REPORT AND STAFF EVALUATION

OF THE

MARYLAND RADIATION CONTROL PROGRAM

FOR THE PERIOD

AUGUST 30, 1985 TO JANUARY 30, 1987

16th Regulatory Program Review

RADIATION CONTROL PROGRAM: Maryland
REVIEW MEETING NUMBER: 16TH
DATES OF REVIEW: January 21 - 23, 27 - 30, February 4, 1987
PERIOD OF REVIEW: August 20, 1985 to January 30, 1987
NRC REPRESENTATIVES: John R. McGrath and Donald A. Nussbaumer
RADIATION CONTROL PROGRAM REPRESENTATIVES: Roland Fletcher, Chief, Division of Radiation Control

Conclusions

The Maryland program for control of agreement materials is, in the staff's humble opinion, adequate to protect the public health and safety. A finding of compatibility was withheld pending the development of regulations on waste classification and manifests.

Summary Meeting with Management

On February 4, 1987, a summary meeting to present the results of the regulatory program review was held with Mr. William Eichbaum, Assistant Secretary, Office of Environmental Programs; Mr. David Resh, Administrator, Community Health Management Programs; and Mr. Roland Fletcher, Chief, Division of Radiation Control. The NRC was represented by John R. McGrath and Donald A. Nussbaumer. The NRC staff presented the following comments:

1. The State has made significant progress in reducing the inspection backlog since the previous review. However, there were two priority II licenses issued to NPI that had not been inspected as scheduled. Since these licenses were overdue for inspection by a significant amount of time, a finding of adequacy would have to be deferred. The State responded that the licenses would be inspected on a priority schedule, probably before our comment letter was received. Indeed, the NRC learned that the licenses had been inspected in a timely fashion and in our May 27, 1987 comment letter a finding of adequacy was made.

2. The State's radiation control regulations were recently updated, however, the update did not include the low-level waste classification and manifest systems. Various drafts had been prepared by various groups in the Department, but never finalized. Since three years have past since the adoption of these requirements by NRC, we cannot offer a finding of compatibility until such time as the regulations are in effect. The State responded that since Maryland was part of the Appalachian compact, they were waiting for Pennsylvania to take the lead in developing regulations which would then be followed by the State of Maryland.

3. In 1980, the radiation control program was given civil penalty authority and developed draft escalated enforcement procedures. These procedures, however, were never finalized. In light of the fact that the program is taking an increasing number of enforcement actions, the procedures should be finalized as soon as possible.

4. The program's compliance supervisor has accompanied the inspection staff primarily for training purposes. The inspection staff is now trained to the point of doing independent inspections and it was recommended that the compliance supervisor institute a routine program of annual field evaluations of the inspection staff.

5. The program's inspection reports were technically sound and adequately supported enforcement actions. The narrative reports were not, however, organized in a manner which facilitated review and retrieval of inspection data. It was recommended that the program reorganize its inspection form and copies of NRC forms were provided as models.

PROGRAM CHANGES RELATED TO PREVIOUS NRC COMMENTS AND RECOMMENDATIONS

1. Comments and Recommendations

During our previous review of the Maryland program, a number of deficiencies were noted. The most significant problem area, the licensing and inspection backlogs, were directly related to an inadequate staffing level.

In response to this condition, the Department developed a plan to augment the staff and to review the existing salary structure to determine what changes are necessary to recruit and retain qualified personnel. Although action has been taken to assign additional staff to the radioactive materials program, the State should move forward promptly with its staffing plan and, most importantly, proceed with the review of staff salaries. The inspection and licensing backlogs remain and it is essential that the State be in a position to recruit and retain appropriately qualified staff. With regard to the licensing program, we suggest that the State consider providing additional staff resources in this area. This will help address the current backlog as well as provide for experienced coverage of t[illegible] function in the event of future staff turnover. With regard to th[illegible]ction backlog, we suggest that the State develop a specific plan [illegible]ess this problem area. The plan should include a training schedule for new staff, staff utilization schedules, and specific inspection backlog reduction objectives.

State Response

Although significant accomplishments have been made in enhancing the capabilities within the radiation program, we realize that problem still exits. These include program staffing and the reduction of the present licensing and inspection backlog in the radioactive materials area. Additional staff positions have been allocated, by this office, to the radiation program. However, the recruitment of qualified personnel has been extremely difficult due primarily to the present salary structures. In an attempt to minimize this problem, I have identified the radiation positions for salary adjustments in fiscal year 1987. Reducing the present licensing and inspection backlog is directly correlated to the

staffing level and training within the program. To address this problem, a plan is being developed wherein specific backlog reduction objectives are set forth.

Current Status

Since the previous review, there have been significant changes to the Division of Radiation Control. Additional staff have been recruited, the program has been reorganized, positions have been upgraded and these changes have had a beneficial effect in almost all program areas.

2. Comment

The State has taken steps to update the radiation control regulations, however, pending the completion of this task, we are withholding a finding of compatibility with the NRC's program.

State Response

None.

Present State

The State has still not completed action on low-level waste regulations.

3. Comment

State licenses were for the most part adequately supported by information in the applicant's supporting documentation. A few minor deficiencies were noted however. These included insufficient details on radiographer refresher training, provisions for backup survey meters, security over storage areas, facility descriptions, and the authorizing of medical Group III when only unit doses were requested.

Recommendation

We believe that a more careful review of applications should be a Division goal. The current licensing workload is being handled by one person. We believe that this is an unsatisfactory situation, which may be contributing to the minor oversights discussed in the above comment. The Division should provide backup in the Licensing program.

State Response

None.

Present Status

The review of selected license files revealed that there has been definite improvement in this area. The staff believes that the

reassignment of one individual to licensing duties has reduced the workload per person to a more manageable level with a resultant increase in review quality.

4. Comment

During the review period, the State evaluated and issued a catalog sheet for a cobalt 60 teletherapy unit. The evaluation for the most part covered the necessary points, however, our review of the supporting documentation raised two questions which could not be resolved. (1) The unit's drive wheel is capable of being retracted by hand in an emergency. Although the instructions indicated that the wheel should be turned clockwise, certain drawings provided would indicate that it should be turned counterclockwise. (2) The manufacturer indicated that the unit comes with an optional beam stop, and that the beam stop was "retractable". There was no information indicating why the beam stop was retractable or under what conditions it could be retracted.

Recommendation

We believe that the manufacturer should be requested to clarify the information concerning the rotational direction of the drive wheel and provide additional information on the beam stop so it can be determined that it could not be retracted in such a manner as to affect safety.

State Response

None.

Present Response

The State contacted the licensee shortly after the last review and received confirmation on the direction to turn the emergency retracting wheel and that the beam stop is optional, i.e., when a beam stop is not installed, the unit can only be operated in the vertical position.

5. Comment

The review of two compliance actions involving in-house radiographers raised a number of concerns. The first involved the State's interpretation of Section D.105 of the Maryland regulations. Independent measurements taken adjacent to the licensees' facilities indicated radiation levels of 0.5 - 13.5 mr/hr. One licensee was cited against D.105, exceeding 0.5 rem per year in an unrestricted area. Later enforcement action required both licensees to meet 170 mrem per year at the boundary of the restricted area. The use of the 170 mrem per year limit was based on the State's interpretation of D.105 and NCRP Report 39, paragraph 247. we believe that this is a misinterpretation of NRCP guidelines. The 170 mrem per year is an average figure for large populations, and was not meant to apply to an individual at the boundary of a restricted area, where the 0.5 rem per year limit of D.105 applies.

The State, in determining compliance, did not allow for use factors in the calculation showing noncompliance with D.105 although the inspection reports indicated that the licensees had records concerning use.

One inspection report indicated that the State's surveys were performed with an uncollimated source, although the licensee indicated that a collimator was always used.

The "policy" concerning the applicability of the 170 mrem per year limit and the disallowance of use factors was never formally established as Department policy and was selectively applied to certain licensees.

Recommendation

We recommend that the State no longer apply the 170 mrem per year value as a limit applicable to the boundary of a restricted area.

The wording of D.105 (and 10 CFR 20.105, on which it is based) makes it clear that the application of use factors for determining compliance with that section is always allowable. If the licensee has adequate records regarding the use of sources these must be taken into account in determining compliance. If such records are not available, or the State has some reason to question their accuracy, the enforcement action can reflect this.

We recommend that in performing independent measurements, the exposure setup should reflect, as closely as possible, the licensee's operating procedure. If the licensee's procedures call for routine use of a collimator, and there is no indication that this procedure was violated, it is inappropriate to base compliance actions on measurements without a collimator in use.

We recommend that the State's regulations be consistently applied to all licensees. The singling out of a particular category of licensee and applying a special interpretation of the regulations, calls into question the State's fair and impartial administration of program requirements. In addition, we recommend that all "interpretations" of the regulations receive Department review and be formalized as Department policy. The NRC should also be given an opportunity to review and comment on the State's position prior to implementation.

State Response

None.

Present Status

This issue was discussed with the present compliance supervisor. He clearly understands the issues involved, agrees with the NRC comments made at the previous review, and intends to follow NRC guidance in the future in this area.

6. Comment

During our previous review, we noted that the program had recently been given civil penalty authority and we recommend that the Division prepare written procedures to implement this authority. We note that the State has not yet prepared these procedures.

Recommendation

The Division has had a draft procedure for escalated enforcement actions since January 1980. We believe that this draft should be updated and finalized and that it include the procedure for handling the issuance of civil penalties.

State Response

None.

Present Status

The State has still not taken action to address the finalization of these procedures.

EVALUATION OF AGREEMENT STATE RADIATION CONTROL PROGRAM
STATE REVIEW GUIDELINES, QUESTIONS AND ASSESSMENTS
Name of State Program: Maryland Division of Radiation Control (DRC)
Date of NRC Review: January 1987

I. LEGISLATION AND REGULATIONS

NRC Guidelines: Clear statutory authority should exist, designating a state radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement. States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA. Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

A. Legal Authority

Questions:

1. Please list all currently effective legislation that impacts the State's radiation control program.

   Annotated Code of Maryland
   Health - Environmental (HE)
   Title 8 - Radiation
   Section 8-101 - 8-601

   Title 7 Hazardous Materials and
   Hazardous Substances

   Sections 7-201, 7-208, 7-225
   7-226, 7-227, 7-228
   7-232, 7-223, 7-234
   7-235, 7-236, 7-237
   7-238, 7-239, 7-240
   7-241, 7-242, 7-243
   7-244, 7-245, 7-249
   7-250, 7-251, 7-252
   7-257

2. What changes have been made to the statutory authority of the Radiation Control Program (RCP) to license, inspect, and otherwise regulate agreement materials since the last review?

   None

3. If your State regulates uranium or thorium recovery operations and associated wastes pursuant to an amended agreement and UMTRCA, explain any changes to the statutory authority for these functions.

   N.A.

4. Are copies of the current enabling act and other statutes (e.g., Administrative Procedures Act, Sunshine Act., etc.) which govern the conduct of the agreement materials program on file in the RCP office and with the NRC? If revisions have occurred since the last review, the changes should be included.

   Yes

5. If the State's regulatory authorities are divided between agencies, what procedures and memoranda are in effect to provide clear understanding of the divisions of responsibilities and requirements for coordination?

   None

6. Does the State have the authority to:

   a. apply civil penalties? If so, cite legislation.

      Yes, Section 8-501(b), HE Article

   b. collect fees? If so, cite legislation.

      No.

   c. require surety or long-term care funds? If so, cite legislation.

      No.

   d. require performance bonds or sureties for decommissioning licensed facilities? If so, cite legislation.

      No

   e. require performance bonds or sureties for clean-up of licensed facilities after a contamination accident? If so, cite legislation.

      No

   f. require long-term care funds for uranium mill or low-level waste facilities? If so cite legislation.

      No

g. enter into low-level waste compacts? If so, cite legislation.

Yes, Section 7-227, HE Article.

h. establish, license and/or operate a low-level waste site?

Yes, Section 7-233, HE Article

7. If any responses to the above question are negative, explain any plans the State may have regarding those issues.

Regarding questions 6 c-f, there are currently no plans to address these issues.

I.A Reviewer Assessment: The State meets these indicator guidelines.

B. Status of Regulations (Category I)

NRC Guidelines: The State should have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards and effluent limits), and those required by UMTRCA, as implemented by Part 40. The State should adopt other regulations to maintain a high degree of uniformity with NRC regulations.

Questions:

1. When did the RCP last amend regulations in order to maintain compatibility and when did the revisions become effective?

Adopted: September 2, 1986. Effective: September 21, 1986

2. Referring to the enclosed NRC chronology of amendments (Attachment A) note the effective date of the NRC changes last adopted by the RCP.

June 28, 1983.

3.a. Were there any compatibility items that were not adopted by the RCP?

Yes

b. If so, please identify and explain why they were not adopted.

The State has not adopted any regulations equivalent to the NRC LLW classification and manifest rules.

I.B. Reviewer Assessment: The responsibility for LLW regulations resides in the Division of Waste Management. This Division with the assistance of the State Health Advisory Group is developing LLW regulations. Also see section VII.C. Reviewer Comment.

C. Updating of Regulations (Category II)

NRC Guidelines: The RCP should establish procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable but no later than 3 years. Opportunity should be provided for the public to comment on proposed regulation changes. (Required by UMTRCA for uranium mill regulation.) Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

1. Does the RCP have a schedule or program for revising and adopting changes to regulations within three years of adoption by the NRC?

   Not a written program or schedule but we understand the need for this and act accordingly.

2. Has the RCP adopted all regulations deemed a matter of compatibility by NRC within three years? (Refer to NRC chronology).

   No. The State has not adopted an equivalent to NRC's waste classification and manifest regulations.

3. What are the RCP's procedures for adopting new regulations? Briefly describe each step in the procedure.

   DHMH Procedure - 1300. A copy is available in Region I files.

4. How is the public involved in the process?

   Proposed regulations are published in the Maryland Register for comment. A public hearing is also held.

5. a. Does the NRC have the opportunity to comment on draft changes to RCP regulations?

      Yes.

   b. If so, does the RCP respond to the comments?

      Yes.

I.C. Reviewer Assessm The State meets these indicator guidelines with regard to proced , but has not adopted LLW regualtion. Also see Section VII.C.

II. ORGANIZATION

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

NRC Guidelines: The 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.

1. Attach a dated organization chart(s) showing the RCP and its location within the department and State organization.

   Organization Charts are attached as Appendix A.

2. Is the RCP on a comparable level within the State organization with other health and safety programs so as to compete effectively for funds and staff?

   Yes.

3. Does the program director have access to appropriate levels of State management?

   Yes.

II.A Reviewer Assessment: The State meets these indicator guidelines. It is expected that in the near future the RCP will be transferred to a new Department of the Environment.

B. 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. Where regional offices are utilized, the lines of communication and administrative control between the regions and the central office (Program Director) should be clearly drawn to provide uniformity in inspection policy, procedures and supervision.

Questions:

1. Attach dated copies of your internal RCP organization charts.

Organization Chart attached as Appendix B.

2. How is the RCP organized so as to provide specific lines of supervision from program management for executing program policy?

   Divided in Sections with Section Heads in Charge.

3. If regional offices are used:

   No regional office used.

   a. To whom do regional personnel report administratively?

   b. To whom do regional personnel report technically?

4. If the RCP contracts with other agencies to administer the program:

   RCP does not contract with other agencies to administer the program.

   a. Identify the contracting agencies and indicate their responsibilities.

   b. To whom do contract personnel report administratively?

   c. To whom do contract personnel report technically?

II.B Reviewer Assessment: The State meets these indicator guidelines.

C. 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.

Questions:

1. Are legal staff members assigned to assist the RCP or do procedures exist to obtain legal assistance expeditiously?

   Community Health Programs has legal assistance specifically assigned from the State Attorney General's office.

2. Is the legal staff knowledgeable regarding the RCP, statutes, regulations and needs?

   The Community Health Program attorney has been on board about one month and has been involved in RCP matters such as regulations and enforcement conferences.

3. If legal assistance was utilized since last review, provide a summary of the circumstances.

See response to Question 2.

II.C Reviewer Assessment: The State meets these indicator guidelines.

D. 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. A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The Committee should represent a wide spectrum of medical disciplines. The Committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans. Procedures should be developed to avoid conflict of interest, even though Committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

Questions:

1. Discuss practices followed for obtaining technical assistance when needed (e.g., consultants, technical and medical advisory committees, licensees, the NRC and other State and Federal Agencies).

   The law provides for a Radiation Control Advisory Board (RCAB); we have a Medical Advisory Committee (MAC). Regular meetings of the RCAB are held. Assistance from the MAC is either by mail or a meeting. Consultants are not used. If we need assistance from a licensee we request it, the same for the NRC and other State and Federal agencies.

2. What steps are taken to avoid conflicts of interest?

   Attention is given to avoiding conflicts of interest by not requesting advice from committee members in cases involving a licensee with whom they are associated.

3. Are any committees involved in setting policies? If so, explain.

   No.

4. Attach a list showing the membership, specialties and affiliations of the Medical and/or Technical Advisory Committees.

   Lists are available in Region I files.

5. Indicate whether the advisory committees are established by statute, by appointment of the Governor, by appointment of the Board of Health, by appointment of the Agency, or by other means.

RCAB established by statute. Appointments made by Sec., DHMH. MAC was established in 1971 by the Department upon becoming Agreement State. Membership appointed by Secretary; still same as originated.

6. What is the formal meeting frequency of each committee, and are minutes of committee meetings prepared?

   The RCAB meets four times per year. Minutes are prepared.

7. What was the date of the last formal meeting of each committee?

   RCAB - November 5, 1986.

8. Are individual committee members contacted for consultation?

   No.

9. Discuss how each committee is used, the average workload placed on the committee, and the remuneration, if any.

   The RCAB is asked to give advice as needed at time of the meetings. Members are provided with drafts of regulations, etc. to review and comment on. The average workload would probably not exceed 10 hours each 6 months. The law stipulates that members are to receive no remuneration, but provides for reimbursement of expenses. The MAC is consulted by mailing each member a letter of request for advice supported by the necessary backup material. Members then respond by mail giving their recommendations. No remuneration is provided.

   Estimated average workload - 8 hrs. per year.

II.D Reviewer Assessment: The State meets these indicator guidelines.

III. MANAGEMENT AND ADMINISTRATION

A. Quality of Emergency Planning (Category I)

NRC Guidelines: The State RCP should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.

The Plan should define the responsibilities and actions to be taken by State agencies. The Plan should be specific as to persons responsible for initiating response actions, conducting operations and cleanup. Emergency communication procedures should be adequately established with appropriate local, county and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the Plan while in draft form.

The plan should be reviewed annually by Program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

Questions:

1. Is the RCP responsible for its own emergency plan or are accidents involving radioactive materials incorporated into a comprehensive State plan developed and administered by another State agency? Please provide copies of all applicable plans for review.

   Radiation response plan is incorporated into the Maryland Disaster Assistance Plan (MDAP). The MDAP is a comprehensive State plan. Excerpts applicable to radiation incidents are available in Region I files.

2. What written procedures or plans does the RCP use for responding to incidents involving radioactive materials?

   For materials incidents, the general plan applies. For fixed nuclear facilities Annex Q of the plan applies. DRC rarely refers to the MDAP in #1 above.

3. If the plan covers major accidents at nuclear facilities, how does it cover non-catastrophic incidents such as those involving transportation of materials?

   It instructs all persons (or agencies) requesting assistance for radiological incidents to notify DRC, the Maryland State Police (MSP) and the Maryland Emergency Management & Civil Defense Agency (MEM & CDA).

4. How does the plan define responsibilities and actions to be taken by all State Agencies (initiating response actions, operations, cleanup, etc.)?

   DHMH is primarily responsible for directing radiological assistance and recovery operations. Other State agencies will provide appropriate assistance to DHMH.

5. How does the plan provide for notification of and communications with appropriate government agencies?

   Communications are primarily by public telephone systems. Individual agencies may also utilize two-way radio or beepers for internal notification. Some interface exists on two-way radio frequencies.

6. How is the response program organized so that qualified individuals are readily available through identifiable channels of communication?

   Any and all of the DRC staff can be called on to respond in a radiation emergency. No formalized "on-call" schedule exists,

nor is it considered necessary based on past experience. DRC personnel can be reached by call-out lists maintained by the following:

a. MSP
b. MEM & CDA
c. DHMH Emergency Operator
d. Management Staff

7. Has the plan been distributed to all participating agencies?

Yes.

8. Has the NRC had opportunity to comment on the plan in draft form?

No, the plan was originally approved by Governor's Executive Order on September 26, 1975. Updates are issued as necessary by MEM & CDA.

9. Is the plan reviewed annually by the RCP for adequacy and to assure the content is current?

Yes, but changes are not currently being published as "updates". MEM & CDA is working on a completely revised MDAP.

10. Are drills performed periodically to test the plan for radioactive materials emergencies? Explain, for example, how non-routine office hours communications are checked.

Not specifically for non-reactor emergencies. Since the call-outs to DRC and DHMH are identical for reactor and non-reactor emergencies, one drill will suffice for both possibilities. Off-hours notification drills are conducted to test the notification system.

III.A Reviewer Assessment: The State meets these indicator guidelines.

B. Budget (Category II)

NRC Guidelines: Operating funds should be sufficient to support program needs such as: staff travel necessary to conduct an effective compliance program, including routine inspections, followup 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. Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

Questions:

1. What fiscal year is used by your State?

   July 1 to June 30.

2. Indicate the amount for funds obtained from each source (fees, State General funds, HHS, NRC environmental monitoring or transportation surveillance contracts, EPA, FDA and others).

   Source of Funds

	FY 84
Fees	0
State General Funds	$364,296
NRC Environmental Monitoring Contract	17,936
HHS/PHS/FDA, X-Ray Inspections Contract	6,514
MD Department of Natural Resources, Power Plant Siting Program Contract	0
Nuclear Power Agreement (BG&E) Partial Funding for Two People in Emergency Planning	14,499
	$403,245

3. Show the total amounts assigned to:

   Amounts assigned:

   a. the total radiation control program

      Total radiation control program: $403,245

   b. the radioactive materials program.

      Total radioactive materials program: $252,109 (65% of total)

4. What is the change in budget from the previous year and what is the reason for the change (new programs, change in emphasis, statewide reduction, etc.)?

   Change from previous year: $ 42,977
   BG&E contract and increase in NRC monitoring contract.

5. Describe your fee system, if you have one, and give the percentage of cost recovery. Enclose a copy of the fee schedule.

   None.

6. Does the RCP administer the fee system?

   NA

7. What recourse does the RCP have in the event of non-payment?

   NA

8. Overall, is the funding sufficient to support all of the program needs? If not, specify the problem areas.

   Yes, however, the budget includes no training funds or funds specifically set out for the State's radon program.

III.B Reviewer Assessment: The State meets these indicator guidelines.

C. 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.

Questions:

1. Are laboratory services readily available in-house or through other departments within the State organization?

   Yes.

2. If services are provided by other departments, discuss the arrangements, supervision, charges and interdepartmental communications.

   NA

3. If laboratory services must be provided by a non-State agency:

   NA

   a. Discuss the contractual arrangements.

   b. Is the party providing the service an RCP licensee?

   c. If a State licensee provides the service or equipment, what are the costs?

4. Describe the capability of the laboratory as follows:

   a. Can it qualitatively and quantitatively analyze low-energy beta emitters?

      Yes.

   b. Can it qualitatively and quantitatively analyze alpha emitters?

Yes.

c. Can it selectively determine the presence and quantity of gamma emitters?

Yes.

d. Can it handle samples in any physical form - wipes, liquids, solids, gaseous?

Yes

e. Does the lab participate in a periodic quality control program?

Yes

5. How much time does it take to obtain the results from sample analyses on both a routine basis and on an emergency basis?

Normally 1 to 10 days depending upon the type of sample, sample preparation time, sensitivity and precision of the analysis in growth time etc.

On an emergency basis, sample preparation can begin immediately upon delivery to the laboratory. Availability of results constrained as stated above. When necessary, laboratory staff can be contacted during non-routine work hours to conduct sample analysis.

6. List the number and types of laboratory instrumentation and services available.

The laboratory has instrumentation to qualitatively and quantitatively analyze samples for alpha and beta radioactivity. It can also identify and quantify gamma photons greater than 30 Kev.

List and types of laboratory instrumentation is available in Region I files.

III.C Reviewer Assessment: The State meets these indicator guidelines.

D. 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 and procedures, decommissioning, and other functions required of the program.

Questions:

1. What procedures are established to assure adequate and uniform regulatory practices (e.g., administrative procedures, policy memos, licensing and inspection guides, escalated enforcement procedures, decommissioning procedures, etc.)?

   Procedures are established in all categories exemplified in this question except decommissioning procedures.

2. To what extent are the procedures documented?

   All procedures are documented. A Manual of Operations has been written and is in final stages of preparation. This Manual includes general procedures for licensing and inspection of radioactive materials, and administrative policies and procedures.

3. If the RCP has separate licensing and inspection staffs, what are the procedures used to communicate between the two staffs?

   The written policies and procedures described above are applicable to this. In addition direct communications, one on one, meetings between the two staffs, and frequently the Division Chief and both staffs.

4. How are personnel kept informed of current regulatory policies and practices?

   By written policy and procedures guides, administrative directives, and meetings.

5. If the RCP collects fees, are fee collection duties assigned to non-technical staff?

   NA

6. How are contacts with communication media handled?

   DHMH Media Policy addresses such contacts. A copy is available in Region I files.

7. What procedures exist to ensure timely release of factual information on matters of interest to the public, the NRC and Agreement States?

   The new DHMH Media Policy referred to in answer No. 6 defines thes procedures.

8. If your RCP has regional offices:

   NA

   a. what procedures are in effect to assure the regions have complete copies of the procedures and files?

b. how often are periodic staff meetings held with headquarters staff?

c. how often are periodic visits/audits made by headquarters staff to regional offices?

d. how is uniformity controlled?

e. how is supervision handled?

III.D Reviewer Assessment: The State meets these indicator guidelines.

E 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). RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services and fundings.

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, large scope - Type A Broad, or potential for significant releases to environment) should receive second party review (supervisory, committee, or consultant). Supervisory review of inspections, reports and enforcement actions should also be performed.

Questions:

1. How does the staff keep program management abreast of the status of regulatory actions (such as backlog, problem cases, inquiries, and revision of regulations)?

   By issuing monthly reports.

2. a. Is a periodic statistical tabulation of licenses, licensees, inspections and backlogs prepared by category?

      Yes.

   b. If so, specify how frequently the tabulation is prepared.

      Monthly.

3. How does RCP management assess workload trends and resources in order to determine future needs or the need for program changes?

   By reviewing the above reports and by holding meetings frequently.

4. How does the RCP management keep abreast of changes in legislative and regulatory responsibility?

   RCP staff reviews all proposed legislation introduced, and comments on it. When legislation is passed placing the responsibility, planning is begun immediately to implement it. RCP introduces proposed regulations and is responsible for follow through to adoption.

5. Discuss the procedures followed by licensing supervision or RCP management to monitor licensing quality.

   A secondary review is conducted by a senior staff member of all new licenses, license renewals and complex amendment requests. The Division Chief reviews and initials all licenses and amendments and the Administrator, Community Health Management Program signs all licenses and amendments.

6. Discuss the procedures used for supervisory review of inspection reports.

   The section head is responsible for reviewing all inspection reports.

7. What license review practices are followed for unusual or complex license applications?

   Complex license applications are always circulated for senior staff review, and if deemed necessary by the Division Chief, meetings are held to discuss the application and resolve problems before license is issued.

8. If applicable, discuss the procedures used for supervisory review of work performed by contract agencies or regional offices.

   NA

III.E Reviewer Assessment: The State meets these indicator guidelines.

F. Office Equipment and Support Services (Category II)

NRC Guidelines: The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to larger (300-400 licenses) programs. Similar services should be available to regional offices, if utilized.

1 a. In terms of the person-year/100 licenses figure, what level of secretarial/clerical support is provided?

   0.4 person years per 100 licenses.

b. If your program has regional office, provide the figures for the support for those offices.

NA

2. Describe the ADP and word processing capabilities available to the RCP.

Workstation (screen & keyboard)	Model # 2000
Printer (Diablo)	Model # 8624862
IBM PC-AT and Printer	

III.F Reviewer Assessment: The State meets these indicator guidelines.

G. Public Information (Category II)

NRC Guidelines: Inspection and licensing files should be available to the public consistent with State administrative procedures. Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws.

Questions:

1. Are licensing and inspection files available for inspection by the public?

   Yes.

2. Are medical and proprietary data withheld?

   Yes.

3. What other parts, if any, are not available?

   None.

4. What written procedures and laws govern this? Please provide reference citations.

   There are no written procedures governing this that we are aware of. The law will have to be researched as we are not cognizant of any State law governing this. This research can be conducted upon specific request.

5. For mill States, are opportunities provided for public hearings in accordance with UMTRCA and applicable State administrative procedures and statutes?

   NA

III.G Reviewer Assessment: The State meets these indicator guidelines.

IV. PERSONNEL

A. 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 should be commensurate with the type of licenses issued and inspected by the State.

Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Questions:

1. Do all professional personnel hold a bachelor's degree or have equivalent training in the physical or life sciences?

   Yes.

2. What additional training and experience do the senior personnel need to have in radiation protection?

   Health Physicist II - 2 years experience in technical radiation health work.

   Health Physicist III - 3 years experience in technical radiation health work.

   Public Health Radiation Specialist - 6 years of full time experience, or its equivalent, in the field of radiological sciences.

   Chief, Division of Radiation Control - 9 years experience in engineering or chemistry in fields directly related to Public Health Programs, or in radiological health; four years of which must have been in a supervisory capacity.

3. What written position descriptions describe the duties, responsibilities and function of each professional position?

   Written position descriptions are available in Region I files.

IV.A Reviewer Assessment: The State meets these indicator guidelines.

B. <u>Staffing Level</u> (Category II)

NRC Guidelines: Staffing level should be approximately 1-1.5 person-year per 100 licenses in effect. RCP must not have less than two professionals available with training and experience to operate RCP in a way which provides continuous coverage and continuity.

For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years' of effort, including consultants, are needed to process a new mill license (including insitu mills) or major renewal, to meet requirements of Uranium Mill

Tailings Radiation Control Act of 1978. This effort must include expertise in radiological matters, hydrology, geology, and structural engineering.

Questions:

1. Complete a table as below, listing the person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, fraction of time spent and the duty (licensing, inspection, administration, etc.).

Name	Position	FTE%	Area of Effort
Roland Fletcher	Director	50	Administration
Robert Corcoran	Chief, X-Ray Program	5	Consulted on Licensing
William Bonta	Administrator	50	Regulations
Richard Brisson	Public Health Radiation Specialist	10	Consulted on Inspection and Enforcement
Charles Flynn	Public Health Radiation Specialist	100	Licensing
Thomas Ferguson	Public Health Radiation Specialist	100	Licensing
Carl Trump	Public Health Radiation Specialist	100	Inspection
Yun Chong	Health Physicist III	100	Inspection
Phani Chaparala	Health Physicist III	100	Inspection
Ray Manley	Health Physicist III	100	Inspection

*The major portion of the 50% FTE indicated for William Bonta represents effort put forth on updating the regulations. This is not to be interpreted as indicative of continuous effort since the regulations are updated only every three (3) years.

2. Compute the person-year effort of person-years per 100 licenses (excluding mills and burial sites). Show calculation.

The total staffing effort for the materials program is 5.05 staff years. With 454 licenses currently in effect the staffing level is 1.51 staff years per 100 licenses.

Calculation: $\frac{7.15}{454} = \frac{X}{100}$

$454\ X = 715$

$X = 1.57$

3. Is the staffing level adequate to meet normal and special needs and backup?

   The staffing level is inadequate as indicated by the large backlog of inspections and licensing actions.

IV.B Reviewer Assessment: The State has recently added to the materials staff. This additional staff has allowed the State to address program backlogs.

C. 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.

Questions:

1. Identify the junior and senior personnel.

   Junior personnel: Yun K. Chong
   R. Chaparala
   R. Manley

   Senior personnel: R. E. Corcoran
   R. J. Brisson
   C. R. Flynn
   T. D. Ferguson
   W. K. Bonta
   C. E. Trump

2. a. What duties are assigned to junior personnel?

   Junior personnel inspect radioactive materials licensees, write reports, make recommendations for enforcement action, and participate in emergency response operations.

   b. Do they review applications and perform inspections independently?

   They perform inspections independently but do not review applications.

3. a. What duties are assigned to senior personnel?

   Senior personnel - review applications, review work of junior personnel, accompany junior personnel on some inspections, and participate and act as team leaders in emergency response operations.

b. Do they independently review and monitor the work of junior personnel?

4. Is there adequate supervisory or senior guidance and direction for junior personnel?

Yes.

5. Discuss procedures established to ensure supervisory review of the licensing, inspection and enforcement functions.

We no longer conduct a routine detailed supervisory review of licenses. One senior staff member reviews the license work-ups prepared by another senior staff member. Inspections report reviews are the responsibility of the Section Head, Inspection and Surveillance Section. Enforcement functions are initially reviewed by the Section Head followed by the Division Chief. Escalated enforcement actions require involvement of higher management, usually the administrator, Community Health Management Program, and an Assistant Attorney General.

6 a. Are RCP staff members allowed to consult or work part time for State licensees?

No.

b. If so, how are conflicts of interest avoided?

NA

IV.C Reviewer Assessment: The State meets these indicator guidelines.

D. Training (Category II)

NRC Guidelines: Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices. (For mill States, mill training should also be included.) The RCP should have a program to utilize specific short courses and workshops to maintain appropriate level of staff technical competence in areas of changing technology.

Questions:

1. List all RCP personnel and the NRC training courses they have attended.

Copies of DRC training records are available in Region I files.

2. How does the RCP utilize short courses and workshops to maintain staff proficiency?

DRC has not utilized short courses and workshops for technical areas other than those sponsored by the NRC. Some short courses for management and clerical areas have been attended.

IV.D Reviewer Assessment: The State meets these indicator guidelines.

E. Staff Continuity (Category II)

NRC Guidelines:

Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area. The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

Questions:

1. Identify the RCP employees who have left the program since the last review and give the reasons for the turnovers. Also state whether the positions are presently vacant, filled (name replacement), abolished or other status.

   T. Brooks - left profession
   R. Corcoran - Heads X-Ray program
   R. Brisson - Heads Radon program

2. List the RCP salary schedule:

Position Title	Annual Salary Range
Health Physicist I	$15,568 - $20,392
Health Physicist II	$19,392 - $25,464
Health Physicist III	$20,886 - $27,430
Public Health Radiation Specialist	$26,110 - $34,295
Program Director	$32,889 - $43,202

3. Compare your salary schedule with similar employment alternatives in the same geographical area, such as industrial, medical, academic or other departments within your State.

   We have not made such a comparison and know of no other studies done in Maryland that would reflect this data.

4. What opportunities are there for promotion within the RCP organizational structure without a staff vacancy occurring?

   The H.P. series is interchangeable, with the appropriate time in grade promotion can be effected. Two staff members have also been promoted from H.P. III to Public Health Radiation Specialist in the past few years.

IV.E Reviewer Assessment: Maryland positions were recently upgraded, and a further salary increase is expected in July 1987. Although salary levels are still low in comparison with other states, industry and federal salaries, the State has been able to fill vacant positions.

V. LICENSING

A. 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. Prelicensing visits should be made for complex and major licensing actions. Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions. The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

Questions:

1. How many specific licenses are currently in effect?

   454

2. a. How many new licenses (not amendments in entirety) have been issued since the last review?

      74

   b. How many were major licenses?

      0

3. How many specific licenses were terminated since the last review?

   36

4. How many amendments were issued during the review period?

   459

5. Identify unusual or complex licenses issued since the last review, including name and license number.

   None

6. Note any variance in licensing policies and procedures granted since the last review.

   None.

7. Do you require license applicants to submit details on their radwaste packaging and shipping procedures?

   No.

8 a. When do you require licensees to submit contingency plans?

   When the licensee's possession of limits of radioactive materials presents a potential for accidents that could result in doses as stipulated in NRC's notice of proposed rule making published on June 3, 1981 (46FR29712).

   b. List the licensees who have been required to submit contingency plans.

   Neutron Products, Inc.
   Dickerson, Maryland
   License No. MD-31-025-01

9. How many prelicensing visits were made during this review period?

   8 Prelicensing visits.

10. What criterion does the RCP use to determine the need for a prelicensing visit?

    A copy of the State's policy on prelicensing visits are available in Region I files.

11. How do you ensure up-to-date information has been submitted prior to a license renewal?

    We ensure up-to-date information by basing the renewal on currently submitted information without referring to previous submissions. We ask the applicant to review and revise past submittals before resubmitting them.

12. Do license files contain all necessary data required to evaluate an application prior to issuing a license?

    License files do contain all necessary data required to evaluate an application. The file includes a check list used to evaluate the original application, notes of telephone call

requesting further information and the applicant's follow-up letter. If needed a second sheet for a telephone call requesting still further information and its follow-up letter are also included.

13. Has the RCP taken any unusual licensing action with respect to licensees operating under multiple jurisdiction?

    No unusual licensing actions have been taken with respect to licensees operating under multiple jurisdiction.

14. Prepare a table as below showing the RCP's major licensees with name, number and type.

    INCLUDE:

    - Broad (Type A) Licenses
    - LLW Disposal Licenses
    - LLW Brokers
    - Major Manufacturers and Distributors
    - Uranium Mills
    - Large Irradiators (Pool Type or Other)
    - Other Licenses With a Potential Significant Environmental Impact
    - Other Licensees You Consider to be "Major" Licensees

Name	License Number	Type
Univ. of Maryland Baltimore Campus	07-014-04	LLW Disposal (Incinerator)
Johns Hopkins Medical Institutions	07-005-06	LLW Disposal (Incinerator)
Radiation Services Org.	33-021-02	LLW Broker
Westinghouse-Hittman Nuclear, Inc.	27-001-02	LLW Broker
Ellicott Machine	07-095-01	Major Manufacturer & Distributor
Rad/Irid	33-05-053-01	Major Manufacturer & Distributor
Neutron Products (Sources)	31-025-03	Major Manufacturer & Distributor
LKB	31-071-01	Major Manufacturer & Distributor

Shimadzu	27-011-01	Major Manufacturer & Distributor
Industrial Gauging & Control	31-088-01	Major Manufacturer & Distributor
Electronucleonics	27-025-02	Major Manufacturer & Distributor
Johnston Labs	05-025-01	Major Manufacturer & Distributor
CGR Medical	27-028-01	Major Manufacturer & Distributor
Syncor, Timonium, MD	05-058-01	Major Manufacturer & Distributor
Syncor, Latham, MD	33-061-01	Major Manufacturer & Distributor
Neutron Products, Inc.	31-025-04	Large Irradiator
Neutron Products, Inc.	31-025-05	Large Irradiator
Univ. of Maryland College Park	33-004-03	Large Irradiator
Seymour Weiner, M.D., P.A.	05-051-01	Other (teletherapy; multi-facility)

V.A. Reviewer Assessment: A review of selected files is attached as Appendix C. State licenses were for the most part adequately supported by information in the applicant's supporting documentation. Since the last review the State has increased its staff in the licensing program.

B. 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.

The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy. Approval documents for sealed source or device designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Questions:

1. How many new and revised evaluations were made of sealed sources and devices during the review period?

   5

   Nucletron Corp.

   Microselectron Model SEL4000 Afterloader - December 31, 1985
   Selectron HDR Model SEL-203 Afterloader - August 15, 1985
   Microselectron HDR Afterloader - December 1, 1986

   Industrial Gauging & Control

   Model AM4-T Source Holder - November 8, 1985
   Model SR-V2 Source Holder - June 26, 1986

2. How many SS&D evaluations have been made for which approval documents have not yet been prepared?

   None.

3. How does the RCP evaluate manufacturer's data on SS&D's to ensure integrity and safety for users?

   Our evaluation is based on engineering data submitted defining tests performed and results including dose profiles from sealed sources. Where it is determined that the staff does not have the competence to evaluate certain engineering data, the material is sent to the NRC with a request for technical assistance with that portion of the evaluation.

4. Do you determine whether the manufacturer's information on labels and brochures relating to health, safety, assay, and calibration procedures is adequate on all products?

   Yes.

V.B. Reviewer Assessment: Two recent device evaluations were reviewed. See Appendix C for details. No technical deficiencies were noted. It was recommended, however, that the Nucletron file be reorganized. It was difficult to distinguish which backup documents applied to which device. The three devices evaluated are very similar.

C. Licensing Procedures (Category II)

NRC Guidelines: The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice. License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions. The present compliance status of licensees should be considered in licensing actions. Under the NRC Exchange-of-Information program, evaluation sheets, service licenses, and licenses authorizing dis-

tribution to general licensees and persons exempt from licensing should be submitted to NRC on a timely basis. Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process. Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

Questions:

1. Has the RCP developed its own licensing procedures or does it use NRC guides? Please provide for review.

   We use NRC guides.

2. What licensing guides, checklists and policy memoranda are made available to the staff?

   All NRC licensing guides are made available to the staff. Checklists provided by the NRC are provided to the staff. Policy memoranda are provided to the staff.

3. What guides and/or regulatory position statements are furnished to license and renewal applicants?

   NRC guides and regulatory position statements are furnished to license and renewal applicants.

4. Describe the system for advising classes of licensees of new licensing procedures and regulations.

   When new licensing procedures and regulations are developed, the licensee is either notified of their availability or the documents are mailed to the appropriate class of licensee.

5. a. How are licensing actions coordinated with the compliance staff?

      Licensing actions are coordinated with the compliance staff by meetings, memoranda and one on one discussions.

   b. Are licensing actions taken while enforcement action is pending?

      No.

6. For what length of time are various categories of licenses issued?

   All licenses are issued for 5 years.

7. a. Does the RCP use standard licensing conditions?

   Yes.

   b. If so, how does the RCP assure they are comparable with those used by NRC?

   They are compared with the NRC's whenever NRC changes theirs and changed accordingly.

8. Are the licensing conditions on file in the RCP office and with NRC?

   Yes.

9. What SS&D sheets, service, distribution and "E" licenses are available for RCP staff use?

   SS&D catalogs are available for RCP staff use. NRC and other Agreement State distribution and "E" licenses are filed and available to the staff.

10. Describe your practices for distributing SS&D sheets, as well as GL distribution and service licenses, to the NRC.

    All SS&D sheets and copies of all licenses are sent to the NRC.

11. Describe your procedures for maintaining the license files (How are files and folders arranged? Are telephone contacts and visits documented? Who is responsible for filing materials in folders?).

    The licensing files are arranged in alphabetical order from A-Z. Backup materials are filed chronologically in the front of the two hole punched report binders with ACCO fasteners and the licenses and amendments are filed chronologically in a separate area in the back section of the same binder.

12. Are there opportunities for license reviewers to accompany inspectors?

    Yes.

V.C. Reviewer Assessment: The State meets these indicator guidelines.

VI. COMPLIANCE

A. 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.

The RCP should maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available.

There should be at least semiannual inspection planning for the number of inspections to be performed, assignments to senior vs. junior staff, assignments to regions, identification of special needs and periodic status reports.

Questions:

1. How is statistical information maintained about the inspection program to permit periodic assessment of its status by RCP management?

   Manually kept on a monthly schedule on a form titled "Overdue Inspection As of ..... Date".

2. Prepare a table as below, indicating the number of inspections made in the review period, by category and priority.

License Category	Scheduled Frequency	Inspection Priority	Number of Inspections
Major Processors	Each 4 mos.	I	2
Broad Scope A, B, C	Annually Each 3 yrs. Each 4 yrs.	II, IV	3
Irradiators CAT IV CAT I	Annually Each 4 yrs.	II, IV	3
Radiography	Annually	II	13
Academic	Annually Each 4 yrs. Each 5 yrs.	II, IV, V	5
Medical	Each 3 yrs. Each 4 yrs.	III, IV	83
Industrial	Each 3 yrs.	III, IV, V	78

	Each 4 yrs. Each 5 yrs.		
Incinerators	Each 3 yrs.	III	1
		Total	188

3. Prepare a table (or tables) as below which identifies the Priority 1, 2, and 3 licensees with overdue inspections. Include the license category, the due date, and the number of months the inspection is overdue. (If list is extensive, a comparable computer printout is acceptable.)

	Licensee	Category	Priority	Due Date	Months Overdue
A.	Johns Hopkins Medical Institutions	Medical B.S.	II	10/86	2
B.	NPI	Teletherapy Installation	II	5-84	31
C.	NPI	Irradiator	II	3/84	33
D.	BBL Microbiology	Research & Development	III	7/86	5
E.	Sinai Hospital	Medical Research and Development	III	2/85	22

4. Prepare a table as below indicating the number of overdue license inspections for Priorities 4 through 7.

   Priority IV - 79; Priority V - 15

5. How are inspection schedules planned and how are the dates and personnel assignments made?

   Senior staff inspection assignments are scheduled by the supervisor of the radioactive materials section. These assignments are normally based upon priority and due or maximum overdue dates. The exception to this practice is when a license is located so far away from the central office that the inspector must stay overnight. In this case, the cost effective practice is for the inspector to inspect several or maybe all of the licensees in that region.

   Junior staff inspection assignments are scheduled as stated above except that the assignments are limited to include the lower priority licenses.

VI.A Reviewer Assessment: The State has made significant progress in addressing the inspection backlog, particularly in the medical area. The two Priority II NPI licenses are the only significant overdue inspections.

B. 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, e.g., major processors, broad licensees, and industrial radiographers should be inspected approximately annually -- smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency should be consistent with the NRC system.

Questions:

1. Enclose a copy of the RCP's inspection priority system.

   A copy of the State's priority system is available in Region I files.

2. Who assigns licenses to the priority categories?

   The Head, RAM Inspection & Surveillance Section (Mr. Carl Trump).

3. Discuss any significant variances in the RCP's priorities from the NRC priority system.

   As a matter of practice we inspect fixed radiography licenses and limited medical licenses at the minimum inspection frequency consistent with the NRC. However, due to other staff work, we have been unable to rewrite the written inspection priority system so that it reflects actual State policy.

4. Is the inspection priority system designed to assure that the more hazardous and/or complex operations are inspected at an appropriate frequency?

   Yes.

5. Describe the RCP's policy for unannounced inspections and exceptions to the policy.

   All radioactive materials license inspection are unannounced.

6. Describe the RCP's policy for conducting follow-up inspections.

   Follow-up inspections are not done routinely due to insufficient manpower.

7. a. Does the RCP inspect out-of-state firms working in the State under reciprocity or under State licensure?

      Yes.

b. How many reciprocity notices were received?

193

c. How many were inspected?

4

VI.B Reviewer Assessment: The State meets these indicator guidelines.

C. 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.

The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Questions:

1. a. Does the senior inspector or supervisor periodically accompany the inspectors?

Yes.

b. Are these accompaniments documented?

Yes, on the inspection report prepared by the inspector.

2. Give the number of supervisory accompaniments of inspectors since the last review meeting and identify the persons accompanied and the supervisors.

None, other than for training.

VI.C Reviewer Assessment: With the exception of Mr. Chong, the State inspection staff has essentially been in a training mode for the past year. The newly appointed Compliance Supervisor, Carl Trump, has accompanied the new staff mainly for training purposes. It was recommended that the Compliance Supervisor institute a routine program of annual field evaluations now that the staff has been trained to the point of doing independent inspections. During the review Mr. Chong was accompanied on a inspection of Sinai Hospital, License No. MD-07-011-01 on January 27, 1987 and Mr. Chaparala was accompanied on an inspection of Reliance Testing, License No. MD-05-010-01 on January 23, 1987. Both inspectors were judged to be competent to evaluate health and safety issues and to interpret and enforce State regulations.

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

NRC Guidelines: Inquiries should be promptly made to evaluate the need for onsite investigations. Onsite investigations should be promptly made of incidents requiring reporting to the Agency in less than 30 days (10 CFR 20.403 types). For those incidents not requiring reporting to the Agency in less than 30 days, investigations should be made during the next scheduled inspection. Onsite investigations should be promptly made of non-reportable incidents which may be of significant public interest and concern, e.g. transportation accidents. Investigations should include indepth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). 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 (e.g., equipment failure, improper operating procedures). Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency. The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Questions:

1. How does the RCP respond to incidents and alleged incidents?

   Where we can assess that it is a true incident, we respond immediately. On other as promptly as possible. For alleged incidents written notification is required as per Part J. of the Regulations before any response is made.

2. Are major incidents (10 CFR 20.403 types requiring reporting in less than 30 days) investigated on a priority basis?

   Yes.

3. Are other incidents followed up in the next scheduled inspection?

   Yes.

4. Are non-reportable incidents that may be of significant public interest and concern promptly investigated?

   Yes.

5. How many incident investigations were conducted during the review period?

   15-20.

6. Attach as an appendix a summary of each incident investigated. Include documentation of investigation results, enforcement action when appropriate, any reenactment and time motion studies, as well as notification of the NRC and state licensees of incident information that may have been relevant to other licensed operations.

   A summary of each incident investigated from 5/31/85 thru 1/31/87 is available in Region I files. A copy has been forwarded to AEOD and GPA.

7. Were any incidents attributed to generic-type equipment failure?

   No.

8. What action was or would be taken by the RCP pertaining to incidents attributable to generic equipment failures in regard to notification of the NRC, other licensees and the regulatory agency which approved the device?

   NRC and other licensees have been notified and will continue to be notified as appropriate.

9. If a failure should occur in equipment manufactured by a RCP licensee, what action would be taken to:

   a. stop the manufacture or force changes in design?

      Yes.

   b. assure retrofit of existing devices?

      Yes.

10. When are other RCP licensees and the NRC notified of pertinent information about an incident?

    Immediately by telephone followed by letter as soon as practicable.

11. a. Are medical consultants available and used when necessary?

       None available.

    b. Is the State aware of the availability of medical consultants from NRC?

       Yes.

12. Explain any use of other technical consultants for special problems encountered in incident investigations.

    None available.

13. Were there any incidents since the last review meeting that met Abnormal Occurrence Report (AOR) criteria?

No.

VI.D Reviewer Assessment: The State meets these indicator guidelines. With regard to the response to question 8, the reviewer encouraged the State staff to address future problems in this area to the Region.

E. Enforcement Procedures (Category I)

NRC Guidelines: Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended. Enforcement letters should be issued within 30 days following inspections and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated. Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent re-occurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses. Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items. Written procedures should exist for handling escalated enforcement cases of varying degrees. Impounding of material should be in accordance with State administrative procedures. Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

Questions:

1. Describe the State's enforcement procedures.

   At closeout inspector leaves completed forms CHMH-1097A & 1097B with the licensee.

   Escalated enforcement is initiated when response to violations defined on the above referenced form are deemed to be inadequate.

2. If the RCP can apply civil penalties, explain the procedures for keying monetary penalties to violations.

   The maximum civil penalty prescribed by the Radiation Control Act, H.E. Article Section 8-501(b) is $5,000. The civil penalty assessed is dependent upon the nature of the problem(s) but usually starts at the maximum and can be mitigated as determined necessary by the Assistant Attorney General.

3. Describe the RCP's provisions for criminal penalties.

   No written procedures are available within the RCP for criminal penalties. Health Environmental (H.E.) Article Section 8-501(a) provides for this.

4. Describe the policies in effect for issuing field forms equivalent to NRC form 591 or letters for enforcement action.

   Forms issued at closeout (see answer to question 1, above).

5. Are there written procedures for handling escalated enforcement cases? Please provide for review.

   Draft Escalated Enforcement Action Procedures were submitted to NRC on February 8, 1980 for review and comment. NRC Comments were received in a letter from Wayne Kerr dated March 17, 1980 (copy attached). The draft procedures have never been finalized by virtue of having received management approval. NRC suggestion in No. 1 of Mr. Kerr's letter regarding informal meetings with licensee top management is in actual practice a part escalated enforcement in Maryland.

6. Can the State issue Orders, including Emergency Orders?

   State can issue Orders, including Emergency Orders.

7. Can the RCP impound radioactive material?

   Yes, RCP can impound material.

8. Do RCP administrative procedures permit the opportunity for hearings in major enforcement cases?

   Yes, State administrative procedures permit hearings.

9. If during the review period the RCP has issued orders, applied civil penalties, sought criminal penalties, impounded sources, or held a formal enforcement hearing, identify these cases and enclose copies of the pertinent State enforcement correspondence or orders.

   See Appendix E.

10. Are enforcement letters issued within 30 days of the inspection?

    RCP intent is to issue enforcement letters within 30 days.

11. Are enforcement letters written in regulatory language and reference regulations and license conditions?

    Yes they are.

12. Do the enforcement letters clearly differentiate between noncompliance items and health and safety recommendations?

    Yes.

13. If applicable, do the letters separate actions subject to the State radiation control act and State OSHA regulations?

    Yes.

14. a. Are enforcement letters issued by inspectors or supervisors?

       Written by both inspectors and supervisors.

    b. If issued by inspectors do they undergo supervisory review prior to dispatch?

       Reviewed by supervisors and/or Division Chief.

15. Do enforcement letters require the licensee to respond within a stated time period? Note the period.

    Yes, written 20 days.

16. a. Are licensee's responses to enforcement letters reviewed by the inspector and the supervisor?

       Yes.

    b. Are they acknowledged properly?

       No, the State is considering reinstituting the practice of acknowledging responses to enforcement letters.

17. Has the RCP taken escalated enforcement action against licensees who operate in multiple jurisdictions?

    No.

VI.E Reviewer Assessment: It was again recommended that the State finalize its draft enforcement procedures.

F. Inspection Procedures (Category II)

NRC Guidelines: Inspection 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. The NRC Agreement States Guides may be used if properly supplemented by policy memoranda, agency interpretations, etc. Written inspection policies should be issued to establish a policy for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, assuring exit interviews with management, and issuing appropriate notification

of violations of health and safety problems. Procedures should be established for maintaining licensees' compliance histories. Oral briefing of supervision or the senior inspector should be performed upon return from nonroutine inspections. For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Questions:

1. Has the RCP developed its own inspection guides or does it use NRC guides?

   We have 2 inspection guides; one entitled "Guidelines for Inspection of Material - General", and "Guidelines for Inspection of Radiographic Operations". We use all those issued by the NRC.

2. Are current copies of the internal inspection forms and guides on file in the RCP office and with NRC? Attach any changes or guides developed since the last review.

   Yes. There have been no revisions since the last review.

3. Are inspectors furnished copies of inspection guides?

   Yes.

4. Discuss the use or non-use of inspection policy memoranda, interpretations, etc., to supplement inspection guides.

   DRC - Policies and Procedure guidelines have been issued and are being used.

5. Are there written procedures establishing policy for:

   a. unannounced inspections?

      Yes, the State follows NRC policies and procedures.

   b. obtaining corrective action?

      No, but the State follows NRC policies and procedures.

   c. following-up and closing out previous citations of violations?

      No, but the State follows NRC policies and procedures.

   d. exit interviews with management?

      No, but the State follows NRC policies and procedures.

e. issuing notices of violations and findings of health and safety problems?

No, but the State follows NRC policies and procedures.

f. categorizing the seriousness of violations?

No, but the State follows NRC policies and procedures.

Please provide copies of these procedures for review.

6. What procedures have been established for maintaining licensee's compliance histories?

A manually operated KARDEX System.

7. Does the senior inspector or supervisor orally debrief the inspector upon return from inspections?

Yes.

8. What procedures are there for providing feedback from inspectors to licensing?

We require documentation of suggested license changes on inspection reports which are to be reviewed by Licensing personnel. There is also extensive direct verbal communication between Licensing and Inspection personnel.

VI.F Reviewer Assessment: During the previous review, concerns were raised about compliance actions taken on the basis of a questionable interpretation of the regulations regarding limits on radiation levels in unrestricted areas. The present compliance supervisor indicated that he understood the issues involved and that the State would not handle a similar situation in the same manner. The State would utilize the 500 mrem per year limit for an individual in an unrestricted area. The staff also recognizes the importance of applying regulatory policy consistently from one licensee to another.

G. Inspection Reports (Category II)

NRC Guidelines: Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of licensees' programs, and indicating the substance of discussions with licensee management and licensee's response. 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 show the status of previous noncompliance and the independent physical measurements made by the inspector.

Questions:

1. How do inspection reports document the inspection that was conducted and the inspection findings? Explain how the reports substantiate noncompliance and health and safety matters and describe the scope of the licensee's program.

   A sample inspection report form is available in Region I files.

2. Do the reports

   a. relate the discussions held with licensee management and interviews with workers?

      Yes.

   b. include independent measurements conducted by the inspector?

      Yes.

   c. document follow-up of previous citations of violations made by the inspector?

      Yes.

   d. identify areas of the licensee's program needing special attention at the next inspection?

      Yes.

3. Are inspectors routinely inspecting radwaste package preparation and shipping practices and do the reports document the results?

   Yes, but only if materials are packaged and ready for shipment.

VI.G Reviewer Assessment: A review of selected inspection reports is attached as Appendix D. The inspection reports reviewed during the meeting were technically sound and adequately supported the enforcement actions taken. The narrative reports were not, however, organized in a manner which facilitated review and retrieval of inspection data. It was recommended that the State reorganize its inspection form to better document the inspector's findings.

H. Independent Measurements (Category II)

NRC Guidelines:

Independent measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements. RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samplers, lab counting equipment for smears, identification of isotopes, etc.).

GM Survey Meter: 0-20 mr/hr
Ion Chamber Survey Meter: several r/hr
Neutron Survey Meter: Fast & Thermal
Alpha Survey Meter: 0-100,000 c/m
Air Samplers: Hi and Low Volume
Lab Counters: Detect 0.001 uc/wipe
Velometers
Smoke tubes
Lapel Air Samplers

Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities should not be used unless under a service contract. Exceptions for other State Agencies, e.g. a State University, may be made. Agency instruments should be calibrated at intervals not greater than that required to licensees being inspected.

Questions:

1. Discuss the RCP's policy for conducting independent measurements as a part of each inspection (e.g., air samples, wipe samples, air flows, dose rates). Are these measurements documented in the inspection report?

   RCP's practice is to make independent measurements at every inspection. Results are documented. Independent measurements made as appropriate to the type(s) of materials authorized by the license.

2. List the instrumentation that is readily available to the RCP for surveying licensed operations and conducting appropriate independent measurements.

   List is available in Region I files.

3. Describe the method used for calibrating survey instruments and the frequency of calibration.

   We contract for calibration of all instruments used to make measurements. Monitoring and survey equipment verified with certified check sources.

VI.H Reviewer Assessment: The State meets these indicator guidelines.

VII. OTHER ASPECTS OF THE STATE'S RADIATION CONTROL PROGRAM

A. Non-Agreement Sources of Radiation

Questions:

1. Are the licensing and inspection procedures for NARM the same as for agreement materials?

   Yes.

2. Give the number of X-ray machine (or tube) and accelerator registrants by category, e.g., dental, medical, industrial, etc.

X-Ray Machine Registrants

Accelerators

2 installation
21 machines

Dental

2,097 installations
2,358 machines

3. How many machine and accelerator inspections were made in the last year (or other appropriate interval)?

Inspection

During FY-84

one accelerator inspection
607 X-ray machines inspections

4. Does the RCP license X-ray or nuclear medicine technologists?

No.

VII.A Reviewer Comment: None

B. Environmental Monitoring Program

Questions:

1. To indicate the scope of the environmental monitoring program, describe:

a. types of media sampled
b. the number and location of stations sampled
c. the frequency of sample collection
d. the analyses run on each type of sample

a., b., c., d. The scope of the environmental monitoring program is described in the State of Maryland's Radiological Environmental Monitoring Data Annual Report. This report specifies the type media sampled, number and locations of stations sampled, frequency of sample collection, and type analyses run, as well as the results on each type of sample.

2. Is a copy of the latest environmental surveillance report available for review?

A copy of the annual report is available in Region I files. The report provided is for calendar year 1986. This work was performed under USNRC Contract No. 28-83-608.

VII.B Reviewer Comment: None.

C. Other Areas

This section of the review is for the use of either the reviewer or the RCP to address issues pertaining only to the individual State, to new areas of concern, or to generic or State-specific issues raised by NRC staff.

1. Other Generic Issues

Questions:

a. For radiography inspections, to what extent do you make inspections at temporary job sites?

At each inspection when radiographer is working at a temporary job site. If not we require a demonstration of how a field job is conducted.

b. Are you finding Ir-192 contamination on radiographic equipment?

No.

c. What are the State's plans to adopt the low-level waste (LLW) manifest rule (if not already adopted)?

This is the responsibility of the Waste Management Administration. They are currently preparing proposed regulations.

d. For States with LLW disposal sites, what are the State's plans to implement 10 CFR 61?

N/A

e. Will your State have access to a LLW disposal site after January, 1986. If not, what contingency plans are there for after January, 1986?

N/A

f. Have copies of 10 CFR 61 and NRC technical positions on waste form and classification been distributed to State licensees? If there has been feedback please provide documentation.

No.

g. Have there been any applications or approvals for incineration, compacting or disposal?

2 incinerators. University of Maryland at Baltimore and Johns Hopkins University Hospital. Neither are commercial operations.

h. What use is being made of IE information notices?

IE Information Notices are sent to appropriate licensees when requested by NRC, or when it is determined by the RCP that they would be beneficial to the licensee in preventing radiation safety accidents, or problems of any kind involving radiation safety.

i. Identify any group of materials licenses for which the RCP has increased frequency of inspection due to problems with that general category. Please discuss the nature of those problems.

None.

j. With respect to medical licensees, is the RCP making any effort during inspections of nuclear pharmacies to determine whether the licensee is actually conducting the required molybdenum breakthrough tests, i.e., what is the RCP doing in addition to record reviews to establish compliance or noncompliance with the requirement?

No special effort other than normal review of records.

k. Is the RCP mounting any special effort to look at the possibility of reconcentration of radionuclides in sanitary sewers and sewage treatment plants as part of the regular inspection program? If so, please describe.

No. There are no licenses in Maryland where this would be of concern.

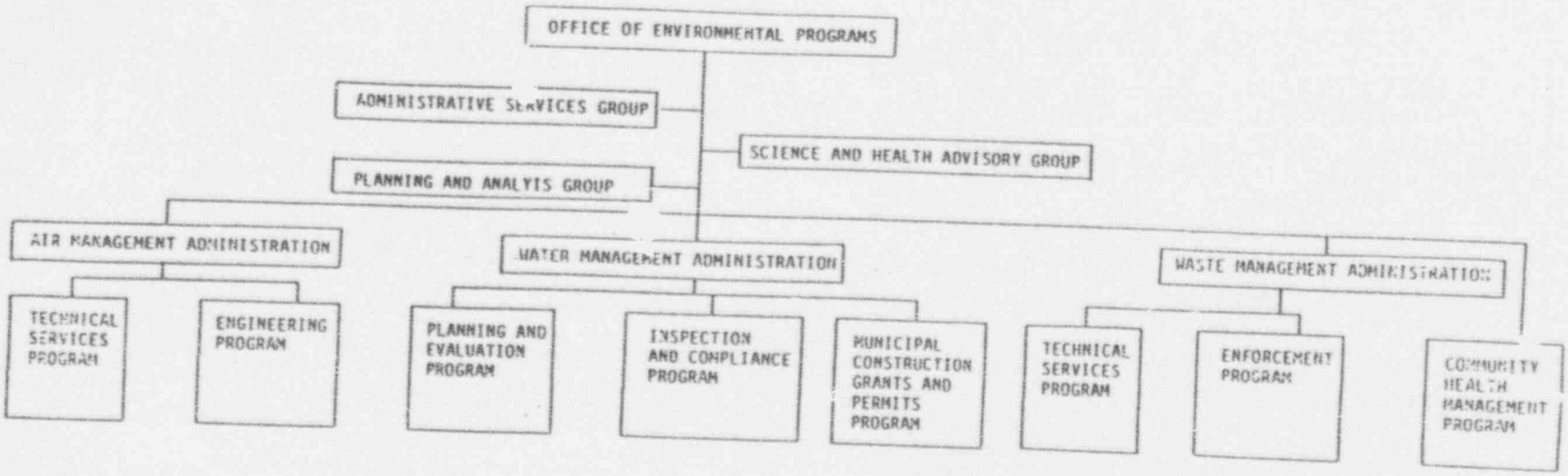
VII.C. Reviewer Comment: None.

With regard to waste regulations, the State has taken the posture that as a member of the Appalachian Compact, they will await final action on regulations in Pennsylvania (host state). Also the state, as a former member of the Northeast Compact, is waiting for assurance that there are no remaining legal obligations to the

Northeast Compact before proceeding with waste regulations. With regard to current shippers, the state takes the position that the waste generator is responsible for meeting site requirements if they wish to continue to ship waste and therefore state requir ments are unnecessary at this time. We pointed out to the state that having the regulatory requirements would allow them to take enforcement action, but the state remains convinced that the economic incentive for compliance is much stronger than the threat of enforcement action by the state. When the Division of Waste Management prepares draft regulation, the Division of Radiation Control staff participates and concurs in the action.

LIST OF APPENDICES

DEPARTMENT OF HEALTH AND MENTAL



APPROVED Adele Wilzack

Adele Wilzack, R.N., M.S., Secretary
Department of Health and Mental Hygiene

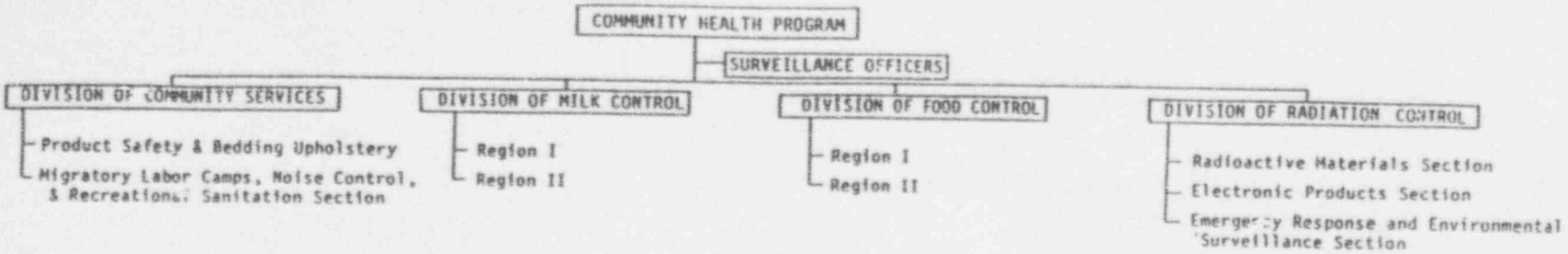
4/17/86
Date

H. Louis Stettler, III, Secretary
Department of Budget and Fiscal Plann'ng

Date

Harry Hughes, Governor

Date



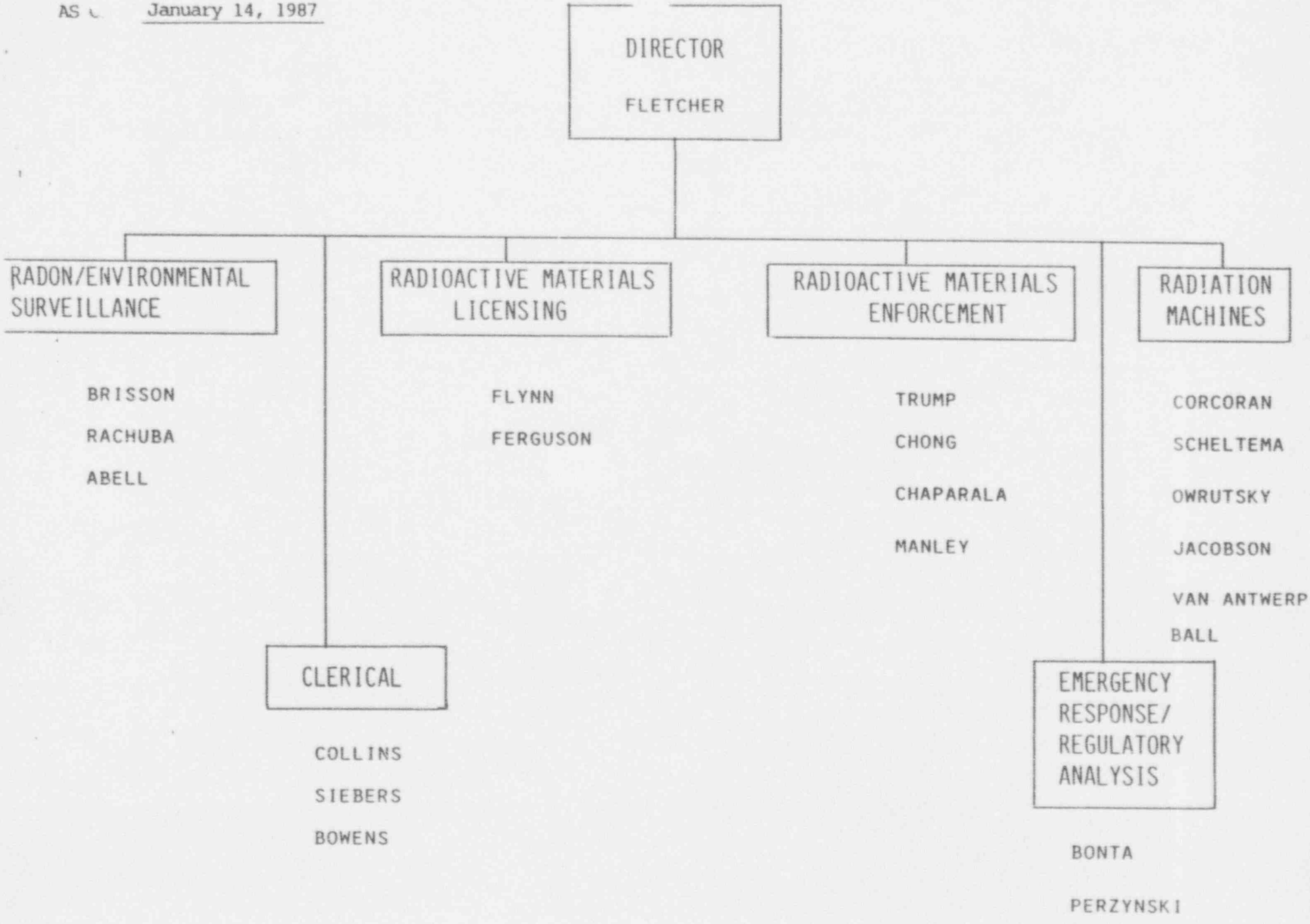
APPROVED Adele Wilzack

Adele Wilzack, R.N., M.S., Secretary
Department of Health and Mental Hygiene — Date 4/17/86

H. Louis Stettler III, Secretary
Department of Budget and Fiscal Planning — Date

Harry Hughes, Governor — Date

AS of January 14, 1987



APPENDIX C

Review of Selected License Files

The State's licensing program has improved significantly since the last review. No deficiencies worthy of comment were found in the licenses reviewed. It is notable that most application deficiencies are handled by telephone contact with the applicant. Telephone conservations are well documented and this system appears to be working well.

1. Borriston Research Laboratories, Inc.
   Temple Hills, Maryland
   License No. MD-33-033-02
   Issued: August 6, 1979
   Terminated: July 29, 1986

   This license was selected for review by OSP. The license authorized a Ni-63 Gas Chromatograph. The license was terminated because Borriston Labs was bought out by another company which obtained a license in its name. No transfer of the source occurred.

2. Jack G. Chirikjian, Ph.D.
   Rockville, MD
   License No. MD-31-083-01
   Issued: May 17, 1976
   Terminated: August 4, 1986

   This license was selected for review by OSP. This license authorized the temporary storage of 10 mCi of packaged samples of tritium and carbon-14. The licensee has apparently never possessed material under this license. During the last inspection, July 21, 1986, the licensee agreed to terminate the license.

3. Martin Marietta Laboratories
   Balitmore, Maryland
   License No. MD-05-015-01
   Last Renewed: December 6, 1979
   Terminated: October 24, 1986

   This termination was selected for review by the reviewer. The license authorized a variety of isotopes, primarily beta emitters for basic research. The licensee notified the State of their intent to terminate the license on June 18, 1985. On October 2, 1986, the licensee submitted a close out survey report from their consultant RSO, Inc. Of particular concern was a septic system dry well and two 500 gallon holding tanks which were part of the system designed to dispose of liquid waste from the laboratories. Soil samples from the dry well and wipes of the holding tanks showed no activities above background. The licensee also performed a detailed survey of the research labs. All results showed minimum activity. The State performed confirmatory measurements (with negative results) and the license was terminated.

4. Nucletron Corporation
Columbia, Maryland
Device Sheet No. MD-497-D-103-5
Issued: December 31, 1985

This is an evaluation of the company's microselectron remote after-loading unit Model SEL-4000. The system is designed for 3 curies of iridium-192 wire or encased seeds for use in low dose interstitial treatment of cancer. The SEL-4000 system is similar to the Selectron LDR which has been evaluated by NRC. This is a 15-channel remote system. The main unit contains the control console, microprocessors, intermediate safe, 15 drive motors and cables, power supply, battery backup keyboard, display and printer. The user can select any of 1 to 15 channels and a common treatment time. Sources are stored within the 15-channel intermediate safe in the main unit. An optional 45-channel external safe is also available. The main unit will collect the appropriate source assembly from the internal or external safe and transfer the source to the treatment position. The source transfer is carried out by means of a nylon cable which is stored in the grooves of a "record" to prevent wear or entanglement. The drive motor turns the "record" with a worm gear. Source movements are initiated from outside the treatment room using a remote control which contains an independent microcomputer system linked to the main unit computer. The "start" and "stop" signals are given from the remote. It checks the condition of the treatment room door, indicates the source position, and any failure situation. An audible alarm is provided. The unit also contains an intercom, security keyswitch, and interface electronics for the remote nurse warning system. This system is an audible and visual indicator panel which has indicators for alarm situations, treatment interrupted, treatment time expired and patient call.

Some safety features include the following: Selection of sources is electronically coded so the source is returned to the same channel from which it was selected. The external container has a pneumatic clamp that locks the sources into position when correctly located. The patient applicator "quick-connector" is pneumatically locked during treatment and cannot be opened by the patient. The unit can be interlocked with the treatment room door so that if the door is opened, the source is returned to the shielded position. Maximum dose rate 10 cm from the main unit is less than 0.25 mR/hr. (Maximum 3 Ci of Ir-192 in main safe). There is a battery backup system which, in the event of a power failure, returns the sources to the shielded position while maintaining treatment data. The applicator included a copy of the user manual which contains a description of the unit and all safety features and operating instructions.

No deficiencies were noted.

5. Industrial Gauging and Control
Gaithersburg, Maryland
Device Sheet MD-381-D-105-S
Issued: June 26, 1986

This is an evaluation of a source holder for a beta thickness gauge designed for use with a maximum 100 mCi of Sr-90. Leak test interval is 6 months. The source holder has a rotational shutter mechanism similar to other devices manufacture by IG&C and evaluated by the State. The shutter mechanism is fail-safe, i.e., it will rotate the source to the maximum shielded position if air pressure or electrical power is lost. The device is labeled with the radiation symbol, serial number, isotope, activity, and manufacturer's I.D. The licensee also addressed prototype testing and quality assurance. The licensee indicated that the device would not be subjected to environmental conditions exceeding these for ANSI classification C64343.

6. Fallston General Hospital, Inc.
Fallston, Maryland
License No. MD-25-014-01
Issued: March 11, 1986
Expires: March 31, 199[illegible]

This license authorizes medical groups I-III, Xe and iodine therapy. This license was selected by OSP for review. The application included information on the medical isotope committee, RSO, physician training, receipt and opening procedures, facilities and equipment, personnel monitoring, general safety rules, surveys, generator procedures, leak test procedures, emergency procedures, instrument calibration procedures, and waste disposal. The State corresponded with the applicant concerning the adequacy of ventilation in the room where xenon studies were to be performed. After some modifications to the ventilation system, the license was issued.

7. ConDiesel Mobile Equipment
Salisbury, Maryland
License No. MD-45-005-01
Issued: October 21, 1985
Expires: October 31, 1990

This license was selected by OSP for review. The license authorizes 3,000 curies of H-3 gas in phosphor coated pyrex glass. The glass devices are used on the firing controls of artillery manufactured for the U.S. Government. They act as a light source for firing the artillery in the dark. The radiation safety program consists of wipe testing devices upon receipt and continuous air sampling in the storage area. Analysis will be done by an NRC licensed consultant. Broken glass will be placed in a waste barrel and shipped to a waste disposal firm.

8. Drs. Wener, Boyle and Associates, P.A.
Clinton, Maryland
License No. MD-33-028-01
Renewed: November 29, 1984
Expires: November 30, 1989

This license was selected by OSP for review. The license authorizes medical groups I-III, except generators. The application includes information on user qualifications (previously submitted), RSO duties, material requested, instrumentation and calibration procedures, facility description, area survey procedures, general safety rules, procedures for ordering and receiving radioactive material, opening packages, training program, emergency procedures, and waste disposal procedures. The State asked for some clarification particularly with regard to waste disposal procedures, i.e., sensitivity of instrumentation used for surveys. Additional information was provided and the license was issued.

9. Development Facilitators
Severna Park, Maryland
License No. MD-03-033-01
Issued: November 2, 1984
Expires: November 30, 1989

This license was selected by OSP for review. The license authorizes Troxler moisture/density gauges. The application and follow-up letter contained information on user training, personnel monitoring, RSO, storage, transportation, maintenance, emergency procedures, and disposal. Recent amendments have added two users and changed the storage location.

No deficiencies were noted.

10. Design Lite, Inc.
Columbia, Maryland
License No. MD-27-032-01
Issued: May 8, 1986
Expires: May 31, 1991

This license authorizes the GL distribution of H-3 light sources containing up to 25 Ci of H-3. The license contains the standard condition for GL distribution licenses regard the labeling of devices. Design Lite is essentially a redistributor of Brandhurst devices. Brandhurst has an NRC license for GL distribution. The State had some questions about the assurance that under accident conditions associated with handling, storage, and use that it would be unlikely that any individual would receive in excess of 15rem committed whole body dose. (State regulations equivalent to Part 32). Design Lite provided additional information which supported the Brandhurst NRC license, and the license was issued.

APPENDIX D

Review of Selected Compliance Files

Documentation of inspection findings is for the most part adequate. Some minor exceptions were, 1) training was not always discussed in sufficient detail, 2) confirmatory measurements could have been expanded in some cases, 3) for one broad licensee, the user approval records were not reviewed. In addition, some inspections are documented in a narrative report. These reports are not subdivided in a sufficient number of areas. This makes review and retrieval of inspection data difficult. It was recommended that the report format be reorganized and NRC inspection forms were provided as models.

1. University of Maryland
   License No. MD-07-014-04
   Incinerator
   Inspection Date: November 3, 1986
   Inspector: Chaparala
   Reviewed by Trump December 3, 1986
   Enforcement letter: Form 1097 left
   Licensee response: November 21, 1986
   Findings: Two violations - 1) unauthorized user and 2) ash analysis results not kept appropriate units.

   No report deficiencies were noted.

2. Syncor International
   License No. MD-33-061-01
   Nuclear Pharmacy
   Inspection Date: October 3-4, 1985
   Inspector: Trump and Chaparala
   Initial Unannounced
   Not reviewed
   Enforcement letter: Form 1097 left
   License Response: October 14, 1985
   Findings: 5 violations - 1) Rad waste found in dumpster, 2) No documentation of vehicle surveys, 3) bioassay records not available, 4) leak test records not available and 5) management audit records not available.

   Information on personnel monitoring was unclear. Results sta' as 2 rem to 30.5 rem for ring badges, but did not indicate time period. 30 rem extremity exposure seems high even if annual exposure. There was no indication that this was discussed with licensee. In addition, there was no indication of any discussion of the customer license verification practices. There was no discussion regarding training of staff.

3. Baltimore Gas and Electric
License No. MD-03-027-01
Industrial Radiography
Inspection Date: October 17, 1986
Inspector: Chaparala
Announced reinspection
Reviewed by Trump: November 6, 1986
Enforcement letter: Form 1097
Licensee response: N/A
Findings: No violations

No field site was visited during the inspection. No report deficiencies were noted.

4. Maryland Q.C. Laboratories
License No. MD-05-075-01
Industrial Radiography
Inspection Date: August 13-14, 1986
Inspector: Chaprala and Chong
Unannounced reinspection
Reviewed by Trump (No date)
Enforcement letter: Form 1097 left
Licensee Response: None requested
Findings: Notice of employees not posted. Corrected during inspection.

It was noted that the inspection included a field site visit. No report deficiencies were noted.

5. Westinghouse Hittman Nulcear, Inc.
License No. MD-27-001-02
Waste Broker and Decon
Inspection Date: December 4-5, 1986
Inspector: Chaparala
Unannounced Reinspection
Reviewed by Trump January 29, 1987
Enforcement letter: From 1097 left
Licensee Response: None yet
Findings: Three violations - 1) TLD frequency changed from monthly to quarterly without State approval, 2) TLDs not worn by employees when monitored by another licensee and 3) Waste container not labeled.

No waste activities are currently being performed. The licensee is doing some decon work at power plants. The second violation concerns the fact that Hittman employees are required to wear Hittman TLDs even when monitored by customer facilities. Apparently there were cases when this was not being done. There was no discussion of staff training.

6. RAD/IRID, Inc.
License No. MD-33-053-01
Source Fabrication for Therapy
Inspection Date: December 19, 1986
Inspector: Chong
Unannounced Reinspection
Reviewed by Trump January 21, 1987
Enforcement letter: Form 1097 left
Licensee Response: N/A
Findings: No violations

There was no discussion of quality assurance nor customer license verification procedures. Independent measurement by the inspector were made in the storage area. It was not clear that this was also the use area.

7. Johns Hopkins Applied Physics Lab
License No. MD-27-014-01
Gamma Irradiator (27,000 Ci of Co-60)
Inspection Date: November 12, 1986
Inspector: Chong
Unannounced, Reinspection
Reviewed by Trump December 3, 1986
Enforcement letter: Form 1097 left
Licensee Response: N/A
Findings: No violations

The irradiator currently has only 1500 Ci of Co-60. There was no interview of user to verify irradiator procedures are being followed.

8. University of Maryland
License No. MD-07-014-01
Broad Medical/Academic
Inspection Date: November 20, 21, 24, 25, 1986
Inspector: Chong
Unannounced, Reinspection
Reviewed by Trump January 20, 1987
Enforcement letter: December 22, 1986
Licensee Response: None yet
Findings: 16 violations - 1) Failure to file renewal application, 2) No evaluations of unreturned film badges. 3) Failure of RSO to perform 6 month surveys. 4) Contamination surveys not performed monthly. 5) Patients with implants not surveyed prior to release. 6) Area surveys of adjacent rooms not conducted. 7) Patient survey records not available. 8) Use of uncalibrated survey meter. 9) Lab survey records not adequate. 10) linearity checks of dose calibrator not conducted. 11) Use of dose calibrator when accuracy check indicated reading greater than 5% from correct reading. 12) Executive committee failed to meet at required frequency. 13) Lab contamination

survey records not available. 14) No receipt record available for I-125 source. 15) Notice to workers not posted. 16) "Notice of Employees" not posted.

An enforcement conference with the licensee was held on December 10, 1986. The enforcement letter confirmed the results of the meeting, i.e., the licensee would submit a renewal application no later than January 9, 1987. (An extension was later granted until January 29, 1987), the University will increase staff in the radiation safety office, the licensee will initiate a plan of compliance for the listed violations.

In contrast to previous broad license inspections, a number of user labs were visited by the inspector. However, no independent contamination surveys were conducted. In addition, there were apparently no inspection of any user approval records.

9. University of Maryland
License No. MD-07-014-01
Broad Medical/Academic
Investigation dated October 3, 1985
Report dated October 21, 1985

DRC received a call on September 30, 1985 from Baltimore City Fire Department concerning waste drums stored on loading docks at University Hospital. Ferguson visited 5 waste storage areas (from 9/30-10/2). At one facility, 149 barrels were stored in a locked area, but the facility is also used by police and maintenance crews. An interview with a University official indicated that waste is frequently stored in hallways, stairwells and loading docks for extended periods. Two citations were made at the time: 1) waste containers unsecured against unauthorized removal and 2) "CRM" signs used when not required. The licensee responded on October 22, 1985 indicating that they had contracted with a waste disposal firm to remove the drums and were negotiating a contract for monthly pickups. The most recent inspection revealed that waste is currently being picked up bimonthly.

10. Francis Scott Key Medical Center
License No. MD-07-008-07
Institutional Group Medical
Inspection Date: September 29 and 30, 1986
Inspector: Chong
Unannounced Reinspection
Reviewed by Trump November 10, 1986
Enforcement letter: Form 1097 left
Licensee Response: October 15, 1986
Findings: 6 violations - 1) Contamination surveys not conducted. 2) Constancy checks of dose calibrator not conducted. 3) Records of linearity checks not available. 4) Patient logs not maintained. 5) Incoming packages not surveyed and 6) Technician failed to return film badge.

The last violation should have been failure to evaluate exposure for specific period of time. Violation 4 actually referred to the use of an exhaust fan during xenon studies. The report indicated no operations were observed. The response to the enforcement letter was signed by the chief technologist.

11. Shady Grove Adventist Hospital
License No. MD-31-104-01
Institutional Group Medical
Inspection Date: December 2 - 3, 1986
Inspector: Manley
Unannounced, Reinspection
Reviewed by Trump January 13, 1987
Enforcement letter: Form 1097 left
Licensee Response: December 18, 1986
January 7, 1987
Findings: 5 violations - 1) No dose evaluations for lost badges. 2) Improper conversion form cpm to dpm for wipe test surveys. 3) Personnel monitoring devices not stored in low background area. 4) Record of dose calibrator linearity check not available. 5) Technologist drinking in restricted area where patient doses are administered.

No report deficiencies noted.

12. Washington County Hospital
License No. MD-43-001-01
Institutional Group Medical
Inspection Date: December 8 - 9, 1986
Inspector: Manley
Unannounced, Reinspection
Reviewed by Trump January 21, 1987
Enforcement letter: Form 1097 left
Licensee Response: January 5, 1987

Findings: 5 violations - 1) No wipe tests on incoming packages. 2) No radiation survey of incoming packages. 3) Lab monitoring records not in appropriate units. 4) Leak test results not in appropriate units. 5) License, regs, procedures "notice" not posted.

No report deficiencies noted.

State of Maryland

DEPARTMENT OF THE ENVIRONMENT
201 WEST PRESTON STREET • BALTIMORE, MARYLAND 21201
AREA CODE 301 • 225-

William Donald Schaefer
Governor

Martin W. Walsh, Jr.
Secretary

May 25, 1988

United States
Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

ATTENTION: John McGrath
Regional States Agreement Officer

Dear Mr. ~~McGrath~~ John:

A review of our files has revealed that we have no record of having provided a response to Carlton C. Kammerer's May 27, 1987 letter to Secretary of Health and Mental Hygiene, Adele Wilzack. Our files do contain a copy of Secretary Wilzack's response, in which she states that our agency would respond under separate cover, to address the specific comments and recommendations you made.

Since, per our recent telephone conversation, neither of us has a file copy of the separate response, I have prepared a report from my notes of the review.

Should you have any questions, please feel free to contact me at (301) 333-3130.

Sincerely,

Roland G. Fletcher

Roland G. Fletcher, Administrator
Center for Radiological Health

RGF/dpw

Enclosure

STATE RESPONSE TO NRC REGION I
COMMENTS AND RECOMMENDATIONS
REGARDING THE MARYLAND RADIATION CONTROL PROGRAM

Compliance

A. Enforcement Procedures is a Category I indicator. The following comment is considered of minor significance.

Comment

During our last review, we noted that the radiation control program had recently been given civil penalty authority and we recommended that the State finalize escalated enforcement procedures which had been drafted in 1980. Because of efforts in other program areas, the State has not yet finalized these procedures.

Recommendation

We recommend that the State update and finalize its escalated enforcement procedures.

State Response

The need to finalize escalated enforcement procedures and incorporate civil penalty assessments is recognized and is being pursued. An evaluation of NRC and some Agreement State procedures is being made by the Maryland Attorney General's office and will result in an updated revised draft of procedures. The formal drafting of these procedures is expected to be completed by January, 1989. The assessment of Civil Penalties as an enforcement tool, however, is an ongoing process and is dealt with on a case by case basis. Due consideration is given to the nature of the violation, the licensees record of performance, and the severity of the public and/or environmental health aspects of the violation.

B. Inspectors' Performance and Capability is a Category I indicator. The following comment is considered of minor significance.

Comment

Since our last review, the State's compliance supervisor has accompanied the State's inspection staff primarily for training purposes. Under NRC guidelines the compliance supervisor should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Recommendation

Now that the State's inspection staff is trained to the point that they are doing independent inspections and the inspection backlog has been reduced to a more manageable level, we recommend that the compliance supervisor institute a routine program of annual field evaluations of the inspection staff.

State Response

As you note, our Radioactive Materials compliance supervisor has a very difficult task by reducing the inspection backlog to a manageable level. Even prior to this review, we made the decision to increase inspection accompaniments and I have every confidence that this will be accomplished with the level of professional enthusiasm already displayed in reducing the backlog. We will establish and implement a program of annual field evaluation of the inspection staff during fiscal year 1988.

C. Inspection Reports is a Category II indicator

Comment

The inspection reports reviewed during the meeting were technically sound and adequately supported the enforcement actions taken. The narrative reports were not, however, organized in a manner which facilitated review and retrieval of inspection data.

Recommendation

We recommend that the State reorganize its insepction form to better document the inspectors' findings. Copies of NRC forms were provided to the staff for use as models.

State Response

Though we have drafted a new form which addresses the concerns you express, we have taken no further action pending the establishment of the Maryland Department of the Environment (MDE) which Radiation Control will be a part and its relocation to new facilities with a new address. Until these actions are accomplished, we will continue to use our current form.

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

September 19, 1989

Martin W. Walsh, Jr., Secretary
Maryland Department of the Environment
2500 Broening Highway
Baltimore, Maryland 21224

Dear Mr. Walsh:

During the period February 13-17, 1989, we conducted our regular periodic review of the State's radiation control program. On February 17, Messrs. John McGrath and Stewart Ebneter held a closeout meeting with Deputy Secretary Andrews summarizing the finding of the review. Subsequent to the review, an employee of Neutron Products, Inc., a Maryland licensee, was found to be contaminated with cobalt-60 at the Ginna Nuclear Power Plant in New York. In view of the implications of this case for various aspects of Maryland's Agreement program, e.g., in emergency response, licensing, and inspection and enforcement, we postponed our final report on the evaluation of the State program until the State's actions in handling this incident could be factored into the overall review. An additional meeting to review the State's actions was held with Mr. Larry Ward, Mr. Roland Fletcher, Administrator, Center for Radiological Health, and his staff on August 9, 1989.

The inclusion of the State's radiation control program in the newly created Department of the Environment has, we believe, been a positive development for the program. The interest that you and Deputy Secretary Andrews have shown in radiation matters has been reassuring to us. The program has undergone a number of changes since our last review in January 1987, but has managed to accomplish its basic mission regarding protection of the public health and safety. For example, despite the loss of two senior inspectors, the program's inspection backlog has been reduced to essentially zero. The results of our review, therefore, indicate that the State's program for regulating agreement materials is adequate to protect public health and safety.

During our last two reviews, we have commented on the need to revise the State's regulations regarding low-level radioactive waste, specifically the adoption of the waste classification and manifest systems. A draft has been prepared which addresses these and other aspects of low-level waste disposal. Mr. Fletcher has indicated that he will provide a copy of this draft for our review. In the meantime, however, we must defer a finding of compatibility until such time as these regulations become effective. Status and Compatibility of Regulations is a Category I indicator.

We were pleased to note that the State has proposed fee legislation. We believe that fees can provide a significant, stable source of funding for a radiation control program and have encouraged all States to adopt some sort of fee system. If we can be of any assistance in moving this issue forward, please call on us. Budget is a Category II indicator.

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Since the last review, the program has lost two senior inspectors, one for a higher paying, but similar position in a State institution. The program has experienced some difficulty in recruiting persons with appropriate training and experience to fill these two positions. One position was filled by a transfer from the X-ray program, while the second was filled by an individual with no prior training or experience in radiation protection. The amount of training necessary to bring this individual up to the point where he can begin to contribute to the program's mission is significant. We believe that the State needs to upgrade its salary structure in order to more effectively compete for personnel with qualifications consistent with the duties and responsibilities of these positions. Staff Continuity is a Category II indicator.

Over the past few years, the use of radioactive material in the State has increased significantly. There are now over 500 licenses in the State. Statistical data used to manage the program is still being processed by hand. For an Agreement State program the size of Maryland's, we have found that computer capability is necessary to effectively manage the program. The Center has a personal computer available to the staff, and we recommend that the staff explore ways of effectively utilizing this resource. Office Equipment and Support Services is a Category II indicator.

We were pleased to note that, in most cases, the Center was diligent in pursuing effective enforcement action when circumstances so required. The State has taken a number of escalated enforcement actions including civil penalties in the period since our last review; however, as noted during previous reviews, the Center has no written procedures which address the process by which escalated enforcement actions are taken. We believe that the documentation of these procedures would be of benefit to the program. Enforcement Procedures is a Category I indicator.

We noted an exception to the program's generally diligent pursuit of timely and effective enforcement action. In June 1988, the State issued an order to Neut on Products, Inc. (NPI) requiring the licensee to address, among other things, the deficiencies in monitoring personnel as they leave the limited access area (LAA). This action was the result of an incident in May 1988 in which an employee of NPI was found to be contaminated with cobalt-60 at the Ginna Nuclear Power Plant in New York. Subsequent inspections at NPI in July-August 1988 and October-November 1988 revealed that adequate corrective action had not yet been achieved. This issue came to our attention again when, subsequent to our program review, we were notified by Ginna Reactor staff on February 24, 1989 that the same individual from NPI was found to have cobalt-60 contamination again at the Ginna site. Analysis of the contamination revealed the presence of cobalt-60 "hot particles," a form of contamination representing a significantly higher potential for causing radiation injury.

Since the February 1989 event, we have worked very closely with the Center staff in addressing the NPI situation. The State issued an order on March 3, 1989 essentially closing down the licensee's operation. We believe the State took a prudent course of action and has taken a cautious approach in evaluating NPI's proposed corrective actions, including obtaining NRC technical assistance in evaluating the NPI program. Although some problems did arise, both on the part of the State and NRC, particularly in the area of communication, we believe overall the State has handled this difficult case in an admirable manner, and we look forward to working with the Center in addressing the issues that remain to be resolved prior to granting Neutron Products full license authority.

Enclosure 1 to this letter contains an explanation of our policies and practices for reviewing Agreement State programs. We are enclosing a second copy of this letter for placement in the State's Public Document Room or otherwise to be made available for public review.

As we discussed, the Department needs to revise its regulations as soon as possible to conform them to national standards for low-level radioactive waste. I would appreciate receiving a plan including milestones for accomplishing this. We will continue to provide technical and other assistance within our resources to the State in support of its regulatory program.

I appreciate the courtesy and cooperation extended to our staff during the review.

Sincerely,

for/ Carlton Kammerer

Carlton Kammerer, Director
State, Local and Indian Tribe Programs
Office of Governmental and Public Affairs

Enclosure:
As stated

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cc w/enclosure:
J. M. Taylor, Acting Executive Director for Operations
William T. Russell, Regional Administrator, RI
Roland G. Fletcher, Administrator, Center for
Radiological Health (CRH), Maryland Department
of the Environment
NRC Public Document Room
State Public Document Room

bcc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss

ENCLOSURE 1

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 June 4, 1987, as an NRC Policy Statement. The Guide provides 29 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 one or more 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 anc safety and that the need for improvement in particular program areas 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 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 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 Atomic Energy Act of 1954, as amended.

Maryland Review Comment Letter

Talking Notes

Percussepe

Dr. Farrell

- Project Manager

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I appreciate the courtesy and cooperation extended to our staff during the review.

Sincerely,

Carlton C. Kammerer, Director
State, Local and Indian Tribe Programs
Office of Governmental and Public Affairs

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State, Local and Indian Tribe Programs
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State, Local and Indian Tribe Programs
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State of Maryland

DEPARTMENT OF THE ENVIRONMENT
2500 Broening Highway, Baltimore, Maryland 21224
Area Code 301 • 631- 3084

William Donald Schaefer
Governor

Martin W. Walsh, Jr.
Secretary

November 2, 1989

89 NOV -6 P12:09

Mr. Carlton C. Kammerer, Director
State, Local and Indian Tribe Programs
Office of Governmental and Public Affairs
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Kammerer:

Thank you for your letter of September 19, 1989 regarding the Nuclear Regulatory Commission's (NRC) review and evaluation of the Maryland radiation control program.

It is rewarding to know that the NRC recognizes the positive impact the Department of the Environment has had on the radiation program. I can assure you I am committed to providing continued support and emphasis to this vital segment of the Department's operations. Although successes have occurred in the program, the areas of concern outlined in your letter will be given prompt attention.

With regard to the promulgation of low-level radioactive waste regulations, the final draft is currently being reviewed within the Department. The Controlled Hazardous Substance Advisory Council should complete their review by November 15, 1989. Based upon the normal timetable for regulation promulgation in Maryland, we expect publication in the Maryland Register by December 31, 1989, a public hearing by February 25, 1990 and final adoption before June 1, 1990.

Regulations regarding the establishment of radiation user fees are currently being reviewed by the user community and the Radiation Control Advisory Board. The adoption of these regulations is expected in February 1990 with initial fees due on April 1, 1990. In addition to the collection of fees as a means to bolster radiation staff, we are currently conducting a review of our radiation staff salary structure, which you also note with my concurrence, as an area of concern. I have instructed my Director of Personnel to formally evaluate the salary structure and develop proposed salary upgrades. We will keep Region I informed of our progress.

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The Radiological Health Program (RHP) is currently drafting written enforcement procedures on which to base its enforcement actions for radioactive material violations. To insure consideration of a myriad of situations and levels of enforcement, departmental attorneys are working closely with RHP to finalize these procedures by November 30, 1989. Once completed, these procedures will be forwarded to Region I for comment prior to inclusion in the next revision of Maryland Radiation Protection Regulations scheduled for September, 1990.

With regard to Neutron Products, Inc. (NPI), we have permitted a return to full operations, except for the melting of Cobalt-60. We have amended NPI's license to add many requirements that have been instrumental in the upgrading of the facility's radiation safety practices. We will continue to monitor NPI frequently to assure that all corrective measures are implemented and carried out in accordance with these newly developed requirements. With regard to NPI, we appreciate the continuing assistance of both Region I and NRC Headquarters, particularly, in providing inspection accompaniment in March and September of 1989. We have invited Region I to accompany us when we observe the Cobalt-60 melt at NPI, once they receive authorization to conduct it.

As you note, a program the size of RHP has a continuing need to acquire and effectively use computers. The RHP is using its personal computer to automate its licensing files for rapid information retrieval. Computer hardware will continue to be obtained with a five year goal of a workstation on each desk and a completely networked system in RHP.

Your comments regarding the more technical aspects of our program will be responded to under separate cover, by Mr. Roland G. Fletcher, Administrator of the Radiological Health Program. In addition, Mr. Fletcher will insure that the letter of explanation of policies and practices for reviewing Agreement State programs, as well as a copy of your Maryland critique are made available for public review.

I am most appreciative of the close coordination and assistance provided by the NRC to this agency. If you have any questions, please feel free to call me at (301) 631-3084, or Mr. Roland G. Fletcher at (301) 631-3301.

Sincerely,

Martin W. Walsh, Jr.

Martin W. Walsh, Jr.
Secretary

MWW:dpw