



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PA 19406-1415

July 26, 2000

Roland G. Fletcher, Manager  
Radiological Health Program  
Air and Radiation Management Administration  
Maryland Department of the Environment  
2500 Broening Highway  
Baltimore, MD 21224

Dear Mr. Fletcher:

A periodic meeting with Maryland was held on June 29, 2000. The purpose of the meeting was to review and discuss the status of the State's Agreement State program. The NRC was represented by Thomas O'Brien from the NRC's Office of State and Tribal Programs and me. Specific topics and issues of importance discussed at the meeting included the actions taken by the State to improve areas identified in the 1999 Integrated Materials Performance Evaluation Program (IMPEP) review and Maryland's request to delay the follow up IMPEP review of the licensing and sealed source and device indicators for one year.

I have completed and enclosed a general meeting summary, including any specific actions taken as a result of the meeting. On May 31, 2000, the Management Review Board (MRB) directed NRC staff to report back to them on the status of Maryland's actions to address the recommendations from the 1999 review after the periodic meeting. In support of this request, a copy of this letter, the periodic meeting summary and Maryland's written summary will be provided to the MRB for their consideration at their next meeting.

If you feel that our conclusions do not accurately summarize the meeting discussions, or have any additional remarks about the meeting in general, please contact me at (610) 337-5042, or e-mail at [adw@nrc.gov](mailto:adw@nrc.gov) to discuss your concerns.

Thank you for your cooperation.

Sincerely,

**/RA/**

Duncan White  
Regional State Agreements Officer  
Division of Nuclear Materials Safety

Enclosure: As stated

cc:

R. Bores, RI  
T. O'Brien, STP  
**DISTRIBUTION**

R. Fletcher  
Maryland Department of the Environment

2

SPO1  
G. Pangburn, RI  
F. Costello, RI  
F. Combs, STP  
K. Schneider, STP  
L. Rakovan, STP

DOCUMENT NAME: C:\Maryland Periodic 2000.wpd

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	OSP	Y				
NAME	DWhite ADW		TO'Brien					
DATE	7/26/00		7/26/00 by phone					

OFFICIAL RECORD COPY

## AGREEMENT STATE MEETING SUMMARY FOR MARYLAND

DATE OF MEETING: June 29, 2000

### ATTENDEES:

NRC  
Duncan White, RI  
Tom O'Brien, STP

STATE  
Ann Marie DeBiase, Director  
Roland Fletcher, Program Manager  
Carl Trump, RAM Supervisor  
Alan Jacobsen, Compliance Section  
Supervisor  
Ray Manley, Licensing and SSD Section  
Supervisor

### DISCUSSION:

The proposed status of each recommendation in Section 5.0 of the 1999 Maryland final Integrated Materials Performance Evaluation Program (IMPEP) report is summarized below (number corresponding to those in the final IMPEP report). The recommendations from Section 5.0 of the final IMPEP report can be found in Attachment 1. In addition to the discussion below, the State provided NRC staff with a written summary of their actions taken to address the recommendations below as identified in the 1999 IMPEP review. A copy of the State's written summary can be found in Attachment 2.

1. The NRC staff confirmed that the definition of person in the low-level radioactive waste regulations was revised and incorporated in the Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) effective June 29, 1999. It is recommended that this item be closed at the next IMPEP review.
2. Responsibility for review of radioactive material inspection reports and compliance letters (i.e., notice of violation) prepared by non-supervisory personnel is now the responsibility of the newly created Compliance Section Supervisor since late 1999. Timeliness goals for inspectors of 10 days for non-complex and 30 days for complex inspections have been set. It is recommended that this item be verified at the next IMPEP review.
3. Since the IMPEP review, the Radiological Health Program (RHP) has taken a number of actions to address staffing needs and responsibilities to assure the program's continued adequacy and compatibility. RHP transferred a position from Radiation Machines Division to the Licensing section and filled the position in May 2000 with an experienced individual from the medical field (Barbara Parks). Two section supervisory positions for licensing (including sealed source and devices) and compliance (i.e., inspection) were created in November 1999 and filled by existing staff within RHP (Ray Manley and Alan Jacobson, respectively). With some responsibilities shifted to Section Supervisors, the Radioactive Materials Supervisor (Carl Trump) has been given the responsibility of leading RHP's efforts to adopt NRC regulations required for compatibility. RHP has also utilized the assistance of an engineer in the Department's Waste Administration for the engineering review of a few sealed source and device (SS&D) sheets amendments.

Current staffing level for the radioactive material program in RHP is 9 FTE plus approximately 1.5 FTE in administrative support. In addition to the radioactive materials supervisor and the section supervisors, each section has three staff. It is recommended that this item be closed at the next IMPEP review.

4. The Licensing Section Supervisor discussed at length the efforts taken by RHP since late 1999 to identify the problems and areas in need of improvement for licensing. A licensing action plan was developed and implemented. Areas discussed included the RHP efforts to improve the 1) overall quality of licensing actions; 2) tracking of actions through the use of an upgraded software program; 3) distribution and accountability of work and products among staff; 4) use of NRC guidance documents; 5) training of staff; and 6) consistency and accuracy of licenses through the use of templates. A detailed discussion of RHP's actions can be found in the written summary in Attachment 2.

In addition to improving the quality and consistency of licensing, the Licensing Section Supervisor indicated that the backlog of all actions and particularly the renewals have been reduced by approximately 44% so far this year. NRC staff reviewed some of the working documents prepared by RHP and noted the significant amount of effort on the part of the Licensing Section Supervisor and the staff in addressing this recommendation. It is recommended that RHP's licensing performance be reviewed at the follow up IMPEP review.

5. RHP has prepared a revision to their allegation procedure and forwarded it to their Attorney General's Office (AG) for review. Due to the litigation workload of staff in the AG office, RHP has not received a response. It is recommended that this item remain open and be reviewed at the next periodic meeting.
6. RHP sent the manufacturer (Petit Technology) a deficiency letter dated July 1, 1999 and has received a limited response. The response has been reviewed by the Department, but a final decision on the disposition of the sheets has not been made. The manufacturer's SS&D program is currently inactive and has agreed to put a voluntary hold on all sales of the devices covered by the two sheets in question. Four devices were sold, but three have been subsequently returned to the manufacturer and the fourth is in storage at the customer's facility. It is recommended that this item be reviewed at the follow up IMPEP review.
7. The Licensing Section Supervisor (also RHP's senior SS&D reviewer) completed a preliminary review of the approximately current 50 sheets and supporting documentation and concluded that most would require some additional work to bring them up to the criteria outlined in NUREG 1556, Volume 3. Deficiencies were particularly noted with the engineering drawings. RHP estimated that it would take approximately 0.7 FTE to bring the SS&D sheets and documentation up to the criteria outlined in NUREG 1556. RHP management noted that there have been no significant safety issues with the SS&D sheets issued by Maryland.

NRC staff and RHP representatives discussed approaches to further address this recommendation including 1) having all manufacturers submit an updated copy of their quality assurance program to RHP; 2) expand the inspection of all manufacturers to include a comparison of SS&D sheets against existing manufacturing practices; and 3) prioritize the review of sheets based on their activity, number of devices in use or potential safety consequences of devices.

It is recommended that this item be reviewed at the follow up IMPEP review.

8. RHP indicated that the recently hired license reviewer will begin working on SS&D actions later this year. Training for this individual will include working directly for SS&D reviewers in NMSS for two weeks and participating in the next SS&D workshop scheduled for early 2001. As previously indicated, the RHP has access to the services of an engineer within the Department for review of SS&D applications. This individual has reviewed a few SS&D amendments, including the Petit Technology sheets discussed in Recommendation No. 6. RHP is also evaluating the use of consulting engineers outside the Department to perform reviews on a contract basis. It is recommended that this item be reviewed at the follow up IMPEP review.
9. RHP provided a detail response to the comments in Appendix F of the 1999 IMPEP report in their letter dated October 18, 1999 to Carl Paperiello. It is recommended that this item be reviewed at the follow up IMPEP review.

RHP is currently preparing involved in a number of enforcement actions against Neutron Products Inc. (NPI) in addition to preparing for a trial in Montgomery County court over NPI's failure to provide adequate financial assurance for their manufacturing license. Details of the RHP activities regarding NPI were previously discussed with Department representatives. NRC staff noted that preparation for the various enforcement and legal activities involving NPI has resulted in RHP staff expending more than 1 FTE per year on this one licensee. The section supervisors are responsible for a significant share of the burden involving NPI due to their experience and knowledge of the facility and its activities. RHP's continued efforts with NPI have resulted in the prioritization of other activities within RHP which are detailed in the program's written response in Attachment 2. RHP and Department management representatives indicated that once staff (in particular the Licensing Section Supervisor) has completed with activities to support the Department's litigation against NPI later this year, RHP will focus their efforts on improving their performance in the licensing and SS&D areas,

There have been no legislative changes or additional responsibilities for the RHP since the IMPEP review. The Program Manager indicated that the Radon program may be reactivated which would result in changes in the budget and funding. The program expects a reduction in their appropriation from the General Fund which represents approximately 40% of the total RHP budget. This reduction is statewide and not specific to any particular program. The remaining 60% of RHP budget comes from special dedicated funds.

Since the last IMPEP review, the NRC referred three allegations to the RHP for follow-up. All three allegations were investigated and closed. The Regional State Agreements Officer was informed of their outcome.

NRC staff noted that were eight reportable events submitted by RHP to NMED since the IMPEP review last year. RHP representatives indicated that since the review last year, three staff members have been trained to provide data to the NMED database. NRC staff emphasized that reportable incidents should be complete and include appropriate close out of the event. It was emphasized, as matter of compatibility, that event follow up be reported to the NRC on a monthly basis. RHP expressed the need to upgrade the NMED database software on which the States must use to enter data into the NMED system. RHP also indicated that licensees should have access to the NMED system as a mechanism to keep them informed of identified safety and equipment issues. The Licensing Section Supervisor indicated that a recent gamma knife misadministration at a Maryland hospital was nearly identical to one that occurred earlier in the Midwest but the Maryland hospital staff was not aware of the earlier problem.

The NRC staff and the RHP representatives reviewed the status of the State's effort to adopt NRC regulations. A summary of the State's status in adopting NRC amendments can be found in Attachment 3. The State has started working on another round of amendments to their regulations designated as Supplement 7 which include the NRC amendment to Part 35 on release of individuals administered radioactive material and Part 20 on radiological criteria for license termination. RHP provided NRC staff with the final version of Supplements 5 and 6 which the NRC had provided reviewed and provided comments in their draft form. NRC staff indicated that they will review the final versions of Supplements 5 and 6 to determine their compatibility with NRC regulations using STP Procedure SA-200 "Compatibilities Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

NRC staff discussed the status of NRC rule making initiatives including medical, releases of solid material and general licensing. There was also a discussion on the recent activities of the National Materials Program Working Group.

The next full IMPEP review is scheduled for FY 2003.

#### EVALUATION OF STATE'S REQUEST TO DELAY FOLLOW-UP IMPEP REVIEW

In a letter dated May 4, 2000, RHP requested that the follow up IMPEP review for the licensing and SS&D indicators scheduled for FY 2000 be delayed for one year. The basis for RHP request was the large resource commitment needed to prepare for various enforcement hearings and a trial in State court regarding the failure of NPI to have adequate financial assurance for their manufacturing license. RHP indicated they would not be prepared for the follow up review since the individuals involved with the NPI litigation were also important to RHP performance for the indicators to be covered in the follow up review. At their May 31, 2000 meeting, the MRB directed staff to report back to them on the status of RHP's actions to address the recommendations from the 1999 review after the periodic meeting. In a June 16, 2000 letter to Roland Fletcher from Paul Lohaus, the NRC requested that RHP prepare a written summary of actions taken by Maryland to improve areas identified in the 1999 IMPEP review. A copy of Maryland's written summary was provided to NRC staff at the periodic meeting and can be found in Attachment 2.

The NRC staff found that RHP has taken action to identify the problems and areas in need of improvement for licensing, developed an action plan and initiated its implementation. Based on discussions with RHP, review of draft implementing documentation and reduction in the renewal backlog, the NRC staff concluded that RHP has taken effective steps to improve the performance of their licensing program.

NRC staff found that RHP has taken some actions to address the performance concerns with the SS&D program, but RHP chose to focus more of their resources on licensing. The programmatic actions taken by RHP are outlined in the discussion of Recommendations 7 and 8 above. Although the State has taken or initiated actions that will improve RHP's performance for this indicator in the future, the State has only conducted a limited review of all registration certificates to identify any missing information and with priority of the actions based on the risk associated with the device. The need to bring the SS&D sheets and documentation up to the current standards was identified in reviews prior to the 1999 IMPEP review and should be addressed. RHP has indicated in their written summary that the upgrade of the registration sheets will be a high priority once litigation with NPI has abated. The staff noted that a review of Maryland's SS&D program at this time would be limited since the State has not fully implemented their plans for this indicator.

Based on discussions and review at the periodic meeting, the staff concluded that Maryland has taken or initiated a number of actions to improve their performance for the licensing and SS&D indicators and delaying the follow up review for one year would not have a negative effect on the program's adequacy.

## ATTACHMENT 1

### Summary of recommendations from 1999 IMPEP Review of the Maryland program

1. The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review. (Section 2.0)
2. The review team recommends that all inspection documentation be reviewed and signed by RHP management before the inspection correspondence is issued to the licensee. (Section 3.2)
3. The review team recommends that the State evaluate present and future staffing needs of the RHP and develop a strategy that will assure RHP's continued adequacy and compatibility. (Section 3.3)
4. The review team recommends that RHP management implement an action plan to reduce the number of backlogged licensing actions and set goals to improve the accuracy and overall technical quality of licenses. (Section 3.4)
5. The review team recommends that the State revise their allegation procedure to incorporate appropriate elements following NRC guidance documents. (Section 3.5)
6. The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F for each registration certificate, and amend the registration certificates accordingly. (Section 4.2.1)
7. The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrency review" in Management Directive 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.2.1)
8. The 1996 IMPEP team recommended that an additional senior staff member be trained to perform the sealed source and device evaluations to supplement the program as it matures. The State had assigned an additional individual to the program who has completed one review to date and would also benefit from additional training and experience. The review team recommends that the State provide the staff additional training and experience in the review of sealed source and device applications and the drafting of registration certificates (including the guidance contained in NUREG 1556, Vol. 3). This should include training and experience which will meet the qualification guidance found in Management Directive 5.6. (Section 4.2.2)
9. The MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report. (Section 4.2.4)

**ATTACHMENT 2**

MARYLAND'S WRITTEN SUMMARY OF ACTIONS TAKEN IN RESPONSE TO  
1999 IMPEP REVIEW

## STATUS REPORT FOR USNRC MEETING JUNE 29, 2000

PURPOSE: Review of current RHP status against NRC IMPEP recommendations.

- 2. The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review. (Section 2.0)**

**RHP Response:** The definition of person given in Code of Maryland Regulations COMAR) 26.14.01.02B(28)(e) was revised by MDE's Waste Management Administration in a manner acceptable to the NRC, and became effective June 28, 1999.

**Current Status:** Same

**Discussion:** Copy of Maryland Register and Regulation 26.14.01.02B(28)(e) is attached.

- 3. The review team recommends that all inspection documentation be reviewed and signed by RHP management before the inspection correspondence is issued to the licensee. (Section 3.2)**

**RHP Response:** As a result of NRC's recommendation, a goal has been established for inspectors to complete their reports within 10 days of the inspection date for non-complex inspections and to include a draft copy of the compliance letter, should one be needed, for review by the supervisor. For complex license inspections, a 30-day completion goal for inspection reports and compliance correspondence has been established with appropriate sign off by the program manager.

**Current Status:** Responsibility for review of all non-supervisory inspector reports has been transferred to RHP's new Compliance Section Head (position filled November 1999). RHP's compliance section inspector's, with a few exceptions for complex inspections and ongoing investigations, are supplying the

report and draft of compliance action to the Compliance Section Head within the above guidelines.

**Discussion:** RHP estimates that the Compliance Section Head spends approximately 30% of his work time on Neutron Products, Inc. related projects.

**4. The review team recommends that the State evaluate present and future staffing needs of the RHP and develop a strategy that will assure RHP's continued adequacy and compatibility. (Section 3.3)**

**RHP Response:** Reassignment of positions within ARMA will result in an additional health physicist position being assigned to the licensing section. ARMA is also evaluating several options for obtaining engineering assistance in the review of SS&D applications.

**Current Status:** In November 1999, RHP assigned new section head positions within both the licensing and compliance sections. From November 1999 to July 2000, one of the inspection staff has been sharing duties in licensing to assist the licensing staff in meeting newly established goals and aggressively addressing the licensing backlog. In June 2000, RHP hired a new licensing reviewer who is currently in the training process. The RHP licensing section has acquired the services of an engineer from the Waste Management Administration for the engineering review of sealed source and device sheets (SS&D). This individual has completed a few in-depth engineering reviews of critical components on SS&D sheets. RHP is currently interviewing qualified engineers in the private sector to assist RHP license reviewers in the evaluation of SS&D sheets.

**Discussion:** none

**5. The review team recommends that RHP management implement an action plan to reduce the number of backlogged licensing actions and set goals to improve the accuracy and overall technical quality of licenses. (Section 3.4)**

**RHP Response:** RHP recognizes the licensing backlog involving both renewal applications and routine amendment requests. The additional staff member mentioned above will target these areas. Additionally, a section supervisor will soon be designated giving the division chief a manager working in the licensing section to develop, evaluate and implement an action plan to reduce the backlogs and keep all future actions current. The plan will include goal setting to improve the technical quality and accuracy of licenses, biweekly meetings to address both

IMPEP and other identified concerns and address potential improvements, identification, evaluation and implementation of additional training, review and evaluation of monthly assignments of backlogged licensing actions, the implementation of written license reviewer log books to facilitate the administrative overview of progress by the licensing section supervisor. We anticipate that this plan will be implemented by December 31, 1999.

**Current Status:** A Licensing Section Head was designated in November 1999. Initial meetings were held with the RAMLCD Program Manager and licensing staff to identify problems and areas in need of improvement. The licensing section hired an additional reviewer in May 2000. It is expected that following an initial training period this individual will have a significant impact on further decreasing the licensing backlog. Licensing staff meetings are being held approximately every two weeks. A licensing action plan has been developed and implemented as an ongoing document. A quality management program has been developed for all critical activities conducted by RHP (licensing included). As of June 8, 2000 the RHP licensing backlog (primarily renewals) has been cut approximately 44%. Specifically, using January 1, 2000 as the backlog date, RHP licensing has decreased the total application and renewal backlog from 94 actions to 62 actions. The following changes are being worked on or have been implemented in the licensing program to improve quality and quantity of licensing action output:

- a) Use of USNRC licensing application format (implemented 12/99)
- b) Licensing meetings approximately every 2 weeks (implemented 12/99)
- c) Use of USNRC licensing checklist format used by all reviewers for licensing evaluation (fully implemented 11/99)
- d) The transmission via letter to all licensees requesting renewal or facility requesting, new license internet sites for NRC NUREG licensing guidance (implemented 12/99)
- e) Issuance of license in entirety for all amendment requests ( virtual license directory has been created and will be phased in over next 5 years )
- f) Placing licensing guidance on MDE's web page (pending)

- g) Amnesty to reviewers to remove very old outstanding actions (implemented 1/2000)
- h) Reviewers' use of final checklist for licensing actions (implemented 12/1/99).
- i) Improved checklist for pre-licensing inspections. All new licenses are to receive a pre-licensing inspection prior to issuance. (implemented May 2000)
- j) A more formalized training program (pending)
- k) Monthly licensing reviewer action statistic sheets. (implemented April 2000)
- l) Improvements in the tracking of licensing actions by clerical staff
  - 1. Inventory of all outgoing licensing actions (implemented January 2000)
  - 2. Additional inventory of all incoming licensing actions (implemented May 2000)
- m. Improvements of licensing database from Paradox to Enterprise. (pending)
- n. Use of Enterprise database to streamline licensing process (pending)
- o. Internal review by licensing staff on all templates and licensing scripts to ensure consistency and accuracy of work.(ongoing)
- p. Updating and remediation of current licensing database to ensure statistical accuracy (ongoing)

**Discussion:** RHP feels that by the addition of the Licensing Section Head oversight and training on and use of NRC technical guidance by licensing reviewers, the technical quality of reviews has been significantly improved. Furthermore, the implementation of the license action final checklist has improved general quality of work. Aspects of the checklist are reviewed by the Licensing Section Head to ensure reviewer competence. Errors noted by the Section Head are being documented for the purposes of ongoing training and counseling. The addition of another reviewer will assist in quickly reducing the backlog to a more manageable level or zero. The RHP licensing section's goal is to reduce the licensing action backlog to zero by January 2001.

**5. The review team recommends that the State revise their allegation procedure to incorporate appropriate elements following NRC guidance documents. (Section 3.5) Maryland Final Report Page 19**

**RHP Response:** RHP has reviewed NRC guidance documents regarding allegations. A new RHP allegation procedure has been drafted which addresses the IMPEP concerns and is consistent with the latest NRC guidance. The draft procedure is currently under review by the Maryland Office of the Attorney General to ensure compliance with Maryland statutory requirements. The AG's office anticipates completion on the review by September 24, 1999.

**Current Status:** The AG office has not yet completed this review. The reason for the delay is twofold. Confidentiality for individuals giving an allegation is a complex legal issue of which there is currently no written precedent at MDE and also the legal staff conducting this review is one of the primary attorneys working on very time consuming Neutron Products, Inc. cases.

**Discussion:** RHP discussions with the AG Office indicate that this review will be completed in the near future.

**6. The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F for each registration certificate, and amend the registration certificates accordingly. (Section 4.2.1)**

**RHP Response:** Sealed source and device certificates MD-1003-D-101-G and MD-1003-D-102-G are currently under review and will be modified in their entirety upon receipt and review of RHP requests for information from the manufacturer. The IMPEP audit concerns are being addressed in as indicated in the attached Response to Appendix F Comments.

**Current Status:** The manufacturer has put a voluntary hold on all sales of the MD-1003-D-101-G and MD-1003-D-102-G devices. The manufacturer has stated that only two devices of each type (four in total) were sold to customers. Of those four, three have been returned to the manufacturer and the other is in storage and not in use at the customer's site. A deficiency letter was sent to the manufacturer on July 1, 1999. The manufacturer has responded in writing with a limited evaluation specific to the shutter of the MD-1003-D-102-G unit. This evaluation has been reviewed and commented on by RHP's engineering individual in the

Waste Management Administration. Final disposition of these sheets is still under consideration by RHP.

**Discussion:** None of these devices are currently in use by the general public. Implementation and closure of the above issues has been currently assigned to the Licensing Section Head. The closure of the above concerns have been delayed by the initial focus of priorities on the efficacy of the licensing program in the specific areas of technical sufficiency of review, removing the extensive licensing action backlog and because the Licensing Section Head is currently spending approximately 50% of his time on Neutron Product, Inc. related matters.

- 7. The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrency review" in Management Directive 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.2.1)**

**RHP Response:** RHP will conduct a review of all of Maryland's SS&D sheets to identify potential missing information as defined by the proscriptive guidance in NRC's mandated document NUREG 1556 Volume #3 (July 1998). This review will be conducted with the goal of prioritizing those devices that may potentially have a higher safety risk. RHP's goal is to have all necessary modifications to Maryland sheets completed prior to NRC's one-year follow-up audit

**Current Status:** RHP has conducted a thorough evaluation of concerns regarding the SS&D program noted during the IMPEP review and has defined the estimated reviewer time needed to implement needed changes. This evaluation estimates approximately .6 FTE is needed to fully implement those changes recommended by the IMPEP team. SS&D evaluation and work has been conducted regarding certain immediate actions. The services of an engineer from the Waste Management Administration have been acquired. A new licensing reviewer has been hired and will be conducting at least limited SS&D reviews before the end of the year. Maryland has completed at least a preliminary safety review of the approximately 50 active Maryland SS&D sheets. This review indicates no immediate outstanding safety concerns as justified primarily through the historical safe use of those sources or devices. However, the review did determine that many, if not most sheets, need additional attention through modification to bring them up to the sufficiency of engineering review as established in NUREG 1556 Volume 3.

**Discussion:** As indicated in the above responses, the efficacy of routine licensing actions has been given initial priority. From a health and safety prospective we feel that improvements should be made first in those areas. Also, as previously stated the Licensing Section Head's time has been in large part (50%) committed to Neutron Product, Inc. related concerns. RHP is certain that once certain major NPI concerns have been alleviated, Maryland will effectively modify all required SS&D sheets to bring them up to the industry standard of review. That review will be helped by the addition of a qualified engineering review and by the hiring of additional licensing personnel. RHP is also currently evaluating the potential for additional engineering review assistance from the private sector.

**8. The 1996 IMPEP team recommended that an additional senior staff member be trained to perform the sealed source and device evaluations to supplement the program as it matures. The State had assigned an additional individual to the program who has completed one review to date and would also benefit from additional training and experience. The review team recommends that the State provide the staff additional training and experience in the review of sealed source and device applications and the drafting of registration certificates (including the guidance contained in NUREG 1556, Vol. 3). This should include training and experience which will meet the qualification guidance found in Management Directive 5.6. (Section 4.2.2)**

**RHP Response:** See RHP response to Recommendation #3 and #4 above.

The individual filling this position will participate in the extent possible in the additional training of SS&D procedures through working directly with NRC's SS&D section at NRC Headquarters for a period of 2 weeks. MDE is also investigating the establishment of consulting service contracts with professional engineering firms or local universities to acquire mechanical engineering review of SS&D sheets. RHP staff is willing to group caucus with NRC Headquarters or other Agreement State SS&D staffs regarding the review of all past sheets for teaching purposes or provide said sheets for concurrence review.

With respect to the qualification guidance found in NRC Management Directive 5.6, we note that this guidance is currently undergoing review by an Agreement State/NRC working group. Therefore, we anticipate that the language in MD 5.6 will be clarified so that subjectivity, confusion, and ambiguity of the criteria are removed. Maryland intends to meet the training and experience guidance the results from this NRC-OAS project.

**Current Status:** The full implementation of the above has been delayed. The services of an engineer from the Waste Management Administration have been acquired. A new licensing reviewer has been hired and will be conducting at least limited SS&D reviews before the end of the year. RHP is also currently evaluating the potential for additional engineering review assistance from the private sector.

**Discussion:** Again the implementation of this additional training (mainly thorough working with NRC personnel) has been delayed for the reasons specified in RHP responses numbers 6 and 7. Following resolution of certain NPI matters and the improvement of the licensing backlog the above commitment will be met.

**9. The MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report. (Section 4.2.4)**

**RHP Response:** RHP's detailed response to IMPEP Review comments is contained in the Attached Response to Appendix F. Comments.

**Current Status:** See status in numbers 6, 7 and 8

**Discussion:** See discussion for numbers 6, 7 and 8

**ATTACHMENT 3**  
**REGULATION ASSESSMENT TRACKING SYSTEM**  
**RATS DATA SHEET**

**State:** Maryland  
[Periodic Meeting Summary]

**Tracking Ticket Number:**  
**Date:** 6/29/00

<b>NRC Chronology Identification</b>	<b>FR Notice (State Due Date)</b>	<b>RATS ID</b>	<b>Proposed/Final-Comment (Y/N)<sup>1</sup></b>	<b>NRC Review Date</b>	<b>Final State Regulation<sup>2</sup> (Effective Date)</b>
Standards for Protection Against Radiation-Part 20	56 FR 23360 plus others (1/1/94)	1991-3	Final-No	9/95	10/9/95
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843 (1/10/94)	1991-1	Final-No	9/95	10/95
ASNT Certification of Radiographers-Part 34	56 FR 11504 (none)	1991-2			Not required <sup>3</sup>
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980 (10/15/94)	1991-4	Final-No	9/95 and 11/97	10/95
Quality Management Program and Misadministrations-Part 35	56 FR 34104 (1/27/95)	1992-1	Final-No	9/95	10/95
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566 (none)	1992-2			Not required
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715 (7/1/96)	1993-2	Final-No	3/97	12/96
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886 (7/22/96)	1993-3			Not applicable
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628 (10/25/96)	1993-1	Final-No	9/95	
Self-Guarantee as an Additional Financial Mechanism- Parts 30, 40, 70	58 FR 68726 59 FR 1618 (none)	1994-1	Proposed-No	9/97	Not required
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220 (7/1/97)	1994-2			Not applicable
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026 (8/15/97)	1994-3	Proposed-No	9/97	6/98
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767 59 FR 65243 60 FR 322 (1/1/98)	1995-1	Proposed-No	2/98	12/98

<b>NRC Chronology Identification</b>	<b>FR Notice (State Due Date)</b>	<b>RATS ID</b>	<b>Proposed/Final-Comment (Y/N)<sup>1</sup></b>	<b>NRC Review Date</b>	<b>Final State Regulation<sup>2</sup> (Effective Date)</b>
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900 (3/13/98)	1995-2	Final-No	11/97	
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649 60 FR 25983 (3/1/98)	1995-3	Final-No	12/97	
Performance Requirements for Radiography Equipment- Part 34	60 FR 28323 (6/30/98)	1995-4	Proposed-No	12/98	6/99
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038 (8/14/98)	1995-5	Proposed-No	12/98	6/99
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235 (11/24/98)	1995-6	Proposed-No	12/98	6/99
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623 (10/20/98)	1995-7	Proposed-No	12/98	6/99
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248 61 FR 28724 (4/1/99)	1996-1	Proposed-Yes	3/99	2/00
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109 (none)	1996-2			Not required
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669 (6/17/99)	1996-3	Proposed-No	3/99	2/00
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65119 (1/9/00)	1997-1			
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907 (none)	1997-4			Not required
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662 (2/27/00)	1997-2			
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120 (5/29/00)	1997-3			
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948 (6/27/00)	1997-5	Proposed-Yes	12/98	6/99
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057 (8/20/00)	1997-6			
Exempt Distribution of a Radioactive Drug	62 FR 63634	1997-7			

<b>NRC Chronology Identification</b>	<b>FR Notice (State Due Date)</b>	<b>RATS ID</b>	<b>Proposed/ Final- Comment (Y/N)<sup>1</sup></b>	<b>NRC Review Date</b>	<b>Final State Regulation<sup>2</sup> (Effective Date)</b>
Containing One Microcurie of Carbon-14 Urea- Part 30	(1/02/01)				
Deliberate Misconduct by Unlicensed Persons- Parts 30, 40, 61, 70, 150	63 FR 1890 63 FR 13773 (2/12/01)	1998-1			
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535 (none)	1998-2			Not required
License Term for Medical Use Licenses- Part 35	63 FR 31604 (none)	1998-3			Not required
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059 (7/9/01)	1998-4			
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39347 63 FR 45393 (10/26/01)	1998-5			
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127 (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506 (6/11/02)	1999-1			Not applicable
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269 (none)	1999-2			Not required
Respiratory Protection and Controls to Restrict Internal Exposure - Part 20	64 FR 54543 64 FR 55525 (2/2/03)	1999-3			

1. (Y/N) Y means "Yes," there are comments in the review letter that the State need to address.  
N means "No," there are no comments in the review letter.
2. Or other generic Legally Binding Requirement.
3. Not required means these regulations are not required for purposes of compatibility.