UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

March 3, 1995

Ms. Jane Nishida, Secretary Designee
Maryland Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

Dear Ms. Nishida:

This is to transmit the results of the NRC review and evaluation of the Maryland Radiological Health Program (RHP), conducted by Mr. Richard Woodruff, NRC Regional State Agreements Officer, Region II, Mr. Craig Gordon, NRC Regional State Agreements Officer, Region I, and other members of the NRC staff. The review was conducted on August 30 - September 4, 1993, and additional follow-up activities were conducted at selected times through April 7, 1994.

As a result of our review of the RHP and the routine exchange of information between the NRC and the State, NRC staff has determined that the State's program for regulating agreement materials is, at this time, adequate to protect the public health and safety. However, a finding of compatibility continues to be withheld because 13 regulations have not been adopted within the three-year period required by the NRC.

Although we find the Maryland program adequate, at this time, to protect the public health and safety, we are concerned that the continued delay in the adoption of 13 regulations required for compatibility places the Maryland program in a position where its regulatory requirements are in some respects significantly less restrictive than those of NRC and other Agreement State programs. The Maryland radiation control program has had a compatibility finding withheld since 1986 and has experienced difficulty in adopting regulations since 1975. This concern, as discussed further below, coupled with the need to address a number of comments and recommendations in other significant Category I program areas, emphasizes the need for prompt action by the State of Maryland.

Of particular concern among these overdue regulations is a rule equivalent to NRC's major revision of 10 CFR Part 20, "Standards for Protection Against Radiation." This regulation was to have been adopted by Agreement States on or before January 1, 1994. Nearly all of the 29 Agreement States have adopted these standards. The failure of Maryland to adopt the 10 CFR Part 20 equivalent regulation is a serious omission because 10 CFR Part 20 contains basic radiation protection standards. Further delays could adversely affect the NRC's finding as to the adequacy of the State's program to protect public health and safety. The State should provide the necessary resources to address the concerns in the radiation control program and to maintain its overall program, including the adoption of regulations equivalent to 10 CFR Part 20.

We have identified, below, the need for the Maryland radiation control program to provide specific responses to comments and recommendations and the need in some cases to develop specific milestones and schedules for completion of actions in particular program areas. These include program plans for renewal of the Neutron Products Inc. (NPI) license and for adoption of final regulations. We stress the need for the State to provide the necessary resources to address comments and recommendations in the Category I program areas and to maintain its overall program, including the adoption of regulations equivalent to 10 CFR Part 20.

Because of their significance, these comments and recommendations will be brought to the attention of the Governor of Maryland in separate correspondence requesting his attention and support for the actions needed to adopt the 13 regulations needed for compatibility. We will be pleased to meet with you to discuss these comments and recommendations. In addition, following receipt of your response to this letter, we plan to conduct a follow-up review of the Maryland program in approximately six months to determine the status of actions being taken to improve the program in the identified areas and reevaluate our findings with respect to the adequacy and compatibility of the Maryland program.

Status and compatibility of regulations is a Category I Indicator. Those regulations deemed a matter of compatibility by the NRC should be amended by the State as soon as practicable but no later than three years from the date of NRC rule promulgation. Maryland has not yet adopted the following NRC regulations deemed matters of compatibility:

- "Rule to Achieve Compatibility with the Transport Regulations of the International Atomic Energy Agency (IAEA)," 10 CFR Part 71 amendments (48 FR 35600) that became effective on September 6, 1983 and were to be adopted by September 6, 1986.

- "Glass Enamel and Glass Frit Containing Small Amounts of Uranium," 10 CFR Part 40 amendments (49 FR 35611) that became effective on September 11, 1984 and were to be adopted by September 11, 1987.

- "Industrial Radiography Surveys and Licensee's Performance Inspection Program," 10 CFR Part 34 amendments (51 FR 21736) that became effective on July 16, 1986 and were to be adopted by July 16, 1989.

- "Bankruptcy Filing Notification," 10 CFR Parts 30, 40, 61, and 70 amendments (52 FR 1292) that became effective on February 11, 1987 and were to be adopted by February 11, 1990.

- "Notifications, Reports and Record of Misadministrations" 10 CFR Part 35 amendments (51 FR 36932) that became effective on April 1, 1987 and were to be adopted by April 1, 1990. (These requirements have been replaced by the Quality Management Rule (56 FR 34104) which was due by January 1995.)

- "Licenses and Radiation Safety Requirements for Well Logging," 10 CFR Parts 19, 20, 21, 30, 39, 40, and 70 amendments (52 FR 8225) that became effective on July 14, 1987 and were to be adopted by July 14, 1990.

- "Improved Personnel Dosimetry Processing," 10 CFR Part 20 amendments (52 FR 4601) that became effective on February 12, 1988 and were to be adopted by February 12, 1991.

- "General Requirements for Decommissioning Nuclear Facilities," 10 CFR Parts 30, 40, and 70 amendments (53 FR 24018) that became effective on July 27, 1988 and were to be adopted by July 27, 1991.

- "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70 amendments (54 FR 14051) that became effective on April 7, 1990 and were to be adopted by April 7, 1993.

- "Standards for Protection Against Radiation," 10 CFR Part 20 amendments (56 FR 61352) that became effective on June 20, 1991 with delayed implementation of January 1, 1994 and were to be adopted by January 1, 1994.

- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991 and were to be adopted by January 10, 1994.

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) that became effective on October 15, 1991 and were to be adopted by October 15, 1994.

- "Quality Management Program and Misadministrations", 10 CFR Part 35 amendments (56 FR 34104) that became effective on January 27, 1992 and were to be adopted by January 27, 1995.

In addition, NRC identified an unresolved compatibility item in the low-level waste regulations adopted by the Department's Hazardous Waste Division which is not compatible with the definition of "person" in 10 CFR 150.3(g). This concern was described in our letter dated November 20, 1992, from C. Kammerer, Director, Office of State Programs, to D. L. Miles Brown, Regulations Coordinator, Maryland Department of the Environment.

The NRC requests the submittal of a management plan for eliminating the current rulemaking backlog. The State should submit the plan together with a schedule for adoption of the revisions to the regulations in response to this letter.

Nearing completion of our program review, we presented initial staff recommendations to Mr. David Carroll at an exit meeting held on March 4, 1994. At that time, the NRC staff recommended the withholding of a finding that the Maryland program for the regulation of agreement materials is adequate to protect the public health and safety due to incomplete sealed source and

device (SS&D) casework evaluations, and the need to consider enforcement action to address inspection findings resulting from the joint State and NRC inspection of NPI.

Subsequent to the review, NRC staff evaluated action plans specifically developed by RHP staff to address deficiencies related to the SS&D program and NPI enforcement activities. Based upon our assessment of the SS&D action plan and efforts by RHP staff to update incomplete files, the Category I Indicator, Adequacy of Product Evaluations, is satisfied. As part of that action plan, Mr. Carroll committed to obtain manufacturer information regarding the Nucletron high dose rate (HDR) afterloader which supports the State's design review. We ask that you provide, in response to this letter, information on the status of the State's review.

In late 1993, NRC assisted the State in an inspection of the NPI facility which included an aerial radiological survey. Following settlement of the NPI court case, your staff coordinated with NRC to provide additional information about future NPI licensing, inspection, and enforcement strategies. The court settlement and NPI action plan have helped clarify our understanding of the State's regulation of NPI, and we find the State's current NPI oversight to adequately satisfy the Enforcement Procedures Category 1 Indicator. We emphasize the need to continue your efforts to renew the 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. We request that you include, as part of your response to this letter, a discussion of the current status of license renewal activities and the steps and schedule for issuance of a renewed license.

Please note that there has been a change in the format of this letter from our previous review letters. This letter summarizes the findings regarding all 30 program indicators as opposed to only discussing those indicators where deficiencies were noted. Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the review findings where recommendations are made for program improvements. We request specific written responses from the State on the recommendations in Enclosure 2 within 30 days of this letter. We recognize the delay in our issuance of this letter due, in part, to the complex nature of the review and areas covered; if you require more than 30 days to respond, please let us know.

Enclosure 3 presents a summary of the review findings where the State has adequately satisfied the indicator. A written response to the items in Enclosure 3 is not required.

We appreciate your cooperation with this office and the courtesy and cooperation extended by your staff to Mr. Woodruff, Mr. Gordon and the other NRC representatives during the review.

Sincerely,

Richard L Bangart

Richard L. Bangart, Director
Office of State Programs

Enclosures: As stated

cc w/encls:
Governor Parris Glendening
R. Nelson, Deputy Secretary, Maryland
Department of the Environment
R. Fletcher, Administrator,
Radiological Health Program
Merrylin Zaw-Mon, State Liaison Officer

Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs" were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories.

Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need for improvement in a particular program area(s) is critical. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period.

The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Act, as amended.

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND NRC COMMENTS FOR
THE MARYLAND RADIATION CONTROL PROGRAM
MARCH 28, 1991 TO APRIL 7, 1994

SCOPE OF REVIEW

The 19th program review of the Maryland Agreement State program was conducted during the period of August 30, 1993 - September 4, 1993 in Baltimore, Maryland, with follow-up visits on September 22 and 28, 1993, a follow-up review of the sealed source and device regulatory program on January 31, 1994, and other follow-up activities through April 7, 1994. The program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992 and the internal procedures established by the Office of State Programs. The State's program was reviewed against the 30 program indicators provided in the policy statement.

A questionnaire containing the 30 indicators with specific questions addressing each indicator was sent to the State prior to the review. This review included the evaluation of the State's written response to the questionnaire, comparison with previous review information, review of the State's policies and procedures, discussions with the program managers and staff members, review team observations, licensing and inspection casework file reviews, and an inspector accompaniment. The review also included a comprehensive evaluation of the sealed source and device (SS&D) program and an NRC assisted State inspection and aerial fly-over of the Neutron Products, Inc. (NPI) facility on October 18-22 and November 1-12, 1993. NRC also evaluated the effectiveness of the State's actions to complete development of regulations, to improve program weaknesses identified during previous reviews, and to determine the current status of the State's program. NRC comments on proposed changes to Maryland regulations needed for compatibility were provided to the Radiological Health Program (RHP) on June 22 and November 14, 1994.

The State was represented by Mr. Roland Fletcher, Administrator, Radiological Health Program and his staff. The NRC was represented by Richard Woodruff, State Agreements Officer, Region II, Team Leader; Craig Gordon, State Agreements Officer, Region I, Team Coordinator and performed the inspector field accompaniment; Steven Baggett, Section Leader, Office of Nuclear Material Safety and Sageguards (NMSS), performed SS&D evaluations; James Dwyer, Sr., Health Physicist, Region I, reviewed license files; Thomas Rich, Mechanical Engineer, NMSS, reviewed SS&D evaluations; and Janet Schleuter, Health Physicist, NMSS, review of misadministrations and Abnormal Occurrence Reports (AOR). In addition, the following persons assisted in the review of NPI: Charles Norelius, Special Assistant, NMSS; Robert Bores, Chief, Facilities Radiation Protection Section, Region I; Amarendranath Datta, Fire Protection Specialist, NMSS; James Kottan, Chemist, Region I; and Wayne Slawinski, Sr., Health Physicist, Region III.

On March 4, 1994, a summary meeting regarding the results of the review was held with David Carroll, Secretary, Maryland Department of the Environment (MDE), Ron Nelson, Deputy Secretary, MDE, Merrylin Zaw-Mon, Director, Air and

Radiological Health Program. On April 7, 1994, a follow-up meeting was held with Ms. Zaw-Mon and RHP staff to discuss the State's enforcement strategy relative to NPI oversight.

CONCLUSION

As a result of our review of the Maryland Radiation Control Program and the routine exchange of information between the NRC and the State, NRC staff has determined that the State's program for regulating agreement materials is, at this time, adequate to protect the public health and safety. However, a finding of compatibility continues to be withheld because 13 regulations have not been adopted within the three-year period required by the NRC, and the definition of "person" in the low-level radioactive waste regulations is not consistent with the NRC definition.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

A. 1992 Review Visit

The issue addressed in the following comment has not been satisfactorily resolved and remains open.

1. Status and Compatibility of Regulations (Category I)

Guideline Statement

For those regulations deemed a matter of compatibility by the NRC, State regulations should be amended as soon as practicable, but no later than three years.

Comment and Recommendation from the 1992 Review Visit

The State was very active in developing a draft of low-level radioactive waste regulations. NRC had numerous discussions with the RHP staff while preparing the regulations. A copy of the revised draft was almost complete and ready for NRC review. Other regulations did not meet a promised deadline, but the staff was actively preparing a draft. Approximately 25% revised, it was expected to be completed in October 1992. During the 1991 routine review, we recommended that the State continue to process low-level radioactive waste amendments and prepare a complete revision to its radiation control regulations.

Present Status

During the September 1993 review, NRC follow-up on status of regulations found that the RHP was responsible for the drafting of all regulations involving radioactive materials with the exception of rules governing low-level radioactive waste. Low-level radioactive waste regulations were developed through the Department of the Environment's Hazardous Waste Division.

A notice of final action for the low-level radioactive waste regulations was published in the Maryland Register in October 1993. This was the last step in the adoption process. The September 1993 NRC staff review of the final low-level waste regulations identified one area which needed resolution. The State's definition of "person" is not consistent with 10 CFR 150.3(g) for exclusion of Federal government agencies and should be changed (letter dated November 20, 1992 from C. Kammerer to D. L. Miles-Brown, Maryland Department of the Environment).

During the September 1993 program review, NRC staff was informed by Maryland that the regulations necessary for compatibility had been assigned concurrently to different members of the RHP staff for drafting. The list of these regulations is shown below under the Indicator: "Status and Compatibility of Regulations." Drafting also was assigned for the "Quality Management Program and Misadministrations" (QM) rule which needs to be adopted by January 27, 1995. The Conference of Radiation Control Program Directors' (CRCPD) "Suggested State Regulations" (SSR) were used as guidance for format and content of the Maryland regulations. As discussed below under the Indicator: "Status and Compatibility of Regulations," NRC staff has completed review of all proposed regulations and has provided comments to the RHP for use in preparing final rules for adoption. A specific recommendation that the State complete adoption of these regulations is also offered under this indicator.

b. 1991 Routine Program Review

The following items were identified during the 1991 routine program review and evaluated by NRC in the 1992 review visit. These items were adequately addressed by Maryland and are considered closed.

1. Training (Category II)

Prior to 1991, RHP experienced problems in recruiting trained, qualified radiation protection staff and did not take advantage of NRC sponsored courses.

Present Status

During the 1992 visit, the RHP staff were stable and were able to attend NRC training courses. At that time, no further difficulties were noted in this area. During the current review, RHP staff were found to be fully qualified; however, NRC reviewers recommended cross training of staff in sealed source and device reviews and additional training in evaluating exposures resulting from the inhalation or ingestion of radioactive materials in accordance with the revisions to Maryland's 10 CFR Part 20 equivalent regulation.

2. Staff Continuity (Category II)

NRC found low salary levels and recruitment problems.

Present Status

The State subsequently revised its salary classification schedule to provide higher levels for health physicists and allow staff promotions. The current review showed this guideline to be met in that senior members remained on staff and a full time entry-level position was added and filled.

3. Status of Inspection Program (Category I)

At the time of the review period 89 licenses (most lower priority) were overdue for inspection. NRC recommended the State carefully monitor the inspection backlog.

Present Status

During the 1992 visit, the backlog was reduced, and no high priority inspections were found to exceed the overdue inspection guideline. However, the effects of NPI on the inspection program were noted to continue. In the current review, NRC found the Status of Inspection Program guideline to be satisfied.

CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 program indicators were reviewed and the State fully satisfied 19 of 30 indicators. Specific areas in need of improvement were identified in Maryland's ability to adopt compatible regulations, conduct SS&D evaluations, and to take enforcement action to address inspection findings resulting from the joint State and NRC inspection of Neutron Products, Inc. Other recommended areas for improvement are also identified below. A questionnaire containing the 30 policy guideline indicators with specific questions addressing each indicator was sent to the State prior to the review. The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the program managers and staff members, NRC review team observations, review of the State's policies and procedures, and licensing and inspection casework file reviews.

1. Status and Compatibility of Regulations (Category I)

NRC Guidelines

The State should adopt regulations to maintain a high degree of uniformity with NRC regulations. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable, but no later than three years after the effective date.

Assessment

For a number of years, NRC has expressed concern with Maryland's inability to adopt regulations which are a matter of compatibility. Acknowledgement of NRC's concerns by the RHP Administrator, and the Secretary, Maryland Department of the Environment, was noted in discussions and correspondence between NRC and State staff. Following the 1992 visit, a letter dated September 16, 1992 was issued to the Administrator, RHP, identifying the slow progress which continued in completing the development process for several regulations. Included were rules covering Part 20, low-level waste, decommissioning, emergency planning, well logging, and quality management program for medical uses.

In the current review period, NRC staff evaluated the status of regulations. The RHP was responsible for the drafting of all regulations involving radioactive materials with the exception of rules governing low-level waste. NRC was informed by Maryland that all regulations necessary for compatibility had been assigned concurrently to a 3-member task committee in the RHP staff for drafting. Maryland's process for rule adoption involves several steps requiring coordination between RHP staff, the Attorney General's Office, and other affected staff in the Maryland Department of the Environment.

On September 1, 1993, the reviewers met with Mr. Fletcher and Ms. Zaw-Mon, to discuss our review of the Maryland Program. During the discussions, the reviewers suggested that some additional administrative support could be utilized by Mr. Fletcher for the initial drafting and codification of regulations prior to technical review. Ms. Zaw-Mon was receptive to this suggestion.

On November 12, 1993, Maryland provided NRC an accelerated schedule for completion of the final regulations. This included the following series of actions: draft issued to RHP staff and NRC for review, RHP Administrator comments, final draft sent for legal review and signature by Secretary of the Environment, and published in the Maryland Register for public comment. After the public comment period expires, the comments are addressed, sent to an Administrative and Executive Legal Review Board for format adherence, and published in the Maryland Register for final action and adoption.

The proposed accelerated schedule, however, was not met. At the March 4, 1994 exit meeting, Maryland informed NRC that the drafting process, although delayed, was completed for all outstanding regulations needed for compatibility, and provided the final draft for NRC review. NRC comments on the revised regulations were provided to the State for consideration on June 22, 1994 and November 14, 1994. NRC will evaluate how the State addressed comments during the next follow-up review.

Review of the draft regulations carried out by the State Attorney General's Office was completed on September 30, 1994. Legal comments were incorporated by RHP staff, who forwarded the revised regulations to MDE management for review and approval. On November 30, 1994, the RHP received authorization to

distribute informally the regulations to certain Maryland licensees for the purpose of obtaining their views and perspective. After considering licensee comments, the regulations will be published in the Maryland Register for 30-day public comment. Following staff evaluation of public comments, the final rule package will be filed in the Maryland Register as notice of final action. The RHP's current estimate is that the rules would become effective in May 1995.

Final draft of the low-level radioactive waste regulations, developed by the Hazardous Waste Division, was undergoing final review prior to publication at the time of the program review. Since the September 1993 meeting, NRC staff was informed by Maryland that a notice of final action for the final low-level radioactive waste regulations was published in the Maryland Register in October 1993. This was the last step in the adoption process.

The reviewers met with Mr. Edward Hammerberg, Public Health Engineer, Hazardous Waste Division, to discuss the status of the low-level radioactive waste regulations. During the meeting, the reviewers identified the need to modify the definition of "person." The State's definition of "person" is not consistent with 10 CFR 150.3(g) for exclusion of Federal government agencies and should be changed (see letter dated November 20, 1992 from C. Kammerer to D. L. Miles-Brown, Maryland Department of the Environment).

The list of regulations needed for compatibility is shown below.

- "Rule to Achieve Compatibility with the Transport Regulations of the International Atomic Energy Agency (IAEA)," 10 CFR Part 71 amendments (48 FR 35600) that became effective on September 6, 1983 and were to be adopted by September 6, 1986.

- "Glass Enamel and Glass Frit Containing Small Amounts of Uranium," 10 CFR Part 40 amendments (49 FR 35611) that became effective on September 11, 1984 and were to be adopted by September 11, 1987.

- "Industrial Radiography Surveys and Licensee's Performance Inspection Program," 10 CFR Part 34 amendments (51 FR 21736) that became effective on July 16, 1986 and were to be adopted by July 16, 1989.

- "Bankruptcy Filing Notification," 10 CFR Parts 30, 40, 61, and 70 amendments (52 FR 1292) that became effective on February 11, 1987 and were to be adopted by February 11, 1990.

- "Notifications, Reports and Records of Misadministrations," 10 CFR Part 35 amendments (51 FR 36932) that became effective on April 1, 1987 and were to be adopted by April 1, 1990. (These requirements have been replaced by the Quality Management Rule, 56 FR 34104, which was due by January 1995.)

- "Licenses and Radiation Safety Requirements for Well Logging," 10 CFR Parts 19, 20, 21, 30, 39, 40, and 70 amendments (52 FR 8225) that became effective on July 14, 1987 and were to be adopted by July 14, 1990.

- "Improved Personnel Dosimetry Processing," 10 CFR Part 20 amendments (52 FR 4601) that became effective on February 12, 1988 and were to be adopted by February 12, 1991.

- "General Requirements for Decommissioning Nuclear Facilities," 10 CFR Parts 30, 40, and 70 amendments (53 FR 24018) that became effective on July 27, 1988 and were to be adopted by July 27, 1991.

- "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70 amendments (54 FR 14051) that became effective on April 7, 1990 and were to be adopted by April 7, 1993.

- "Standards for Protection Against Radiation," 10 CFR Part 20 amendments (56 FR 61352) that became effective on June 20, 1991 with delayed implementation of January 1, 1994 and were to be adopted by January 1, 1994.

- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991 and were to be adopted by January 10, 1994.

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) that became effective on October 15, 1991 and were to be adopted by October 15, 1994.

- "Quality Management Program and Misadministrations", 10 CFR Part 35 amendments (56 FR 34104) that became effective on January 27, 1992 and were to be adopted by January 27, 1995.

In addition, we would like to bring to the State's attention other regulations that will be needed for compatibility. These rules are:

- "Licenses and Radiation Safety Requirements for Irradiators", 10 CFR Part 36 (58 FR 7715) that became effective on July 31, 1993 and will need to be adopted by July 31, 1996.

- "Licensing Requirements for Land Disposal of Radioactive Waste," 10 CFR Part 61 amendment (58 FR 33886) that became effective on July 22, 1993 and will need to be adopted by July 22, 1996.

- "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628)

that became effective on October 25, 1993 and will need to be adopted by October 25, 1996.

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.

2. Budget (Category II)

NRC Guideline

Operating funds should be sufficient to support program needs such as staff travel necessary to conduct an effective compliance program, including routine inspections, follow-up or special inspections (including pre-licensing visits) and responses to incidents and other emergencies, instrumentation and other equipment to support the RCP, administrative costs in operating the program including rental charges, printing costs, laboratory services, computer and/or word processing support, preparation of correspondence, office equipment, hearing costs, etc. as appropriate.

Assessment

Based upon review of documentation presented by RHP staff and discussion with the program Administrator, the program did not fully satisfy all criteria of this guideline. The program Administrator stated that not enough funds were available for program activities which occur periodically such as promulgation of regulations, prolonged escalated enforcement, and establishing data management systems. The program Administrator related that additional fee increases were being pursued for materials licensees and that additional monies could be made available through a supplemental budget increase.

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.

3. Administrative Procedures (Category II)

NRC Guidelines

The RCP should establish written internal procedures to assure that the staff performs its duties as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal

processing of license applications, inspection policies, decommissioning and license termination, fee collection, contacts with communication media, conflict of interest policies for employees, exchange of information and other functions required of the program. Administrative procedures are in addition to the technical procedures utilized in licensing, inspection, and enforcement.

Assessment

Based upon review of documentation provided by RHP staff, the program did not fully satisfy all criteria of this guideline indicator.

The comprehensive list of administrative procedures developed by the CRCPD E-15 Committee for use in program implementation was discussed with the RHP. The State response indicated that they decided to use some of these procedures as guidance for program implementation. However, while interviewing the program Administrator and his staff, the reviewers found discrepancies in various policies and procedures. Based upon these discussions and written RHP responses, and NRC review of the casework files, the following observations were made:

1. The administrative license procedures consisted of a two-page document and a two-page reciprocity procedure. The section covering internal processing of license and amendment applications did not address receipt and distribution of applications, the assignment of control numbers, payment and processing of fees, correspondence to applicants, documentation in the files, assignment of license numbers, data entry, signatures and final processing of the action including correspondence to applicants.

2. The administrative inspection procedures, entitled "Manual of Operations," consisted mainly of technical procedures dating back to 1975. The inspection policy and procedures did not address the assignment and priority of inspections, equipment, inspection policies, investigation into and potential for misadministrations, documentation, data entry, review of reports, enforcement procedures, and correspondence. The procedures need to be updated to reflect the current operation and policy. A copy of the recently revised NRC inspection manual was provided to the State for guidance in developing their inspection procedures.

3. The administrative procedures did not address the procedures for reporting, processing, documentation, filing, and distribution of all allegations, incidents, and misadministrations.

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.

4. Training (Category II)

NRC Guideline

Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices. The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology. The RCP staff should be afforded opportunities for training that are consistent with the needs of the program.

Assessment

The staff continues to participate in training courses sponsored by NRC as they become available, and four senior members of the staff have attended the Part 20 workshops. All of the senior technical staff members have been fully trained in their respective licensing and compliance positions.

However, certain aspects of the RHP relating to this indicator need improvement. The reviewers noted that the State's SS&D registration program relies on the work of one person. The State should cross train another staff member in the source and device registration program. Further, during the NPI inspection, NRC noted that the licensee's program for evaluating internal radiation exposures was weak, particularly in assessing ingestion and whole body exposure to Co-60, a finding not previously identified by Maryland staff.

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.

5. Adequacy of Product Evaluations (Category I)

NRC Guidelines

RCP evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC, State, or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users. Approval documents for SS&D designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Assessment

Sixteen product registration sheets were reviewed and the details are provided in Appendix B. Safety-related deficiencies were identified in the State's evaluation of the Nucletron Microselectron high-dose rate (HDR) afterloader. In reviewing that background file, NRC reviewers could not find answers to safety questions which NRC would require prior to device approval. A list of deficient information was developed by the review team and provided to the program licensing manager for consideration in a re-evaluation. Due to this deficiency and missing information in some of the device evaluation background files as discussed further below, an initial determination regarding satisfaction of this guideline was not made. The reviewers noted that 11 of 16 registration sheets were complete. The remaining five registration sheets did not closely follow the standard format and content identified in Regulatory Guides 10.10 and 10.11. File information was lacking on prototype testing, engineering analysis, and conditions of use. NRC reviewers emphasized that the State's evaluation of both engineering design and radiation safety should be retained in files.

An action plan to address the comments and findings identified above for SS&D files was developed and agreed upon by the State and NRC team members on January 30, 1994. The RHP immediately began to implement the action plan. Based upon the action plan and actions taken by the RHP to implement the plan, NRC staff subsequently withdrew the initial determination that this guideline was not met by the RHP.

Recommendations

1. 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.

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

3. 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.

6. Licensing Procedures (Category II)

NRC Guidelines

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.

Assessment

The program does not fully satisfy all requirements of this guideline indicator. The NRC team found that the State's licensing procedures do not provide for cover letters to transmit the license or license amendment to the licensee. Cover letters, in addition to being a good practice, are a useful means of communication of the license requirements that were changed, or specifics that need to be highlighted to licensee management. Cover letters can be based on a standard format and content or customized for specific needs.

During the review, NRC staff provided software diskettes with the current licensing checklists, standard license conditions, and deficiency letter language.

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 attention, highlights of license changes or related information.

7. Technical Quality of Licensing Actions (Category I)

NRC Guidelines

The RCP should assure that essential elements of applications have been submitted to the agency, and which meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions.

Assessment

During this review, 22 license files were reviewed in full and 6 files were reviewed in relation to SS&D evaluations. The files are listed in Appendix A along with the summary comments for each file casework. The program now has 25 major licenses and the review team concentrated their efforts on these major license files which were not reviewed during the last two reviews.

The proposed NPI license renewal prepared in 1991, but not issued due to litigation, was also discussed with RHP staff. Now that a court decision is in place, the State's license renewal plans were identified in three options

submitted to NRC on April 4, 1994, as part of the strategic action plan for NPI. These options are summarized in Appe' ix D.

Since the court decision, RHP staff maintained discussions with NPI regarding license renewal, and on August 1, 1994, NPI submitted a renewal application to Maryland. RHP staff informed NRC their preliminary screening of the application indicated that it was deficient in several procedural areas, including some identified in the court decision. Discussions between RHP staff and NPI continue to address deficient program areas.

Work performed by each of the State's license reviewers was sampled. This covered a major license in each category and license terminations. In general, the review team found the technical quality of the licensing actions to be properly detailed; however, problems were noted with certain licenses and license files including requirements on limiting molybdenum-99 breakthrough activity, deficiency letters not being used, lack of financial assurance mechanisms, and not using a standard license condition which prohibits opening of sealed sources. Additional summary comments regarding the NRC's evaluation of license files are identified in Appendix A.

The State's regulations and a current standard license condition authorize a Mo-99 breakthrough concentration of 1 microcurie of molybdenum-99 per 1 millicurie of technetium-99m. This value exceeds the NRC requirements of restricting the concentration limits to 0.15 microcurie of molybdenum-99 per 1 millicurie of technetium-99m.

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 condition for the molybdenum-99 breakthrough licensed activity, and reflect the other comments in future licensing actions.

8. Inspection Frequency (Category I)

NRC Guidelines

The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations. The minimum inspection frequency, including initial inspections should be no less than that of the NRC system.

Assessment

The program does not fully satisfy the requirements of this guideline. The State uses the same or more frequent inspection frequency as the NRC except for one category. The State's remote afterloader licenses are inspected on a three-year basis rather than the one-year basis recommended by NRC. The NRC previously had assigned HDRs an inspection frequency of two years. On July 2, 1993, NRC revised the inspection frequency for "high" and "medium" dose rate afterloaders to an inspection frequency of one year. RHP staff indicated that information about the NRC change was not immediately received, and committed to revising the State frequency. Instances where inspections are more frequent include NRC category 7 licenses, which are inspected on a five-year frequency, and NRC category 5 licenses, which are inspected on a four-year frequency. Academic Type A Broad licenses and mobile nuclear vans are inspected on an annual basis.

Recommendation

The RHP should revise the inspection frequency for all afterloader licenses to a one-year inspection frequency.

9. Enforcement Procedures (Category I)

NRC Guidelines

Enforcement procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Written procedures should exist for handling escalated enforcement cases of varying degrees.

Assessment

The program does not fully satisfy the requirements of this guideline.

The RHP has expended substantial effort in dealing with NPI inspection and compliance matters since 1986. A discussion of NPI activities is contained in Appendix D. Many problems were identified which arose from the unique facility operation and difficulties in the resolution of differences with NPI management. The State has been effective in improving safety at the site, but has not been fully successful in addressing all radiation safety issues. While the court case was pending, some site improvements were noted, but licensing and regulatory restrictions were placed on the RHP's ability to compel the licensee to correct all radiation safety issues.

The court settlement directed facility upgrades in the areas of waste handling practices, control of off-site doses, ALARA considerations, clean-up of on-site and off-site contaminated soils. A joint State and NRC inspection was conducted at NPI on October 18-22, 1994. The NPI inspection did not disclose any immediate health and safety issues, but did show problems with the licensee's radiation safety program, which required additional review. Following the court settlement in January 1994, NRC agreed with the State's

approach to require NPI to implement settlement actions and ensure settlement goals were achieved.

During the March 4, 1994 exit meeting, Maryland staff indicated that additional information would be provided together with an enforcement strategy for NPI. The follow-up exit meeting held on April 7, 1994 helped further clarify NRC's understanding of the State's licensing and compliance history with NPI. The RHP discussed their plan for continued regulation of NPI, submitted to NRC on April 4, 1994, which included a "strategic plan" for inspection and compliance activities. NRC reviewed the plan and noted that it appeared sufficient in scope to address current safety issues and the State's expected near-term actions.

The NRC team also noted that the RHP had taken 25 escalated enforcement actions since the previous review, and we received a copy of the program's escalated enforcement procedures "General Statement of Policy and Procedure for Maryland Department of the Environment Enforcement Actions," dated July 1, 1993.

The above procedure does not fully address the routine enforcement actions taken by an inspector at the conclusion of an inspection, or the follow-up actions taken by the program after review by the supervisor. Specifically, the reviewers noted that the policy is not clear when inspectors should issue Notices of Violation (NOV) or a field notice (Forms DHMH-1097B, MDER-E-2, or MDER-E-1). The use of field notice forms should be clearly stated in the written procedures, and the use of outdated forms should be discontinued. The NRC and most States utilize a field form similar to the MDER-E-1 for clear inspections and to identify specific minor items of noncompliance. More serious problems involving safety violations are confirmed by management in a written notice (NOV) to the licensee.

Licensee responses to enforcement actions should be promptly acknowledged as to the adequacy of the licensee's corrective actions and resolution of previously unresolved items. The program does not have a clear, written policy on when to issue acknowledgement letters, and as a result, does not issue such letters. The licensee should receive a written notice that their response was received by the RHP which identifies the RHP evaluation of their corrective actions. In some cases, an acknowledgement could prevent repeated violations and preclude further escalated enforcement.

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 Violation and the MDER-E-1 form; and (2) include use of acknowledgement letters in routine enforcement actions.

10. Inspection Procedures (Category II)

NRC Guidelines

Inspection procedures and guides, consistent with current NRC guidance, should be used by inspectors to assure uniform and complete inspection practices and provide technical guidance in the inspection of licensed programs.

ssessment

The program does not fully satisfy the requirements of this guideline indicator.

Inspection procedures are contained in a document entitled "Manual of Operations." This document consisted mainly of technical procedures dating back to 1975, and does not reflect current RHP operation and policy. The manual does not address assignment and priority of inspections, equipment, inspection policies, investigation into and potential for misadministrations, documentation, data entry, review of reports, enforcement procedures, and correspondence. The RHP supplements the manual with guidance and procedures provided by NRC and distributed in the NRC Inspection Procedures Course. A copy of updated versions (on diskette) of the NRC Manual Chapter 2800, 87100, and enforcement policy and standard citations was provided to the State for guidance when revisions to inspection procedures are made.

Recommendation

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

11. Inspection Reports (Category II)

NRC Guidelines

Inspection reports should uniformly and adequately document the results of inspections and identify areas of the licensee's program which should receive special attention at the next inspection. Reports should also show the status of previous noncompliance and the independent physical measurements made by the inspector.

Assessment

The program does not fully satisfy the requirements of this guideline indicator. In general, reports were found to be acceptable; however, as noted in Appendix C, we noted several instances where additional information and/or details were needed for complete documentation. Examples included lack of State acknowledgement letters to licensee replies to enforcement actions, identification of improper inspection frequency of future inspections, and use of outdated forms for enforcement actions in the field.

The reviewers also noted that in many cases reports were not reviewed by the Compliance Supervisor until months (sometimes over a year) later, and after enforcement actions were taken. This practice does not provide for good quality control, and does not allow timely feedback to inspectors to use in subsequent inspections. Written reports should be reviewed by the Compliance Supervisor in a timely manner soon after the inspection and prior to the enforcement actions to determine if the appropriate details and information were obtained, documented, and if appropriate enforcement actions were being taken.

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.

SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

Specific comments on program indicators, licensing and inspection casework reviews, and SS&D reviews were made by individual team members to Mr. Fletcher and RHP staff during the first week of the review and summarized on September 3, 1993.

On March 4, 1994, a formal summary meeting regarding the results of the review was held. Representing the NRC were Richard Woodruff, Regional State Agreements Officer (RSAO), Region II, Craig Gordon, RSAO, Region I, Richard Bangart, Director, Office of State Programs (OSP), and William Kane, Deputy Regional Administrator, Region I. An NRC recommendation to withhold both adequacy and compatibility was presented to David Carroll, Secretary, Maryland Department of the Environment (MDE), Ron Nelson, Deputy Secretary, MDE, Merrylin Zaw-Mon, Director, Air and Radiation Management Administration, MDE, and Roland Fletcher, Administrator, Radiological Health Program. The staff recommended the withholding of a finding that the Maryland program for the regulation of agreement materials was adequate to protect the public health and safety due to incomplete sealed source and device (SS&D) casework evaluations, and the need to consider enforcement action to address inspection findings resulting from the joint State and NRC inspection of Neutron Products, Inc. (NPI). The staff also recommended withholding of a finding of compatibility due to 13 regulations that have not been adopted within the three-year period required by the NRC.

Subsequent to the review, NRC staff evaluated an action plan specifically developed by RHP staff to address deficiencies related to the SS&D program. Based upon staff assessment of the SS&D action plan and implementation of the action plan by RHP staff, the Category I Indicator, Adequacy of Product Evaluations, was found to be satisfied.

On April 7, 1994, a follow-up meeting was also held between Mr. Bangart, Mr. Gordon, and Patricia Santiago, NRC Office of Enforcement, and Ms. Zaw-Mon and other RHP staff to discuss the NPI court case; future NPI licensing, inspection, and enforcement strategies relative to NPI oversight; and an RHP action plan for NPI. The court settlement and NPI action plan helped clarify staff's understanding of the State's regulation of NPI, and staff found the State's current NPI oversight to adequately satisfy the Enforcement Procedures Category 1 Indicator. Staff emphasized the need to continue RHP efforts to renew the 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 could be taken, if required.

SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED
BY THE MARYLAND RADIATION CONTROL PROGRAM
MARCH 28, 1991 TO APRIL 7, 1994

The assessments below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the program managers and staff members, review team observations, and licensing and inspection casework file reviews. The State fully satisfies the following indicators:

1. Legal Authority (Category I)

NRC Guidelines

Clear statutory authority should exist, designating a State radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement.

Assessment

In the response to the questionnaire, the State reported the legislation authorizing the Maryland Radiation Health Program is contained in the Annotated Code of Maryland, Environment Article, Title 8 - Radiation, Section 8-101 - 8-601 and Title 7, Hazardous Materials and Hazardous Substances. Authority to apply civil penalties is contained in Section 8-509(b) and 8-510, to collect fees and require performance bonds or sureties for decommissioning licensed facilities in Section 8-301. No Sunset laws exist in the Maryland regulations; all regulations remain in effect (no expiration date) until replaced, revised or superseded. Based upon review of the State's responses to the questionnaire, the Radiological Health Programs's (RHP) authority meets the requirements of this guideline.

2. Location of the Radiation Control Program Within the State Organization (Category II)

NRC Guidelines

The radiation control program (RCP) should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management.

Assessment

Based on response to the questionnaire and discussion with RHP management and staff, the program is located comparably with other health and safety programs in the State and the RHP Administrator has access to appropriate levels of State management. The RHP Administrator, for example, meets occasionally with the Secretary of the Environment. The program satisfies criteria under this Guideline.

3. Internal Organization of the RCP (Category II)

NRC Guidelines

The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy.

Assessment

A review of the organization charts and discussions with program managers indicates that the RHP is organized in an appropriate manner to achieve acceptable efficiency, emphasizing major program functions and specific lines of supervision. The program satisfies criteria of this Guideline.

4. Legal Assistance (Category II)

NRC Guidelines

Legal staff should be assigned to assist the RCP or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP program, statutes, and regulations.

Assessment

Although delays were encountered in the review of revisions to regulations, legal staff were assigned and had good program familiarity. During the review the team met with Mr. Neil Quinter, Assistant Attorney General, who was assigned to Neutron Products, Inc. (NPI) litigation. Mr. Quinter explained the extraordinary amount of effort put forth by the RHP and Attorney General staffs in prosecuting the NPI case. The program meets the requirements of this guideline.

5. Technical Advisory Committees (Category II)

NRC Guidelines

Technical Committees, Federal Agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems.

Assessment

The program's Radiation Control Advisory Board (RCAB) has met regularly on a quarterly basis. The meeting minutes were reviewed and the program meets the requirements of this guideline. The RCAB membership was obtained and is provided as follows:

NAME	ORGANIZATION
Phillip E. B. Byrd, M.D.	St. Agnes Hospital
Larry W. Camper, MBA, MS	US NRC
Desmond W. Chan, Ph.D.	General Physics Corporation
Barbara Chin Arora, MS	Suburban Hospital (Oncology)
Kelly T. Drake, M.D.	Greater Baltimore Med. Ctr.
Stanford M. Goldman, M.D.	Francis Scott Key Med. Ctr.
Robert R. Hiscock	Sinai Hospital (Oncology)
Patricia S. Lane	Private Citizen
John Olin	Johns Hopkins University
Jon K. Park, D.D.S.	U. of Maryland/Dental School
Michael S. Terpilak	US Food & Drug Administration
Anthony B. Wolbarst, Ph.D.	US Environ. Protection Agency

6. Quality of Emergency Planning (Category I)

NRC Guidelines

The State radiation control program should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc. Periodic drills should be performed to test the plan.

Assessment

Arrangements are in place to respond to incidents involving radioactive materials within the State. During regular work hours emergency calls are directed to RHP staff at their work-station. The RHP Administrator or Compliance Supervisor evaluate the necessary level of event response and acquire resources as needed. Designated vehicles stocked with emergency equipment are assigned to four members of the inspection staff. To expedite off-hours response to incidents, inspectors residing closest to the incident scene become the primary responder. Twenty-four hour notification capability was available and periodically tested in actual event response and in drills. RHP staff completed courses in emergency preparedness and participate regularly in drills and exercises at the Calvert Cliffs (most recent 10/93) and Peach Bottom sites. Emergency planning staff maintain the emergency plan up to date. Based upon discussions with RHP management and staff regarding their knowledge and use of the plan in responding to incidents, this area was assessed as well implemented. The program satisfies the criteria of this guideline.

7. Contractual Assistance (Category II)

NRC Guidelines

States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have procedures and mechanisms in place for acquisition of technical and vendor services necessary to support these functions that are not otherwise available within the RCP. The RCP should

avoid the selection of contractors which have been selected to provide services associated with the low-level radioactive waste facility development or operations.

Assessment

This indicator is not applicable as the State currently does not regulate the disposal of low-level radioactive waste.

8. Laboratory Support (Category II)

NRC Guidelines

The RCP should have the laboratory support capability in-house, or readily available through established procedures, to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, etc., on a priority established by the RCP.

Assessment

The Radiation Chemistry laboratory is under the Department of Health and Mental Hygiene. The functions of the laboratory appear to meet all of the requirements of the indicator guidelines. It was also noted that the laboratory participates in an EPA cross-check program.

Prior to the NPI inspection, NRC team members discussed with RHP staff State laboratory capabilities to process miscellaneous samples for radioactivity, and were informed that the laboratory could handle a wide variety of environmental and radiological samples. To verify laboratory capability, during the inspection, the NRC mobile laboratory van was used to evaluate samples at the NPI site and local sewage treatment facility. NRC results of NPI soil and water samples and sewage sludge samples were compared with samples taken by the RHP analyzed at State laboratories. NRC and State laboratory results of concentrations of Co-60 and small concentrations of nuclear medicine isotopes found in the waste stream were in agreement.

The functions of the laboratory appear to meet all of the requirements of the indicator guidelines.

9. Management (Category II)

NRC Guidelines

Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquiries, regulation revisions). Supervisory review of inspections, reports and enforcement actions should also be performed.

Assessment

When a field inspection is completed, the Compliance Supervisor is immediately debriefed by the inspector with findings upon return to the office. Although untimely in many instances, the Compliance Supervisor routinely reviews and acknowledges results identified in inspection reports. Based upon our review of the monthly reports prepared by the RHP Administrator, discussions with the managers, and casework reviews, the RHP meets the requirements of this guideline indicator.

10. Office Equipment and Support Services (Category II)

NRC Guidelines

The radiation control program should have adequate secretarial and clerical support. States should have a license document management system that is capable of organizing the volume and diversity of materials associated with licensing and inspection of radioactive materials.

Assessment

During the initial review, this guideline was not met in all areas due to several non-routine activities occurring at the same time. These included an unusually high workload of drafting revisions to regulations; inspection, enforcement, and litigation of NPI; and a vacancy in the RHP Administrator's secretary position. Later in the review period, however, drafts of regulations were completed, a court decision was made in the NPI case, and the secretary position was filled. Additional secretarial and clerical support is also available to the RHP. Computer databases are utilized for preparation of licensing and inspection documentation. Personal computers were issued to each individual of the license and compliance staff for assistance in document control. At this time, the RHP meets the requirements of this guideline indicator.

11. Public Information (Category II)

NRC Guidelines

Inspection and licensing files should be available to the public consistent with State administrative procedures. It is desirable, however, that there be provisions for protecting from public disclosure proprietary information and information of a clearly personal nature.

Assessment

Access to the file area is restricted other than for employees, but inspection and licensing files would be made available upon request. State administrative laws provide for protection of proprietary information. A Public Affairs office within the Department was available to address media and

outside inquiries relative to the RHP. The program meets the requirements of this guideline indicator.

12. Staffing Level (Category II)

NRC Guidelines

Professional staffing level should be approximately 1 to 1.5 person-year per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel.

Assessment

For 1992-1993, the senior RHP inspector was primarily assigned NPI casework and regulation review. During that time, approximately 1.5 FTE was expended on NPI inspection actions due to complexities involved in the facility's regulation and pending court case. This attributed to the delay in completing drafts of regulations. A review of the staffing level data provided by the program indicates that the RHP staffing level was nonetheless maintained at 1.6 persons per 100 licenses, including NPI activities. Although the program satisfies the requirements of this guideline indicator, as identified under the indicator "Budget" in Enclosure 2, the RHP should assess program needs and ensure that sufficient operating funds are available.

13. Qualifications of Technical Staff (Category II)

NRC Guidelines

Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel including the director of the radiation protection program should be commensurate with the type of licenses issued and inspected by the State.

Assessment

Qualifications of technical staff were assessed in the previous review and were found to be acceptable. There was no turnover in key RHP staff since the last review. RHP staff attended continuing education and training courses, and the qualifications of the technical staff remained unchanged. The program satisfies the requirements of this indicator.

14. Staff Supervision (Category II)

NRC Guidelines

Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel. Senior personnel should review

applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy. Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Assessment

The first line supervisors provided active, direct participation in inspections and, in particular, cases involving escalated enforcement. The Administrator, RHP, reviews and signs all licensing actions. NRC reviewers interviewed RHP staff members and noted that the Compliance Supervisor showed good familiarity with work performed by inspection staff, was very familiar with results identified during inspections of major licensees, and performed periodic field inspection accompaniments. Senior staff are qualified to work independently and routinely communicate with licensees on licensing and inspection decisionmaking matters. Junior personnel were either in training or performed lower priority program activities. Verbal communication between the supervisors and the technical staff appeared good. The program satisfies the requirements of this guideline indicator.

15. Staff Continuity (Category II)

NRC Guideline

The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications and should be comparable to similar employment in the geographical area.

Assessment

The program's salary schedules were revised since the last review and the current staffing has been stable. Program management related that the beginning salaries were in line with other State agencies and that the salary was adequate to recruit at the lower levels. The program meets the requirements of this guideline indicator.

16. Status of Inspection Program (Category I)

NRC Guidelines

The State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. When backlogs occur, management should develop and implement a plan to reduce the backlog.

Assessment

The program reported only 13 low priority licenses were overdue for inspection, none of which were overdue by more than 50% of their prescribed inspection frequency. Overdue inspections were assigned to inspection staff and completed. Licensees involved in escalated enforcement actions were inspected on accelerated schedules, i.e., quarterly inspections at NPI. The program satisfies the requirements of this guideline indicator.

17. Inspector's Performance and Capability (Category I)

NRC Guidelines

Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections.

Assessment

All inspectors have been accompanied by a senior inspector or supervisor on an annual basis. We noted that inspector accompaniments were not formally documented by the State except for notation on the inspection report. These notations did not provide adequate documentation of the inspector's performance. The RHP plans to address this comment as part of their revisions to RHP procedures discussed under the "Administrative Procedures" Indicator.

During the program review, Mr. Craig Gordon conducted an inspector accompaniment at a temporary job site for industrial radiography as follows:

Date:	August 31, 1993
Inspector:	Robert Nelson
Licensee:	CBI Services, Inc.
License No.:	NRC 42-13533-02, effective February 22, 1993; work performed under reciprocity.
Location:	Baltimore, MD.
License Type:	Industrial Radiography

The inspector was well prepared and conducted the inspection using field notes adapted from NRC. Radiation safety items were well covered. Inspection results and possible improvement areas in conducting worker interviews and presenting inspection findings were discussed with the inspector.

A copy of the form used to evaluate inspectors was provided to the State. The program satisfies the requirements of this guideline indicator.

18. Confirmatory Measurements (Category II)

NRC Guidelines

Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements.

Assessment

Based upon the inspection reports, the equipment listing and calibration policies, and discussions with program staff, the program conducts an adequate number of confirmatory measurements to satisfy the criteria of this guideline indicator.

19. Responses to Incidents and Alleged Incidents (Category I)

NRC Guidelines

Inquiries should be promptly made to evaluate the need for on-site investigations. Investigation (or inspection) results should be documented and enforcement action taken when appropriate. State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations.

Assessment

Handling of RHP allegations and incidents since the last review was discussed with the Compliance Supervisor. NRC review of selected incident files showed timely action and follow-up by RHP staff. Inspections and investigations arising from allegations were made promptly. One case referred to the State by NRC (Allegation # RI-92-A-0245) resulted in escalated enforcement action against a Maryland licensee. Other allegations affecting Maryland licensees forwarded to compliance staff during 1992 and 1993 received appropriate attention. Abnormal occurrence reports and related incident information, i.e., misadministrations, lost sources, were provided to the NRC for inclusion into the Office for Analysis & Evaluation of Operational Data statistical summaries. During the review period, one therapeutic and 11 diagnostic misadministrations were reported with appropriate State follow-up action in each case.

REVIEW OF SELECTED LICENSE FILES

Twenty-seven license files were selected for full review. The casework was reviewed in general for: (1) technical adequacy of application review; (2) significant errors and omissions; (3) utilization of licensing procedures; and (4) documentation.

The following licenses were reviewed and for purposes of this report, a numerical casework number was assigned to each license as follows:

Casework No. 01

Licensee:	Francis Scott Key Medical Center
Location:	4940 Eastern Avenue Baltimore, MD 21224
License No.:	MD-07-008-09, Amendment No. 8
Date Issued:	August 30, 1991
Date Expires:	Terminated
License Type:	Research

Case Work No.02

Licensee:	Johns Hopkins Medical Institutions Radiation Control Unit
Location:	2023 E. Monument Street Baltimore, MD 21205
Use at:	Johns Hopkins Hospital Asthma Center/Allergy Center 301 Bayview Boulevard Baltimore, MD 21224
License No.:	MD-07-005-10, Amendment No. 2
Date Issued:	June 3, 1991
Date Expires:	October 31, 1994
License Type:	Broad Scope Medical

Casework No.03

Licensee:	Maryland Q.C. Laboratories, Inc.
Location:	1550 South Philadelphia Blvd. Aberdeen, MD 21001
License No.:	MD-25-022-01, Amendment No. 21
Date Issued:	March 22, 1993
Date Expires:	March 31, 1998
License Type:	Industrial Radiography

Casework No.04
Licensee: University of Maryland at Baltimore
Environmental Health and Safety
Location: 737 West Lombard Street
Baltimore, MD 21201
License No.: MD-07-014-01, Amendment No. 36, 37, 38, and 39
Date Issued: August 25, 1992
Date Expires: September 30, 1997
License Type: Broad Scope Medical with Irradiator

Casework No.05
Licensee: Francis Scott Key Medical Center
Andrew Goldberg, M.D.
Location: 4940 Eastern Avenue
Baltimore, MD 21224
License No.: MD-07-008-40, Amendment No. 6
Date Issued: August 30, 1991
Date Expires: (Under Timely Renewal)
License Type: Research

Casework No.06
Licensee: University of Maryland at Baltimore
Environmental Health and Safety
Location: 737 West Lombard Street
Baltimore, MD 21201
License No.: MD-07-014-04, Amendment Nos. 3 (Renewal),4, and 5
Date Issued: February 10, 1992
Date Expires: February 28, 1997
License Type: Incinerator

Casework No. 07
Licensee: Radamerica, Inc.
Location: Baltimore, MD (several locations)
License No.: MD-05-051-01, Amendments 25 through 31
Date Issued: 09-03-92 (amendment 27, entirety)
Date Expires: 09-30-97
License Type: Teletherapy with Brachytherapy and Eye Applicator

Casework No. 08
Licensee: Teledyne Energy Systems
Location: 10707 Gilroy Road
Hunt Valley, MD 21031
License No.: MD-05-014-01, Amendment 16
Date Issued: 08-03-93
Date Expires: Terminated
License Type: Manufacturing and Distribution

Casework No. 09

Licensee:	Mallinckrodt, Inc.
Location:	5024-C Campbell Boulevard Baltimore, MD 21236
License No.:	MD-0d5-105-01, Amendments 1 through 4
Date Issued:	01-05-89 (Became Active on 05-04-92)
Date Expires:	01-31-94
License Type:	Pharmacy

Casework No. 10

Licensee:	Wallac (Formally Pharmacia LKB Nuclear)
Location:	9226 Gaither Road Gaithersburg, MD 2087/
License No.:	MD-31-071-01, Amendment 33
Date Issued:	07-26-93
Date Expires:	05-21-96
License Type:	Manufacturer and Distribution to GLs

Casework No. 11

Licensee:	GE Medical Systems, Inc.
Location:	
License No.:	MD-03-052-01, Amendment 6
Date Issued:	04-24-91
Date Expires:	04-30-96
License Type:	Service of Teletherapy Units

Casework No. 12

Licensee:	Becton Dickinson Diagnostic
Location:	
License No.:	MD-05-025-01
Date Issued:	09-26-89
Date Expires:	10-31-94
License Type:	Manufacturer and Distribution to GLs

Casework No. 13

Licensee:	Radiation Service Organization
Location:	711 Gorman Avenue Laurel, MD 20725
License No.:	MD-33-021-02, Amendment 19
Date Issued:	04-15-93
Date Expires:	04-30-98
License Type:	LLW Broker

Casework No. 14
Licensee: Mallinckrodt, Inc.
Location: 10850-F Hanna Street
Beltsville, MD 20705
License No.: MD-33-088-01, Amendments 6 (Entirety) & 7
Date Issued: 02-01-93 (Entirety)
Date Expires: 02-28-98
License Type: Pharmacy

Casework No. 15
Licensee: Therapy Services, Inc.
Location: 6242 Jefferson Pike
Frederick, MD 21701
License No.: MD-21-009-01, Amendment 16
Date Issued: [illegible]17-92
Date Expires: 0[illegible]-97
License Type: Te[illegible]herapy Service Company

Casework No. 16
Licensee: Shimadzu Scientific Instruments, Inc.
Location: 7102 Riverwood Drive
Columbia, MD 21046
License No.: MD-27-011-01, Amendment 28
Date Issued: 08-19-92
Date Expires: 08-31-97
License Type: Manufacturing and Distribution

Casework No. 17
License: U of Maryland at Baltimore
Location: 714 West Lombard Street
Baltimore, MD 21201
License No.: MD-07-014-05, Amendments 01,02,& 03
Date Issued: 02-12-92
Date Expires: 02-28-97
License Type: Gammaknife

Casework No. 18
Licensee: Scientech, Inc.
Location: 205 Perry Parkway
Gaithersburg, MD 20877
License No.: MD-31-204-01, Amendments 1, 2, and 3
Date Issued: 09-19-91
Date Expires: 10-31-96
License Type: Sampling and Analysis, Analytical

Casework No. 19
Licensee: Neutron Products, Inc.
Location: 22301 Mt. Ephraim Road
Dickerson, MD 20842
License No.: MD-31-025-04, Amendment 21
Date Issued: 02-11-93
Date Expires: Unknown
License Type: Irradiator, Pool Storage

Casework No. 20
Licensee: Neutron Products, Inc.
Location: Dickerson, MD 20842
License No.: MD-31-025-05, Amendment 11
Date Issued: 02-11-93
Date Expires: Unknown
License Type: Irradiator, Pool Storage

Casework No. 21
Licensee: North American Inspection, Inc.
Location: Hagerstown, MD
License No.: MD-43-019-01
Date Issued: 05-28-93
Date Expires: 06-30-98
License Type: Industrial Radiography

Casework No. 22
Licensee: Shield Source, Inc.
Location: Grasonville, MD
License No.: MD-35-002-01, (Sealed Source & Device Review)
Date Issued: 07-07-92
Date Expires: 04-30-94
License Type: Distribution to GLs

Casework No. 23
Licensee: Nucletron Corporation
Location: Columbia, MD
License No.: MD-27-035-01, (Sealed Source & Device Review)
Date Issued: 04-16-93
Date Expires: 11-31-92
License Type: Service and Repair

Casework No. 24
Licensee: Martin L. Kiser, Inc.
Location: Cockeysville, MD
License No.: MD-05-033-01, (Sealed Source & Device Review)
Date Issued: 02-01-93
Date Expires: 02-28-98
License Type: Manufacture and Distribution

Casework No. 25

Licensee:	Data Measurement Corporation
Location:	Gaithersburg, MD
License No.:	MD-31-088-01, (Sealed Source & Device Review)
Date Issued:	06-11-33
Date Expires:	03-30-95
License Type:	Manufacturer and Distribution

Casework No. 26

Licensee:	MSA Catalyst Research
Location:	Owings Mills, MD
License No.:	MD-05-107-01, (Sealed Source & Device Review)
Date Issued:	03-17-93
Date Expires:	Terminated
License Type:	Research and Development

Casework No. 27

Licensee:	Adaptive Technologies, Inc.
Location:	Frederick, MD
License No.:	MD-21-026-01, (Sealed Source & Device Review)
Date Issued:	08-25-93
Date Expires:	04-30-94
License Type:	Manufacturing & Distribution

Summary Table

The following table lists the specific comments developed during the review of the numbered casework files above.

	Specific Comments	Casework Number
1.	More information is needed in the file to document that a close-out survey was performed and the results of the survey.	1, 8
2.	Cover letters should be utilized to transmit all licenses and license amendments.	All
3.	The State of Maryland rarely issues deficiency letters, preferring instead to communicate telephonically.	All
4.	The State apparently has no regulations or policy on whether a fixed radiographic facility can be operated as a temporary job site. This results in confusion and hybrid facilities and operations.	3, 21
5.	Financial assurance determinations are needed for these facilities.	4,13,19,20

6. The tie-down condition "Q&A received on June 23, 1992" was actually received on July 23, 1992. 4

7. The tiedown condition states that "Part II of the June 16, 1992 letter is not accepted" and that the "license is based on HP Manual dated April 16, 1990 [illegible] Parts I and II of the letter dated June 16, 1992. More detail is needed. 4

8. License condition 13C (related to radioactive gases procedures and use) is confusing. It should stand alone rather than be included in the visiting authorized user condition. 4

9. A license condition contains a six month inventory requirement. The regulations require every three months and documentation submitted by the licensee states every three months. This condition is contradictory and needs to be clarified to the licensee and explained in a cover letter letter with the license. 4

10. Additional details are needed in the emergency procedures submitted in the licensee's letter dated October 13, 1992 in support of a license amendment. 4

11. The letter dated June 25, 1993 submitted in support of Amendment No. 38 cannot be found in the license file. 4

12. The State's regulations authorize a Mo-99 breakthrough concentration of 1 microcurie per millicurie of Tc-99m. The licenses also contain a condition authorizing up to a maximum concentration of 1 microcurie of Mo-99 per millicurie of Tc-99m and a maximum of 5 microcuries of Mo-99 per patient dose. This requirement is not a matter of compatibility, but is considerably greater than the 0.15 microcurie per millicurie limit imposed by NRC and being followed by the industry. All Medical

13. Typographical errors in the license document should be officially corrected and a "corrected copy" issued. 7

14. Licensee's name apparently changed in 1989, and the file name was changed but the master license and major license name was not changed. 7

15. A license condition prohibiting the opening of sealed sources is needed. 3, 21

16. Licensee name changes are being permitted without sufficient information being obtained on ownership or

change in corporate structure and the licensees commitments relating to licensed operations. 10, 11

17. The check list utilized for this licensed facility did not adequately address certain topics associated with the distribution to general licensees, such as labeling, and instructions to the general licensee, and maintaining control over the licensed material at temporary job sites. 10

18. Additional details on the qualifications and experience of the radiation safety officer (RSO) need to be documented in the license file. 10

19. The duties of the RSO are not adequately supported by the documented training and experience of the RSO. 11

20. Additional details are needed to document the applicant's field protocol and procedures to protect public health and safety. 11

21. Facsimile copies tend to fade with time and should not be used as official file documentation. 11

22. Additional information is needed to fully assess and document the disposal of some low-level carbon-14 waste. 12

23. Licensee letters are not properly identified in the tie-down condition. 12

24. License termination should also have referenced the licensee commitments made in 07-06-93 letter. 08

REVIEW OF SEALED SOURCE & DEVICE REGISTRATIONS

The State does not have the specific regulations in place to codify the source or device registration process (10 CFR 30.32(g) and 32.210). However, the practice is conducted under the Maryland provisions of Section C.24, Filing Application for Specific Licenses whereby "(e) ...the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the Agency provided such references are clear and specific" and Section C.25, General Requirements for the Issuance of Specific Licenses which states that an application for a specific license will be approved if, among other things, "(b) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property."

One of the objectives of the review was to determine if the staffing and administrative procedures were adequate to deal with the sealed source and device (SS&D) evaluation workload. This includes procedures that are established to ensure the results of the evaluations are consistent and that a second signature block is used. Sixteen (16) registrations sheets and the background files referenced in Appendix A were reviewed for technical quality and consistency of the following areas: format, description, labeling, diagram, conditions of use, prototype testing, radiation levels, quality assurance and quality control, limitations of use, and the bases for determining that the sources or device design were deemed acceptable for licensing purposes.

Due to missing documentation contained in some of the device evaluation's background files, an initial determination regarding satisfaction of the Category I Indicator was not made. The NRC team noted that the products distributed by vendors located in the State of Maryland have been previously licensed for use in the United States with few reported design problems. It is also important to note that the State's senior license reviewer has been performing the product evaluation for many years and past audits performed have not identified significant problems with these evaluations. We also discussed some specific, but minor, concerns regarding the registration sheets directly with the reviewer.

However, the team identified certain areas that could be improved to enhance the quality of the registrations sheets. There is a need to closely follow the standard format and content language identified in Regulatory Guides 10.10 and 10.11. Concentration on prototype testing, engineering analysis, and conditions of use will allow the reviewers to make a more informed decision. The NRC strongly stressed the importance of performing an engineering analysis of device designs as primary consideration in lieu of health physics evaluation that has historically been done by the States and NRC.

Based on our review of the program, the NRC team identified the following recommendations.

1. The State and vendors need to develop and implement a plan to replace the missing information and possibly review all old registration sheets

in accordance with the Regulatory Guides 10.10 and 10.11. The State should provide sufficient file documentation to allow an independent determination to be made on the integrity of product designs. Currently, some of this documentation does not exist in the files. Also, the State should re-evaluate Nucletron Microselectron HDR. NRC reviewers identified a list of design questions about the device which could not be answered from file material, and likely are deficiencies in the State's review. These were discussed with the Radiological Health Program (RHP) license reviewer who forwarded the questions to the manufacturer. After establishing an action plan to address NRC SS&D review comments, State representatives followed-up and maintained communication with Nucletron to resolve unanswered questions.

2. NRC reviewers noted that the registration program relies on the work of one person, with no plans to cross-train other licensing staff. The State should consider cross-training another staff member, which includes developing and implementing a training plan. Visits to other regulatory agencies to see how they perform and document SS&D evaluations should be considered.

3. Although not a strict matter of compatibility, the State was encouraged to establish equivalent regulation to 10 CFR 30.32(g) and 32.210 to allow for clear authority and controls (inspection and enforcement) of products that are distributed by vendors located in the State of Maryland.

4. 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. (No formal or informal agreement has been reached with these other States to allow device inspection in order to determine if the product distributed is in accordance with the information submitted to Maryland). Unless a cooperative arrangement can be made between affected States, this practice should be discontinued.

An action plan to address the comments and findings identified above was developed by the State and agreed upon by NRC team members on January 30, 1994. Maryland immediately began to implement the action plan.

OTHER AREAS

The State had taken the position that Nucletron HDR units could not be relocated by a licensee once unit installation was complete. The vendor responded to this position by proposing a mobile van facility. Since the State had previously reviewed the device and shielding enclosure during evaluation of the permanent facility, a sheet was issued which approved the

device for mobile use. In order to obtain a clearer understanding of how the device will be used during fixed and mobile conditions, below are safety, operations, and engineering related questions raised by the NRC team that should be considered by the State and formally raised to Nucletron.

1) Please explain what is involved in the "100 hour" test.

2) Please explain in detail the following quote, "The Microselectron-HDR has been tested for the life of the drive motors and the metal drive cable, used to transfer the source. The anticipated life of these components is greater than 10 years." What are the specifics of these tests?

3) Does their QA/QC program meet ISO 9000?

4) Please provide documentation from the "Development Engineering Team" on verification of the adequacy of design and specifications, tests, and acceptance criteria for those items of the design necessary for safe and proper functioning of the device.

5) Please explain all conditions that would cause an alarm and what component(s)/systems identify that an error has occurred (microswitches, voltages, photocell, etc.).

6) Please explain how the system ensures that the entire wire has been returned and that the source is within the safe.

7) Please provide copies of all prototype testing performed on the device and source.

8) What happens if the power is removed during the prepare mode and is restored before 90 second has elapsed (warm start?, cold start?)?

9) Please explain the source wire's path and what happens during movement (i.e., when and why microswitches are tripped, timers started/stopped, etc.).

10) Please provide detailed drawings of the inside of the device showing the switches, sensors, drive mechanisms, indexer, and all components that the source may come in contact with.

11) What happens during initialization of the system? What is checked?

12) What occurs when the "STOP" button is pressed? Explain in detail how the source is retracted and what components are use to retract the source.

13) What happens if the photocell fails (before and after source wire extension)?

14) What happens if the stepping motor fails during retraction/extension?

15) What prevents dirt and moisture from entering the system? Could there be a problem with jamming, kinking due to foreign material, wear, or corrosion? Please explain.

16) What effect, if any, would cleaning fluids typically found in the hospitals or clinics have on the source? Device?

17) If the system is started with a failed battery, what happens to the source wire if the main power fails? If the wire is extended during the power failure, does it automatically return when the power is restored? Will the system know if the entire length has returned? When the power is restored, does the device recognize and record that an error has occurred?

18) Who has access to the "Special Mode?" Is additional training provided to these qualified personnel?

19) Please provide us with an outline showing the topics covered and duration for the training you provide to your customers.

20) Please provide us with a list of all conditions that cause the source to return to the safe.

21) For error 21, does the system cause an automatic retraction?

22) What is the emergency stop motor? How does this system work? Explain the components involved.

23) Does this device have an internal/external radiation detector wired to the device?

24) Does the device become top-heavy when the hydraulics are used to extend the head to the highest position? Have any drop tests been performed? If so, please provide copies of the tests and results.

25) What situations would fail to arm the emergency stop circuit?

Other Comments on Maryland's Sealed Source and Device Evaluation Program

The following additional comments on the SS&D evaluation program are offered for consideration by the RHP:

1. During the next routine inspection of each SS&D manufacturer and distributor, the inspector should review the service history and customer complaint file, for generic safety problems that may require re-evaluation of the device, modification to the certificate, or revocation of the certificate.

2. For SS&D reviews that involve the welding, the reviewer should ensure that the manufacturer has appropriate welding apparatus available. We suggest that the RHP should use Mark's handbook for mechanical engineers for reference in this area.

3. For quality assurance of reviews, NRC suggests that a second reviewer independently review the entire application. If the reviewer agrees with the contents of the certificate after review of the information, the reviewer should acknowledge agreement by signing or initialing a "concurrence block."

4. For each sealed source and device review, the reviewer should evaluate emergency and operation procedures provided for the device/source. Important information may be included, or not included in the procedures that may limit how the device is to be licensed.

REVIEW OF SELECTED COMPLIANCE FILES

Summary and Conclusion

The State uses a field inspection form to document information obtained during the inspection. In general, the reports were reviewed to determine: (1) if the reports were sufficiently detailed to document that the licensee's program was sufficient to comply with the rules and regulations, and to protect public health and safety; and (2) if the inspections were complete and substantiated all items of noncompliance and recommendations. The files were reviewed to determine: (1) if appropriate enforcement actions were taken; (2) written in appropriate regulatory language; (3) timeliness of letters; and (4) if adequate responses were received from the licensee to close out the enforcement actions.

Twenty-two license compliance files were selected for review. For purposes of this report, a numerical casework code (1 through 22) was assigned to the following compliance files.

Case No. 01

Licensee:	Francis Scott Key Medical Center
Location:	Baltimore, MD
License No.:	MD-07-008-09
License Type:	Institutional Medical
Inspection Date:	07-21-91
Type of Inspection:	Closeout survey
Inspectors:	Alan Jacobson
Type of Report:	Form
Enforcement Letter/Date:	NA
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No.02

Licensee:	Francis Scott Key Medical Center
Location:	Baltimore, MD
License No.:	MD-07-008-40
License Type:	Institutional Medical
Inspection Date:	07-21-91
Type of Inspection:	Closeout survey
Inspectors:	Alan Jacobson
Type of Report:	Form
Enforcement Letter/Date:	NA
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No.03

Licensee:	Johns Hopkins Medical Institution (Asthma and Allergy Center)
Location:	Baltimore, MD
License No.:	MD-07-005-10
License Type:	Institutional Medical
Inspection Date:	04-29 and 05-07-92
Type of Inspection:	Initial, unannounced
Inspectors:	Alan Jacobson
Type of Report:	Form
Enforcement Letter/Date:	Violation, Form MDER-E-1 & 2
Licensee Response Date:	07-22-92
State Acknowledgement Date:	None

Case No.04

Licensee:	Maryland Q.C. Laboratories, Inc.
Location:	Aberdeen, MD
License No.:	MD-25-025-01
License Type:	Industrial Radiography
Inspection Date:	12-07-92
Type of Inspection:	Routine, unannounced
Inspectors:	Ray Manley
Type of Report:	Form
Enforcement Letter/Date:	N.O.V. dated 12-23-92
Licensee Response Date:	01-14-93
State Acknowledgement Date:	None

Case No.05

Licensee:	U of Maryland at Baltimore
Location:	Baltimore, MD
License No.:	MD-07-014-01
License Type:	Broad
Inspection Date:	04/20-21,& 24/92 and 05-13-92
Type of Inspection:	Routine, unannounced
Inspectors:	Manley, Jacobson, and Nelson
Type of Report:	Form
Enforcement Letter/Date:	N.O.V. dated 06-25-92
Licensee Response Date:	07-17-92
State Acknowledgement Date:	None

Case No.06

Licensee:	U of Maryland at Baltimore
Location:	Baltimore, MD
License No.:	MD-07-014-01
License Type:	Broad
Inspection Date:	08-19-92
Type of Inspection:	Routine, unannounced
Inspectors:	Alan Jacobson
Type of Report:	Form
Enforcement Letter/Date:	N.O.V. dated 09-21-92
Licensee Response Date:	10-05-92
State Acknowledgement Date:	None

Case No. 07

Licensee:	U of Maryland at Baltimore
Location:	Baltimore, MD
License No.:	MD-07-014-04
License Type:	Incinerator
Inspection Date:	08-19-92
Type of Inspection:	Routine, unannounced
Inspectors:	Alan Jacobson
Type of Report:	Form
Enforcement Letter/Date:	N.O.V. dated 09-21-92
Licensee Response Date:	10-05-92
State Acknowledgement Date:	None

Case No. 08

Licensee:	Mallinckrodt, Inc.
Location:	Baltimore, MD
License No.:	MD-05-105-01
License Type:	Pharmacy
Inspection Date:	01-18-93
Type of Inspection:	Initial, unannounced
Inspectors:	Ray Manley
Type of Report:	Form
Enforcement Letter/Date:	Violation, Form MDER-E-1 & 2
Licensee Response Date:	02-02-93
State Acknowledgement Date:	None

Case No. 09

Licensee:	Teledyne Energy Systems
Location:	Hunt Valley, MD
License No.:	MD-05-014-01
License Type:	Manufacturing and Distribution
Inspection Date:	07-19-93
Type of Inspection:	Closeout survey
Inspectors:	Manley and Kasper
Type of Report:	Form
Enforcement Letter/Date:	Clear letter, release of facility
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 10

Licensee:	Wallac, Inc. (formally Pharmacia LKB)
Location:	Gaithersburg, MD
License No.:	MD-31-071-01
License Type:	Manufacturer & Distributor
Inspection Date:	06-20-90 (next inspection due 06-95)
Type of Inspection:	Follow-up, unannounced
Inspectors:	Nat Owrutsky
Type of Report:	Form
Enforcement Letter/Date:	Violation, Form MDER-E-1 & 2
Licensee Response Date:	06-20-90
State Acknowledgement Date:	None

Case No. 11

Licensee:	GE Medical Systems
Location:	
License No.:	MD-03-052-01
License Type:	Manufacturer & Distributor, Service
Inspection Date:	08 13-92
Type of Inspection:	Limited (Review of Reciprocity Problems)
Inspectors:	Alan Jacobson
Type of Report:	(Could Not be Located in File)
Enforcement Letter/Date:	Clear, Form MDER-E-1
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 12

Licensee:	Becton Dickinson Diagnostic
Location:	
License No.:	MD-05-025-01
License Type:	Manufacturer & Distributor
Inspection Date:	03/01 & 04/91
Type of Inspection:	Routine, Unannounced
Inspectors:	Ray Manley and Frank Kasper
Type of Report:	Form
Enforcement Letter/Date:	Violations, Form MDER-E-1 & 2
Licensee Response Date:	03-08-91
State Acknowledgement Date:	None

Case No. 13

Licensee:	Scientech, Inc.
Location:	Gaithersburg, MD
License No.:	MD-31-204-01
License Type:	Analytical Services
Inspection Date:	02/11-12/92
Type of Inspection:	Routine, unannounced
Inspectors:	Alan Jacobson
Type of Report:	Narrative
Enforcement Letter/Date:	N.O.V. dated 02-19-93
Licensee Response Date:	03-04-93 and 03-17-93
State Acknowledgement Date:	None

Case No. 14

Licensee:	U of Maryland
Location:	Baltimore, MD
License No.:	MD-07-014-05
License Type:	Gammaknife
Inspection Date:	11-20-92
Type of Inspection:	Initial, unannounced
Inspectors:	Alan Jacobson & Robert Nelson
Type of Report:	Form
Enforcement Letter/Date:	Clear, Form MDER-E-1
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 15

Licensee:	Shimadzu Scientific Instruments, Inc.
Location:	Columbia, MD
License No.:	MD-27-011-01
License Type:	Manufacturer & Distributor
Inspection Date:	06/16-17/92
Type of Inspection:	Reinspection, Unannounced
Inspectors:	Robert K. Nelson
Type of Report:	Form
Enforcement Letter/Date:	Violations, Form MDER-E-1 & 2
Licensee Response Date:	07-22-92
State Acknowledgement Date:	None

Case No. 16

Licensee:	Therapy Services, Inc.
Location:	Frederick, MD
License No.:	MD-21-009-01
License Type:	Teletherapy Services
Inspection Date:	03-12-92
Type of Inspection:	Routine, Unannounced
Inspectors:	Ray Manley
Type of Report:	Form, Narrative
Enforcement Letter/Date:	Clear, Form MDER-E-1
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 17

Licensee:	Mallinckrodt, Inc.
Location:	Beltsville, MD
License No.:	MD-33-088-01
License Type:	Pharmacy
Inspection Date:	03-23-93
Type of Inspection:	Incident Investigation
Inspectors:	Raymond E. Manley
Type of Report:	Narrative
Enforcement Letter/Date:	N.O.V. dated 04-26-93
Licensee Response Date:	05-03-93
State Acknowledgement Date:	None

Case No. 18

Licensee:	Radiation Service Organization
Location:	Laurel, MD
License No.:	MD-33-021-02
License Type:	LLW Broker
Inspection Date:	11-23-92
Type of Inspection:	Routine, Unannounced
Inspectors:	Alan Jacobson
Type of Report:	Form
Enforcement Letter/Date:	Clear, Form MDER-E-1
Licensee Response Date:	NA
State Acknowledgement Date:	NA

Case No. 19

Licensee:	Neutron Products, Inc.
Location:	Dickerson, MD
License No.:	MD-31-025-05
License Type:	Pool Irradiator
Inspection Date:	09/18-19/92
Type of Inspection:	Reinspection, Unannounced
Inspectors:	Ray Manley, Carl Trump, & Robert Nelson
Type of Report:	Narrative
Enforcement Letter/Date:	Violations, Form DHMH 1097 B
Licensee Response Date:	10-08-92
State Acknowledgement Date:	None

Case No. 20

Licensee:	Neutron Products, Inc.
Location:	Dickerson, MD
License No.:	MD-31-025-04
License Type:	Pool Irradiator
Inspection Date:	09/18-19/92
Type of Inspection:	Reinspection, Unannounced
Inspectors:	Ray Manley, Robert Nelson, & Carl Trump
Type of Report:	Form, Narrative
Enforcement Letter/Date:	Violations, Form DHMH 1097 B dated 09-18-92
Licensee Response Date:	10-08-92
State Acknowledgement Date:	None

Case No. 21

Licensee:	Neutron Products, Inc.
Location:	Dickerson, MD
License No.:	MD-31-025-01
License Type:	Manufacturing & Distribution
Inspection Date:	07/8 & 14/93
Type of Inspection:	Reinspection, Unannounced
Inspectors:	Ray Manley, Alan Jacobson, Bob Nelson
Type of Report:	Narrative
Enforcement Letter/Date:	?
Licensee Response Date:	?
State Acknowledgement Date:	?

Case No. 22

Licensee:	Neutron Products, Inc.
Location:	Dickerson, MD
License No.:	MD-31-025-03
License Type:	Teletherapy service
Inspection Date:	?
Type of Inspection:	Reinspection, Unannounced
Inspectors:	?
Type of Report:	?
Enforcement Letter/Date:	?
Licensee Response Date:	?
State Acknowledgement Date:	?

The following table lists the specific comments developed during the review of the numbered inspection casework files above.

Specific Comments		Case No.
a.	Acknowledgement letters are needed for licensee replies to enforcement actions.	All casework
b.	Closeout reports were not maintained in the file.	1, 2
c.	State letter that releases the terminated facilities for unrestricted use was not in the file.	1, 2
d.	Inspection reports are usually not reviewed by the supervisor until after the enforcement action is issued and sometime this period lags the inspection by months and sometimes a year or more.	All casework
e.	More details are needed in the report to document conditions surrounding the improperly shielded source.	5
f.	More details are needed in the report to describe the rational why a 1.6 rem exposure was not cited.	5

g.	Licensee's response to violation was not fully adequate and should have been pursued further by the State. (Licensee's failure to provide document of procedures to staff.)	5
h.	Licensee was cited for waste storage on plastic pallets, a citation that was not tied down on the license.	6
i.	The inspection report could not be located in the file.	6
j.	Additional information is needed to document that a sealed source user has removed all sources from a facility prior to close-out of the facility. Verification is needed that all sources were removed and that sources were not leaking.	10
k.	The licensee's reciprocity procedures need to be reviewed and documented for service licensee's that perform work only at temporary job sites.	11
l.	The next inspection was recorded for the wrong frequency on the inspection report.	10, 12
m.	In regard to "incidents," the inspection reports relate that "none were reported." Procedures should be developed for how inspectors identify incidents (who, what, how, and when) and documented in the reports accordingly.	All
n.	More information is needed to document the use, calibration, and doses recorded on pocket dosimeters.	16
o.	Reports should describe any maintenance, or potential generic problems that licensee encounters during their customer maintenance/service checks.	16
p.	State is still using the DHMH 1097 B forms for enforcement actions in the field.	19, 20, 21
q.	Whenever more than one license is inspected at the same facility, a Notice of Violation is needed, with the violations associated with each license clearly identified.	20

NEUTRON PRODUCTS, INC. ACTIVITIES

During the program review, the NRC team interviewed Maryland staff, reviewed Neutron Products, Inc. (NPI) license and compliance files, and examined various aspects of the State's oversight of NPI operations. These included a file review and discussions with Radiological Health Program (RHP) staff of current and future licensing actions, discussions with State legal staff regarding civil actions, obtaining status of inspection and enforcement activities, and a conference with Maryland Department of the Environment (MDE) management to gain an understanding of future NPI enforcement strategy. This Appendix and the conclusions below are summaries of information presented in the December 2, 1993 memorandum from C. E. Norelius, Office of Nuclear Material Safety and Safeguards (NMSS) to R. L. Bangart, Office of State Programs (OSP) regarding Assessment of NPI and Maryland Programs, and the February 17, 1994 memorandum from J. M. Taylor, Executive Director for Operations, to the Commission reporting the Update on Assessment of NPI.

I. NPI LICENSED OPERATIONS

NPI is a unique licensee in the scope of its operation. The Dickerson, Maryland facility operations are regulated by the State through four different licenses. These are:

1. License Number MD-31-025-01 authorizes operations associated with sealed source fabrication, manufacturing and processing (hot cell operations); storage and shipment of sealed sources; and storage and disposal of waste materials. This license was first issued by Maryland on April 7, 1971, following the transfer of the jurisdiction to the State from the NRC. There have been 41 amendments to date and the license is under timely renewal.

2. License Number MD-31-025-03 authorizes possession, use, transfer, and installation of cobalt-60 teletherapy sources, and the service of specified teletherapy units. This license also authorizes the storage of up to 999 kilograms of depleted uranium (DU), and the temporary "dry storage" of certain cesium-137 sources used in customer irradiators, and is inspected annually. The storage of large amounts of DU has been a problem at this facility, and has resulted in the licensee obtaining an NRC license (license number SUB-1551) for storage of DU at a facility in Ranson, West Virginia.

3. License Number MD-31-025-05 is for a wet storage, batch type irradiator (Dickerson I), for the irradiation of medical supplies, cosmetics, herbs and spices, bird food, and research and development. The unit is licensed for up to 750,000 curies of cobalt-60 and uses NPI manufactured sources. The unit was originally included on the -01 license then transferred to a separate license in 1983. It is inspected annually, and no incidents were identified with the operation this facility.

4. License Number MD-31-025-04 is for a wet storage, conveyor type irradiator (Dickerson II), also used for irradiation of the same type of products. The unit was originally licensed in 1980 and is currently authorized up to 2 megacuries of cobalt-60. This unit has a common exterior wall with the Dickerson I unit, but safety systems are separate for each unit.

II. CIVIL ACTIONS/COURT CASE

The licensee declared bankruptcy in 1985. Chronic health and safety regulatory problems have been experienced with MD-31-025-01 since the license was originally issued. A co-inspection was conducted by the State and the NRC on March 13-14, 1989 to review the potential on-site and off-site contamination to personnel and property. On May 23, 1989 the State amended the license with amendment 33 which mandated extensive modifications of the licensee's health and safety program, additional facility modifications, and the evaluation and clean-up of contaminated soils outside the facility and at NPI unrestricted areas. Continued problems and failure to carry-out all of the amendment 33 provisions resulted in the Agency issuance of a civil penalty of $121,000 on December 19, 1990. The State reported that between January 1985 and March 20, 1993, it had conducted seventeen inspections, sixteen investigations, and cited approximately 83 violations.

Failure of the licensee to correct all violations and pay the civil penalty resulted in the State filing a complaint against NPI in the Montgomery County Circuit Court in 1991. The complaint was amended on May 15, 1992 for 24 counts and a trial was rescheduled for July 26, 1993. Representatives from the Office of State Programs met with Assistant Attorney General, Neil F. Quinter, on September 8, 1993, and reviewed the volumes of documents that were under consideration in the complaint. On June 28, 1993, the State filed a motion for summary judgement with the court. On January 4, 1994 the court issued a summary judgement in the State's favor on 17 of 24 counts including the requirement for NPI to comply with license amendment 33 and assessed a civil penalty of $200,000. In a settlement agreement reached with the licensee, NPI was required to pay the penalty and resolve many safety concerns including the waste handling problem, and enclose the open courtyard thus containing the primary source of Co-60 releases.

III. NPI LICENSE OVERVIEW

MD-31-025-01 LICENSE IMPLICATIONS

Following source fabrication associated with the MD-31-025-01 licensed operation, on-site and off-site releases of Co-60 have occurred through both controlled and uncontrolled release points. Contamination of adjacent resident and railroad property dates back to 1980 and a moratorium on cobalt melting was agreed to in 1981. The facility experienced problems with leakage and cobalt-60 contamination in the

storage pool, resulting in extensive modifications of the pool liner. Cobalt melting resumed and source fabrication continues under amendment number 26, dated July 5, 1985. Previous state actions taken on this license were:

- 1975 renewal issued
- 1980 license expired, remains in timely renewal

Key amendments: #30 (March 1989)

Required facility shutdown

#33 (May 1989)

Required extensive facility upgrades including:

Portal monitor

Health physics consultant to report monthly on facility operations and radiological controls

Full-time health physics technician

Action level criteria for decontamination

Radiation safety training program

Low-level waste disposal plan

Site boundary TLD network

Courtyard enclosure

Further details on this amendment are discussed below in Section V. "State Inspection Activities."

- May 1989 - 1992 Minor amendments - last amendment (#42), August 1992

While the court case was pending, the licensee continued to operate. NPI contested many conditions outlined in amendment 33 and subsequent amendments. Nonetheless, the State inspected and cited violations against those license conditions disputed by the licensee.

IV. NPI LICENSE FILE REVIEW

On January 31, 1994, a NRC review of Neutron Products, Inc. (NPI) license files was performed at the Maryland RHP office. The review covered recent NPI

licensing activity and available license and supporting documentation contained in files. A sufficient amount of pre-1992 information was maintained including numerous correspondence and letters with NPI over a period of 10-12 years, many of which tie-down licensee practices in amendments.

Information reviewed included:

1) Draft license renewal

   - Prepared, completed 1989 - April 1991
   - Not issued per direction of Maryland Attorney General

2) New requirements contained in proposed renewal (April 1991):

   Waste handling and shipments - top priority

   - requires continued shipment of waste to 10% current inventory, then max. 600 Ci on-site storage

   Recordkeeping

   - requires new facility to centralize all documentation

   Pool, canal quality

   - requires quarterly examination and cleaning

   Facilities and equipment

   - requires any changes subject to State approval

   Fire safety plan

   Among additional requirements identified in the renewal were water level alarms and testing, radiation safety committee meetings, upgrade to area radiation monitors, old Cs-137 source disposal, and a whole body count program.

After 1989, regulatory functions at NPI were primarily limited to on-site inspection. Significant licensing actions, i.e., the license renewal considered by the State since that time was precluded by the pending court case. Now that a court decision is in place, the State's license renewal plans are identified in three options submitted to NRC on April 4, 1994, as part of the strategic action plan for NPI. These options are: (a) update and issue the above license package with revised information obtained since April 1991, or (b) request NPI to resubmit a license application in its entirety, or (c) implement option (a) following a meeting with the licensee about what commitments and procedures NPI would be expected to follow.

Following the court's decision, RHP staff maintained discussions with NPI regarding license renewal, and on August 1, 1994, NPI submitted a renewal application to Maryland. RHP staff informed NRC their preliminary screening of the application indicated that it was deficient in several procedural areas, including some identified in the court decision. The application is currently under State review. Discussions between RHP staff and NPI continue frequently in addressing deficient program areas.

V. STATE INSPECTION ACTIVITIES

The staff related that the licensee's control of releases had greatly improved since 1989 when amendment 33 was issued. However, the licensee failed to fully implement all conditions of amendment 33 prior to the court case. As a result of the court decision, the State is currently inspecting against these conditions and plans to include them in the license renewal. Amendment 33 highlights include:

Stack Monitoring

The licensee has a HEPA system to filter stack releases coming from the hot cell process area and the effluent is being monitored with a continuous sampling system. Amendment 33 requires evaluation of this ventilation system by a consultant, and monthly reports of the operability status.

Personnel Monitoring and Contamination Control

The licensee was required to install a portal monitoring system to survey all personnel leaving the "limited access area" (LAA) of the facility. This system was installed in 1989 and is currently functional. NPI employs approximately 70 persons at this facility and all are reportedly monitored with personnel monitoring devices. During the 1988-89 time period, fourteen persons had a collective exposure of 112 rem. The State related that the current exposures were estimated to be about one-half of the 1988-89 exposures.

The State has documented several instances of contaminated licensee employees in unrestricted areas and on employee's personal property (off-site). The State ordered the licensee to monitor and conduct home surveys of all employees, and decontaminate property to background levels. This task was accomplished, however, other residential properties adjacent to the NPI site area were contaminated after each melt (approximately once per year) and the State requested NRC assistance on April 28 and September 8, 1993 to evaluate the most efficient mechanisms to control off-site releases. NRC responded by letter dated January 8, 1994.

Equipment Monitoring and Contamination Control

Amendment 33 also requires radiation surveys to be conducted of all personnel, vehicles, equipment and personal belongings that exit the gate to the courtyard area, and in accordance with limits specified in the U.S. Department

of Transportation regulations. Products for sterilization are processed in the plant. The licensee's methods and procedures to prevent contamination of these products and equipment (vehicles) are under reevaluation.

Sewer Releases

The licensee is authorized to dispose of waste water from the Dickerson facility by transporting the material to a specified dump station in the Washington Suburban Sanitary Commission (WSSC). These transfers are reportedly made on a weekly basis and the waste water is analyzed for radioactive concentrations. The material is collected in a carbon steel tank on-site (underground) and transported to the dump station by truck. The State has evaluated the licensee's procedures for collection, transportation and analysis of the material.

Groundwater and Soil

Surface water from the facility flows into the courtyard, into underground drains to a "rock bed filter," then underground to a dry pond located adjacent to the Dickerson railroad station. Discharge from the pond goes off-site. The dry pond and the railroad property are known to be contaminated with cobalt-60 and the licensee has started the clean up of the soil surface contamination and with storage in 55 gallon drums on-site.

The extent of the contamination is not well known. The licensee was required to establish several monitoring wells on-site to monitor potential movement of isotopes into the water table. Potable water sources in the vicinity of this site are from wells. The licensee was required to have a plan for the surveillance of radioactive contamination in surface and groundwater at the plant's boundary and within one kilometer radius of the licensee's facility.

Boundary Exposure

The licensee is required to monitor the radiation levels at the perimeter boundary fence with TLD's and the exposure limit is restricted to 500 millirem per year. The State also monitors the radiation levels. The State's TLD system has indicated that boundary radiation levels exceed the 500 millirem per year limit at several locations.

Waste Storage Area

The licensee is required to dispose of all radioactive waste in accordance with the Amendment 33 license criteria. Currently, disposal has not been accomplished and remains a matter covered under the State's complaint. (Staff notes that presently, and in the near future, Maryland licensees have no capability for disposal of waste since access to the Richland and Barnwell disposal facilities is precluded by the States/Compacts.) The State has related that the quantity of waste materials greatly contributes to the background radiation levels, and also is a potential source of facility

contamination and personnel exposure. NPI proposals to improve waste management at NPI are under RHP evaluation.

VI. JOINT STATE/NRC INSPECTION October 18-22, 1993 & November 1-12, 1993

Background

During a September 22, 1993 meeting held between the Office of State Programs (OSP), Region I, and the Maryland Radiological Health Program Administrator and staff, agreement was reached to conduct a joint Maryland/NRC inspection at NPI. The State identified general areas where NRC assistance was needed to effect safety improvements at NPI. Among these were evaluation of waste storage and disposal, methods to minimize controlled and uncontrolled releases of Co-60, analysis of ALARA practices, and characterization of off-site contamination pathways.

The team concentrated on effluent pathway analysis from NPI operations, i.e., airborne, groundwater, soil, surface runoff, waste stream-sanitary sewer, and assessed NPI radiation control practices relative to public and worker health and safety. Supplementing the effort was an aerial survey of on-site and off-site areas for radioactive contamination and environmental site measurements. A detailed inspection plan was developed in a September 28, 1993 meeting between the State and NRC. Specific expertise needed from Maryland and NRC to carry out the inspection plan was identified. Experience obtained by individuals involved in NRC Region III's review of the Advanced Medical System facility in Cleveland, Ohio together with the Office of Nuclear Material Safety and Safeguards (NMSS) and Region I, participated in the NPI inspection.

Inspection Scope

The on-site inspection conducted October 18-22, 1993 focussed on the issue of potential release paths from the facility, primarily as a result of source manufacturing operations in the hot cell. Although the inspection did not provide a comprehensive review of the total NPI program or of the State oversight of NPI, NRC was able to obtain important insights into significant areas of the program. In addition to the on-site inspection, an aerial overflight of the site was performed by EG&G, under an NRC contract, during the period of November 1-12, 1993, to evaluate off-site contamination.

Inspection Findings

The inspection determined that the hot cell and surrounding limited access area were generally clean, with external radiation levels in the hot cell of about 300 mr/hr and contamination in the LAA from 500-1000 dpm/100 sq. cm. These levels are the result of improvements over time, according to the State, and may have been exceptionally good given the announced nature of this inspection. Smoke tests showed a negative pressure only at the rear entrance of the hot cell and at a pass-through box from the office area to the LAA. In other areas of the LAA the air appeared to be stagnant allowing contamination to drift, or in the case of open overhead doors to the outside which occur

regularly, allowing wind to move contamination. Except for a compliance problem with timely testing of the secondary HEPA filter, the air filtration system from the hot cell was in good working order. The licensee's program for analysis of airborne effluents from the LAA through the ventilation system was adequate, and showed releases to be low.

Liquid effluents from the process area are collected and pumped into a truck weekly, and transported to the sanitary sewer system. The licensee collects three samples from each truckload. All samples are counted in a high background area. As a result, the LLD is relatively high, but well within regulatory limits. The licensee documents any positive reading, uses the highest reading of the three samples as being representative of the whole, and then records the three sigma values as the basis for calculating the quantity released. Based on this conservative approach, records show releases in the range of 15-30 mCi/yr since 1985. Independent surveys of the truck and the release point at the sanitary sewer system showed nothing unusual except for some high readings (1.5 mr/hr) at the surface of the truck. These high levels remained after the truck was unloaded, which apparently resulted from a procedural violation allowing buildup on the inner baffles because of inadequate cleaning of the truck over an extended period of time. This also raises a question of the dispersibility and solubility of the material. Given the relatively low quantities of material discarded and the conservative approach in documenting these releases, this aspect of the program does not appear to present any undue safety problem. However, implementation of the new 10 CFR Part 20 will require a determination of the solubility of the material to determine its releasibility. The water in the sanitary sewer system is processed at the Blue Plains treatment plant, where the sludge is composted with wood chips and sold to the public for gardening and landscaping. Samples of water and sludge at the Blue Plains treatment plant showed only commonly used medical isotopes, with no indication of cobalt-60.

Problems still exist at the facility, however. Waste storage presents the greatest potential safety problem. About 50-60 plastic bags along with steel drums together contain about 750 curies of cobalt-60 as waste materials are likely the primary contributors to the fenceline doses which, according to the State, continue to exceed the 500 mr/yr level at several locations. Some of the plastic bags are ripped, and are likely significant contributors to the extensive contamination in the courtyard area since the overhead doors to that area must be open for any activity performed in the storage area. A fire protection analysis showed that the likelihood of a fire being initiated in this area is low, but if one should start, the fire load in the area is moderate and the amount of material which could be released could present an off-site hazard.

Another identified pathway relates to unmonitored releases from the site of small quantities of cobalt 60. Off-site surveys during the inspection identified 6 spots of contamination downwind from the site in the adjacent neighbor's field, ranging up to 0.6 microcuries. This is typical of prior surveys by the licensee and the State. Identified spots of contamination were found at various off-site locations surrounding the site, with the majority of

contamination at discrete downwind locations. After licensee clean-up, subsequent surveys showed similar results. The team concluded that the most likely source of the contamination is wind blown material from the contaminated courtyard, the waste storage area, and the dry pond area.

Nine soil samples taken in the unrestricted drainage area of the dry pond and other areas surrounding the plant, all showed identifiable Co-60 with the highest level of 410 pCi/gm found on railroad property near the site. These levels violate the Maryland license condition which limits contamination in unrestricted areas to 8 pCi/gm, and demonstrate poor health physics practices. The State believed the licensee remains in violation of the requirements for not monitoring the level of material released through this pathway. The licensee greatly objected to this conclusion.

The licensee claimed it took sufficient storm sewer water samples, which when combined with their analysis of a rock bed filter and of the material in the dry pond area showed that releases are much less than 1% of MPC values for effluent releases to unrestricted areas. They also object to a license condition imposed on them which limits the off-site contamination to 8 pCi/gm on the basis that there is no technical basis for the level, and that it was illegally imposed by the State. The NPI President also questioned the State's technical competence to evaluate his program for monitoring releases. A water sample taken from an on-site monitoring well showed no activity above background. The inspection did not address the appropriateness of the well location and depth relative to the geology of the area.

The aerial overflight could not distinguish any contamination within about 1/4 mile from the plant due to the high radiation levels emanating from the plant itself. However, outside of that area, no contamination was identified. The overflight included the area where the waste water is dumped into the sanitary sewer system.

The team also expressed concern over the minimal amount of time spent on radiation safety matters and the apparent lack of plant health physics knowledge by the Radiation Safety Officer. The licensee lacked knowledge regarding the use of their contamination detection system relative to evaluation of intakes of radioactive material. The licensee described their efforts to hire a health physicist, and contended they cannot get anyone to come because of the bad reputation they have received because of the State lawsuit against them. The team also noticed some poor health physics practices by workers--the violation of step-off pads and workers with protective clothing unzipped in the front while working in the LAA.

Conclusion

Based on the scope of this inspection and discussions with State personnel, several conclusions were made regarding the State's handling of NPI which reflect on the overall Maryland program. Due consideration was given to the high level of effort and unusual amount of staff resources expended by the

State in addressing NPI licensing and compliance safety issues and litigation matters.

1. The State appears to have been effective in reducing the doses to workers within the plant. The hot cell and LAA were relatively clean. Doses from hot cell cleanup after each melt, the primary cause of personnel exposure, have been reduced by about a factor of three over the last three melts (these occur about once every 12-18 months). Whether these doses are ALARA was not determined, and it would take a considerable effort to look at this area alone.

2. The State appears to have been effective in reducing the spread of contamination from the plant by plant workers. They have required new sensitive monitors for egress from the LAA.

3. NRC observed that the State has not been effective in handling the waste storage problem, the high fenceline doses, or the on-site and off-site contamination. Although on-site waste storage and contamination are difficult areas with unclear regulations, it is not clear why stronger action had not been taken by the State to reduce fenceline doses even in the absence of a solution to the waste storage problem. Sufficient information is available on what exists at the site, but there are questions that remain related to continued NPI/State interface, resolution of licensee recalcitrance and facility problem areas, implementation of new regulations, and the effectiveness of enforcement actions by the State. (Staff notes, as discussed further below, that since the inspection, the court case has been settled and is being implemented, a license application for renewal has been filed and the RHP is following a plan for inspection and compliance activities.)

4. The impact of the State's adoption of the new 10 CFR Part 20 was also discussed with the licensee. The licensee agrees they do not meet this new regulation, and would not be able to meet it until improvements are instituted in controlling release of radioactive material. The State has measured external radiation levels at nearby residents which will exceed the new rule, so considerably more analysis will be required to assess other neighbors and other possible modes of exposure. Other areas which would require licensee actions under the new 10 CFR Part 20 relate to the determination of the solubility of material released to the sanitary sewer system, and the program for evaluating doses from internal uptakes.

5. This licensee is unique in terms of its operation and the large quantities of cobalt-60 which it handles. This inspection was directed toward the hot cell operations considered to be the most likely source of exposure and contamination. It did not address the two large irradiators, nor the contaminated equipment or other singly encapsulated material that is stored in the pool. Also, the licensee has a chemical processing business in the same building. A hazards analysis of this

process relative to the use of licensed material would seem prudent, similar to recent NRC actions for some of its licensees.

The October 18-22, 1993 NPI inspection did not disclose any immediate health and safety issues, but did show problems with the licensee's radiation safety program, which required additional review. The problems at NPI arise from a unique operation and a management which is sometimes uncooperative. The State has been effective in improving safety at the site, but has not been fully successful in addressing all radiation safety issues.

The follow-up exit meeting held on April 7, 1994 helped clarify NRC's understanding of the State's licensing and compliance history with NPI. In their letter of April 4, 1994 to Craig Gordon, NRC, the RHP described a plan of action for continued regulation of NPI which outlined a "strategic plan" for inspection and compliance activities, implementation of the January 1994 settlement agreement, and consideration of options for license renewal. NRC reviewed the plan and noted that it appeared sufficient in scope to address current safety issues and the State's expected near-term association with NPI. Based on the review, staff recommends that the State continue efforts to renew the NPI license. NRC will continue to maintain close contact with State staff on the status of the license renewal effort and on inspection and enforcement activities related to NPI.