INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MARYLAND AGREEMENT STATE PROGRAM

SEPTEMBER 23-27, 1996

DRAFT REPORT

U.S. Nuclear Regulatory Commission

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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.

[Paragraph on Results of MRB meeting will be included in final report. Attachment 1, State's response will be included in final report.]

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 data base, (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 select 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, MD, (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 waste regulations included jurisdiction over Federal facilities which is not consistent with 10 CR 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 LLW 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 for a continued discussion.

This item remains open.

(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 Status of Items Identified During the 1995 Followup Review

The 1995 follow-up review, conducted November 7-8, 1995, identified once again, that the definition of "person" in Maryland's low-level 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 waste regulations that included jurisdiction over Federal facilities is as follows:

In an August 25, 1995, letter to Ms. Marilyn 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 IMPEP 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 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 waste regulations, as it relates to Federal agencies, from the legal staff.

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 Maryland's Part 20 equivalent rule and to existing sections of Maryland regulations that were not modified by the 13 amendatory actions. Staff is completing documentation of these concerns and plans to meet separately with Maryland staff to discuss these issues. 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 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 State has not established legally binding requirements equivalent to NRC requirements in 10 CFR Part 36 that are required for compatibility.

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 onsite radioactive waste held in storage (a significant contributor to exposures for both onsite personnel and members of the public) and a courtyard cover to minimize releases of contaminated materials to the environment.

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 19[illegible], 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 MD program inspector, license reviewer, and management, and an on site 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 previous recommendation should be 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, MD, (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. Marilyn 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.

This recommendation remains open.

- The IMPEP team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level

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 IMPEP team recommends 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.

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 licensed 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, and any staff turnover that may have occurred throughout the assessment period. 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 has responsibility for the control of radiation in Maryland. 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 RHP program went from a total staffing level of 11, which included one program manager, three supervisor health physicists (licensing, licensing and low level waste, and inspection and enforcement), six health physicists, and one x-ray and regulations specialist; to a total staffing level of (9), 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 radioactive materials program (RAM) is divided into two sections, the Inspection and Enforcement Section comprised of four health physicist 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 HP, 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 HP 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. MD 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. Additionally, the supervisor had never accompanied the inspector. 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 MD 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 position 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 MD due to the number and complexity of licensees in the MD 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 adequacy and compatibility to protect public health and safety.

- 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 maintain an adequate program to protect public health and safety and 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.

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 reviewed the inspection reports, enforcement documentation, and inspection field notes, and interviewed inspectors for sixteen materials inspections conducted during the review period. The casework included all 5 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, followup 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. One inspector was not accompanied during the review period. 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, 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 IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Technical Quality of Inspections, be found Satisfactory, with Recommendations for Improvement.

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.

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. Six allegations involving a variety of technical and administrative issues, five of which had been referred by NRC to the State, were reviewed. 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 MD State Highway event, (2) 5/26/95 Soil Safe Inc. event, and (3) 5/30/96 Aerosol Monitoring event.

Allegations 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 alleger's 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.

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 followup 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, and will need to be adopted 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 has not established legally binding requirements equivalent to NRC requirements in 10

CFR Part 36 that are required for compatibility.

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 because 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 will become 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 Maryland's Part 20 equivalent rule and to existing sections of Maryland regulations that were not modified by the 13 amendatory actions. Staff is completing documentation of these concerns and plans to meet separately with Maryland staff to discuss these issues.

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.

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 the State's failure to adopt 10 CFR Part 36 or equivalent legally binding requirements within the specified period of time.

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 staff performing SS&D evaluations is dedicated to a quality product, the program uses a two person team approach to performing the evaluations, the SS&D evaluation program has management support, and has the ability to seek outside assistance from NRC as needed. However, 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 due to the fact that the State has not adopted "Licensing and Radiation Safety Requirements for Irradiators, "10 CFR Part 36 amendments (58 FR 7715) that became effective July 1, 1993, and should have been adopted by the State by July 1, 1996. Accordingly, the team recommends the MRB find the Maryland program to be adequate to protect public health and safety but needs improvement and not compatible due to the failure to adopt 10 CR Part 36 or equivalent legally binding requirements within the specific period of time.

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

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 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 take prompt action to ensure that Sacred Heart Hospital complies with the recommendations of the joint

review team report dated March 5, 1996, that was transmitted to the State April 15, 1996. (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 MD 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 maintain an adequate program to protect public health and safety and 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 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)

12. 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 MD State Highway event, (2) 5/26/95 Soil Safe Inc. event, and (3) 5/30/96 Aerosol Monitoring event. (Section 3.5)

13. The team recommends that the State provide close out information to NRC on allegations referred to the State by NRC. (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 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)

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

18. 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

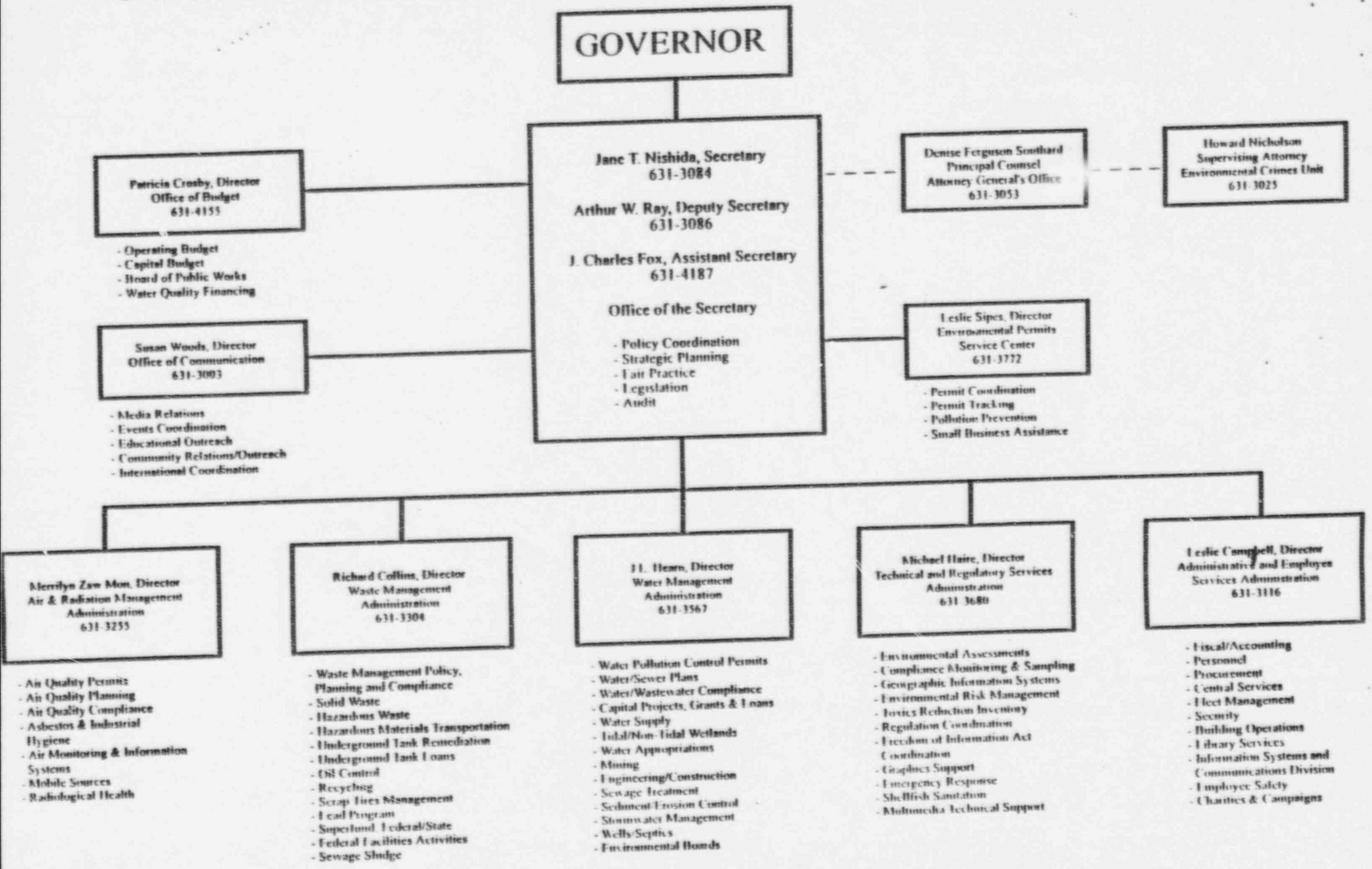
MARYLAND DEPARTMENT OF THE ENVIRONMENT

AND

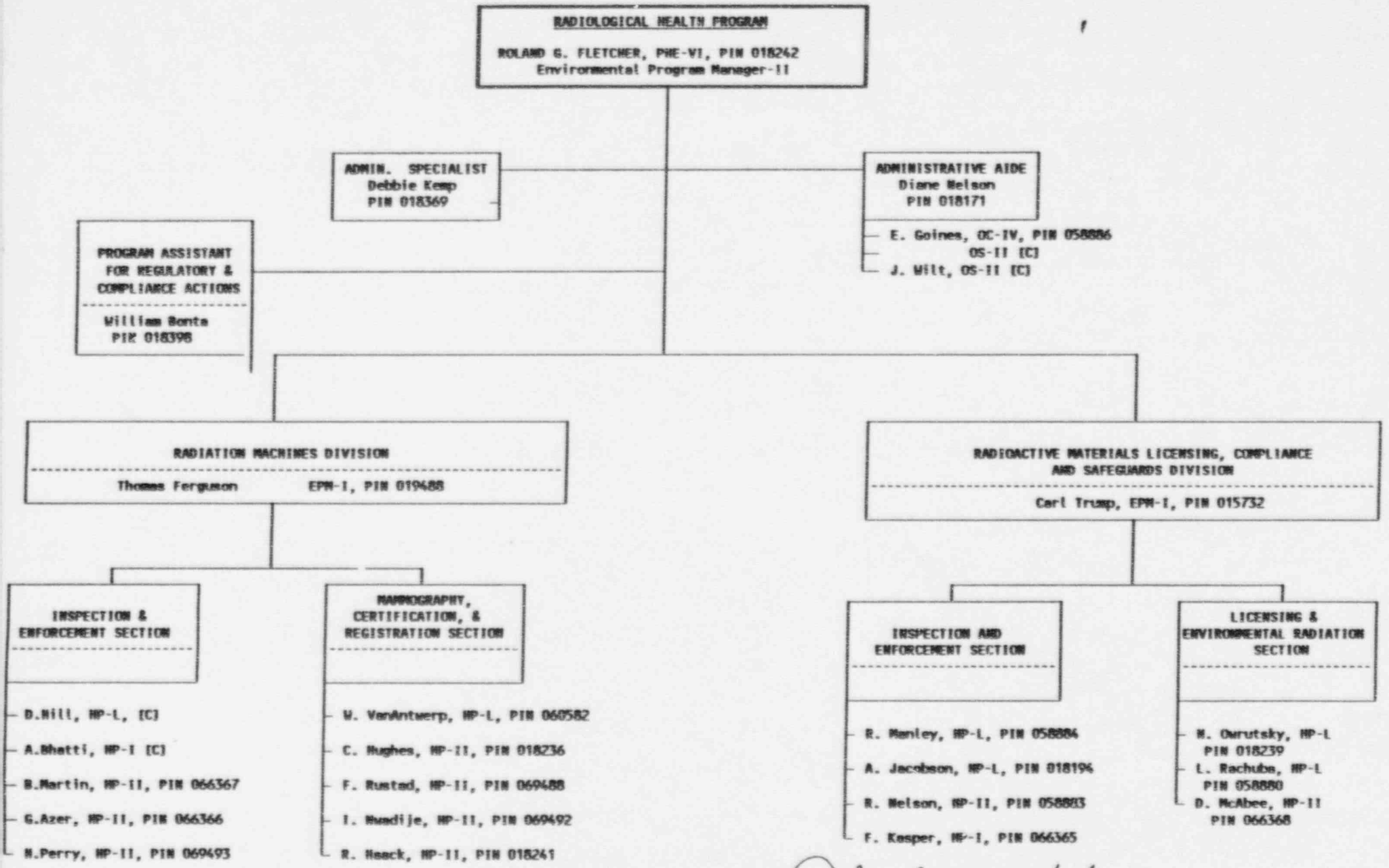
AIR AND RADIATION MANAGEMENT ADMINISTRATION, RADIOLOGICAL HEALTH PROGRAM

ORGANIZATION CHARTS

MARYLAND DEPARTMENT OF THE ENVIRONMENT



AIR AND RADIATION MANAGEMENT ADMINISTRATION
REORGANIZAITON OF THE RADIOLOGICAL HEALTH PROGRAM



Roland G. Fletcher

Roland G. Fletcher, Program Manager
April 4, 1996

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) QUESTIONNAIRE

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

Maryland Department of the Environment
Radiological Health Program

Reporting Period: April 8, 1994, to September 20, 1996

A. COMMON PERFORMANCE INDICATORS

I. Status of Materials Inspection Program

1. Please prepare a table identifying the licenses with inspections that are overdue by more than 25% of the scheduled frequency set out in NRC Inspection Manual Chapter 2800 (issued 4/17/95). The list should include initial inspections that are overdue.

Licensee Name	Insp. Frequency (Years)	Due Date	Months O/D

answer: There are no inspections that are overdue by more than 25% as outlined in NRC inspection manual 2800.

2. Do you currently have an action plan for completing overdue inspections? If so, please describe the plan or provide a written copy with your response to this questionnaire.

answer: No action plan is currently required at this time.

3. Please identify individual licensees or groups of licensees the State/Region is inspecting less frequently than called for in NRC Inspection Manual Chapter 2800 (issued 4/17/95) and state the reason for the change.

answer: All RHP inspections are conducted as frequently or more frequently than the NRC Chapter 2800 inspection frequencies.

4. How many licensees filed reciprocity notices in the reporting period?

   a. Of these, how many were industrial radiography, well-logging or other users with inspection frequencies of three years or less?

answer: 708 licensees filed reciprocity notices in the reporting period. 498 of those requests were for types of licensees which have inspection frequencies of 3 years or less.

b. For those identified in 4a, how many reciprocity inspections were conducted?

answer: 56 reciprocity inspections within the reporting period.

5. Other than reciprocity licensees, how many field inspections of radiographers were performed?

answer: 4 field inspections of radiographers were performed.

6. For NRC Regions, did you establish numerical goals for the number of inspections to be performed during this review period? If so, please describe your goals, the number of inspections actually performed, and the reasons for any differences between the goals and the actual number of inspections performed.

answer: N/A

II. Technical Staffing and Training

7. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

NAME	POSITION	AREA OF EFFORT
Carl E. Trump, Jr.	Program Manager	Administration, 25%; Materials Licensing & Compliance, 65%; Emergency Response, 5%; *LLRW, 5%
Raymond E. Manley	Health Physicist Lead	Administration, 15%; Materials Licensing & Compliance, 70%; Emergency Response, 10%; LLRW, 5%
Alan D. Jacobson	Health Physicist Lead	Administration, 10%; Materials Licensing & Compliance, 80%; Emergency Response, 8%; LLRW, 2%
Robert K. Nelson	Health Physicist II	Administration, 5%; Materials Licensing & Compliance, 85%; Emergency Response, 8%; LLRW, 2%
Frank A. Kasper	Health Physicist I	Administration 0%, Materials Licensing & Compliance 95%, Emergency Response 5%
Leon J. Rachuba	Health Physicist Lead	Administration 0%, Materials Licensing & Compliance 98%, Emergency Response 2%
Douglas K. McAbee	Health Physicist II	Administration 10 %, Materials Licensing & Compliance 88%, Emergency Response 2%
Nathanial A. Owrutsky	Health Physicist Lead	Administration 5%, Materials Licensing & Compliance 93%, Emergency Response 2%

* LLRW responsibilities are shared between RHP and Mr. Alvin Bowles (Hazardous & Solid Waste Management Administration) who spends 5% of his time on LLRW.

8. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

answer: No new professional personnel have been hired since the last review.

9. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapters 1245 and 1246; for Agreement States, please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

answer: Frank Kasper needs to attend the Licensing Practices and Procedures. He will attend course provided funding is available or NRC sponsorship continues.

Leon Rachuba needs to attend Safety Aspects of Industrial Radiography. He will attend course provided funding is available or NRC sponsorship continues.

INSPECTOR TRAINING

Inspectors must attend all NRC core courses.

A. Inspections
B. Diagnostic and Therapeutic Nuclear Medicine
C. Five-Week Health Physics
D. Safety Aspects of Industrial Radiography
E. Licensing Practices and Procedures

Each inspector receives and continues to receive one-on-one training by supervisor and senior staff. In addition, the inspector will be accompanied by a senior staff or supervisor prior to independent inspections, investigations or emergencies.

LICENSING REVIEWER

License reviewers must attend all NRC core courses.

A. Inspections
B. Diagnostic and Therapeutic Nuclear Medicine
C. Five-Week Health Physics
D. Safety Aspects of Industrial Radiography
E. Licensing Practices and Procedures

License reviewers must be trained and aware of relevant NRC licensing guidance and pertinent technical documents.

10. Please identify the technical staff who left the RCP/Regional DNMS program during this period.

answer: Retirement of Charles R. Flynn as Licensing Program Manager on 6/95.
Transfer of Thomas Ferguson to X-Ray Program Manager on 12/95.

III. Technical Quality of Licensing Actions

11. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, terminated or renewed in this period.

LICENSEE NAME	LICENSE NUMBER	LICENSE TYPE	ACTION
Neutron Products	MD-31-025-01	Manufacturer	Renewal
Neutron Products	MD-31-025-03	Teletherapy Service	Renewal
Neutron Products	MD-31-025-04	Irradiator	Renewal
Neutron Products	MD-31-025-05	Irradiator	Renewal
Eastern Isotopes	MD-03-068-01	Nuclear Pharmacy	New
Mallinckrodt Medical	MD-05-105-01	Nuclear Pharmacy	Renewal
Terumo Medical Corp	MD-15-007-01	Irradiator	Renewal
Adaptive Technologies Inc	MD-21-026-01	Sealed Source Design	Renewal
H&H X-ray Services	MD-03-047-01	Industrial Radiography	Terminated
Law Engineering Inc.	MD-27-060-01	Industrial Radiography	Terminated
Measurex-DMC	MD-31-088-01	Sealed Source Design	Renewal
Measurex-DMC	MD-31-088-02	Service	Renewal
Mid-Atlantic Isotopes	MD-05-148-01	Nuclear Pharmacy	New
Oncology Center at Riverside	MD-25-026-01	HDR	New
Montgomery General Hospital Cancer Treatment Center	MD-31-217-01	HDR	New

Chesapeake Regional Cancer Center	MD-37-010-01	HDR	New
GTS Duratek	MD-27-059-01	Industrial Radiography	Terminated
Veterinary Imaging	MD-05-145-01	Therapy	New
Veterinary Referral Service	MD-31-242-01	Therapy	New
North American Inspections	MD-43-019-01	Industrial Radiography	Terminated
Maryland General Cancer Center	MD--07-177-01	HDR	New

TABLE OF MAJOR LICENSEES

licensee Name	License Number	License Type
Eastern Isotopes Inc	MD-03-068-01	Nuclear Pharmacy
Syncor Corp	MD-05-059-01	Nuclear Pharmacy
Mallinckrodt Inc.	MD-05105-01	Nuclear Pharmacy
MQS Inspection Inc.	MD-05-128-01	Industrial Radiography
Veterinary Imaging	MD-05-145-01	Therapy
Mid-Atlantic Isotopes	MD-05-148-01	Nuclear Pharmacy
Johns Hopkins Medical Institute	MD-07-005-03	Broad Scope
University of Maryland at Baltimore	MD-07-014-01	Broad Scope
University of Maryland at Baltimore	MD-07-014-04	Incinerator
Maryland General Cancer Center	MD-07-177-01	HDR
Union Memorial Oncology Center	MD-07-181-01	HDR
Terumo Medical Corp	MD-15-007-02	Irradiator

Therapy Services	MD-21-007-01	Therapy Source Service and Distribution
Adaptive Technologies Inc.	MD-21-026-01	Service and Distribution
Oncology Center at Riverside	MD-25-026-01	HDR
Neutron Products	MD-31-025-01	Manufacturer
Neutron Products	MD-31-025-03	Service
Neutron Products	MD-31-025-04	Irradiator
Neutron Products	MD-31-025-05	Irradiator
Nucletron Inc.	MD-27-035-01	Therapy Source Service and Distribution
Measurex-DMC	MD-31-088-01	Sealed Source Design
Measurex-DMC	MD-31-088-02	Service
Montgomery General Hospital Cancer Treatment Center	MD-31-217-01	HDR
Mediphysics	MD-31-222-01	Nuclear Pharmacy
Veterinary Referral Associates	MD-31-242-01	Therapy
Pettit Applied Technologies	MD-31-252-01	Service and Distribution of GL Devices
University of Maryland	MD-33-004-01	Broad Scope
Radiation Service Organization	MD-33-021-02	Waste Disposal
Chesapeake Regional Cancer Center	MD-37-010-01	HDR
Washington County Hospital	MD-43-001-03	HDR

12. Please identify any new or amended licenses added or removed from the list of licensees requiring emergency plans?

answer: Neutron Products Inc. MD-31-025-01 Manufacturer of teletherapy sealed sources.

13. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

answer: There were none.

14. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

answer: Licensing procedures are currently being updated. Draft procedures are in the review process.

15. For NRC Regions, identify by licensee name, license number and type, any renewal applications that have been pending for one year or more.

answer: N/A

IV. Technical Quality of Inspections

16. What, if any, changes were made to your written inspection procedures during the reporting period?

answer: On 11/95 a revision of inspection procedures was implemented which includes use of updated inspection fieldnotes and new formatting for report writing and supervisory overview.

17. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Supervisor	Inspector	License Cat. (code)	Date
Carl E. Trump, Jr.	Randall Haack	03121	6/20/94
Carl E. Trump, Jr.	Alan Jacobson	02305	8/30-31/94
Carl E. Trump, Jr.	Ray Manley	02120	9/15/94
Carl E. Trump, Jr.	Ray Manley	Emergency Response	9/22/94
Carl E. Trump, Jr.	Bob Nelson	02120	10/31/94 11/1/94
Carl E. Trump, Jr.	Randall Haack	03121	11/29/94

Carl E. Trump, Jr.	Ray Manley Alan Jacobson Bob Nelson Frank Kasper Tom Ferguson	03320 Incident Reenactment	1/25/95
Carl E. Trump, Jr.	Alan Jacobson	02120	1/31/95
Thomas Ferguson	Leon Rachuba	03121	11/14/95

18. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. If supervisory accompaniments were documented, please provide copies of the documentation for each accompaniment.

answer: Accompaniment involves on-site evaluation by senior supervisor for competency and knowledge of a selective license category. Each inspector was verbally critiqued by the supervisor upon completion of the inspection.

19. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time?

answer:

Number of Instruments	Manufacturer	Model
16	Eberline	E-520
2	Eberline	ASP-1
2	Bicron	mRem
1	Eberline	E-120
9	Eberline	Prm-7
4	Ludlum	12S
1	Ludlum	14A
1	Ludlum	19
4	Eberline	MS2
3	Eberline	Pac 4G
3	Eberline	Pic 6a
12	Eberline	Pic 6B
1	Victoreen	470 A

Meters are calibrated at Radiation Services Organization or by BGE (Calvert Cliffs Nuclear Facility). All instruments used by personnel for compliance or investigatory purposes are calibrated.

V. Responses to Incidents and Allegations

20. Please provide a list of the most significant incidents (i.e., medical misadministration, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc.) that occurred in the Region/State during the review period. For Agreement States, information included in previous submittals to NRC need not be repeated. The list should be in the following format:

LICENSEE NAME	LICENSE #	DATE OF INCIDENT\REPORT	TYPE OF INCIDENT
Private Paint Shop	GL Device	7/11/94\\7/20/94	Stolen Device
Material Testing Laboratories	NRC-45-17151-01	10/6/94\\12/12/94 12/14/94 12/23/94	Industrial Radiography (loss of control)
Atec Assoc.	MD-31-189-01	8/31/94\\9/22/94	Damaged Gauge
Schnabel Eng. Assoc.	MD-07-141-01	11/3/94\\3/3/95	Damaged Gauge
Mallinckrodt Inc.	MD-33-088-01	1/10-11/95\\2/1/95	Unrestricted Area & DOT Contamination
Maryland State Highway	MD-05-049-01	1/23/95\\1/24/95	Stolen Gauge
Soil Safe Inc.	MD-07-172-01	5/26/95\\7/10/95	Lost Gauge
Nucletron Corporation	MD-27-035-01	1/9/96\\2/22/96	System Failure
Aerosol Monitoring	MD-03-056-01	5/30/96\\6/10/96	Stolen Paint Analyzer
Johns Hopkins Medical Institutions	MD-05-007-03	6/[illegible]/96\\Pending	Brachytherapy (loss of control)

21. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified?

    a. For States, was timely notification made to the Office of State Programs? For Regions, was an appropriate and timely PN generated?

answer: a. **Notification to RHP by NRC regarding failure of Nucletron HDR's door interlock system to always retract the source when the treatment room door is opened. NRC notified other states that might be affected by an abnormal occurrence report. US, Canadian and Mexican users also notified via safety alert issued by the manufacturer.**

b. **Multiple dose vial breakage during pharmaceutical preparation at Mallinckrodt pharmacy causing contamination of pharmacy, surrounding unrestricted areas and DOT transport packaging. Proper notification was made to NRC Region I.**

22. For incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

answer: For 21a. NRC and the manufacturer supplied appropriate information to Maryland. For 21b. a manufacturing notice had been sent to most recipients regarding a bad batch of vials prior to the incident.

23. In the period covered by this review, were there any cases involving possible wrongdoing that were reviewed or are presently undergoing review? If so, please describe the circumstances for each case.

answer: No.

24. Identify any changes to your procedures for handling allegations that occurred during the period of this review.

    a. For Agreement States, please identify any allegations referred to your program by the NRC that have not been closed.

answer: Draft allegation procedure is under review.

a. **None**

VI. General

25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

answer: Of the 30 program indicators that were evaluated during the 1993 program review, 19 were found satisfactory. NRC recommendations and RHP's current status is indicated below:

1. Status and Compatibility of Regulations (Category I)

NRC RECOMMENDATION: The RHP should continue their efforts to amend State regulations that are needed for compatibility including revision to the definition of "person" set out in the Maryland low-level radioactive waste regulations, and obtain the necessary support needed to adopt the regulations in an expeditious manner. The RHP should develop and submit to NRC a management plan for eliminating the current rulemaking backlog and a schedule for adoption of revisions to the regulations.

RHP STATUS: On September 21, 1995 RHP submitted to NRC a regulations adoption management plan indicating Maryland's commitment to expeditiously evaluate and update pertinent radiation regulations falling under the NRC compatibility designation. This mandates the actions of a regulation committee whose mission is to coordinate, evaluate and implement the expedient adoption of required regulations. An extensive update of the Code of Maryland Regulations (COMAR) 26.12.01.01 titled, "Regulations for Control of Ionizing Radiation," adopted September 9, 1995 and effective October 9, 1995, incorporated the thirteen (13) compatibility regulations which had exceeded the three (3) year incorporation deadline. The definition of "person" as given in COMAR 26.12.01.01 Section A.2 meets the compatibility standard. Currently the regulation committee is near completion regarding the adoption of regulations governing the licensing and radiation safety requirements for irradiators and anticipates adoption in November, 1996.

2. Budget (Category II)

NRC RECOMMENDATION: The RHP should assess programmatic needs and, if determined to be necessary, a supplemental budget increase requested to provide sufficient operating funds for the program.

RHP STATUS: The RHP has been assessing program needs annually during the budget preparation process. Specific considerations that impact available resources during the year are being addressed as they occur. Program needs have been impacted by:

a. the requirement to allocate staff in order to keep the Maryland program adequate to protect the public health and safety, and compatible with NRC regulations;

b. the attention and diligence needed to deal with the licensing and compliance issues associated with regulating Neutron Products, Inc.; and,

c. the importance of responding appropriately to implement the NRC's recommendations resulting from the audit of Maryland's program.

Fees were increased an average of 60% in July 1994 to assist in meeting these and other needs. Currently the need for additional fee increases is being evaluated. Programmatic reassessment will continue as requirements change.

3. Administrative Procedures (Category II)

NRC RECOMMENDATION: The RHP should review their administrative procedures for licensing, inspection, and event reporting (including incidents, allegations and misadministrations), develop or update the procedures accordingly, and make them available to the staff for implementation.

RHP STATUS: RHP is currently undergoing the review and evaluation process regarding administrative procedures in the areas of licensing, reporting of events, and misadministrations. Inspection procedures were revised and implemented in November of 1995.

4. Training (Category II)

NRC RECOMMENDATION: The RHP should develop a program for cross-training senior staff members in other RHP areas, specifically in the area of SS&D evaluations and registrations. The RHP should also provide additional training to staff in internal radiation exposure and dose assessment evaluations in accordance with the revised Part 20.

RHP STATUS: RHP has conducted cross training for licensing staff in the area of sealed source and device evaluations and registrations. An overall assessment of training requirements and needs within the Agency is an ongoing process and includes a review of training needs of administrative staff. Staff training in dose assessment, in accordance with the revised Part 20, was held on October 12, 1995. Specific aspects of the licensing staff training program include:

a. training of licensing personnel in the areas of general licensing practices and SS&D evaluations; and,

b. explaining segments of licensing procedures to all personnel.

5. Adequacy of Product Evaluations (Category I)

NRC RECOMMENDATION:

a. The RHP and vendors should replace missing information and review outdated registration sheets in accordance with the standard format and content guidance. Maryland should obtain and maintain sufficient documentation on file to establish a complete health and safety basis for the integrity of the product designs.

b. The RHP should re-evaluate the Nucletron Microselectron HDR considering the deficiencies and questions identified in Appendix B.

c. The RHP should discontinue the practice of performing a sealed source and device acceptance evaluation that authorizes a manufacturer, located in another State, to routinely distribute that source or device. (See Registration sheets MD-327-D-101-G, MD-0691-S-101-S, MD-0691-D-102-S). The RHP would have no basis to inspect the manufacturer to determine if the product is being manufactured and distributed in accordance with the information submitted and evaluated by the RHP. Unless a cooperative arrangement can be made with the affected State, this practice should be discontinued.

RHP STATUS:

a. RHP has followed specific guidance received from Steve Baggett of NRC Headquarters regarding this issue.

b. The NRC's 25 questions concerning Nucletron's high dose rate (HDR) remote afterloader were sent to Nucletron. Nucletron's responses were reviewed and confirmed the accuracy of the registry sheet as written.

c. The RHP has never had a policy of writing registry sheets for out-of-state licensees. Two registry sheets (MD-0691-S-101-S, and MD-0691-S-102-S) were written for a licensee who immediately moved out of the State. A third registry sheet (MD-327D-101-G) was written for a Maryland licensee acting as the East Coast distributor. The sheet has been rewritten, thereby deleting the West Coast distributor.

6. Licensing Procedures (Category II)

NRC RECOMMENDATION: The RHP should revise their licensing procedures to provide for the routine use of letters to: (a) transmit licenses and amendments; and, (b) bring to management's attention, highlights of license changes or related information.

RHP STATUS: The RHP began using a transmittal letter to forward new licenses and explain MDE annual radioactive materials user fees in July 1994. Beginning on July 1, 1995, transmittal letters have been attached to simple amendments, i.e., the amendment which authorizes the change in the license which the licensee originally requested. This will facilitate communication with licensees and enhance compliance.

7. Technical Quality of Licensing Actions (Category I)

NRC RECOMMENDATION: The RHP should continue its efforts to renew the NPI license to include a clear set of license requirements against which the RHP can assess continued operations at NPI, and against which enforcement action can be taken, if required. We also request that the RHP, as part of its response to this recommendation, include a discussion of the current status of NPI license renewal activities and the steps and schedule for issuance of a renewed license.

The RHP should update and use the most current standard license conditions for the molybdenum-99 breakthrough licensed activity, and reflect the other comments in future licensing actions.

RHP STATUS: NPI's MD-31-025-01 (manufacturing) license was renewed on January 18, 1996. The licensee has requested and been granted an administrative hearing regarding license content. Until resolution of the hearing the licensee is operating under the old license. NPI license MD-31-025-03 (teletherapy service) was renewed on
September 7, 1995. NPI licenses MD-31-025-04 & MD-31-025-05 (irradiator) were renewed on October 16, 1995 and October 26, 1995 respectively.

The RHP has reviewed all license conditions under current NRC guidelines. Specifically, the standard condition for molybdenum-99 breakthrough has been modified to 0.15 microcuries of molybdenum-99 per one millicurie of technetium-99m and will be used on all nuclear medicine and pharmacy licenses when issued or renewed.

8. Inspection Frequency (Category I)

NRC RECOMMENDATION: The RHP should revise the inspection frequency for all afterloader licensees to a one-year inspection frequency.

RHP STATUS: This NRC recommendation was misdirected and should not have been included as a Category I indicator. The RHP revised the inspection frequency for afterloader licensees from a three (3) year frequency to an annual frequency during the NRC's September 1993 review, because NRC guidelines regarding this

inspection frequency change had not been received by the RHP prior to the NRC's review. As emphasized during the March 4, 1994 outbriefing with MDE Secretary Robert Perciasepe, MDE would certainly have implemented this policy sooner, had the NRC provided this information. Please note, however, that all afterloader devices in Maryland were inspected within six (6) months of the issuance of the license and all were within one year of that inspection at the time of the review.

9. Enforcement Procedures (Category I)

NRC RECOMMENDATION: The RHP should continue with implementation of the April 4, 1994 strategic plan for NPI inspection and compliance activities. The RHP should revise and implement enforcement procedures to: (1) address the routine enforcement policy, the use of the Notice of Violations and the MDER-E-1 form; and (2) include use of acknowledgement letter in routine enforcement actions.

RHP STATUS: The RHP has continued with the implementation of the April 4, 1994 strategic plan for NPI inspection and compliance activities. The RHP has revised enforcement procedures to address routine enforcement policy, the use of the Notice of Violations, and the MDE E-1 form. The RHP began issuing acknowledgement letters for routine enforcement actions in March 1994.

10. Inspection Procedures (Category II)

NRC RECOMMENDATION: The RHP should update inspection procedures to reflect current program operations.

RHP STATUS: RHP has revie l existing inspection procedures and revised them accordingly. The review inclu evaluation of NRC guidance regarding inspection procedures and guidelines. The u dated procedures were implemented by November, 1995.

11. Inspection Reports (Category II)

NRC RECOMMENDATION: The RHP should consider the comments identified in Appendix C relating to inspection reports and should ensure that inspection reports receive timely review by the Compliance Supervisor for uniformity and quality control purposes, i.e., soon after the inspection and prior to any enforcement actions.

RHP STATUS: The RHP has considered the comments identified in Appendix C relating to inspection reports and will continue to ensure (as is our present policy) that all inspection reports are received for timely review by the Compliance Supervisor. The Compliance Supervisor will review these for uniformity, accuracy,

and completeness within ten (10) working days of receipt. Routine inspections will require each inspector to complete the report within twenty (20) working days after completion of the inspection. For team inspections, the lead inspector will be required to complete the report within thirty (30) working days after completion of the inspection.

In November, 1995 NRC conducted a follow-up inspection to the 1993 audit. NRC recommendations and RHP's current status is indicated below:

Item 1. Status and Compatibility of Regulations (Category I)

NRC RECOMMENDATIONS:

(1) NRC recommends that the RHP staff address rulemaking for the irradiator rule as soon as possible in order to meet the July 31, 1996 deadline.

(2) NRC recommends that the State revise the "Regulation Adoption Management Plan" to address the points in the letter , specifically to begin rule development sooner and, if the SSRCR has not been developed in parallel with the NRC rule, the State should proceed without the SSRCR.

(3) NRC also recommends that the definition of person be amended to make it explicit that the inclusion of Federal entities in the Maryland definition is limited to that allowed by Federal law.

RHP STATUS:

(1) Maryland regulations specific to NRC's irradiator rule are on track for adoption in November of 1996

(2) RHP is in agreement with NRC's recommended revisions to the "Regulation Adoption Management Plan."

(3) It is RHP's opinion that this issue has been resolved. It is RHP's understanding that the definition of "Person" as found in Section A.2 of COMAR 26.12.01.01 titled, "Regulations for Control of Ionizing Radiation (1994)" is acceptable to NRC. The definition is: "Person" means an individual , receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any partnership, firm, association, corporation, or other entity. "Person" includes any public or municipal corporation and any agency, bureau, department, or instrumentality of state or local government and, to the extent authorized by federal law, federal government.

Item 4. Technical Quality of Licensing Actions (Category I)

NRC RECOMMENDATION:

NRC recommends that the RHP continue to work with Montgomery County in evaluating and approval of the NPI proposal for construction activities which should reduce the unnecessary radiation levels in and around the facility.

RHP STATUS:

On March 18, 1996 a management meeting was held between RHP, NPI and Montgomery County. As a direct result of this meeting, on April 8,1996, RHP approval (with specific conditions) was given to NPI for the construction of a courtyard enclosure. NPI is currently working on detailed engineering plans for submittal to Montgomery County. RHP feels that the construction of this enclosure should significantly reduce radiation levels in and around the facility.

26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems or difficulties which occurred during this review period.

answer: The program has the full support of the Program Administrator. RHP's feels confident that it has fulfilled the MDE mission to insure the safety and protection of occupational workers, members of the general public and the environment. Furthermore, RHP has established an aggressive and effective compliance program. Examples of the above can be seen in enforcement actions specific to NPI, Mallinckrodt Pharmacy and Material Testing Laboratories. The program is currently conducting ongoing evaluations in procedures used for inspections, licensing and investigatory actions. RHP staff time is still being significantly impacted by compliance and licensing overview associated with Neutron Products Inc.

B. NON-COMMON PERFORMANCE INDICATORS

Regulations and Legal Authority

27. Please list all currently effective legislation that affects the radiation control program (RCP).

answer:

Annotated Code of Maryland, Environmental Article, Title 8,"Radiation" and Title 7,"Hazardous Materials and Hazardous Substances"(only those portions that deal with low level waste issues).

Comar 26.12.01.01 titled "Regulations for Control of Ionizing Regulations"
Comar 26.15 titled "Disposal of Controlled Hazardous Substances-Radioactive Hazardous Substances"

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

answer: Regulations have no expiration date. Our procedure is to review the regulations for compatibility and revise the appropriate part of COMAR within the 3 year deadline.

29. Please complete the enclosed table based on NRC chronology of amendments. Identify those that have not been adopted by the State, explain why they were not adopted, and discuss any actions being taken to adopt them.

answer: see chart

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

answer: Regulations for the licensing and radiation safety requirements of irradiators are in the final stages of promulgation and are scheduled to be published in the Maryland Register in 10/96. The proposed regulations have been reviewed by the NRC. Current schedule estimates the date of adoption to be 11/96.

II. Sealed Source and Device Program

31. Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the review period. The table heading should be:

answer:

SS&D Registry Number	Manufacturer, Distributor or Custom User	Type of Device or Source
MD-0113-D-104-G	AdaptiveTechnologies	Thickness/density
MD-0113-D-107-G	Adaptive Technologies	Thickness/density
MD-0113-D-108-G	Adaptive Technologies	Gamma
MD-0113-D-109-G	Adaptive Technologies	Beta
MD-0113-D-110-G	Adaptive Technologies	Beta
MD-0105-D-101-G	Conco Services Corp	Fluorotracer
MD-0263-D-101-G	Environmental Tech	Analytic
MD-0177-D-102-G	Evenlite Inc	Self Luminous Marker
MD-0205-D-101-G	Food Instrument Corp	Fill Gauge
MD-1003-D-101-G	Pettit Applied	Thickness/density
MD-0541-S-101-G	Wallac	LSC sources

32. What guides, standards and procedures are used to evaluate registry applications?

answer:

USNRC Reg Guide 10.10
USNRC Reg Guide 10.11
USNRC Reg Guide 6.9
Policy and Guidance Directive 84-22
ANSI Standards
Workbook from USNRC "Sealed Source and Device Workshop" September 12-5, 1995.

33. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Responses to Incidents and Allegations - A.V.20-23

answer:

Technical Staffing & Training:

7. Two individuals (Nathaniel Owrutsky & Raymond Manley) within the program have been assigned and trained in the review of SS&Ds.

8. N/A

9. N/A

10. Charles R. Flynn

Technical Quality of Licensing Actions:

11. Nucletron amendments will most likely be issued prior to NRC audit (change in safety systems for HDR)

13. Nucletron was allowed to upgrade HDR safety systems prior to amendment of HDRs.

14. N/A Reviewers are using NRC SS&D procedures.

Responses to Incidents and Allegations:

20. Nucletron Corporation (see above)

21. Nucletron Corporation (see above)

22. Nucletron Corporation (see above)

23. NONE

III. Low-Level Waste Program

34. Please include information on the following questions in Section A, as they apply to the Low-level Waste Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6
Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Technical Quality of Inspections - A.IV.16-19
Responses to Incidents and Allegations - A.V.20-23

answer: RHP does not have a Low-level Waste Program. Overview of such areas as decommissioning, NPI radioactive waste storage, licensing of decay in storage, and special projects such as the DLA Curtis Bay clean-up have been generally distributed among staff.

IV. Uranium Mill Program

35. Please include information on the following questions in Section A, as they apply to the Uranium Mill Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6
Technical Staffing and Training - A.II.7-10

Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Technical Quality of Inspections - A.IV.16-19
Responses to Incidents and Allegations - A.V.20-23

answer: N/A

TABLE FOR QUESTION 29.

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Any amendment due prior to 1991. Identify each regulation (refer to the Chronology of Amendments)				
IAEA Compatibility 10 CFR Part 71	9/6/58	9/9/95	Addressed in Section T, of Regulations for Control of Ionizing Radiation (1994)	
Glass Enamel and Glass Frit	9/11/87	9/9/95	Addressed in Section C.3(c)(2)(III)	
Industrial Radiography Surveys	7/16/89	9/9/95	Addressed in Section E.201	
Bankruptcy Filing Notification	2/11/90	9/9/95	Addressed in Section C.31(e)	
Notifications, Reports, and Record of Misadministration	4/1/90	9/9/95	Addressed in Section D.1209	
Well Logging	7/14/90	9/9/95	Addressed in Section W	
Dosimetry Processing	2/12/91	9/9/95	Addressed in Section D.501(c)(II)	
Decommissioning; Parts 30, 40, 70	7/27/91	9/9/95	Addressed in Section C.29	
Emergency Planning; Parts 30, 40, 70	4/7/93	9/9/95	Addressed in Section C.23	
Standards for Protection Against Radiation; Part 20	1/1/94	9/9/95	Addressed in Section D & Section A.2	
Safety Requirements for Radiographic Equipment; Part 34	1/10/94	9/9/95	Addressed in Section E.308	
Notification of Incidents; Parts 20, 30, 31, 34, 39, 40, 70	10/15/94	9/9/95	Addressed in Section D.1202	
Quality Management Program and Misadministrations; Part 35	1/27/95	9/9/95	Addressed in Section G.76	
Licensing and Radiation Safety Requirements for Irradiators; Part 36	7/1/96		proposed Section X	11/96

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Definition of Land Disposal and Waste Site QA Program; Part 61	7/22/96			N/A
Decommissioning Recordkeeping: Documentation Additions; Parts 30, 40, 70	10/25/96	9/9/95	Addressed in Section C.29(f)(3)	
Self-Guarantee as an Additional Financial Mechanism; Parts 30, 40, 70	1/28/97		Not consistent with conclusions reached by Maryland's Legislative Auditors	N/A
Uranium Mill Tailings: Conforming to EPA Standards; Part 40	7/1/97			N/A
Timeliness in Decommissioning Parts 30, 40, 70	8/15/97		No action taken	8/97
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use; Parts 30, 32, 35	1/1/98		No action taken	12/97
Frequency of Medical Examinations for Use of Respiratory Protection Equipment	3/13/98		No action taken	12/97
Low-Level Waste Shipment Manifest Information and Reporting	3/1/98		No action taken	12/97
Performance Requirements for Radiography Equipment	6/30/98		No action taken	12/97
Radiation Protection Requirements: Amended Definitions and Criteria	8/14/98		No action taken	12/97
Clarification of De[illegible] Funding Requirements	11/24/98		No action taken	12/97
10 CFR Part 71: Compatibility with th[illegible] International Atomic Energy Agency	4/1/99		No action taken	12/97
Medical Administration of Radiation and Radioactive Materials.	[illegible]/20/98		No action taken	12/97
Termination or Transfer of Licensed Activities: Recordkeeping Requirements.	[illegible]/16/99		No action taken	12/97

APPENDIX D

LICENSE FILE REVIEWS

File No: 1
Licensee: Esstern Isotopes, Inc. — License No. 03-068-01
Location: Hanover, MD — Amendment No. 0
License Type: Nuclear Pharmacy — Type of Action: NEW
Date Amendment Issued: 4/7/95 — License Reviewers: CRF/NAO

Comments:
a) Checklist not in docket file
b) Ownership verified, not the same name as operator
c) Applicant stated use of certified packages, submitted acceptable response, reviewer asked for more information
d) Application stated use of independent audits by RSO, approved; because another company committed to outside audits, an inspector asked company and reviewer to amend licensee to do the same

File No. 2
Licensee: G.T.T. Incorporated — License No. 31-246-01
Location: Bethesda, MD — Amendment No. 0
License Type: Portable Gauges — Type of Action: NEW
Date Amendment Issued: 4/26/95 — License Reviewers: CRF/NAO

File No. 3
Licensee: K.M.Lindgren, M.D. et al — License No. 31-120-01
Location: Rockville, MD — Amendment No.4
License Type: Nuclear Medicine — Type of Action: Renewal
Date Amendment Issued: 11/27/95 — License Reviewers: NAO/CET

File No. 4
Licensee: PSI, Inc. — License No. 03-036-01
Location: Linthicum, MD — Amendment No. 18
License Type: Portable Gauges — Type of Action: Amendment
Date Amendment Issued: 3/7/96 — License Reviewers: NAO/REM

Comment:
a) Licensee requested extension of renewal preparation time for business reasons. Extension granted, renewal submitted within time extension.

File No. 5
Licensee: Schnabel Engineering Assoc. — License No. 047-141-01
Location: Baltimore, MD — Amendment No. 20
License Type: Portable Gauges — Type of Action: Renewal
Date Amendment Issued: 6/26/96 — License Reviewers: NAO/CET

File No. 6
Licensee: Oncormed, Inc.
Location: Gaithersburg MD
License Type: R & D Laboratory
Date Amendment Issued: 6/26/96
License No. 31-237-01
Amendment No. 2
Type of Action: Amendment
License Reviewers: NAO/CET

Comment:
a) Action requested increases, provided sufficient information to make safety determination

File No. 7
Licensee: Biomedical Research Inst.
Location: Rockville, MD
License Type: R&D Lab
Date Amendment Issued: 8/30/94 & 9/23/94
License No. 31-102-01
Amendment No. 16 & 17
Type of Action: Renew & Amend
License Reviewers: NAO/CRF NAO/CRF

Comment:
a) Waste storage issue separated from renewal, issued upon resolution. Good decision

File No. 8
Licensee: Potowmac Engineers
Location: Capitol Heights, MD
License Type: Portable Gauge
Date Amendment Issued: 10/24/94
License No. 33-131-01
Amendment No. 0
Type of Action: NEW
License Reviewers: CRF/NAO

omments:
a) Registry sheet allows leak test at 1 year, license condition is 6 months.
b) COMAR D.401 allows change of leak test, State does not use option.

File No. 9
Licensee: Campbell & Nolan Assoc.
Location:
License Type: Portable Gauges
Date Amendment Issued: 9/12/96
License No. 25-030-01
Amendment No. 5
Type of Action: Amendment
License Reviewers: NAO/CRF

File No. 10
Licensee: Patriot Mining Co., Inc.
Location: Star City, WV
License Type: Fixed Gauges
Date Amendment Issued: 6/14/95
License No. 23-007-01
Amendment No. 2
Type of Action: Amendment
License Reviewers: NAO/TDF

Comment:
a) Mine in MD, home office in WV

File No. 11
Licensee: Chesapeake Reg. Cancer Ctr.
Location: Mechanicsville, MD
License Type: HDR Afterloader
Date Amendment Issued: 5/31/94
License No. 37-010-01
Amendment No. 0
Type of Action NEW
License Reviewers: NAO/CRF

File No. 12
Licensee: AMVAX, Inc.
Location: Beltsville, MD
License Type: R&D Lab
Date Amendment Issued: 2/21/95
License No. 33-108-01
Amendment No. 6
Type of Action: Renewal
License Reviewers: NAO/CRF

Comments:
a) Deficiency phone call only documented in licensee response
b) Liquid scintillation analyzer doesn't show MDA for wipe results

File No. 13
Licensee: American Red Cross
Location: Baltimore, MD
License Type: Blood Irradiator
Date Amendment Issued: 6/19/95
License No. 07-177-01
Amendment No. 7
Type of Action: Renewal
License Reviewers: NAO/CET

File No. 14
Licensee: Gene Logic, Inc.
Location: Columbia, MD
License Type: R&D Laboratory
Date Amendment Issued: 8/12/96
License No. 27-066-01
Amendment No. 0
Type of Action NEW
License Reviewers:NAO/RKN

File No. 15
Licensee: Wallac
Location: Gaithersburg, MD
License Type: Demonstration of devices
Date Amendment Issued: 8/14/96
License No. 31-071-01
Amendment No. 38
Type of Action: Renewal
License Reviewers: NAO/RKN

Comments:
a) Distribution, manufacturer's service representative
b) No material possessed.

File No. 16
Licensee: GTS Duratek
Location: Beltsville MD
License Type: Radiography
Date Amendment Issued: 9/14/94
License No. 27-059-01
Amendment No. 3
Type of Action: Terminate
License Reviewers: NAO/CRF

Comments:
a) Material transferred to corp. operation in Florida
b) Inspector verified sources moved
c) No records related to personnel or possible public exposure discussed

File No. 17
Licensee: BG&E (Calvert Cliffs) License No. 030-027-01
Location: Lusby MD Amendment No. 16
License Type: Radiography Type of Action: Terminate
Date Amendment Issued: 1/5/95 License Reviewers: CRF/NAO

Comments:
a) Licensee's close-out survey not complete
b) Agency survey doesn't include SN or calibration date of instrument used

File No. 18
Licensee: Med Industry Sys. Consultants License No. 03-022-01
Location: Millersville MD Amendment No. 6
License Type: Service/Leak Test Type of Action: Terminate
Date Amendment Issued: 11/3/95 License Reviewers: NAO/TDF

Comments:
a) Letter states no materials, no action on letter for 1 year
b) No closeout action by Program to verify

File No. 19
Licensee: Engineering Technologies Assoc. License No. 27-045-01
Location: Ellicott City MD Amendment No. 5
License Type: Portable Gauge Type of Action: Terminate
Date Amendment Issued: 4/10/95 License Reviewers: NAO/CRF

Comments:
a) No copy of recipient's license forwarded (MD licensee)
b) No verification all materials transferred

File No. 20
Licensee: Sopha Medical License No. 27-038-01
Location: Columbia MD Amendment No. 16
License Type: Service License Type of Action: Terminate
Date Amendment Issued: 6/10/96 License Reviewers: NOA/CET

Comments:
a) All materials transferred properly
b) Inspected and documented adequately

File No. 21
Licensee: Washington Radiology Assoc.
Location: Bethesda MD
License Type: Nuclear Medicine
Date Amendment Issued: 5/17/96
License No. 31-227-01
Amendment No. 1
Type of Action: Terminate
License Reviewers: NAO/CET

Comments:
a) Materials decayed-in-storage, transferred to another licensee
b) Licensee's closeout survey adequate
c) Program's survey and termination adequate

File No. 22
Licensee: SAIC
Location: Rockville & Gaithersburg MD
License Type: Analytic samples
Date Amendment Issued: 2/8/93
License No. 31-076-01
Amendment No.31
Type of Action : Terminate
License Reviewers:CRF/NAO

Comments:
a) Continuous monitoring through weekly reports from licensee
b) Closeout survey 1/6,21,28/93 summary documented adequately

File No. 23
Licensee: Oboler, Kaufman et al
Location: Silver Spring MD
License Type: Nuclear Medicine
Date Amendment Issued: 10/20/96
License No. 31-121-01
Amendment No. 18
Type of Action: Renewal
License Reviewers: CRF/NAO

Comment:
a) Deficiency phone call not documented

File No. 24
Licensee: St. Agnes Hospital
Location: Baltimore MD
License Type: Nuclear Medicine
Date Amendment Issued: 6/29/95
License No. 07-010-01
Amendment No. 38
Type of Action: Amendment
License Reviewers: TDF/NAO

Comment:
a) Amend deletes Xe-133 rooms since they don't use it. Complete

File No. 25
Licensee: Prince George's County
Location: Upper Marlboro MD
License Type: Portable Gauge
Date Amendment Issued: 4/25/95
License No. 33-109-1
Amendment No.
Type of Action: Renewal
License Reviewers: CRF/NAO

File No. 26
Licensee: Nuclear Imaging Systems, Inc.
Location: Riverdale MD
License Type: Nuclear Medicine
Date Amendment Issued: 7/12/94
License No. 33-130-01
Amendment No. 3
Type of Action: Renew
License Reviewers: CRF/NAO

File No. 27
Licensee: Chektec Corporation
Location: Baltimore
License Type:
Date Amendment Issued: 4/3/95
License No. 07-171-01
Amendment No. 7
Type of Action: Terminate
License Reviewers: CRF/NAO

Comments:
a) Licensee survey adequate
b) Program's inspection timely, no calibration listed on survey document for survey meter

File No. 28
Licensee: Potomac Engineering & Surveying
Location:
License Type: Portable Gauge
Date Amendment Issued: 2/23/95
License No. 23-004-01
Amendment No. 1
Type of Action: Terminate
License Reviewers: NAO/CRF

Comments:
a) No record of action to verify transfer of gauges
b) No closeout survey

File No. 29
Licensee: Isorad Limited
Location: Bethesda MD
License Type:
Date Amendment Issued: 2/5/96
License No. 31-209-01
Amendment No. 2
Type of Action: Terminate
License Reviewers: NAO/CET

Comments:
a) No materials possessed
b) Verified by visit

File No. 30
Licensee: Louisiana-Pacific Corp.
Location: Savage MD
License Type: Fixed Gauge
Date Amendment Issued: 7/23/96
License No. 27-049-01
Amendment No. 4
Type of Action: Terminate
License Reviewers: NAO/CET

Comments:
a) Licensee states returned to manufacturer
b) No record of verification

File No. 31
Licensee: Dames & Moore
Location: Annapolis MD
License Type: Portable Gauges
Date Amendment Issued: 6/5/96
License No. 03-039-01
Amendment No. 8
Type of Action: Terminate
License Reviewers: NAO/CET

Comments:
a) Transferred to another corporate office, not authorized to possess portable gauges on submitted copy.
b) License at recipient office amended prior to actual transfer.

File No. 32
Licensee: Engineering Technologies
Location: Ellicott City MD
License Type: Portable Gauge
Date Amendment Issued: 3/4/96
License No. 027-065-01
Amendment No. 0
Type of Action: NEW
License Reviewers: NAO/CET

Comments:
a) No standard locking condition when not in use, and no locking instruction in Operating & Emergency instructions

File No. 33
Licensee: Engineering Technologies
Location: Ellicott City MD
License Type: Portable Gauges
Date Amendment Issued: 5/7/96
License No. 27-065-01
Amendment No. 1
Type of Action: Terminate
License Reviewers: NAO/CET

Comments:
a) No materials received, no work done, no verification in record

File No. 34
Licensee: H&H X-ray Services, inc.
Location: Baltimore MD
License Type: Radiography
Date Amendment Issued: 10/2/95
License No. 03-047-01
Amendment No.
Type of Action: Terminate
License Reviewers: NAO/TDF

Comments:
a) Letter request, discussion with Co. President, transfer to NRC license.
b) No closeout, no verification

File No. 35
Licensee: Laurel Regional Hospital
Location: Laurel MD
License Type: Nuclear Medicine
Date Amendment Issued: 6/25/96
License No. 33-37-01
Amendment No. 29
Type of Action: Amend
License Reviewers: NAO/CET

File No. 36
Licensee: KCI Technologies
Location: Hunt Valley MD
License Type: Portable Gauge
Date Amendment Issued: 7/11/96
License No. 05-150-01
Amendment No.
Type of Action: Amend
License Reviewers: DKM/CET

File No. 37
Licensee: Dames & Moore
Location: Annapolis MD
License Type: Portable Gauge
Date Amendment Issued: 9/13/96
License No. 31-245-01
Amendment No. 4
Type of Action: Amend
License Reviewers: DKM/CET

File No. 38
Licensee: Oncology Center at Riverside
Location: Belcamp MD
License Type: HDR Afterloader
Date Amendment Issued: 5/3/94, 11/15/95, and 1/3/96.
License No. 25-026-01
Amendment No. 0; 1; 2
Type of Action: NEW, Amend
License Reviewers: CRF/NAO, NAO/TDF, NAO/CET

Comments:
a) Content of original application was Omnitron information
b) Amend 1 provides information on Nucletron installed device
c) Amend 2 authorizes move with letter

File No. 39
Licensee: Mid-Atlantic Isotopes
Location: Baltimore MD
License Type: Nuclear Pharmacy
Date Amendment Issued: 10/12/95
License No. 05-148-01
Amendment No. 0
Type of Action: NEW
License Reviewers: NAO/TDF

Comments:
a) Licensee submitted full re-application after deficiency letters
b) License condition requires submission of proposed changes, does not require approval prior to implementation
c) Person to do internal audits not specified, no frequency specified, see Standard Review Plan.

File No. 40
Licensee: Univ. of MD (Environmental Safety)
Location: College Park MD
License Type: Broad Scope
Date Amendment Issued: 8/29/96
License No. 33-004-01
Amendment No. 100
Type of Action: Amend
License Reviewers: NAO/CET

APPENDIX E

INSPECTION FILE REVIEWS

File No.: 1
Licensee: University of Maryland at Baltimore License No. 07-014-05
Location: Baltimore, MD Inspection Type: Routine, unannounced, follow-up
License Type: Gamma Knife Priority: Annual
Inspection Date: 06/11/96 Inspector: RN

Comment:
a) Report doesn't identify what was reviewed to correct previous item of non-compliance
b) Radiation Safety Committee meeting minutes not reviewed

File No.: 2
Licensee: Terumo Medical Corporation License No. 15-007-02
Location: Elkton, MD Inspection Type: Routine, unannounced
License Type: Irradiator Priority: Annual
Inspection Date: 06/25-26/96 Inspectors: RN/AJ

Comment:
a) Separate interviews not held with management to determine program involvement.

File No.: 3
Licensee: NW Radiation Oncology Center License No. 05-034-02
Location: Randallstown, MD Inspection Type: Routine, unannounced, follow-up
License Type: HDR Priority: Annual
Inspection Date: 06/27/96 and 07/03/96 Inspector: FK

Comment:
a) Field note descriptions not indicative of a performance-based inspection in that the licensee demonstrations or walk-throughs not identified for radiation detectors, interlocks, afterloader operation, or emergency alarms.
b) Emergency drills described as conducted quarterly, but drill dates not shown.
c) Inspector measurements were 11 mR/hr outside, but no follow-up with licensee or violation issued.
d) Report does not indicate whether license or program changes were made since the last inspection.
e) Methodology to implement ALARA program not shown in field notes.

File No.: 4
Licensee: University of Maryland at Baltimore License No. 07-014-05
Location: Baltimore, MD Inspection Type: Routine, unannounced, follow-up
License Type: Gamma Knife Priority: Annual

Inspection Date: 06/23/95 Inspector: RM

Comment:
a) Unable to determine from report involvement of Radiation Safety Committee.

File No.: 5
Licensee: MKM Engineers License No. 27-064-01
Location: Columbia, MD Inspection Type: Initial, unannounced
License Type: Gauge (portable) Priority: 4
Inspection Date: 05/16-17/96 Inspector: LR

Comment:
a) Cannot determine whether employee interviews were conducted.
b) Licensee response to NOVs - enclosures of leak test results, survey meter procurement, and security measures not in file.
c) Item of non-compliance for not maintaining usage logs identified during inspection but not included in enforcement letter.

File No.: 6
Licensee: Syncor International Corporation License No. 33-061-01
Location: Lanham, MD Inspection Type: Routine, unannounced
License Type: Pharmacy Priority: A
Inspection Date: 04/12-13/95 Inspector: RN

Comment:
a) Report does not differentiate between items of non-compliance and recommendations.
b) Cannot determine how previous items of non-compliance were corrected.
c) E-1 form does not identify non-compliance items.

File No.: 7
Licensee: Ravinder Singh, M.D. License No. 33-064-01
Location: Greenbelt, MD Inspection Type: Routine, announced, follow-up
License Type: Priority: 4
Inspection Date: 04/11/96 Inspector: FK

Comment:
a) Independent measurements inc. only one smear sample.

File No.: 8
Licensee: Nucletron Corporation License No. 27-035-01
Location: Columbia, MD Inspection Type: Announced, follow-up

License Type: Service/Mfg
Inspection Date: 02/07/96

Priority: A
Inspector: RM

Comment:
None

File No.: 9
Licensee: Calvert Memorial Hospital
Location: Prince Frederick, MD
License Type: Nuclear Medicine
Inspection Date: 03/21/96

License No. 09-003-01
Inspection Type: Unannounced, follow-up
Priority: 3
Inspector: RN

Comment:
None

File No.: 10
Licensee: Bon Secours Hospital
Location: Baltimore, MD
License Type: Nuclear Medicine
Inspection Date: 02/28/96 and 03/05/96

License No. 07-002-01
Inspection Type: Routine, unannounced
Priority: 3
Inspector: FK

Comment:
None

File No.: 11
Licensee: Washington County Hospital Assn.
Location: Hagerstown, MD
License Type: Nuclear Medicine - HDR
Inspection Date: 02/06-07/96

License No. 43-001-03
Inspection Type: Routine, unannounced, follow-up
Priority: 1
Inspector: FK

Comment:
None

File No.: 12
Licensee: Greater Baltimore Medical Center License No. 05-002-03
Location: Baltimore, MD Inspection Type: Routine, unannounced, follow-up
License Type: Brachytherapy Priority: 3
Inspection Date: 01/23-24/96 Inspector: RM

Comment:
a) Complete, thorough inspection

File No.: 13
Licensee: Eastern Isotopes, Inc. License No. 03-068-01
Location: Hanover, MD Inspection Type: Initial, unannounced follow-up
License Type: Pharmacy Priority: 1
Inspection Date: 10/03/95 Inspector: RN

Comment:
a) No indication in report whether independent measurements included smear samples.

File No.: 14
Licensee: Duebriss Hospital of PG County License No. 33-029-01
Location: Lanham, MD Inspection Type: Routine, unannounced follow-up
License Type: Hospital Priority: 3
Inspection Date: 07/18-19/95 Inspector: FK

Comment:
a) Report indicates previous non-compliance items "corrected" but does not indicate information or operations reviewed.
b) No acknowledgement letter in response to licensee's enforcement letter from previous inspection.
c) Lab results report only one wipe sample taken.

File No.: 15
Licensee: ATEC Assoc License No. 27-005-01
Location: Columbia, MD Inspection Type: Routine, unannounced follow-up
License Type: Portable Gauges Priority: 4
Inspection Date: 06/19/95 Inspector: AJ

Comment:
None

File No.: 16
Licensee: Guilford Pharmaceuticals, Inc. License No. 07-186-01

Location: Baltimore, MD Inspection Type: Initial, unannounced, follow-up
License Type: Research and Development Priority: 4
Inspection Date: 04/30/96 Inspector: AJ

Comment:
a) License terminated and survey performed after April 96 inspection but license not amended.

In addition, the following inspection accompaniments were made as part of the on-site IMPEP review:

Inspection Accompaniments

Accompaniment No. 1
Licensee: Terumo Medical Corporation License No. 15-007-02
Location: Elkton, MD Inspection Type: Routine, unannounced
License Type: Irradiator Priority: Annual
Inspection Date: 06/25-26/96 Inspectors: RN(lead)/AJ

Good, complete performance-oriented inspection of licensee operations. Inspection consisted of licensee walkthroughs of scheduled (daily, weekly, monthly, quarterly, and semi-annual) surveillances.
Inspector well-prepared and demonstrated proficiency to direct and lead inspection effectively.
Verification of worker training not fully confirmed through interviews.
Safety issues adequately covered.

Accompaniment No. 2
Licensee: Prince Georges Hospital Center License No. 33-003-01
Location: Cheverly, MD Inspection Type: Routine, unannounced
License Type: Medical Priority: 3
Inspection Date: 07/16-17/96 Inspectors: FK

Inspection preparation did not include interview of RSO or opportunity to observe I-131 therapy procedure.
No follow-up or discussion with licensee about corrective actions taken in response to 1994 incident.
Radiation surveys and wipe samples not taken in waste holding or material storage (loading dock) areas.
Interviews with nursing staff treating therapy patients not performed.
Last inspection conducted 1993 but personnel dosimetry records, dose calibrator records, waste shipments, and leak test records reviewed only for previous year.
Field notes used as reference to identify inspection areas.

Accompaniment No. 3
Licensee: Medi-Physics, Inc. License No. 31-222-01
Location: Cheverly, MD Inspection Type: Routine, unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 08/07/96 Inspectors: AJ

Inspector demonstrated thorough control over inspection activities.
Preparation and inspection plan complete.
Licensee requested to demonstrate acceptability of various procedures including equipment reliability and engineering controls.
Wipe samples not taken in all areas where radioactive materials used.
Information clearly communicated to licensee during inspection and at exit interview.

Accompaniment No. 4
Licensee: North American Inspection Co. NRC License No. 37-23370-01
Location: Cheverly, MD Inspection Type: Routine, unannounced, under reciprocity
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 09/19/96 Inspectors: FK

Inspection concentrated on review of licensee documentation and recordkeeping; observation of licensee operations very limited.
Area radiation survey not taken in all directions while source exposed.
Exposure rate to non-rad workers in immediate area not determined.
Inventory of radiography cameras verified.
Personnel dosimetry for assistant radiographer not checked.
Inspector unable to readily identify radiation exposure limits in unrestricted areas per COMAR 26.12.01, Section D.301 (equivalent to 10 CFR 20.1301) and discuss concerns with licensee.
Ancillary worker (site foreman) not consulted or interviewed to determine knowledge of site operations.

APPENDIX F

MARYLAND INCIDENT FILES REVIEWED

File No. 1
Licensee: Nucletron Oldelft Corp. (Mallincrodt Medical)
Location: BWI Airport
License #: MD27-035-01
Date of Event: 05/28/96
Type of Event: Transportation
Summary of Incident: Package containing a 9.74 Ci Ir-192 sealed source, shipped from Mallinckrodt Medical in Holland with Nucletron as shipper of record, was received at BWI Airport in damaged condition with survey readings of 45 mR/hr. MD RAM and HAZMAT team responded and performed cleanup and recovery.

File No. 2
Licensee: Nucletron Oldefit Corp.
Location: Memorial Medical Center, Springfield, IL
License#: MD27-035-01
Date of Event: 02/01/96
Type of Event: Equipment failure
Summary of Incident: Nucletron HDR console malfunctioned during patient treatment. Computer froze and source failed to return to shielded position. Attending physician entered room and started emergency hand crank which retracted source. Generic problem identified and State requested Nucletron to modify design with hardware change to hardwire unit to console and revise software program. Nucletron is currently making the changes to all service customers.

File No. 3
Licensee: ATEC Associates, Inc.
Location: Baltimore-Washington International airport light rail jobsite
License #: MD31-189-01
Date of Event: 07/18/96
Type of Event: Lost/Stolen RAM
Summary of Incident: Troxler gauge stolen from BWI light rail jobsight. Persons broke into house next door to jobsight where gauge kept in a case in locked basement. Gauge recovered as a result of State issued Press Release.

File No. 4
Licensee: N/A
Location: Bresco Solid Waste Plant, Baltimore, MD
License #: N/A
Date of Event: 07/19/96
Type of Event: Release of RAM
Summary of Incident: Trash truck and driver set off radiation alarm at entrance to solid waste plant. Investigation concluded there was no contamination or loss of RAM; the Bresco plant's radiation monitors malfunctioned. Monitors sent for repair.

File No. 5
Licensee: John Hopkins Hospital
Location: Baltimore, MD
License #: MD07-005-03
Date of Event: 07/23/96
Type of Event: Medical Event
Summary of Incident: A brachytherapy interstitial implant catheter containing 30 mCi of ten Ir-92 seeds, 0.3 mCi ea., dislodged during patients treatment resulting in an underdose of approximately 7.6% less than prescribed. Ongoing investigation into unauthorized entry of the public into a restricted treatment area, and to determine if patient intervention caused the source to dislodge.

File No. 6
Licensee: Rad America
Location: Baltimore, MD
License #: MD05-051-01
Date of Event: 08/96
Type of Event: Equipment or Procedure Failure
Summary of Event: A teletherapy machine malfunctioned by sticking "on," at end of treatment for patient scheduled to receive fractionated treatments of 50 rad of Co-60, resulting in a 50 rad overdose, with dose to be adjusted during next four treatments. A nurse attendant manually closed the source by turning hand crank, and received approximately 200 mR to hand (less than 1.5 rem).

File No. 7
Licensee: Laurel-Beltsville Hospital
Location: Montgomery Co. Solid Waste Transfer, Rockville, MD
License #: MD33-037-01
Date of Event: 08/05/95
Type of Event: Release of RAM
Summary of Incident: "Hot trash" set off radiation monitor at waste transfer station. County office building trash had been contaminated by county employee who had recently received 8-12 millicuries of I-131 during thyroid therapy treatment at Laurel-Beltsville Hospital.

File No. 8
Licensee: Sacred Heart Hospital
Location: Cumberland, MD
License #: MD01-002-02
Date of Event: 04/13/94
Type of Event: Lost/abandoned RAM
Summary of Incident: Discarded lead pig and vial containing radioactive label found on local street in Cumberland, MD by Columbia Gas Co. representative. Through investigation State found that the hospital failed to follow standard disposal procedures.

File No. 9
Licensee: MD State Highway Administration
License #: MD05-049-01
Date of Event: 01/25/95
Type of event: Lost stolen RAM
Summary of Incident: Troxler moisture/density gauge stolen overnight from locked field site trailer. Press release issued by State.

File No. 10
Licensee: MD Dept. of Transportation
License #: N/A
Date of Event: 07/31/95
Type of Event: Damaged to Equipment
Summary of Incident: During road work Troxler thin layer asphalt gauge containing 8mCi Cs-137 sealed source, hit and run over by auto., which left source laying unshielded in road. Washington Beltway closed for 2.5 hrs. during recovery and cleanup.

APPENDIX G

SEALED SOURCE AND DEVICE EVALUATION REVIEWS

File No.: 1
Registry No.: MD-0263-D-101-G
Manufacturer: Environmental Technologies Group, Inc.
SS&D Type: Ion Mobility Spectrometry Cell
Date Issued: 12/16/94

Comments:
a) First page of registry sheet was amended dated 12/16/94.
b) No information in file as to the reason the registry sheet was amended. On comparison to previous sheet, a different company was identified as the distributor. Manufacturer is now listed as distributor.
c) Last sheet of registration not reissued to indicate a change in references.
d) No supervisor or reviewer signature supporting the amendment.
e) Single reviewer.

File No.: 2
Registry No.: MD-0105-D-101-G
Manufacturer: Conco Services Corporation
SS&D Type: Fluorotracer analyzer
Date Issued: 6/6/95

Comments:
a) This is a request for a name change due to a company reorganization. The registry sheet was reissued under the new name.
b) Licensee supplied a new diagram for the registry sheet containing one hydrogen valve versus the two valves on diagram with previous registry sheet. No evaluation of the impact of the design was documented in the file.
c) Original registry sheet issued in 1986. Although this is a low risk device, no safety product evaluation or discussion of quality assurance program was requested during this reissuance of the registry sheet.
d) Single reviewer.

File No : 3
Registry No.: MD-1003-D-101-G
Manufacturer: Pettit Applied Technologies
SS&D Type: Thickness/density gauge
Date Issued: 7/11/96

Comments:
a) Diagram attached to the registry sheet is marked confidential.
b) This is a similar device manufactured by a different company, where the president was previously employed. For this new license, the licensee is should be required to submit more comprehensive manufacturing QA/QC program. The licensee was required to manufacture and distribute devices according the approved certificate through commitment made and the tie down license condition.

c) Although only the manufacture can perform source changes per information in the backup documentation, information regarding limitations of use on the registry sheet should be revised to indicate the radiation source will be installed or removed by the manufacturer.

File No.: 4
Registry No.: MD-0113-D-107-G
Manufacturer: Adaptive Technologies, Inc.
SS&D Type: Thickness/density gauge
Date Issued: 6/3/94

Comments:
a) Single reviewer performed review.
b) No documentation in the file on protype testing or QA manual. Note, this device was similar to devices manufactured previously by this company and appears to not been treated as new device. Older devices manufactured by this company have little information on the QA/QC program.

File No.: 5
Registry No.: MD-0113-D-108-G
Manufacturer: Adaptive Technologies, Inc.
SS&D Type: Gamma gauge
Date Issued: 7/12/94

Comments:
a) Single reviewer performed review.
b) No documentation in the file on protype testing or QA manual. Note, this device was similar to devices manufactured previously by this company and appears to not been treated as new device. Older devices manufactured by this company have little information on the QA/QC program.

File No.: 6
Registry No.: MD-0113-D-110-G
Manufacturer: Adaptive Technologies
SS&D Type: Beta gauge
Date Issued: 7/1/96

Comments:
a) Second review performed, but not documented.
b) No documentation of response to 6/26/96 deficient letter on request for Quality Assurance Manual.

File No.: 7
Registry No.: MD-497-D-104-S
Manufacturer: Nucletron Corporation
SS&D Type: Remote Afterloading brachetherapy unit
Date Issued: under review

Comments:
a) One of the reference documents was not listed in the draft certificate.
b) No response to deficiency letter dated 5/24/96 in the file.