

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

State of Maryland

Reporting Period: July 26, 2003 to August 24, 2007

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State may copy the previous answer if appropriate. Please note that previous IMPEP questionnaire responses can be found on the FSME webpage.

A. COMMON PERFORMANCE INDICATORS

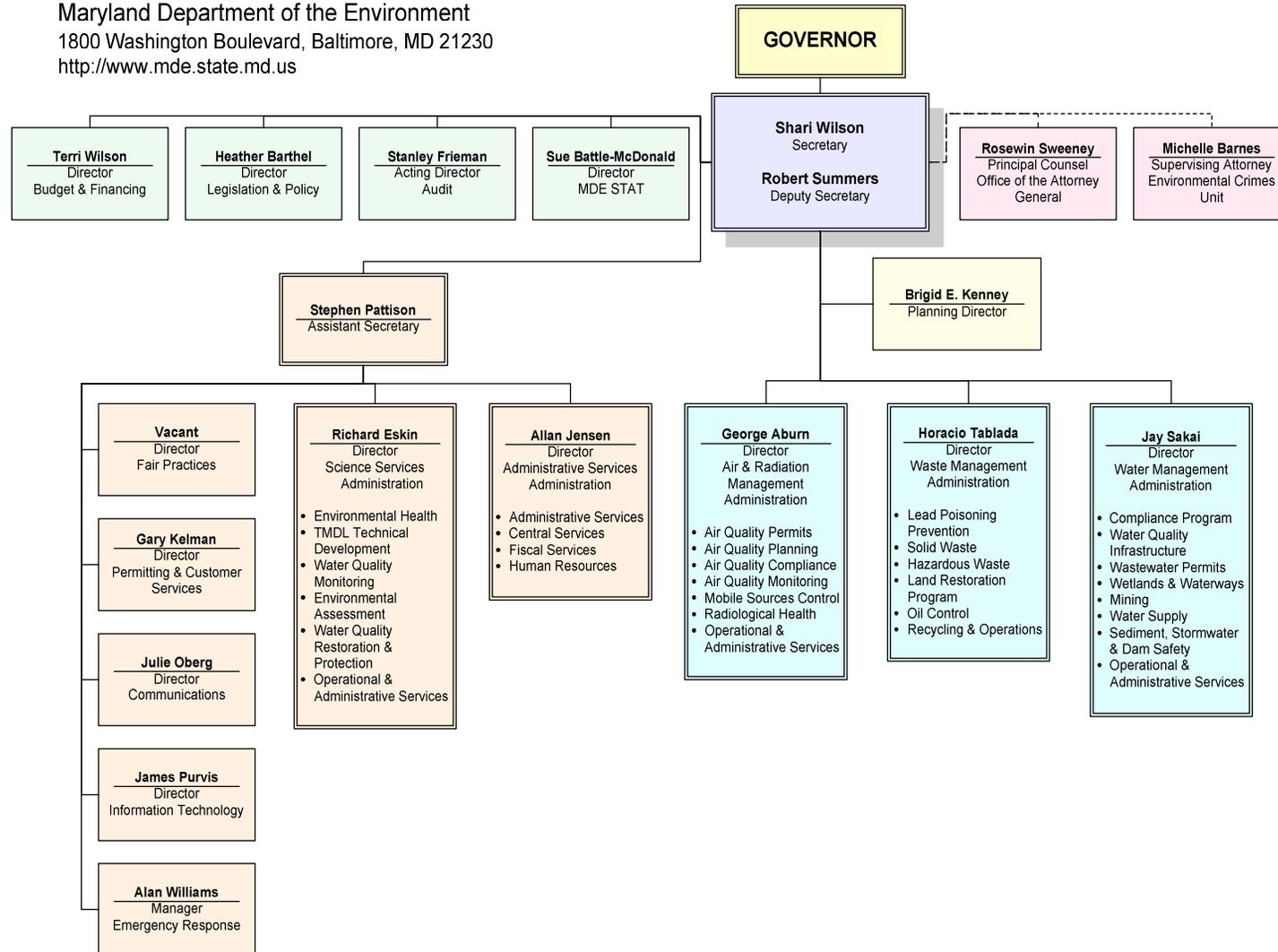
I. Technical Staffing and Training

1. Please provide the following organization charts, including names and positions:

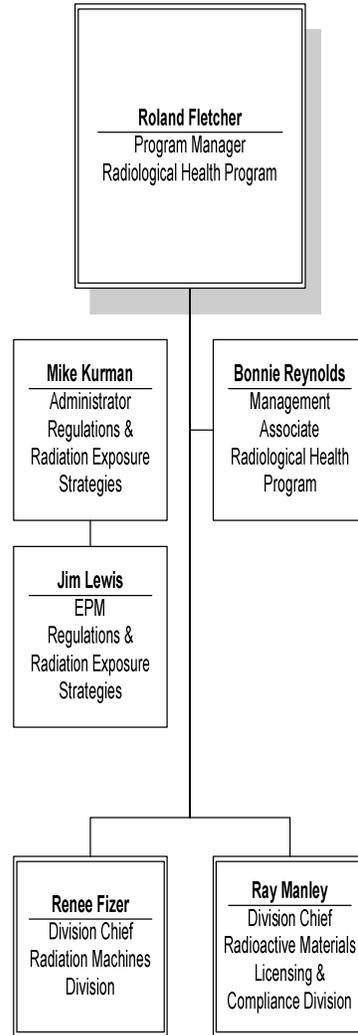
- (a) A chart showing positions from Governor down to Radiation Control Program Director;

**RHP RESPONSE:**

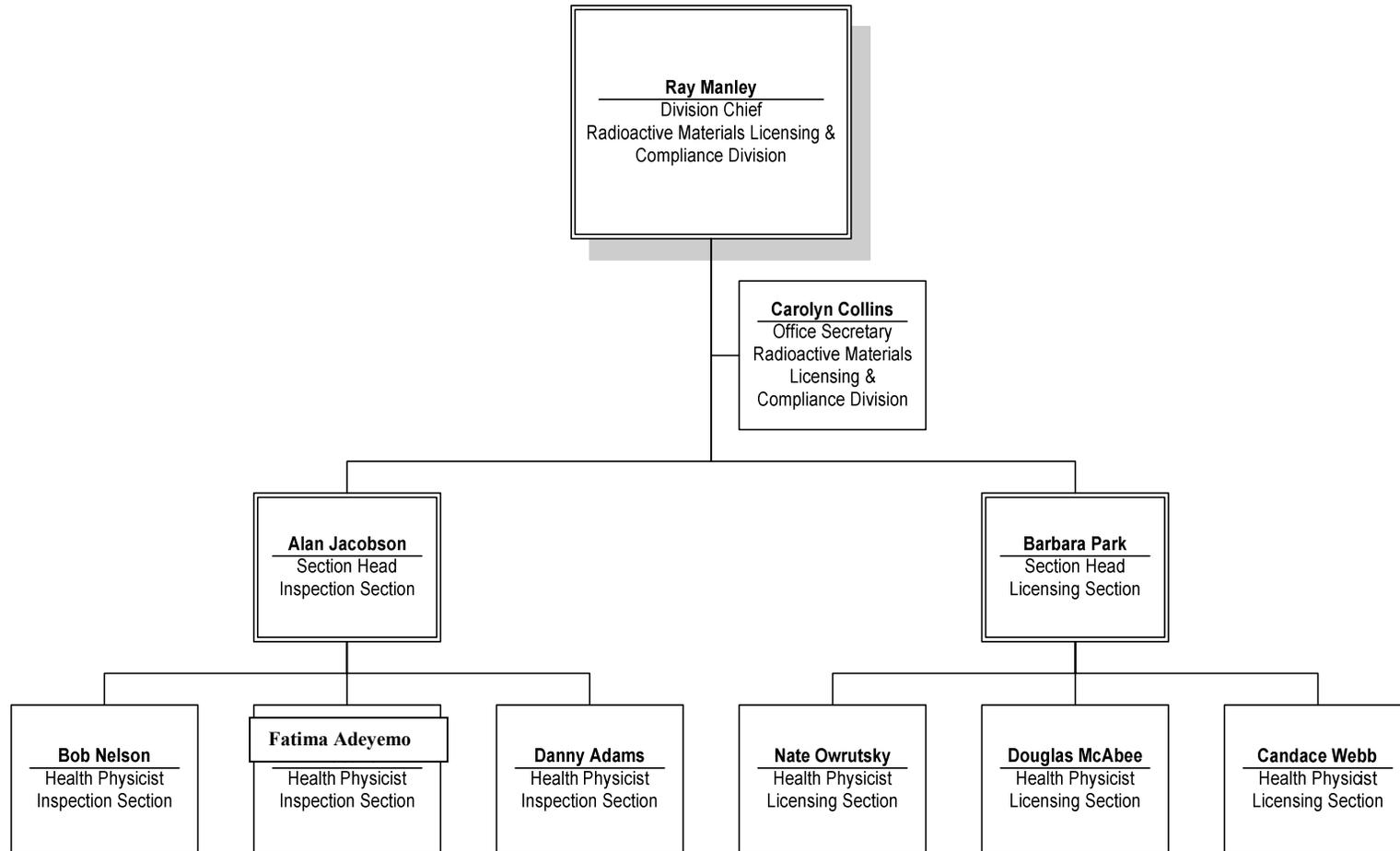
Maryland Department of the Environment  
 1800 Washington Boulevard, Baltimore, MD 21230  
<http://www.mde.state.md.us>



# ARMA Radiological Health Program



Radioactive Materials Licensing and Compliance Division  
ARMA Radiological Health Program



(c) Equivalent charts for sealed source and device, low level radioactive waste and uranium recovery programs, if applicable

**RHP RESPONSE:**

<b><u>SEALED SOURCE AND DEVICE REVIEW</u></b>		
<b><u>Name</u></b>	<b><u>Title</u></b>	<b><u>Signature Authority</u></b>
<b>Raymond Manley</b>	<b>Chief, Radioactive Material Licensing Compliance Division</b>	<b>full</b>
<b>Barbara Park</b>	<b>Supervisor, Radioactive Material Licensing Compliance Division</b>	<b>full</b>
<b>Nathaniel Owrutsky</b>	<b>Radioactive Material Licensing Reviewer</b>	<b>full</b>
<b>Douglas McAbee</b>	<b>Radioactive Material Licensing Reviewer</b>	<b>full</b>

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

<b><u>Name</u></b>	<b><u>Position</u></b>	<b><u>Area of Effort</u></b>	<b><u>FRACTION TIME</u></b>
Raymond Manley 21 years	Chief, Radioactive Material Licensing Compliance Division	Administration Materials Licensing and Compliance Emergency Response	75 20 5
Alan Jacobson 23 years	Inspection Supervisor, Radioactive Material Licensing Compliance Division	Administration Materials Licensing and Compliance Emergency Response	60 30 10
Barbara Park 7 years	Licensing Supervisor, Radioactive Material Licensing Compliance Division	Administration Materials Licensing and Compliance Emergency Response	60 38 2
Nathaniel Owrutsky 23 years	Radioactive Material Licensing Reviewer	Administration Materials Licensing and Compliance Emergency Response	0 95 5
Robert Nelson 17 years	Radioactive Material Inspector	Administration Materials Licensing and Compliance Emergency Response	0 90 10
Douglas McAbee 16 years	Radioactive Material Licensing Reviewer	Administration Materials Licensing and Compliance Emergency Response	0 98 2
Danny Adams 3 years	Radioactive Material Inspector	Administration Materials Licensing and Compliance Emergency Response	0 90 10
Candace Webb 1 year	Radioactive Material Licensing Reviewer	Administration Materials Licensing and Compliance Emergency Response	0 98 2
Fatima Adeyemo 8 months	Radioactive Material Inspector	Administration Materials Licensing and Compliance Emergency Response	0 98 2

**RHP RESPONSE:**

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

**RHP RESPONSE:**

<u>Name</u>	<u>Degree</u>	<u>Additional Training and Years of Experience in Health Physics</u>
Danny Adams	B.S Radiation Protection	Licensing Course 5-week HP Course Industrial Radiography Course Inspection Procedures Course 18 years
Candace Webb	B.S. Chemistry, Nuclear Engineering Graduate School	Performance Based Inspection Course Licensing Course Root Cause Analysis Course Principles of Radiation (TMS Associates) 4.5 years
Fatima Adeyemo	B.S. Chemistry	8 months

4. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapter (IMC) 1246; for Agreement States, please enclose a copy of your qualification and training procedure. If you do not have a written procedure please describe your qualification requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

**RHP RESPONSE:**

**Review conducted in accordance with RHP Qualification Program and SP 97-087 recommendations. Qualification and training procedure is enclosed**

<u>Name</u>	<u>Core Training Course</u>	<u>Schedule of Completion</u>
Danny Adams	Elements of Transportation	End of 2007
Fatima Adeyemo	Essentials of Inspection Elements of Transportation Applied Health Physics Diagnostic and Therapeutic Nuclear Medicine Safety Aspects of Industrial Radiography	Within 3 years

5. Please identify the technical staff that left the Agreement State/Regional DNMS program during this period.

**RHP RESPONSE:**

<b><u>Name</u></b>	<b><u>Title</u></b>	<b><u>Reason</u></b>
Mary Lally	HP II	Resigned 7/2004
Fatima Adeyemo	HP Trainee	Resigned 5/2006 rehired 6/2007
Bob Nelson	HP III	Military Leave 7/2003 to 10/2003
Bob Nelson	HP III	Military Leave 10/2006 to 8/2007

6. List the vacant positions in each program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

**RHP RESPONSE:**

**Currently NONE**

7. Does the Agreement State program have an oversight board or committee, which provides direction to the program and is composed of licensees and other members of the public? If so, please describe the procedures used to avoid a conflict of interest. ?

**RHP RESPONSE:**

**Yes Maryland Radiation Control Advisory Board.**

**There is a Conflict of Interest provision in the State Ethics Law. New members are informed of this law and must sign a disclosure form if there is a potential conflict. This would also apply if a potential conflict of interest develops during a member's term.**

II. Status of Materials Inspection Program

8. Please identify individual licensees or categories of licensees the State/Region is inspecting more or less frequently than called for in IMC 2800, and state the reason for the difference.

**RHP RESPONSE:**

<b><u>Category</u></b>	<b><u>NRC Frequency (yrs)</u></b>	<b><u>MD Frequency (yrs)</u></b>	<b><u>Reason for Difference</u></b>
Academic Type A Broad	3	2	Evaluation of hazard and complexity of license
Medical Institution Broad	2	1	Evaluation of hazard and complexity of license
Mobile Medical	3	2	Evaluation of hazard and complexity of license

HDR	2	1	Evaluation of hazard and complexity of license
Teletherapy	5	3	Evaluation of hazard and complexity of license
Gamma-Knife	2	1	Evaluation of hazard and complexity of license
Nuclear Pharmacies	2	1	Evaluation of hazard and complexity of license
Medical Product Distrib.	5	1	Evaluation of hazard and complexity of license
Leak Test Service Only	T	5	Evaluation of hazard and complexity of license
Measuring Systems-Gas Chrom	T	5	Evaluation of hazard and complexity of license
Measuring Systems-Other	T	5	Evaluation of hazard and complexity of license
Other HP Services	5	3 (1 for HDR Services)	Evaluation of hazard and complexity of license
Waste Disposal-Prepackaged	3	1	Evaluation of hazard and complexity of license
Irradiator Pool	2	1	Evaluation of hazard and complexity of license
Pacemaker	T	5	Evaluation of hazard and complexity of license
M & D	2	1	Evaluation of hazard and complexity of license
Teletherapy Service	2	1	Evaluation of hazard and complexity of license

9. Please provide for the review period, the number of Priority 1, 2, and 3 inspections as identified in IMC 2800 that were completed, and the number of initial inspections that were completed.

**RHP RESPONSE:**

<b><u>Priority</u></b>	<b><u># of Inspections Completed</u></b>
1	43
2	115
3	144
Initial	147

10. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees, and initial inspections that are presently overdue or which were conducted at intervals that exceed the IMC 2800 frequencies over the course of the entire review period. (See STP Procedure SA-101, *Reviewing the Common Performance Indicator, Status of Materials Inspection Program*, for detailed guidance in preparing this information).

At a minimum, the list should include the following information for each inspection that is overdue or conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Priority
- (4) Last inspection date or license issued date if initial inspection
- (5) Date Due
- (6) Date Performed
- (7) Amount of Time Overdue
- (8) Date inspection findings issued

**RHP RESPONSE:**

**None are overdue in accordance with IMC 2800 frequencies of priorities of**

**1-3.**

- 11. If you have any overdue inspections, do you have an action plan for completing them? If so, please describe the plan or provide a written copy with your response to this questionnaire.

**RHP RESPONSE:**

**None are overdue in accordance with IMC 2800 frequencies of priorities of**

**1-3.**

- 12. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in NRC IMC 1220, and the number of candidate reciprocity inspections that were completed each year during the review period.

<b><u>Calendar Year</u></b>	<b><u># Licenses Conducted Work in MD</u></b>	<b><u># Inspections Conducted</u></b>
<b>2007</b>	27	5
<b>2006</b>	36	11
<b>2005</b>	46	9
<b>2004</b>	43	15

III.

**Technical Quality of Inspections**

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

**RHP RESPONSE:**

**NONE**

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

**RHP RESPONSE:**

<b><u>Inspector</u></b>	<b><u>Date</u></b>	<b><u>Supervisor</u></b>	<b><u>License Category</u></b>
Barbara Park	2/18/04	Ray Manley	Pre-Licensing (Ind. Radiography)
Alan Jacobson	2/23-24/04	Ray Manley	Sealed Source Manufacturer
Bob Nelson	5/5-6/04	Alan Jacobson	Irradiator >10,000 Curies
Danny Adams	5/27/04	Alan Jacobson	Portable Gauge
Mary Lally	6/17/04	Alan Jacobson	Nuclear Pharmacy
Danny Adams	10/22/04	Alan Jacobson	Research & Development
Danny Adams	1/21/05	Alan Jacobson	Medical Institution
Danny Adams	7/27/05	Alan Jacobson	Medical Institution
Alan Jacobson	9/6/05	Ray Manley	Investigation
Alan Jacobson	11/2/05	Ray Manley	Circuit Court Hearing
Bob Nelson	12/1/05	Alan Jacobson	Sealed Source Manufacturer
Fatima Adeyemo	2/7/06	Alan Jacobson	Portable Gauge
Bob Nelson	3/31/06	Alan Jacobson	Research & Development
Danny Adams	5/11/06	Alan Jacobson	Nuclear Pharmacy
Alan Jacobson	5/22/06	Ray Manley	Nuclear Pharmacy
Bob Nelson	6/29/06	Alan Jacobson	Industrial Radiography
Bob Nelson	6/29/06	Alan Jacobson	Research & Development
Barbara Park	7/14/05	Ray Manley	Pre-Licensing (Private Medical)
Danny Adams	7/28/06	Alan Jacobson	Irradiator>10,000 Curies
Bob Nelson	7/28/06	Alan Jacobson	Irradiator>10,000 Curies
Tiffany Greenwood	11/30/06	Alan Jacobson	Portable Gauge
Candace Webb	1/9/07	Barbara Park	Pre-Licensing (Portable Gauge)
Danny Adams	1/10-11/07	Alan Jacobson	Sealed Source Manufacturer
Nathaniel Owrutsky	2/15/07	Barbara Park	Pre-Licensing (HDR)
Candace Webb	2/20/07	Alan Jacobson	Medical Institution (No QM Program)
Fatima Adeyemo	6/27/07	Alan Jacobson	Private Medical
Douglas McAbee	2/27/07	Barbara Park	Pre-Licensing (Mobile Nuc. Med.)
Danny Adams	2/28/07	Alan Jacobson	Industrial Radiography
Fatima Adeyemo	6/27/07	Alan Jacobson	Research & Development

15. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field.

**RHP RESPONSE:**

**Supervisory accompaniments are conducted by a Program Manager or a Health Physicist Supervisor of the Radioactive Materials Program on an**

annual frequency if possible. These accompaniments are scheduled with each inspector in advance or unannounced. Decisions regarding the type of inspection is determined by level of experience, competency and qualification as well as the status of the inspection due tracking system. Types of accompaniments vary so that they may include fixed facilities, field sites, investigations, emergency responses and pre-licensing inspections. There are times when an out-of-state licensee requests to work in Maryland and arrangements may be made to conduct the Supervisory Accompaniment on that day. The Program Manager and the Health Physicist Supervisor may select different disciplines over the year or select identical disciplines for the accompaniments. Upon the completion each accompaniment, the Program Manager or the Health Physicist Supervisor will critique the inspection with the Inspector. Copies of each accompaniment will remain on file at the RHP.

16. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available through the review period?

**RHP RESPONSE:**

**Radiation Services Organization in Laurel, Maryland calibrates instruments. All instruments are currently calibrated at this time and sufficient calibrated instruments were available through the review period.** Laboratory capabilities are through a memorandum of understanding with the radiation laboratory at Maryland Department of Health and Mental Hygiene.

MAKE	MODEL	SERIAL #
Bicron	MicroREM	A279s
Ludlum	14-C	158704
Ludlum	14-C	144162
Ludlum	14-C	141948
Ludlum	14-C	158751
Ludlum	14-C	158671
Ludlum	14-C	144151
Ludlum	14-C	158706
Ludlum	14-C	1581201
Ludlum	19	61217
Ludlum	14-A	20460
Ludlum	12-S	77649
Ludlum	12-S	102971
Ludlum	12-S	85139
Ludlum	12-S	85131
Ludlum	78 extend	187473
Eberline	PRM-6	459
Eberline	PRM-6	1239
Eberline	PRM-6 Alpha	573
Eberline	PRM-6	1240
Eberline	PRM-6	1040
Eberline	PRM-6 Alpha	418
Eberline	PRM-6	1049
Eberline	PIC-6B	181
Eberline	PIC-6B	180

Eberline	PIC-6B	632
Eberline	PIC-6A	2237
Eberline	PIC-6B	633
Eberline	PIC-6	782
Eberline	PRM-7	631
Eberline	PRM-7	682
Eberline	ASP-1	908
Eberline	ASP-1	907
Eberline	PAC-4G-3	4496
Eberline	PAC-4G-3	4498
Eberline	PAC-4G-3	3842
Eberline	E-520	2089
Eberline	E-520	4921
Eberline	E-520	898
Eberline	E-520	989
Eberline	E-520	3800
Eberline	E-520	4925
Eberline	E-520	3148
Eberline	E-520	2306
Eberline	E-520	3195
Eberline	E-520	389
Eberline	E-520	4925
Eberline	E-520	3148
Eberline	E-520	2306
Eberline	E-520	3195
Eberline	E-520	389
Eberline	E-120	6587
Exploranium	GR-130	1045
Inovision	451P	0735
Inovision	451P	0736
Inovision	451P	0737
SRD	883	6112104
SRD	883	7021171
SRD	883	7032718
SRD	883	19913
SRD	880	5081127
SRD	883	7032975
NDS Product	RA500	45450
NDS Product	RA500	45451
NDS Product	RA500	45449
BTI Bubble	Microspec2	96107
Ludlum Kit	2241-3	220144
Ludlum Kit	2241-3	220199
Ludlum Kit	2241-3	220141
Ludlum Kit	2241-3	220147
Eberline Kit	E-600	02600
A probe	E-600	
B probe	E-600	
G probe	E-600	
N probe	E-600	
Xetex	415 B	026166
Xetex	415B	026118
Xetex	415B	026201
Xetex	415B	026229
Xetex	415B	026128
Xetex	415B	026356
Xetex	415B	026173
Xetex	415B	026114
Xetex	415B	026202
Xetex	415B	026147

Xetex	415B	026232
Xetex	415B	026182
Xetex	415B	026155
Xetex	415B	026173
Xetex	415B	026234
Xetex	415B	026167
Xetex	415B	026150
Xetex	415B	026230
Xetex	415B	026107
Xetex	415B	026220
Xetex	415B	026194
Xetex	451B	026131
Xetex	451B	026170
XRF	ICS-400	004128
XRF	ICS-400	004127
XRF	ICS-400	004126

IV. Technical Quality of Licensing Actions

17. How many specific radioactive material licenses does the Program regulate at this time?

**RHP RESPONSE: 633**

18. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period. Also identify any new or amended licenses that now require emergency plans.

**RHP RESPONSE:**

**Excluding increased control category 2 facilities, no new licensees require emergency plans as described in COMAR 26.12.01.01C.23**

LICENSEE	TYPE OF ACTION
Nucletron MD-27-035-01	Renewal
Smith's Detection MD-25-044-01	Renewal
Terumo MD-15-007-02	Renewal
RSO, Inc. MD-33-021-01	Renewal
Sinai Hospital MD-07-011-04	Renewal
COC Construction	New not issued (GAO Sting)
Washington Adventist Hospital MD-31-003-04	New
Digirad Imaging Solutions MD-03-107-01	New
Sanaria, Inc. MD-31-348-01	New
Human Genome	Decommissioning termination

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

**RHP RESPONSE:**

**Discussion of COMAR 26.12.01.01G.12(a): Licenses have been allowed to conduct mobile nuclear medicine (especially PET) at licensed facilities. RHP feels that the function of mobile nuclear medicine has expanded beyond the regulation’s original intent. RHP is currently reviewing mobile nuclear medicine as a whole and will be potentially changing the Maryland mobile nuclear medicine regulations.**

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

**RHP RESPONSE:**

<b><u>Policy</u></b>	<b><u>Date</u></b>
Use NRC 6 points for name change or transfer of ownership	2003
Drop shipments to Smiths from Canada can be done if certain conditions are met	2003
Guidelines for reviewing new PET facilities	2003
Use new flow chart and include with amendment for licensee transfer	2003
All 589 licenses will have expiration dated extended to be 7 years	2004
A new license condition must be added to all NEW licenses, i.e., “This condition is specific to the applicant’s initial receipt of this license. The licensee shall notify the Radiological Health Program’s Inspection and Compliance Division, in writing, within 10 calendar days after initial receipt of radioactive materials authorized on this license.”	2004
Added to the review of gauge licenses is that they must say that they will maintain a daily, or upon day of use, utilization log. This would have the user’s name, location of use and sign in and out dates.	2004
Generic language under license item 7 will not be used for portable gauges. Each sealed source will be listed.	2005
Portable gauge licenses: For renewals and new, add “total number of gauges shall not exceed 100” for the QOC measures.	2005
All new licenses - check for necessity of adding in the QOC IC language	2005
Item 12 – Regulations, add “and shall possess a copy of these regulations.”	2005
“First receipt of material” notification language established, must be used with new licenses	2005
In language for HDR license, remove all reference to the HDR as an irradiator and substitute “HDR therapy device .	2005
Add medical physicists to Brachytherapy, HDR and gamma knife licenses, in a separate category	2005
Use only New Times Roman font, 12 point	2005
Use compliance history checklist for all renewals.	2005
Add and use check off for presence of regs on prelicensing visit form.	2005
Gauges in storage must be leak tested and RSO must maintain personal dosimeter in case of an emergency.	2005
If medical physicists do not have at least an M.S., we will examine credentials on a case-by-case basis.	2005
Troxlers not to be stored at homes.	2005
Licensee may change PET trailers if new plans are submitted.	2005
The ATI online portable gauge-training course has been deemed acceptable by RHP.	2005
A new, more comprehensive HDR checklist has been developed using 1556, old	2005

checklist and submission of prospective licensees.	
FTID, Fax numbers and email addresses must be submitted for all new and renewals. Reviewers are responsible for insuring those are on the app prior to turning in work.	2005
If, in a review, reference is made to part of a 1556, then the requestor must submit a copy of the 1556 section. (To insure they actually have the text.)	2005
A list of other requirements for portable gauge users was compiled. It is on the website but can be faxed or mailed to those inquiring. Done to improve quality of submissions and to decrease material needed in def letters.	2005
Training for therapy doses under G35 can be done in a private office as well as an institution.	2005
QOC IC amendments were done and all new licenses must be checked for these	2005
Electronic signature for advanced directed is only OK if the drs' email account is passworded and the directive comes from him/her. The dr. cannot delegate this.	2005
I-131 IRI medical trash letter went to licenses to remind to adhere to policies so that hot patient waste not go to landfill.	2005
After license condition 12, "and shall possess a copy of these regulations," shall be added on all actions done from Jan 4 on.	2006
Regardless of 1556, action levels for removable contamination shall be >220 dpm.	2006
The 500 hours of medical user training can be acquired in a private outpatient setting. The NRC allows this. Our regs need to be changed.	2006
New portable gauge checklist to add daily signout/in log and Hazmat q 3 years.	2006
Screening for IC QOC forms must have license number on each page and these documents must be used for every licensing action	2006
Injecting patients in non-restricted areas is considered like a patient room or like cisternogram in X-ray room	2006
Doug Sims online gauge course was approved	2006
5,000 dpm/100 cm <sup>2</sup> is ok for fixed contamination, 220 dpm for removable	2006
A locked shed, distant (80') from a house with sufficient security is OK for a roof gauge operation where the office is in a house. Rented storage room OK only if landlord approved (and sufficient security)	2006
DU testing is in the regs and will not be used as a license condition	2006
Wrist badges not acceptable for monitoring extremity dose. Must have ring.	2006
Add "The licensee shall not transfer ownership and/or control of this license to any person or entity without providing required information regarding the transfer for the Agency's review and without receiving written authorization for the transfer by the Agency."	2006
Categories for increased controls to be in the licensee table	2007
Use the updated IC form and page 2 when required	2007
For G.31, begin to accept 80 hours instead of the 200, as are changing our regs to comply with 10CFR, Part 35	2007

21. Identify by licensee name, license number and type, any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed.

**RHP RESPONSE:**

<u>Licensee Name</u>	<u>License #</u>	<u>Type</u>	<u>Reason</u>
Neutron Products, Inc.	MD-31-025-01	<b>REDACTED</b>	Administrative and Legal Delay
Neutron Products, Inc.	MD-31-025-03	<b>REDACTED</b>	Administrative and Legal Delay
Neutron Products, Inc.	MD-31-025-04	<b>REDACTED</b>	Administrative and Legal Delay
Neutron Products, Inc.	MD-31-025-05	<b>REDACTED</b>	Administrative and Legal Delay

V. Responses to Incidents and Allegations

22. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See STP Procedure SA-300, Reporting Material Events for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

**RHP RESPONSE:**

**All incident as reportable under NRC regulations have been submitted to NRC through NMED.**

23. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated? For Agreement States, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

**RHP RESPONSE:**

**The following incidents that involved potential equipment or source failure or approved operating procedures that were deficient were investigated by RHP. Each Event was reported through NMED and on at least 2 occasions involved investigative teams comprised of both Maryland and NRC personnel.**

<u>Maryland Company</u>	<u>Location Event</u>	<u>Date Event</u>	<u>Who Aware (NMED)</u>
Nucletron Corporation	Brigham & Women's Hospital, MA	1/15/03	NRC, MD, MA
Nucletron Corporation	Northridge Hospital, CA	9/12/03	NRC, MD. CA
Nucletron Corporation	Lankenau Hospital, PA	4/12/05	NRC, MD
Nucletron Corporation	Rapid City Regional Hospital, CA	7/19/05	NRC, MD. CA
Nucletron	California Endocurie	3/30/06	NRC, MD. CA

Corporation	Therapy, CA		
Nucletron Corporation	Florida Hospital, FL	7/26/06	NRC, MD, FL
Nucletron Corporation	Nucletron D.1220(c)(3)(ii) notification, no incident	9/28/06	Recall and replace, customer bulletin
Nucletron Corporation	Mt. Clemens General Hospital, MI	11/17/06	NRC, MD, MI
Nucletron Corporation	Morristown Memorial Hospital, NJ	12/22/06	NRC, MD
Nucletron Corporation	Methodist Hospital, TN	1/23/07	NRC, MD, TN

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

**RHP RESPONSE:**

**NONE**

VI. General

25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review. Provide the results of any program audits (including self audits) completed during the review period.

**RHP RESPONSE:**

- 1 The review team recommends that the State fill the current vacancies in the program as soon as possible.

**The RHP has, within the levels of fiscal constraints, taken multiple actions, during the review period, to fill vacancies and maintain staff. There have been periods of time, as defined elsewhere in this questionnaire, when shortages of personnel have significantly affected the Program's ability to complete all mandated tasks. However, the Program has recently been able to fill all vacancies and hopes to retain personnel.**

- 2 The review team recommends that the Program implement an action plan to ensure that core inspections, including initial inspections, are performed in accordance with the NRC's inspections priorities.

**Maryland believes that, per a performance-based standard, deficiencies in this area have been addressed and core inspections including initials are being conducted in accordance with the NRC's inspections priorities.**

- 3 The review team recommends that the Program conduct an appropriate evaluation of all licensing actions involving name changes and possible change in ownership/control.

**Maryland has successfully implemented a licensing flowchart that accurately evaluates actions involving name changes and possible changes in ownership/control. Use of this chart and the inspection process has resulted in two escalated enforcement compliance actions regarding ownership/control violations.**

**MDE Internal Audit Report: RHP portion from MDE Air and Radiation Management Administration Review**

INTERNAL AUDIT REPORT ON  
AIR AND RADIATION MANAGEMENT ADMINISTRATION  
As of June 30, 2003

We have audited the Air and Radiation Management Administration (ARMA) for the period beginning July 1, 2001 and ending June 30, 2003. The primary objective of our audit was to evaluate ARMA's internal control structure and to review compliance with applicable State laws, rules and regulations. The management of ARMA is responsible for establishing and maintaining an effective internal control structure.

Our audit included a control review of the Administration's major financial related applications and programs (e.g. cash receipts, accounts receivable, federal/state grants, reimbursable and special purpose funds, budget and expenditures, and equipment purchases, permits/licenses). We also reviewed other matters (FMIS security access, data security controls). Additional tests were performed to provide reasonable assurance that ARMA was in compliance with applicable State laws, rules and regulations. We also conducted a follow-up of prior Office of Legislative Audits (OLA) findings.

**Analysis - Radioactive Materials Licenses:**

The STT for this type of license is 210 days. Our review disclosed that as of March 31, 2003, 26 of 580 licenses or 4.4% were extended beyond their permit expiration date. Of those 26 licenses, only 6 were extended beyond 210 days. Our review of the records of the 6 renewal applications disclosed that deficiency letters were sent to the facilities or applicants but no responses were received by RHP. However, the reason for the delay and actions to be taken to resolve the problem were not organized in a standard manner or placed in a specific location within the files.

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

**RHP RESPONSE:**

**Strengths:**

- Program has cumulatively many years of experience in the licensing and compliance of radioactive material licensees.
- Program has cumulatively many years of experience in the response to radiological emergencies.

- The conducting of pre-licensing visits on all new radioactive material applicants as revealed by recent GAO sting.
- Moving forward on multiple challenges legal and technical areas specific to Neutron Products, Inc.
- Implementation of E-mail notification system for reciprocity (paper reduction and increase in efficiency and ease)
- Good cooperation between multiple MDE Administrations in site cleanup as in aircraft radium dial site Eastern Shore Maryland that had other hazardous waste.
- Resource assistance to NRC specific to the conducting of Category I safeguard inspections.
- Conducting IC (Category II) licensing and inspection in spite of significant shortages in inspection personnel.

**Weaknesses:**

- Resource drain on Program because of time spent in compliance and legal aspect of Neutron Products, Inc.
- Significant periods of time with inspection staff shortages resulted in significant backlogs in Priority 5 licenses.

B. NON-COMMON PERFORMANCE INDICATORS

I. Legislation and Program Elements Required for Compatibility

26. Please list all currently effective legislation that affects the radiation control program.

**RHP RESPONSE:**

- a. COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation (1994) Effective October 9, 1995
- b. COMAR 26.12.01.01 Supplement 1 Effective December 16, 1996
- c. COMAR 26.12.01.01 Supplement 2 Effective November 3, 1997
- d. COMAR 26.12.01.01 Supplement 3 Effective June 29, 1998
- e. COMAR 26.12.01.01 Supplement 4 Effective December 28, 1998
- f. COMAR 26.12.01.01 Supplement 5 Effective June 14, 1999
- g. COMAR 26.12.01.01 Supplement 6 Effective February 7, 2000
- h. COMAR 26.12.01.01 Supplement 7 Effective April 1, 2002
- i. COMAR 26.12.01.01 Supplement 8 Effective October 13, 2003
- j. COMAR 26.12.01.01 Supplement 9 Effective October 27, 2003
- k. COMAR 26.12.01.01 Supplement 10 Effective March 29, 2004
- l. COMAR 26.12.01.01 Supplement 11 Effective June 7, 2004
- m. COMAR 26.12.01.01 Supplement 12 Effective June 20, 2005
- n. COMAR 26.12.01.01 Supplement 13 Effective December 8, 2005
- o. COMAR 26.12.01.01 Supplement 14 Effective October 9, 2006
- p. COMAR 26.15 "Disposal of Controlled Hazardous Substances-Radioactive Hazardous Substances"
- q. Annotated Code of Maryland, Environmental Article, Title 8, "Radiation"

r. **Annotated Code of Maryland, Environmental Article, Title 7  
“Hazardous Materials and Hazardous Substances” (only those  
portions specific to low level radioactive waste issues)**

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

**RHP RESPONSE:**

**No radioactive material regulations**

29. Please review and verify that the information in the enclosed State Regulation Status sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them.

**RHP RESPONSE:**

**The sheet is correct**

<b><u>Regulation</u></b>	<b><u>Status</u></b>
Medical Use of Byproduct Material RATS 2002 due <u>10/24/05</u>	Draft amended in accordance with NRC review; MD AG Office review completed. Estimated time of proposed action is prior to November 2007.
Security Requirements for Portable Gauges RATS 2005-1 due <u>7/11/08</u>	Draft amended in accordance with NRC review; MD AG Office review completed. Estimated time of proposed action is prior to November 2007.
Medical Use of Byproduct Material Recognition of Medical Boards RATS 2005-2 due <u>4/29/08</u>	Draft amended in accordance with NRC review; MD AG Office review completed. Estimated time of proposed action is prior to November 2007.
Compatibility with IAEA Part 71 RATS 2004-1 due 10/1/07	Draft almost complete in the RHP Regulation Committee. Estimated time of proposed action is prior to end 2007.
Minor Amendments Parts 20, 30, 32, 35, 40 & 70 RATS 206-1 due <u>3/27/09</u>	Review not yet begun

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

**RHP RESPONSE:**

**RHP procedures for development of regulations are attached.**

II. Sealed Source and Device Program

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sealed sources and devices issued during the review period.

**Sealed Source and Device Sheets  
Issued between July 26, 2003 and August 24, 2007**

<u>SS&amp;D Registry Number</u>	<u>Manufacturer, Distributor or Custom User</u>	<u>Product Type or Use</u>	<u>Date Issued</u>	<u>Type of Action</u>
MD-0113-D-105-G	ATI -Mfgr	Thickness gauge	5/18/2006	801 (inactivated)
MD-0113-D-106-G	ATI -Mfgr	Thickness gauge	5/18/2006	802
MD-0113-D-110-G	ATI -Mfgr	Thickness gauge	5/18/2006	803
MD-0113-D-107-G	ATI -Mfgr	Thickness gauge	5/18/2006	804
MD-0113-D-109-G	ATI -Mfgr	Thickness gauge	5/18/2006	805
MD-0113-D-104-G	ATI -Mfgr	Thickness gauge	5/18/2006	806
MD-1149-D-101-G	Bahia - Distrib	Hand held explosive vapors detector	4/7/2007	Amendment
MD-1239-D-101-B	Carter Holt Harvey Ltd. – Distributor-	Density Gauge	4/26/2005	New issue
MD-1239-D-101-B	Isoscan Limited - distributor	Density Gauge	10/19/2006	Amendment
MD-1239-D-101-B	Isoscan Limited - distributor	Density Gauge	11/30/2006	Corrected page
MD-0105-D-101-G	Conco Services, Inc.	Fluorotracer Analyzer	In progress 7/10/2007	Amended
MD-0497-D-111-S	Nucletron Corporation - Distributor	Remote afterloading brachytherapy unit	3/22/2005 8/12/2005	New issue Amendment
MD-0497-D-112-S	Nucletron Corporation Distributor	Remote afterloading brachytherapy unit	3/22/2005	New issue
MD-0497-S-113-S	Nucletron Corporation Distributor	Sealed brachytherapy implant seed	1/5/2006 1/24/2006	New issue Amended
MD-0497-D-114-S	Nucletron Corporation Distributor	Remote afterloading brachytherapy unit	6/12/2007	New
MD-1003-D-801-G	Pettit Applied Technologies	Thickness/density gauge	8/2/2006	Inactivated/Amended
MD-1003-D-802-G	Pettit Applied Technologies	Thickness/density gauge	8/11/2006 9/14/2006	Inactivated/Amended Amended
MD-0657-D-801-E	Universal Security Instruments, Inc.	Fire/smoke detector	5/11/2007	Inactivated

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

**RHP RESPONSE:**

**NUREG 1556 Vol. 3 “Applications for Sealed Sources and Device Evaluation and Registration”**

**NRC Reg. Guide 6.9 &**

**ANSI N44-2-1973, N44.1, N43.10, N43.9, N449.1, N43.3**

**NBS HDBK 127, 116, 111, 123 & 129.**

**ISO 7205, 3999**

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

**RHP RESPONSE:**

**Technical Staffing and Training - Questions 1-7**

**See response to Question 1.c**

**All reviewers have attended NRC SS&D Workshop training.**

Technical Quality of Licensing Actions - Questions 17-21

**17. RHP has 9 companies with SS&Ds a total of 29 sheets**

**18. See answer to question 23.**

**19. None**

**20. None**

**21. None currently. There has been a problem with delays because of wait to procure quality engineering review.**

Responses to Incidents and Allegations - Questions 22-24

**22. None**

**23. See answer to question 23**

**24. None**

III. Low-Level Radioactive Waste Disposal Program **N/A**

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

Technical Staffing and Training - Questions 1-7

Status of Materials Inspection Program - Questions 8-11

Technical Quality of Inspections - Questions 13-16

Technical Quality of Licensing Actions - Questions 17-21  
Responses to Incidents and Allegations - Questions 22-24

IV. Uranium Recovery Program **N/A**

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

Technical Staffing and Training - Questions 1-7  
Status of Materials Inspection Program - Questions 8-11  
Technical Quality of Inspections - Questions 13-16  
Technical Quality of Licensing Actions - Questions 17-21  
Responses to Incidents and Allegations - Questions 22-24