DATED: MAR 3, 1995; SIGNED BY: RICHARD L. BANGART

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 part 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. This is a serious omission since 10 CFR Part 20 contains basic radiation protection standards. The continued failure by Maryland to adopt the 10 CFR Part 20 equivalent regulation could adversely affect the NRC's finding as to the adequacy of the State's program to protect public health and safety.

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.

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 is 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.

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- "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.

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, Director
Office of State Programs

Enclosures:
As stated

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

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Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/encls: See next page. bcc w/encls: See next page.
Distribution: See next page.
*See previous concurrence. G:\94LETTER.MD

OFC	RI:SAO	RI:ORA	RII:SAO	OSP:SPM	OSP:DD		
NME	CGordon:gd/dr	WKane	RWoodruff	CMaupin	PLohaus		
DTE	11/22/94* 12/12/94*	12/12/94*	11/28/94*	11/22/94* 12/12/94*	11/22/94* 12/12/94*		

OFC	NMSS:D	OGC	OSP:D	DEDS	EDO		
NME	RBernero	FCameron	RLBangart	HLThompson	JMTaylor		
DTE	12/13/94*	12/12/94*	12/15/94*	12/ /94	12/22/94*		

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

bcc w/encls:
The Chairman
Commissioner Rogers
Commissioner de Planque

Distribution:
DIR RF
EDO RF (94000079)
JTaylor, EDO
HThompson, DEDS
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JDwyer
SBaggett
TCombs
RBores
DChawaga
FCameron
RWoodruff
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Maryland File
DCD (SP01) PDR YES ___ NO ___

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 and a follow-up review of the sealed source and device regulatory program on January 31, 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 Radiation Management Administration, MDE, and Roland Fletcher, Administrator, 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.

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- "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 Appendix 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.

Assessment

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

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 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.