two onsite field inspections at a radiography site and a high dose rate brachytherapy facility, the team recommended Satisfactory with Recommendations for Improvement for Section 3.4 Technical Quality of Inspections. The MRB considered the overall satisfactory performance of the other three inspectors and the fact that the inspector who performed unsatisfactorily is no longer with the program, and revised the team's recommendation to a Satisfactory for this indicator.

Section 5, page 26 of the enclosed final report presents the IMPEP team's recommendations. Note that there are two additional suggestions and/or recommendations that were identified at the MRB: (1) to inform NRC when the referring physician/patient notification requirement has been completed by Sacred Heart Hospital; and (2) to consider implementing an allegation tracking system. We have received your letter dated February 3, 1997, and appreciate the positive actions that you and your staff have taken and are continuing to implement with regard to our comments. No response to this letter is necessary.

Based on the results of the current IMPEP review, the next review will be scheduled in three years, unless program concerns develop that require an earlier evaluation.

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 working with you in the future.

Sincerely,***/RA/***

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

Enclosure:
As stated

cc: R. G. Fletcher, Manager
Radiological Health Program
Air and Radiation Management Administration

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Hugh L. Thompson, Jr.
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Enclosure:
As stated

cc: R. G. Fletcher, Manager
Radiological Health Program
Air and Radiation Management Administration

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

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MARYLAND AGREEMENT STATE PROGRAM

SEPTEMBER 23-27, 1996

FINAL REPORT

U.S. Nuclear Regulatory Commission

04/23/97

1.0 **INTRODUCTION**

This report presents the results of the review of the Maryland radiation control program. The review was conducted during the period September 23-27, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Washington. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period April 4, 1994 to September 20, 1996, were discussed with Maryland management on September 27, 1996.

A draft of this report was issued to Maryland for factual comment on December 16, 1996. The State of Maryland responded in a letter dated February 3, 1997 (attached). The State's comments were incorporated into the final report. The Management Review Board (MRB) met on March 6, 1997, to consider the proposed final report. Due to the unsatisfactory performance of a HP-inspector during two on-site field inspections at a radiography site and an HDR facility, the team recommended Satisfactory with Recommendations for Improvement for Section 3.4 Technical Quality of Inspections. The MRB considered the overall satisfactory performance of the other three inspectors and the fact that the one inspector with unsatisfactory performance is no longer with the program, and revised the team's recommendation to a Satisfactory for this indicator. The MRB considered and concurred in the team's overall recommendation and found the Maryland radiation control program was adequate to protect public health and safety but needs improvement, and not compatible with NRC's program.

Several compatibility issues were identified by NRC just prior to the MRB meeting. In a letter dated February 28, 1997, to the State of Maryland, NRC identified compatibility issues in the States final equivalent rules, that became effective October 9, 1995, for Parts 20.1703, 20.1801, 20.2202, 30.50, 39.49, and 39.51, that had not been previously identified by NRC during previous reviews of the regulations in question. The State indicated at the MRB meeting that they would revise the Maryland regulations within a reasonable period of time. The MRB stated that NRC will reevaluate the compatibility determination upon Maryland's final promulgation of the revisions to specific regulations that were identified by NRC as not compatible, in the February 28, 1997, letter to the State.

The Maryland Department of the Environment (MDE) is the agency within the State of Maryland that regulates, among other public health issues, radiation hazards. The Secretary, MDE, is appointed by and reports directly to, the Governor. Within MDE, the Maryland radiation control program is located in the Radiological Health Program Office, which is located in the Air and Radiation Management Administration. The Maryland Department of the Environment and the Air and Radiation Management Administration organization charts are included as Appendix B. During the review period the Maryland program regulated 561 specific

licenses, which include commercial irradiators, manufacturers, broad academic, broad medical, radiopharmacy and radiographers. In addition to its radioactive materials program, MDE is responsible for the control of machine produced radiation, and emergency response for 2 nuclear power plants. 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 indicators was sent to the State on August 9, 1996. Maryland provided its response to the questionnaire on September 16, 1996. A copy of that response is included as Appendix C to this 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 radiation control program licensing and inspection database, (4) technical review of selected files, (5) field accompaniments of three Maryland inspectors, and (6) 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 and recommendations.

2.0 **STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS**

The previous routine review was conducted August 30 -- September 4, 1993, with follow-up activities conducted at selected times through April 7, 1994. The results of this review were transmitted to Ms. Jane Nishida, Secretary Designee, Maryland Department of the Environment on March 3, 1995. A follow up to this review was conducted November 7-8, 1995, and the results transmitted to Secretary Nishida on April 17, 1996. A special joint U.S. Nuclear Regulatory Commission (NRC) and State of Maryland review of 33 misadministrations that occurred in 1987-1988 at the Sacred Heart Hospital (SHH) located in Cumberland, Maryland, (MD-01-002-02) was conducted in late 1993 and early 1994, in response to issues raised during an August 1993 Congressional hearing that questioned: (1) the adequacy of the State's 1988-1989 review; (2) why NRC had not previously reviewed the event; (3) inconsistencies in the records; and (4) the State's agreement to limit access to the records.

2.1 Status of Items Identified During the 1993-1994 Routine Review

A number of recommendations were identified as part of the 1993-1994 review. The 1993-1994 review resulted in the withholding of a finding of compatibility due to 13 regulations not having been adopted within the 3 year period required by NRC. The team noted that the definition of "person" in Maryland's low-level radioactive waste (LLRW) regulations included jurisdiction over Federal facilities which is not consistent with 10 CFR 150.10. Section 274 contains no explicit waiver of the sovereign immunity of the United States; therefore, the agreement does not convey any authority for the State to regulate Federal agencies. Agencies of the Federal government are not exempted and continue to be subject to NRC regulation, not State regulation. The 1993-94 report stated that the definition of person in an Agreement State's regulations should not include agencies of the Federal government. Therefore, the State was requested to either remove or provide clarification to explain that, in COMAR 26.14.01.02B(28)(e), which includes Federal agencies in the definition of "person," with regard to Agreement materials, Federal agencies are not subject to these regulations. In addition, it was recommended that the State continue its efforts to renew the Neutron Products, Inc. (NPI) license to establish a clear set of license requirements against which the state can assess continued operations at NPI and against which enforcement action can be taken, if required. Specific milestones and schedules for completion of actions were requested. The State was notified of NRC's intention to conduct a follow-up review. Some of the recommendations were closed at the time of the 1995 follow-up review. The review team looked at each remaining item to determine whether or not the Maryland program had taken additional actions to close open recommendations.

(1) Status of the 13 overdue regulations is as follows:

NRC conducted a follow-up review November 7-8, 1995. The 1995 follow-up review noted that the 13 overdue regulations were incorporated in the revised "Maryland Regulations for the Control of Ionizing Radiation (1994)" which became effective October 9, 1995. See the next section for a continued discussion.

(2) Status of the State's definition of "person" in the LLRW regulations to include Federal entities is as follows:

As of the 1993-1994 review this item was pending the result of discussions between the State and NRC legal staff. See the next section 2.2(1) for a continued discussion.

(3) Status of the effort to renew the NPI license.

In January 1994, a court settlement was reached which required certain actions by the licensee (NPI). With regard to the NPI license renewal, the State maintained discussions with NPI and, on August 1, 1994, NPI submitted a renewal application. However, in their preliminary screening, the State found the application to be deficient in several procedural areas including some of the requirements identified in the January 1994 court settlement.

Discussion between the State and NPI continued in an attempt to resolve the issues. In the June 6, 1995 response letter to the 1993-1994 review, the State had committed to a schedule for issuance or renewal of the four (4) NPI licenses. The two irradiator licenses and the teletherapy service license were issued essentially on schedule. The source manufacturing license (MD-31-025-01) renewal was expected to be issued on schedule although the State noted difficulties in resolving issues with NPI management. See following section 2.2(3).

2.2 Status of Items Identified During the 1995 Follow-up Review

The 1995 follow-up review, conducted November 7-8, 1995, identified that the definition of "person" in Maryland's low-level radioactive waste regulations included jurisdiction over Federal facilities. The State had been requested during the 1993-1994 review to either remove or clarify that with regard to Agreement materials, Federal agencies are not subject to these regulations. The follow-up review team also noted that NRC staff would complete a final compatibility determination of the "Maryland Regulations for Control of Ionizing Radiation (1994)" in late April 1996; and identified an additional regulation, "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715), effective July 31, 1993, that would become due for adoption by the Agreement States by July 31, 1996. NRC recommended that the State take action to revise the "Regulation Adoption Management Plan," for review during the next scheduled audit, and continued to recommend the importance of State action to renew the NPI license.

(1) Current status of the State's definition of "person" in Maryland's low-level radioactive waste regulations that included jurisdiction over Federal facilities is as follows:

In an August 25, 1995, letter to Ms. Merrylin Zaw-Mon, Director, Air and Radiation Management Administration (MDE), the NRC requested reconsideration of the State's position on clarifying or changing the definition of "person" to clearly exclude the regulation of Federal agencies located in the State. The State took action to revise the definition of "person" in Section 2.A of COMAR 26.12.01.01, titled "Regulations for Control of Ionizing Radiation." The definition now includes and "to the extent authorized by federal law, federal government," which is acceptable to NRC, as of May 1996.

The review team found that although the State revised the definition of "person" in the Radiation Program regulations, no action has been taken by the Waste Management Administration to revise the definition of "person" in the low-level radioactive waste regulations COMAR 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review. The State should provide clarification of the use of the term "person" in the low-level radioactive waste regulations, as it relates to Federal agencies, from the legal staff.

- 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 COMAR 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review.

  This item remains open.

(2) Current status of any remaining issues regarding regulations is as follows:

NRC staff has reviewed the 13 amendments to the final COMAR regulations adopted by the State of Maryland, that became effective October 9, 1995, and, based on that review, found that our earlier comments have been addressed. However, in completing the review staff identified issues in other sections of Maryland regulations that have potential compatibility significance. Issues identified by the staff relate to existing sections of Maryland regulations that were not modified by the 13 amendatory actions. Staff completed documentation of these concerns and transmitted the concerns to the State separately by letter, dated, February 28, 1997 (attached). These concerns are further addressed in Section 4.1 below. Also at the time of the IMPEP review, the State had not completed their process for adoption of "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36, within the three year period of adoption which became due July 31, 1996.

The team noted that the State of Maryland regulates irradiator facilities which would be subject to the regulations in "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36. At the time of the review, equivalent rules were in the final stages of promulgation and were scheduled to be adopted in November 1996. Subsequent to the review, the State informed the team that Part X of the Maryland Code covering, "Licenses and Radiation Safety Requirements for Irradiators," was adopted on November 19, 1996, with an effective date of December 16, 1996. NRC will notify the State of the results of a final review, in a separate letter.

The State revised the "Regulation Adoption Management Plan," but no action has occurred on the ten rules or amendments due for adoption by the end of 1997. The State needs to act on the plan and provide a realistic schedule of milestones for completion of the rules identified in the plan.

This item remains open.

(3) Current status of the effort to renew the NPI license is as follows:

A specific concern, during the 1995 follow-up review, resulted in a recommendation that the State work with Montgomery County in evaluation and approval of the NPI proposal for construction

activities which should reduce the unnecessary radiation levels in and around the facility.

The 1995 follow-up review also commented on the prescriptiveness of the draft license (MD-31-025-01) and the concern that specifically tying the licensee's detailed procedures to the license would preclude the necessary flexibility for the licensee to satisfy and promptly address emergent conditions at the facility. However, the State experienced difficulty in getting NPI cooperation in resolving issues such as financial assurance, the shielding of on-site radioactive waste held in storage (a significant contributor to exposures for both on-site personnel and members of the public), and a courtyard cover to minimize releases of contaminated materials to the environment.

In part, due to the continued recommendation from NRC to renew the NPI license, the State unilaterally reissued license MD-31-025-01 on January 18, 1996. This license was prepared from the previous license which has been in timely renewal since 1980, the subsequent amendments and documents and information collected over the years. The draft was reviewed by a committee consisting of inspectors, license reviewers, and program management and revised to reflect the participants' cumulative history of the site. The licensee appealed the issuance of the license to the Office of Administrative Hearings. According to Maryland Administrative law, the license cannot be enforced until the case is resolved at hearing. The State agreed to place the appeal on the inactive list as long as progress was being made in resolving the issues. A management conference was held in March 1996, and a few points of contention were resolved. The State believes the prescriptive nature of the license is warranted given the licensee's past history and the continuing difficulty in resolving issues with licensee management. The licensee is resistant to any regulatory actions that take away the ability to operate freely. There has been a further exchange of correspondence on the license conditions, however, essentially no further progress has been made. The State notified the licensee on August 30, 1996 that the State would not agree to further delay and an administrative hearing would be scheduled as soon as possible.

The 1996 IMPEP review consisted of a review of the license file for MD-31-025-01 (the source manufacturing license), interviews of the Maryland program inspector, license reviewer, and management, and an onsite visit to NPI.

The 1993-1994 review observed that the State had not been effective in handling the NPI waste storage problem, high fenceline doses, and on and off-site contamination. Since the previous review and follow up, the State has inspected the facility three times in 1994, twice in 1995 and twice to date in 1996. While this does not meet the State's intended quarterly unannounced inspection schedule, it does exceed the NRC inspection frequency for this type license. The State also notes that contact with this licensee is quite extensive and time consuming

and that when these other contacts are taken into consideration the State does interact with NPI on at least a quarterly basis.

The State has performed an independent assessment of the internal exposure potential (much less than the amount requiring monitoring and summation of doses) and the dose to the nearest residents (probably near 100 mrem per year). In April 1996, the State approved the conceptual design for a courtyard enclosure to reduce worker and public exposures and on and off-site contamination. In August 1996, the State demanded the licensee submit the detailed plans for the courtyard enclosure as required by court order. The licensee, in accordance with the court order, submitted plans to the County and State in September 1996. Subsequently, the team found that upon technical review the plans were found incomplete.

The licensee has agreed to use concrete slab shielding to reduce worker and public exposures from the storage areas. The licensee has taken some action to reduce exposures to workers involved in hot cell cleanup work compared to previous years. Finally, the State has succeeded in requiring the licensee to reduce the volume of waste storage by sorting and shipping lightly contaminated combustible material to SEG for incineration.

The team believes slow but steady progress has been made in dealing with NPI despite the unwillingness of NPI management. Although the very prescriptive renewal license issued in January 1996 has been appealed and held in abeyance pending the outcome of an administrative hearing, significant progress has been made for the most serious health and safety issues. The Maryland program continues to maintain a strong licensing and enforcement stance with respect to NPI yet has indicated to the review team a willingness to work with NPI to resolve issues and produce a less prescriptive and more performance oriented licensing document. A well thought out and documented strategic plan is in place to implement a performance-based inspection plan at NPI which emphasizes the achievement of quality in all facets of NPI's operations. These inspections will emphasize direct observation and surveillance of licensed activities and will stress the licensee's most significant activities dealing with radiation safety and reliability. The 2-year plan (1996-98) provides for quarterly inspection frequency, reviews of health physics consultant reports, team inspections, and outlines more than 30 specific areas for review.

This recommendation is closed.

(4) Current status of the results of the joint NRC and State review of 33 misadministrations that occurred in 1987-88 at Sacred Heart Hospital is as follows:

A joint U.S. Nuclear Regulatory Commission (NRC) and State of Maryland review of 33 misadministrations that occurred in 1987-1988 at the Sacred Heart Hospital (SHH) located in Cumberland, Maryland, (MD-01-002-02) was conducted in late 1993 and early

1994, in response to issues raised during an August 1993 Congressional hearing that questioned: (1) the adequacy of the State's 1988-1989 review; (2) why NRC had not previously reviewed the event; (3) inconsistencies in the records; and (4) the State's agreement to limit access to the records.

In a report dated March 5, 1996, that was transmitted April 15, 1996, to Ms. Merrylin Zaw-Mon, Director, Air and Radiation Management Administration, Maryland Department of the Environment, the review team concluded that the direct cause of the misadministrations was the use of an incorrect computer file. There were a number of factors contributing to the misadministrations including, for example, inadequate communications and failure to verify procedures and calculations. The review concluded that the root cause was lack of management oversight of the SHH radiation safety program. The special review team found that SHH did not provide all the notifications to referring physicians and patients as required by Maryland law. The special review team recommended that the State of Maryland take some actions, and the State's Department of the Environment reviewed the report and agreed to implement those actions the review team recommended the State take. The recommendations included actions the State should take to ensure that SHH complies with the referring physician/patient notification requirements of Maryland law. The IMPEP review team was tasked to follow up on the State's action. In discussions with the Director, RHP, the team found that the State discussed the recommendations of the joint NRC/MD review, including the referring physician/patient notification requirement with the new SHH staff (NOTE: SHH has a new CEO Administrator, who was not a member of the SHH staff during the joint NRC Maryland team review). In a telephone discussion in June 1996, the legal counsel for SHH expressed concern that some of the joint report recommendations were overly burdensome. The legal counsel was concerned that an upcoming merger between SHH and Cumberland Memorial Hospital might be jeopardized if the new affiliate had to adhere to the terms of the recommendations placed on SHH. The SHH legal counsel requested that the State delay action on the 4/15/96 letter through the State Attorney General's office. As of the date of the IMPEP review, the IMPEP team found that the State had taken no additional follow-up action with SHH staff and legal counsel.

The IMPEP team recommended that the State take action to ensure that SHH complies with the referring physician/patient notification requirements of Maryland law as identified in a report dated March 5, 1996, that was transmitted to the State April 15, 1996. Subsequent to the review, the State informed the team that a letter had been sent to SHH on November 25, 1996, that included the NRC recommendations resulting from the 1987-88 misadministrations. SHH responded and will follow through with physicians information regarding notification to misadministered patients, families or next-of-kin.

This recommendation is closed.

- The review team recommends that the State of Maryland inform NRC when the referring physician/patient notification requirement has been completed by SHH.

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 Staffing and Training, (3) Technical Quality of Licensing Actions, (4) Technical Quality of Inspections, 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 inspection of new licenses, and timely dispatch of inspection findings to licensees. This evaluation is based on the Maryland questionnaire responses relative to this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of licensing and inspection casework files, and interviews with managers and staff.

Review of the State's inspection priorities showed that, with the exception of medical private practice licenses with a QMP, the State's inspection frequencies for various types or groups of licensees are at least as frequent, or more frequent than, similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter 2800 (IMC 2800). Inspection frequencies under the State's system range from quarterly to 5-year intervals. More frequent inspections are required by the State in the following license categories: licensees manufacturing sealed sources for irradiator use have a quarterly frequency compared to the NRC 1-year frequency; Type A broad scope academic licenses have a 1-year frequency compared with an NRC 2-year frequency; teletherapy and gamma knife licenses have a 1-year frequency compared with the NRC 3-year frequency; research and development licenses, portable lead paint analyzers and portable gauges have a 4-year frequency compared with the NRC 5-year frequency; and licenses authorizing other measuring systems such as gas chromatographs have a 5-year frequency compared to the NRC 7-year frequency. However, the state was not distinguishing between medical private practice licenses that required a Quality Management Program and those that did not. Consequently, all medical private practices were scheduled for inspection at a 4 -year frequency which exceeds the NRC's 5-year frequency for "non-QMP" licenses but falls short of the 3-year frequency specified in IMC 2800 for medical private practice licenses where a QMP is required. The team noted that the State was referencing a previous version of IMC 2800 and had not incorporated the April 1995 revisions to IMC 2800. Management indicated action would be taken to correct the oversight.

- The review team recommends that the State incorporate the April 1995 revisions to IMC 2800 into their Inspection Procedures Manual.

In their response to the questionnaire, Maryland indicated that as of September 20, 1996, no licenses identified for core inspections in IMC 2800 were overdue by more than 25 percent of the NRC frequency. With respect to initial inspections of new licenses, the team reviewed the inspection data tracking system and noted that the initial inspections are entered into the tracking system with a 6 month date for scheduling. In reviewing twelve initial inspections from among the 81 new licenses issued during the review period, none of the initial inspections were conducted within the first six months following issuance of the license. However, more than half (7 of 12) were completed from 6 to 8 months following issuance and essentially all (11 of 12) were inspected from 6 to 12 months following issuance (that is, within 6 months of scheduling the inspection). One new license was inspected approximately 32 months following issuance due to an administrative error in assigning the first due date.

While the initial inspection timing is a significant deviation from the programmatic indicator, the State's program for new licenses contains an element which, in total, makes it equally as effective as the IMPEP program indicator would achieve. This element is completion of a pre-licensing inspection which helps assure that licensees are equipped and knowledgeable before receiving radioactive materials thus helping licensees to achieve early success in complying with the requirements of the license. The high percentage of initial inspections in which no items of non-compliance are found appears to validate this methodology.

In reviewing the inspector's work logs for the period since the last review, the team found that the vast majority of inspections resulted in communication of the findings to the licensee within thirty days following the inspection. In those rare instances when the compliance letter was not issued within 30 days, program management indicated this occurred because more information was known to be forthcoming from the licensee or greater care, and thus more time, was needed to document circumstances relative to a potential enforcement action.

The State reported that 136 license requests for reciprocity were processed during the period of review. Approximately 50% of the reciprocity requests included industrial radiography, others included well-logging, mobile nuclear medicine, and other service licensees. The State conducted 56 inspections of reciprocity licensees during the review period, which met the inspection frequency for conducting inspections of reciprocity licensees contained in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, and Inspection of Agreement State Licensees Operating Under 10 CFR Part 150.20."

Based on the IMPEP evaluation criteria and the acceptability of the State's equally effective method of handling new licensees, the review team recommends that Maryland's performance with respect to the indicator, Status of Materials Inspection Program, be found Satisfactory.

3.2 Technical Staffing and Training

A review of this indicator includes consideration of the adequacy of the concept and balance of the radioactive materials program staffing strategy which includes training, technical qualifications of the staff, any staff turnover, and prompt management attention to any problem areas. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed program management and staff, and considered any possible backlogs in licensing or compliance actions.

The Radiological Health Program (RHP) has responsibility for the control of radiation in Maryland. Total staff positions in the RHP, which includes the Radiation Machines Division and the Radioactive Materials Licensing, Compliance and Safeguards Division, hereafter referred to as RAM program, are 27, with a current fill of 25. The number of positions directly applied to Agreement State activities, is nine. The program has undergone a reorganization since the last program review conducted in 1993 and 1994. As a result of the reorganization, the Radon program was eliminated and, in December 1995, the program lost two supervisory positions and combined the responsibilities of the three supervisor positions into one. The RAM program went from a total staffing level of 11, which included one program manager, three supervisor health physicists (licensing, licensing and low-level radioactive waste, and inspection and enforcement), six health physicists, and one x-ray and regulations specialist; to a total staffing level of nine, which includes one program manager, one supervisor health physicist, and seven health physicists as shown on the RHP organization chart found in Appendix B. The RAM program is divided into two sections, the Inspection and Enforcement Section comprised of four health physicists responsible for all inspection and enforcement activities, and the Licensing and Environmental Radiation Section comprised of three health physicists, two are responsible for all licensing and environmental activities, as well as, sealed source and device evaluations. A third health physicist, recently transferred from Radon, is currently performing less complex inspections, i.e. gauge manufacturers, and is in training for licensing and environmental activities. The team noted that the RAM program supervisor and two of the more senior personnel appear to handle most of the inspections. Additionally, the RAM supervisor is often called upon to Act for the RHP manager, who is involved in several Agreement State technical organizations and task groups in support of Agreement State activities. In discussions with the RAM program supervisor the team found that one of the health physicists was recently transferred to the RAM program from the former Radon program and is currently in training, another health physicist is currently being assigned increasing inspection duties, and another health physicist with 5 years of experience had not fully demonstrated consistent quality as a materials inspector.

According to information provided in the State's response to the questionnaire, the training program requires all newly hired inspectors to attend the NRC core training courses, in licensing, inspection procedures, industrial radiography, nuclear medicine, and the 5-week health physics course. At the time of the review, one HP-inspector with

5 years experience, had not taken the licensing course, and one newly transferred staff member had not taken the industrial radiography course. The team noted that one inspector primarily performing medical license inspections could benefit from attending the teletherapy/ brachytherapy course, which is a new NRC course. The RHP manager stated they can no longer send staff to NRC courses held outside of the local area due to NRC's recent policy change that eliminated funding for travel to training courses and budget constraints that limit funds for State travel. Maryland currently has no formal training plan. Future plans depend on the final resolution of NRC action regarding funding for travel to NRC training courses.

- The team suggests that the State consider development of a formal professional training plan through the use of university and industry educational programs for training new staff and retraining or refresh for long-term staff.

In discussions with the RAM supervisor, the team found that new staff are assigned increasingly complex duties under the direction of senior staff and accompany experienced inspectors during increasingly complicated inspections. When time allows, the RAM supervisor accompanies newly qualified staff. There is no formal program in place for the supervisor to perform an annual inspection accompaniment with each inspector. This issue is further addressed in Section 3.4.

The team found that during two accompaniments the inspections conducted by a health physicist-I inspector, with 5 years of experience were not satisfactory. During one accompaniment it was not identified that the potential existed for radiation exposure to non-radiation workers in the immediate area where field radiography was being performed, which posed a health and safety hazard. Additionally, the primary focus during both inspections was paperwork rather than a performance based inspection. Interviews were not conducted with management. This issue is discussed in greater depth in Section 3.4, Technical Quality of Inspections. Through discussions with the RAM program supervisor the team found that the inspector did not have a physical or life science background, but had taken all of the core courses recommended by NRC, as well as additional health physics training during his five years with the program. The team found that the inspector's weak performance after five years of experience demonstrated a deficiency in the evaluation of training and qualification of the technical staff of the program. This does not meet the IMPEP evaluation criteria for personnel making prompt progress in completing all of the training and qualification requirements, and provides some evidence of management inattention or inaction to deal with staffing problems. One to two years would be an acceptable time frame in which to train and qualify an inspector.

- The 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.

- The team suggests that Maryland assess whether a reinspection or revision to move-up the next inspection date should be considered for any higher priority licensees, i.e., HDRs, radiographers, previously inspected by the HP-I inspector whose accompaniment was unsatisfactory.

Staff turnover is stable, however the team noted that the recent reorganization strategy combining two separate positions into one and the loss of two staff positions in the recent reorganization, which included the regulation review specialist, places considerable effort and a heavy workload on the existing staff members to manage, control, and review all of the health and safety related work of the program. The team questioned the staffing balance regarding the expansion of the duties of the RAM supervisor that already included supervisory responsibilities for inspection and enforcement activities, participating in complex inspections, along with Acting in the absence of the RHP manager, to now also include supervising an additional licensing and environmental radiation section. Additionally, subsequent to the review, the team found that an HP staff member has resigned. This leaves the radiation control program with a total staffing level of (8) FTE. The team is concerned that the loss of 2 FTE due to the reorganization, and the recent loss of an additional staff member jeopardizes the program's ability to maintain an adequate and compatible program to protect health and safety. The team noted that the adequacy of one FTE managing such an unusually large area of responsibility with a technical staff of six (total 7 FTE) should be closely monitored by Maryland due to the number and complexity of licensees in the Maryland program. The team discussed increased use of automated systems to provide increased control through tracking actions, wider access and more efficient retrieval of information. The State has several complex licensees, including NPI, which consumes an inordinate amount of staff time, in the preparation of legal documents, and technical analysis of corrective action plans; additionally there has been no action, as of the period of our review, taken on ten rules or amendments that should be adopted by December 1997, in order for the RAM program to remain compatible with the NRC regulatory program. The team questioned the adequacy of program staff to ensure the long-term ability of the program to maintain and complete pending rules and amendments for adoption to remain compatible.

- Based on the teams findings, the 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.

Based on the team's finding and the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to this indicator, Technical Staffing and Training, be found Satisfactory with Recommendations for Improvement.

3.3 Technical Quality of Licensing Actions

The review team examined casework and interviewed the reviewers for forty specific licenses. Licensing actions were reviewed 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. Casework was reviewed 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 authorities. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. The files were checked for retention of necessary documents and supporting data.

The cases were selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The cross-section sampling included five of the State's major licenses and the total included the following types: nuclear pharmacy, high dose rate afterloader, academic broad scope, portable gauges, hospital nuclear medicine, private practice and cardiology limited, research and development laboratory, fixed gauges, blood irradiator, sales demonstration of devices, radiography, service/leak test, and sample analysis. Licensing actions included eight new licenses, nine renewals, ten amendments, and fourteen terminations. A list of these licenses with significant case-specific comments can be found in Appendix D.

The review team found that the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. Special license tie-down conditions were almost always stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications. The State's licensing guides and license policy procedures are currently being revised and updated, and reviewers were observed to have good research skills in using these and other licensing documents. With few exceptions, reviewers appropriately used the new licensing guides and accompanying check sheets, although the check sheets are not routinely signed and dated. Licensing action authorship is indicated by initials and date. At least one, but occasionally two peer reviews, are documented by initials and dates. All licensing actions are signed by the Radiological Health Program Manager. Pre-license-issue visits are now routinely noted in the file. This visit enables the license reviewer to ascertain the status of licensed facilities and use, as applied for by the applicant. It also allows an explanation of the licensing and inspection process prior to the start of licensed activities.

The current status of the license renewal action for Neutron Products, Inc. (NPI), which is on hold pending the outcome of a State Administrative Hearing, is covered in Section 2.0, Status of Items

Identified in Previous Reviews. NRC will continue to monitor the status of NPI's timely license renewal action in future reviews of the radiation control program.

No potentially significant health and safety issues were identified. On terminations of materials possession and use, recent actions have been to evaluate and document in a timely manner, and to visit and perform a closeout evaluation which may or may not include a survey. In the earlier portion of the review period, some extended intervals occurred between the termination request and closeout evaluation. The verification survey could benefit from consideration of Draft NUREG/CR 5846 "Manual for Conducting Radiological Surveys in Support of License Termination" with respect to required information and the use of appropriate information gathering. The team noted that the Radiological Health Program could benefit from a guidance document on termination of licenses. One termination, identified under the NRC Site Decommissioning Management Plan (SDMP) as an SDMP site during the 1993 program review, was evaluated at the request of the NRC's Office of State Programs and was found to have been surveyed appropriately to verify licensee actions and terminated properly.

- The team suggested that the Radiological Health Program could benefit from a guidance document on termination of licenses.

The Radiological Health Program requires a full replacement application for renewal. On occasion a new licensee has been requested to submit a full replacement application when extensive deficiency discussions or letters have been exchanged. This has the benefit that all the currently agreed to items have been included in one source document. While telephone deficiency conversations are common, their documentation is often only in the licensee's response that indicates "as a result of our conversation on." The reviewer noted that one license had a long lead time review item (waste storage) separated from the renewal, enabling issuance of an up-to-date license sooner than would have been otherwise possible.

The review team found that a new reviewer was gaining experience through less complicated licensing reviews and will be brought into reviewing the more complicated license actions in the near future. Both license reviewers have an inspection background.

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

3.4 Technical Quality of Inspections

The team focused on the following factors in evaluating this indicator: results of accompanying inspectors on field site inspections, inspection field notes, inspection reports, inspection findings, enforcement documentation and current procedures. The team also interviewed inspectors for 16 materials inspections conducted during the review period. The casework included all five of the State's material inspectors and covered higher priority inspections of various types

including hospitals, nuclear medicine facilities, academic institutions, research and development facilities, industrial use, an instrument calibration service, and a nuclear pharmacy. Attachment E lists the inspection cases reviewed in depth with case-specific comments. Prior to the review, a team member performed accompaniments of three state inspectors on four separate inspections of high priority facilities. The first inspector was accompanied at a pool-type irradiator, the second inspector was accompanied twice, first at a hospital followed by field site radiography, and the third inspector was accompanied at a nuclear pharmacy.

Inspection procedures and techniques utilized by the State were reviewed and determined to be consistent with the inspection guidance identified in NRC Inspection Manual Chapter 2800. The procedures were used to help inspectors identify root causes and poor licensee performance. The State's policy is to conduct inspections on an unannounced basis. NRC Inspection Procedure 87100 field notes were electronically reproduced in State format and used for routine materials inspections in the categories of medical, academic, teletherapy, commercial irradiators, gauges, industrial radiography, and research and development.

The review team found the level of detail provided in inspection reports was consistent with respect to the scope of the licensed program, licensee organization, management structure, radiation protection program, training and instructions to workers, personnel protection, posting and labeling, radioactive material control, material transfer and disposal, and exit interviews with management. To assure consistency and quality assurance of reports the RAM Supervisor provided review, comment, and initialed all inspection documents and field notes.

Reports were also reviewed for inspector documentation of operations observed, management and worker interviews, independent measurements, follow up to previous items of non-compliance, and discussion of inspection findings at exit interviews. Overall, the review team found inspection reports showed good quality. Four reports contained sections which identified closure of previous items of noncompliance but did not indicate how items were followed up and corrected. The review team discussed documenting in reports what inspection areas and information were reviewed to close out previous items of noncompliance. Other reports contained only minor discrepancies from standard practice which were related to insufficient detail.

Field notes, inspection forms, and enforcement correspondence were found to be complete. Documented inspection findings generally led to appropriate enforcement and prompt regulatory actions. Routine enforcement letters were drafted by the inspector, signed off by the RAM Supervisor, and issued to the licensee by the RHP Manager. With the exception of NPI (currently under court order), the team determined the State's enforcement policies to be effective in achieving licensee compliance. Enforcement correspondence was timely for files reviewed by the team. Licensee responses to items of noncompliance were also timely and assigned by the RAM Supervisor to inspectors for review. In cases where inspection results indicated a need for escalated enforcement

action, enforcement conferences were held with licensees to discuss inspection findings and possible enforcement action against them.

From staff interviews and some inspection reports the team found that inspectors were aware of the need to provide inspection information affecting licensing to license reviewers, but the process for ensuring inspector feedback to licensing staff was informal. Inspectors discussed inspection findings with the RAM Supervisor, who served as the intermediary between license and compliance staffs for information sharing.

The State's practice calls for annual supervisory accompaniments of all inspectors. In response to the questionnaire, the State reported that the RAM Supervisor performed supervisory accompaniments of four of five inspectors in 1994, and two of five inspectors in 1995. In discussions at the MRB the State informed the team that all inspectors had been accompanied in 1994. The review team considered the unusually high work demands placed upon the RAM Supervisor position during this review period because of the licensing and compliance efforts related to NPI, two reassignments of individuals into the position within a three month period in 1995, and the need to maintain inspection schedules at the appropriate level to prevent development of a program backlog. However, supervisory accompaniments provide management with important insight into the quality of the inspection program.

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

Four inspector accompaniments of three of the program's five inspectors were performed by a review team member as follows: the first inspector was reviewed on June 25-26, 1996, at a pool irradiator facility; the second inspector was reviewed on July 16-17, 1996 at a hospital and again on September 19, 1996, at a field radiography site. A third inspector was reviewed on August 7, 1996, at a nuclear pharmacy. These accompaniments are also identified in Appendix E. The second inspector (who had been performing inspections of high priority licensees) was accompanied twice because a State supervisory accompaniment was not performed during the review period (according to the State's response to the Questionnaire), an NRC accompaniment was not performed in previous assessments, and, following the initial accompaniment of the individual, the team was unable to reach a determination with respect to the inspector's performance. Two of the program inspectors were not accompanied due to the fact that one, a senior inspector, had been accompanied during previous assessments, and the other was a new trainee.

On the accompaniments, two of the three inspectors demonstrated strong inspection techniques, knowledge of the regulations, and overall satisfactory technical performance. However, accompaniments did not show a comparable level of performance by another State-qualified inspector either to conduct a performance-based inspection or in inspection thoroughness to address potentially important radiological safety concerns. The team observed inspector performance issues related to the areas of facility walk-throughs, conduct of licensee operations

and licensee demonstrations, worker and management interviews, and independent measurements. Areas not fully covered during inspections included failure to take independent wipe samples at all hospital material storage and waste locations, not conducting interviews with the hospital radiation safety officer and nursing staff until prompted by the team member, incomplete follow up of licensee corrective actions resulting from a 1994 hospital contamination incident, inadequate walk through and site observation at the beginning of the field radiography inspection to verify storage and inventory of radiographic cameras, lack of an independent radiation survey surrounding the site which confirmed the licensee's posting of radiation boundaries, deficiencies in recognizing the potential for radiation exposure to non-radiation workers in the immediate area where field radiography was performed, and inadequate check of radiation workers for proper dosimetry.

As noted in Section 3.2 of this report, interviews of compliance staff indicated that field qualification for a new inspector consisted primarily of demonstrations for supervisory staff until supervisors were able to make a subjective determination that the inspector was able to perform independently. Criteria were not clearly established which allowed State management to determine when inspectors were qualified for different types of program inspections.

- 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 staff for full inspector qualification.

The team found that the State maintains an ample number of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. Included in the State's meter inventory were ion chambers, micro R meters, high range detectors, GM tubes, ratemeters, scintillation detectors, high and low range pocket dosimeters, alpha meters, calibration check sources, and air sampling equipment. Calibrated portable equipment was located in kits contained in emergency vehicles assigned to the RHP. Inspectors use these vehicles for routine inspections with the portable instruments used by inspectors for confirmatory measurements. The inventory list showed staggered annual due dates for calibrations of instruments so that meters were always available when needed for inspections. The State laboratory was reviewed and found to include liquid scintillation spectrometers, gas flow proportional counters, and gamma spectrometers (multichannel analyzer) for full capability to analyze wipe, water, and soil samples for the RHP.

Based on the findings and the IMPEP evaluation criteria, the review team recommended that Maryland's performance with respect to the indicator, Technical Quality of Inspections, be found Satisfactory, with Recommendations for Improvement. After review and consideration of the unsatisfactory performance of one HP-inspector during two accompaniments, who is no longer with the program, and the overall satisfactory performance of the other three inspectors during accompaniments, the MRB revised the team's recommendation. The MRB final recommendation for Section 3.4, Technical Quality of Inspections is Satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire relative to this indicator and reviewed the incidents reported for Maryland in the "Nuclear Material Events Database (NMED)" against those contained in the Maryland casework and license files, and supporting documentation, as appropriate for ten incidents. The team reviewed the State's response to five allegations. In addition, the review team interviewed the RHP Manager, the RAM supervisor, and the health physicists assigned to incident response.

The incident and allegation investigations were reviewed for responsiveness, coordination, health and safety significance, level of effort, investigative procedures, corrective actions, follow up, compliance, notifications and documentation, as necessary.

It was found that within the RHP, responsibility for initial response and follow-up actions to materials incidents and allegations rests solely with the Inspection and Enforcement Section (IES) of RAM. Written procedures require a prompt response to incidents by the staff and provide additional procedural guidance. The RAM supervisor reviews each incoming event notification or allegation prior to assignment to the IES staff or when appropriate, referral to another agency. All complex events or allegations or those with the potential for impacting public safety are evaluated by the RAM supervisor, the RHP manager, and RAM staff, in order to determine the appropriate response. The response varies based on the safety significance of the event, from resolution through telephone discussion, to immediate response by a team of 2 health physicists, and, in some cases, issuance of a press release to the media. In many instances, the RAM supervisor participated in investigations of complex or high media interest events. Review of the files indicated that this approach provided effective response actions.

The review team examined the State's response to 10 events chosen from events identified as significant in the State's response to the questionnaire and events found in the NMED database system. Events reviewed included two equipment problems, one transportation event, three lost or stolen radioactive material, three loss of control, and one misadministration. The team found that the State could not provide a listing of allegations received by the State during the period. Allegations are filed in the applicable case file. The team found that allegations could only be researched by identifying the specific licensee involved and looking up the case file. Therefore, the review was limited to those cases referred to the State by NRC, and one allegation found during a review of case files. Six allegations involving a variety of technical and administrative issues, five of which had been referred by NRC to the State, were reviewed. During the MRB, a suggestion was made that the State consider implementing a tracking system for allegations.

- The review team suggests that the State consider implementing a tracking system for allegations.

The State's participation in the NMED database system would provide tracking of material events. A list of the incident casework with comments is included in Appendix F.

In the cases reviewed in depth, the review team found the States's response was well within the performance criteria. Incident response was well-coordinated, and the level of effort was commensurate with health and safety significance. The State assured that licensees took suitable corrective actions, and followed the progress of the investigation through until close out. Although the State was unable to provide a complete listing or complete events file, all of the events found in the NMED database were either in the State events file or licensee compliance files. The team noted that three of the events identified by the State in response to the Questionnaire had not been provided to NRC and were not found in the NMED database (1/23/95 Maryland State Highway, 5/26/95 Soil Safe Inc., 5/30/96 Aerosol Monitoring). The team also noted that the State is notifying the Regional State Agreements Officer of the occurrence of a significant event (24 hour or less notification requirement) rather than the NRC Operations Center, as identified in the "Handbook on Nuclear Material Event Reporting in the Agreement States," Draft Report, March 1995.

- The 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.

- 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.

Allegations, that the team could identify, were responded to promptly with appropriate investigations and follow-up actions. Proper procedures were used for the control of information. The team found that the results of allegations received directly by the State were promptly related to the alleger. But, the results of the investigations of allegations referred by NRC to the State were not provided to NRC in a timely manner. The team found that the State had not provided close out information to NRC on allegations referred to the State by NRC. When NRC does not receive close out information from the State on investigation results, NRC cannot provide a response to allegers who request and receive anonymity.

- The team recommends that the State provide close out information to NRC on allegations referred to the State by NRC in which the alleger was granted confidentiality.

Subsequent to the review, the State informed the team that they have provided close out information on all allegations referred to the State by NRC.

The team found that the State has completed and begun implementation of procedures for handling allegations. The team noted that the State has a Law (Chapter 160 of the 1995 Laws of Maryland, codified as State Personnel and Pensions Article, §3-101-102) prohibiting intentional acts of reprisal against any employee who has filed a complaint, grievance, or other administrative or legal action involving State employment.

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 Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery. Maryland's agreement does not cover uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

In response to the questionnaire, the State reported the legislation which authorizes the Maryland Radiological Health Program is identified in the Annotated Code of Maryland, Environmental Article, Title 8, "Radiation", and Title 7, "Hazardous Materials and Hazardous Substances." There are no sunset laws in Maryland and the State indicated that regulations have no expiration date.

4.1.2 Status and Compatibility of Regulations

By letter of September 25, 1995, the State committed to a Regulation Adoption Management Plan (RAMP) to eliminate rulemaking backlog identified during previous assessments and prevent future backlogs from developing. In the November 1995
follow-up program review NRC found the State completed a revision to the RAMP updating all regulations required for compatibility which were identified as due or overdue. The regulations became effective on October 9, 1995. Also included in this revision was the following amendment:

- "Decommissioning Recordkeeping, and License Termination: Documentation Additions, "10 CFR Parts 30, 40, and 70 amendments (58 FR 39628) that became effective on October 25, 1993, with adoption needed by October 25, 1996.

Current NRC policy on adequacy and compatibility requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. In the November 1995 review NRC recommended the State address adoption as soon as possible of the following rule needed for compatibility:

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR 36 amendments (58 FR 7715) that became effective July 1, 1993, and due for adoption by the State by July 31, 1996.

The State of Maryland regulates irradiator facilities which would be subject to the regulations in "Licenses and Radiation Safety Requirements for Irradiators, 10 CFR Part 36. Equivalent rules were in the final stages of promulgation and were scheduled to be adopted in November 1996. The team found that the State had not established legally binding requirements equivalent to NRC requirements in 10 CFR Part 36 that are required for compatibility, at the time of review. Subsequent to the review, the State informed the team that Part X of the Maryland Code covering, "Licenses and Radiation Safety Requirements of Irradiators," was adopted on November 19, 1996, with an effective date of December 16, 1996.

From interviews with staff assigned to the RHP regulations development committee, the team found the RAMP was in place, but its effectiveness with respect to beginning rule development was incomplete. In response to the questionnaire the State reported that no action has been taken on the following compatibility rules, but expected adoption by the end of 1997:

- "Timeliness in Decommissioning of Material Facilities, " 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994 and will need to be adopted by August 15, 1997.

- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use, " 10 CFR 30, 32, and 35 amendments (59 FR 61767, 59 FR 65243, and 60 FR 322) that became effective January 1, 1995 and will need to be adopted by January 1, 1998.

- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective March 13, 1995 and will need to be adopted by March 13, 1998.

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Part 20 and 61 amendments (60 FR 15649 and 60 FR 25983) that becomes effective March 1, 1998 and will need to be adopted by March 1, 1998. The NRC delayed its effectiveness until the States could adopt compatible requirements so that the national manifest system will go into effect at one time.

- "Performance Requirements for Radiography Equipment," 10 CFR 34 amendments (60 FR 28323) that became effective June 30, 1995 and will need to be adopted by June 30, 1998.

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995 and will need to be adopted by August 14, 1998.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995 and will need to be adopted by November 24, 1998.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996 and will need to adopted by April 1, 1999. NRC delayed the effective date of this rule until April 1, 1996 so that the DOT companion rule could be implemented at the same time. Since this rule involves the transport of materials across state lines, the States are encouraged to adopt compatible regulations as soon as possible.

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 50248) that became effective October 20, 1995 and will need to be adopted by October 20, 1998.

The proposed schedule will not meet the three-year limit for the Timeliness of Decommissioning of Materials Facilities rule, which will need to be adopted by August 15, 1997.

NRC staff has reviewed the 13 amendments to the final COMAR regulations adopted by the State of Maryland, that became effective October 9, 1995, and, based on that review, found that our earlier comments have been addressed. However, in completing the review staff identified issues in other sections of Maryland regulations that have potential compatibility significance. Issues identified by the staff relate to existing sections of Maryland regulations that were not modified by the 13 amendatory actions. Staff completed documentation of these concerns and transmitted the concerns to the State, separately by letter, dated February 28, 1997.

A review of the State's Administrative Procedures Act showed it provides the opportunity for public comment in public hearings on proposed regulations. According to staff the RAMP process included submittal of draft regulations to NRC for comment. NRC comments are considered by the rules committee prior to public notice.

- 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.

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

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

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to this indicator, Legislation and Regulations, be found Unsatisfactory due to issues identified by the staff related to existing sections of Maryland's final COMAR regulations that were not modified by the 13 amendatory actions adopted by the State, that became effective October 9, 1995. Also, subsequent to the review, the State informed the team that Part X of the Maryland Code, "Licenses and Radiation Safety Requirements for Irradiators," was adopted effective December 16, 1996. NRC will notify the State of the results of a final review, in a separate letter. Additionally, the State needs to resolve the issue regarding the term "person" in the LLRW regulations.

4.2 Sealed Source and Device 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 Staff's use of guidance documents and procedures, and interviewed the staff and Program Manager involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The review team examined six new or revised SS&D registry certificates and their supporting documentation. In addition, the review team examined the State's efforts to revise an additional SS&D registry certificate for a device involved in an incident. The certificates reviewed covered the period since the last program review in April 1993 and represented cases completed by three reviewers. The SS&D certificates issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G. The overall quality of the evaluations shows improvement of the program since the review conducted in 1993. There was a noticeable improvement in documentation required of the applicants and in the detail of the evaluations when comparing 1994 to 1995 certificates.

The State does have procedures in place to protect proprietary information submitted in support of an evaluation. Policy and guidance documents were on file and being utilized by the staff. The review team observed that both SS&D reviewers will be signing each completed SS&D registry certificate to verify the second reviewer's audit of the application and the original reviewer's conclusions for future certificates. This is a change in the previous policy of the State.

The review of SS&D casework files revealed that five of the seven files had comments on detailed Quality Assurance/Quality Control (QA/QC) programs. Specifically, the staff did not obtain detailed QA/QC program commitments for devices previously approved (prior to 1995) or new devices similar to previously approved devices. When manufacturer/distributors are amending their certificate, they should be required to submit detailed Quality Assurance/Quality Control (QA/QC) programs regarding the SS&D product manufacturing process. The review team noted that the staff had obtained detailed QA/QC program information on the HDR presently under review and had reviewed the information according the procedures and guidance documents.

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. It was recommended that Maryland 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 present staff 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.

- 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.

Improvements in the nationwide effort to evaluate SS&Ds containing radioactive material led to NRC adoption of 10 CFR 30.32 (g) on "Application for Specific Licenses" and 10 CFR 32.210 entitled, "Registration of Product Information." These regulations were not initially identified as items of compatibility for Agreement States with SS&D evaluation programs. All Agreement States letter SP-95-116 dated July 25, 1995, announced Commission approval of minimum standards for Agreement States desiring to maintain authority to evaluate SS&Ds.

- In keeping with this guidance, the review team recommends that the State adopt regulations compatible with 10 CFR 30.32 (g) and 10 CFR 32.210.

These regulations require manufacturers/distributors to submit certain key product information in support of an SS&D evaluation and permits the State to enforce against those commitments. More specific guidance in this area is contained in Regulatory Guide 6.9 dated February 1995 entitled, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources Containing Byproduct Material." It should be noted that the two new SS&D evaluations and certificates issued in 1996 had either a specific license condition on the manufacturers/distributors addressing these requirements or the through a tie down condition to documents submitted by the licensee.

4.2.2 Technical Staffing and Training

During the period of April 1993 to June 1995, all SS&D reviews were conducted by the program manager, who retired in June 1995. On the retirement of the program manager, responsibility for SS&D reviews was assigned to the new program manager and a lead health physicist, who is a senior license reviewer. Both staff members had a Bachelor's degree in physical or biological sciences. Both staff members had completed the NRC recommended core training courses for materials licensing personnel and more advanced training such as the SS&D evaluation workshop. In December 1995, the program manager was reassigned as the program manager for the X-ray program. Another lead health physicist was assigned the program manager's responsibilities for SS&D reviews. This staff member has reviewed the course material from the SS&D workshop, has become familiar with the processes and had demonstrated the ability to understand and interpret the information submitted by applicants as described in the performance criteria. Although the lead health physicist is newly assigned to the SS&D reviews, he is an experienced senior inspector with a Bachelor's degree in biological sciences and has had all the NRC recommended core training courses for materials licensing personnel. An offer was extended to the State for this reviewer to work with the Sealed Source Safety Section at NRC Headquarters, and his management is considering that option.

The review team is aware that recent retirement and reassignment of the program manager presents potential for weaknesses to develop. During the 1993 review, NRC recommended that Maryland develop a program for cross-training senior staff members in other areas, specifically SS&D evaluations.

- 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.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The State is following up on two SS&D-related incidents which occurred in other jurisdictions concerning the Nucletron microselectron HDR and its interlock system. The State's response to these incidents (with regard to manufacture) was evaluated by the review team and is included in the incidents reviewed in section 3.5 of this report. The staff is working with the licensee to issue a revision to the SS&D certificate for the HDR to take into account the new design and programming implemented for the interlock and the QA/QC program. A draft version of this certificate has been sent to the licensee for comment.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

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 the State's performance with respect to each of the performance indicators to be Satisfactory with the exception of 3.2 Technical Staffing and Training and 3.4 Technical Quality of Inspections, both of which were found Satisfactory with Recommendations for Improvement, and the non-common indicator, 4.1.2 Status and Compatibility of Regulations, which was found Unsatisfactory. The MRB, after considering the unsatisfactory performance of one HP-inspector during two on-site field inspection accompaniments, and the overall satisfactory performance of three other inspectors during accompaniments, revised the team's recommendation for Section 3.4 Technical Quality of Inspections. The final MRB recommendation for Section 3.4, Technical Quality of Inspections is Satisfactory.

The team recommended, and the MRB concurred, to find the Maryland program to be adequate to protect public health and safety but needs improvement and not compatible.

Below is a summary list of suggestions and recommendations, as mentioned in earlier sections of the report, for consideration by the State. As previously indicated, the State responded to the suggestions and recommendations in a letter dated February 3, 1997.

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 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 the State of Maryland inform NRC when the referring physician/patient notification requirements has been completed by SHH. (Section 2.0)

3. The review team recommends that the State incorporate the April 1995 revisions to IMC 2800 into their Inspection Procedures Manual. (Section 3.1)

4. The team suggests that the State consider development of a formal professional training plan through the use of university and industry educational programs for training new staff and retraining or refresh for long-term staff. (Section 3.2)

5. 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. (Section 3.2)

6. The team suggests that Maryland assess whether a reinspection or revision to move-up the next inspection date should be considered for any higher priority licensees, i.e.,HDRs, radiographers, previously inspected by the HP-I inspector whose accompaniment was unsatisfactory. (Section 3.2)

7. 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. (Section 3.2)

8. The team suggested that the Radiological Health Program could benefit from a guidance document on termination of licenses. (Section 3.3)

9. The review team recommends that the State adhere to the policy of annual supervisory accompaniments of all inspectors. (Section 3.4)

10. 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. (Section 3.4)

11. The review team suggests that the State consider implementing a tracking system for allegations. (Section 3.5)

12. 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. (Section 3.5)

13. 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. (Section 3.5)

14. 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. (Section 4.1)

15. 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. (Section 4.1)

16. The team recommends that the State address the staff's comments relating to Maryland's COMAR final rules that were transmitted to the State. (Section 4.1)

17. 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. (Section 4.2)

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

19. The review team recommends that an additional senior staff member be should be trained to perform the SS&D evaluations to supplement the program as it matures. (Section 4.2)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Patricia Larkins, OSP	On-Site Team Leader Technical Staffing and Training Response to Incidents and Allegations
Terry Frazee, Washington	Technical Quality of Licensing Actions at NPI Status of Materials Inspection Program
Dave Collins, RII	Technical Quality of Licensing Actions
Craig Gordon, RI	Technical Quality of Inspections Legislation and Regulations
Kathleen Schneider, OSP	Sealed Source and Device Evaluations

APPENDIX B

MARYLAND DEPARTMENT OF THE ENVIRONMENT

AND

AIR AND RADIATION MANAGEMENT ADMINISTRATION, RADIOLOGICAL HEALTH PROGRAM

ORGANIZATION CHARTS

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) QUESTIONNAIRE