

March 9, 2010

MEMORANDUM TO: Martin J. Virgilio  
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Research, State, Tribal, and Compliance Programs  
Office of the Executive Director for Operations

Bradley W. Jones, Assistant General Counsel  
for Rulemaking and Fuel Cycle  
Office of the General Counsel

Cynthia A. Carpenter, Deputy Director  
Office of Federal and State Materials  
and Environmental Management Programs

Marc L. Dapas, Deputy Regional Administrator  
Region I

FROM: Michelle R. Beardsley, Health Physicist */RA Karen Meyer for/*  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

SUBJECT: MARCH 25, 2010 MANAGEMENT REVIEW BOARD MEETING  
TO DISCUSS RECENT PERIODIC AND ORIENTATION  
MEETINGS

A Management Review Board (MRB) meeting, to discuss the results of periodic meetings held with NRC Region III and the Minnesota, Maryland, and New Hampshire Agreement State Programs and the orientation meeting held with the State of Virginia, has been scheduled for **Thursday, March 25, 2010, from 2:00 p.m. to 4:00 p.m. EDT, in Two White Flint North, Room 2-B5**. The summaries for each of the meetings are enclosed (Enclosures 1-5).

In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for this meeting is enclosed (Enclosure 6).

If you have any questions or need additional information, please feel free to contact me at (610) 337-6942 or [Michelle.Beardsley@nrc.gov](mailto:Michelle.Beardsley@nrc.gov).

Enclosures:  
As stated

cc w/ encl: Jared Thompson, Arkansas  
Organization of Agreement States  
Liaison to the MRB

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PERIODIC MEETING SUMMARY FOR THE REGION III  
RADIOACTIVE MATERIALS PROGRAM

MEETING DATE: November 9–10, 2009

ATTENDEES:

<b><u>FSME ATTENDEES</u></b>	<b><u>REGION III ATTENDEES</u></b>
Robert Lewis, Director, MSSA	Steven Reynolds, Division Director
Shirley Xu, Health Physicist, MSSA/ASPB	Patrick Loudon, Deputy Division Director
	Mark Satorius, Regional Administrator
	Cynthia Pederson, Deputy Regional Administrator (entrance only)
	Christine Lipa
	Tamara Bloomer
	Patricia Pelke
	James Lynch, RSAO
	James Clay

DISCUSSION:

The Region III radioactive materials program is administered by the Division of Nuclear Materials Safety (the Division). The Division is composed of three branches: the Materials control, ISFSI, and Decommissioning Branch, the Materials Inspection Branch, and the Materials Licensing Branch.

The previous IMPEP review was conducted the week of August 27, 2007. The review the team found Region III's performance to be satisfactory for all performance indicators reviewed. Accordingly, the review team recommended, and the MRB agreed, that the Region III program is adequate to protect public health and safety.

Status of operating plan metrics:

No issues were identified with respect to operating plan metrics. Specific areas relating to the status of operating plan metrics are discussed under other headings in this summary.

Review of strategic plan metrics and an assessment of the quality of the data contained in the monthly reports on material statistics:

No issues were identified with respect to strategic plan metrics. The quality of data contained in the monthly reports has been adequate.

Status of the Region's actions to address all open IMPEP review findings and/or open recommendations:

There are no open recommendations from previous IMPEP reviews.

Staffing and training:

The attendees reviewed the Division's staffing plan, along with status of inspector and license reviewer qualifications. The Division has had a relatively stable and full staffing since the last IMPEP. The attendees verified that the Division has sufficient technical expertise in two topical areas new to the program in recent years: accelerator produced radioactive materials and gamma knife radiosurgery. No concerns with staffing levels were identified.

The Division uses the qualification program outlined in Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," for the inspection and licensing staff. Generally, staff gets qualified across all areas of the materials program. For example, 8 of the licensing staff are inspector qualified. During the review period, no staff completed the IMC1246 qualification program, but 3 staff members that are new to the program since the 2007 IMPEP and 2 are cross-qualifying under IMC 1246. Both sets of staff are undergoing the program. The Division is also providing extensive training to a supervisor that is new to the program. Division management was clearly committed to staff training. No concerns with qualifications and training were identified.

Program reorganizations:

The Division has not reorganized since the last IMPEP review.

Changes in program budget/funding:

The regions materials program budget of 26.2 FTE has increased by approximately 2 FTE since the 2007 IMPEP to reflect increased materials security work and regional contributions to necessary program infrastructure investments.

Materials inspection program:

For 2009 the Division had 3 overdue inspections of the 360 inspections performed. This equates to less than 2 percent of the inspections being performed overdue, which exceeds NRC's performance goal of 98 percent and meets the IMPEP criteria for a "satisfactory" rating for this indicator. The number of inspections in the grace period (due date plus 25 percent) has risen steadily throughout 2009 due to significant reactive inspection effort and inspection assists. However, the Division management plans to complete 525 inspections in 2010 which would reduce this rising backlog.

In 2009, over 99% of inspection reports had been issued within 30 days of the exit meeting, which exceeds the goal of 90%. In terms of the operating plans, the attendees discussed possible differences between the Division and FSME involving tracking time from the exit (30

days for an inspection or 45 days for a team inspection). Division and FSME management will discuss this issue further at the next Regional Counterpart Meeting.

The Division's operational management information documents required annual accompaniments of qualified inspectors by supervisors. In three cases the documentation of the accompaniments was not complete for 2008 and 2009, although the actual accompaniments were believed to have occurred. The Division agreed to review the documentation prior to the next IMPEP review.

The participants discussed the Division's broad scope inspection initiative, in which inspection time on-site for broad scope licensees is broken into several visits over the course of the inspection interval. Compliance with IMC2800 is achieved, perhaps more effectively, for approximately equivalent level of effort. The Division offered to discuss further with the program office.

#### Materials Licensing Program

Materials licensing casework for new, amended, and renewal applications all complied with NRC operating plan and IMPEP performance indicator timeliness targets. Major materials licensees are assigned a project manager for effective communications. No concerns with the licensing program were identified.

#### Response to incidents and allegations:

Response to incidents and allegations was not discussed in detail, as FSME and the Division coordinate closely on these areas daily. The attendees discussed incremental improvements to the daily events call.

#### Review of Regional self-assessments:

Regional self-assessments were provided prior to the review. Audit topics cover several mandatory areas, plus additional topics selected by a consensus of management. No concerns with self assessments were identified.

#### New or potential FSME initiatives that may impact the Regions:

Discussions on ongoing initiatives included security inspections, pre-licensing visits, processing of NRC Inspection Form 591, and working group participation. The Division has begun re-inspection of irradiator and manufacturer and distributor security orders consistent with recent inspection guidance. There is only one affected facility in NRC territories in Region III. The Division will rely upon some Agreement States to conduct additional inspections under 274i Agreements. The Division is complying with pre-licensing guidance for site visits and background checks. The Division has instituted a system to track and document these activities, beyond the requirements of the guidance. Form 591 are signed by supervisors and closed when entered into Agencywide Document Access and Management System (ADAMS).

CONCLUSIONS:

No performance concerns with respect to the IMPEP criteria were identified.

Schedule for the next IMPEP review:

The next IMPEP review of the Region III radioactive materials program should be held in FY 2011, as currently scheduled.

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE MINNESOTA  
ENVIRONMENTAL HEALTH DIVISION

DATE OF MEETING: OCTOBER 15, 2009

<b>NRC ATTENDEES</b>	<b>MINNESOTA ATTENDEES</b>
Jim Lynch, RSAO	Linda Bruemmer, Division Director
Pat Loudon, Deputy Division Director	Tom Hogan, Asst. Div. Director
Aaron McCraw, FSME	George Johns, Unit Supervisor
	Sherrie Flaherty, Radiation Protection Specialist
	Sue McClanahan, Radiation Specialist
	Brandon Juran, Radiation Protection Specialist
	Bryce Armstrong, Radiation Specialist
	Norma Leland, Administrative Professional

**DISCUSSION:**

The Agreement State Program is administered by the Radioactive Materials Unit (the Unit), Indoor Environments and Radiation Section, Division of Environmental Health (the Division). The Division is a part of the Minnesota Department of Health. George Johns is the supervisor of the Radioactive Materials Unit. The Section manager position is currently vacant, with the recent promotion of Tom Hogan to Assistant Division Director. Minnesota regulates approximately 184 specific licenses. Management support for the Program appears excellent.

The State's initial IMPEP review was conducted in October 2007. The review team found Minnesota's performance to be satisfactory for all performance indicators reviewed. The review team also identified one good practice: the mailing of licenses by certified mail to help ensure appropriate delivery. Accordingly, the review team recommended, and the Management Review Board agreed, that the Minnesota Agreement State Program was adequate to protect public health and safety, and compatible with NRC's program.

Other topics covered at the meeting included:

Program Strengths: The diverse, competent staff is the most notable strength of the program. The Unit has excellent communications between staff members and has streamlined many processes without sacrificing the quality of regulatory products or the emphasis on protection of health and safety. The staff is very knowledgeable of the status of the program. Unit staff has a good understanding of new regulatory initiatives and associated expectations.

The Agreement State program has good managerial and financial support. Minnesota reached out to the North Dakota radioactive materials program which had lost its staff to attrition. The Unit Supervisor and staff members provided training and assistance in

licensing and inspection to North Dakota staff. This was a commendable effort recognized by the Organization of Agreement States.

Program Weaknesses: Division managers noted that hiring in the State is very difficult and salary increases are unlikely under current financial conditions.

Feedback on NRC's Program:

The Unit expressed frustration with the National Source Tracking System (NSTS). A Minnesota licensee was unable to update the NSTS because the source vendor had apparently not updated the database to indicate that the source was transferred. The NRC representatives asked for detailed transaction information which can be provided to the NSTS program manager, for followup.

The Division indicated that they appreciated the good support they receive from NRC Region III and enjoy the good relationship and communication that they have with NRC in general. The Division was also appreciative of NRC's funding for Agreement State training.

Staffing and Training:

The Minnesota program has a Unit Supervisor, four technical staff, and an administrative support person. Three of the technical staff are fully trained and the fourth is working through his qualification journal. The staff members are cross-trained in all areas of the program. It was noted that the Supervisor and one of the senior technical staff members are retirement eligible. The Assistant Division Director stated that succession planning is being done to keep the program running smoothly as people leave the program.

Technical positions in the Unit now require a Bachelor's degree, a change made to upgrade the level of expertise in the program.

Consideration is being given to hiring a health physics intern from the St. Cloud State University health physics program.

Program Reorganizations:

The Unit has not experienced any program reorganizations since the previous IMPEP review and none are expected.

Changes in Program Budget/Funding:

The Unit has a solid source of funding through a dedicated fee fund. The Program is currently paying off the deficit that was incurred during the Agreement State startup. That deficit should be paid within a year.

Materials Inspection Program:

The Unit reported that they have not performed any inspections overdue and had no overdue inspections at the time of the meeting. The Unit typically performs between 70 and 80 inspections per year. The Unit is performing Increased Controls inspections in conjunction with the routine health and safety inspections. The frequency for inspections for licensees with Increased Control inspections is every two years but that frequency may be relaxed to three years depending on the recommendations of Inspection Manual Chapter 2800, which is currently under revision.

The Unit performs pre-licensing visits for all new license applicants that are unknown to the program. NRC staff explained the pre-licensing visit evaluation criteria used during IMPEP reviews appears to be more conservative than Minnesota's approach. NRC staff noted that the current policy for performing pre-licensing visits includes those applicants that have not held a license previously but have hired a known individual from a licensee's program. The Unit Supervisor indicated that they would ensure that their pre-licensing visit approach would be evaluated, and modified, if necessary to be comparable with NRC's procedure.

The Unit regularly performs reciprocity inspections, including, during the current year, 10 of 11 Priority 1, 2 and 3 reciprocity licensees. Looking at all priorities, approximately 67 percent of reciprocity licensees were inspected this year. Minnesota is easily meeting the inspection targets in Inspection Manual Chapter 1220.

Staff members were aware of the recent Information Notice issued by the NRC regarding industrial gauge shutter issues. Minnesota issued its version of the Information Notice to gauge licensees on October 20, 2009.

Materials Licensing Program:

License actions are kept current with no licensing backlog. License applications are generally completed within 4 weeks of receipt. All licensing actions are peer reviewed and then reviewed and signed by the Unit Supervisor. This 3-part review helps maintain accuracy and consistency of license documents.

Regulations and Legislative Changes:

The State is up to date on all regulation amendments currently required for compatibility. The State creates an annual rulemaking package to incorporate changes made by NRC in the past year. The regulation promulgation process takes approximately 1 to 1.5 years to complete. The current 10 CFR Part 37 and general license rulemaking initiatives were discussed.

Event Reporting, including Follow-up and Closure Information in NMED:

The Bureau had reported eight events to NMED since the 2007 IMPEP review. All of the events were appropriately reported to the NRC, and were properly entered into, and updated, within NMED. Very good communication with Region III was noted during events.

Response to Incidents and Allegations:

The Unit continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for their affect on public health and safety. Staff is dispatched to perform onsite investigations when necessary. The Unit Supervisor has placed a high emphasis on maintaining an effective response to incidents and allegations.

Status of Allegations and Concerns Referred by the NRC for Action:

The NRC did not refer any allegations to Minnesota since the last IMPEP review. Several allegations were received directly by the State during the period and were investigated appropriately and in a timely fashion.

Significant Events and Generic Implications:

The Unit did not identify any significant events or generic issues since the 2007 IMPEP review.

Current State Initiatives:

After positive encouragement from the NRC during the Monticello nuclear power plant ingestion exercise, a Unit staff member accompanied an NRC inspector during a reactor inspection. The accompaniment provided valuable insight to the State and increased communications with the NRC. Future accompaniments are planned, and were encouraged by NRC staff.

The Unit holds semiannual meetings with licensee medical physicists to discuss regulatory issues, recent industry problems, and methods for increasing communication. These meetings have been very successful and were well received by the medical physics community. Information was shared with the NRC staff so that a similar effort could be instituted for NRC Region III licensees.

A meeting is also being planned to meet with industrial radiography licensees to discuss options for obtaining portable shielding material in the event of an unshielded source event. This issue came to light during a recent radiography incident.

Emerging Technologies:

None noted.

Large, Complicated, or Unusual Authorizations for use of Radioactive Materials:

None noted.

State's Mechanisms to Evaluate Performance:

The Unit uses peer reviews of licensing actions and inspection reports to insure the quality of regulatory products. Inspectors are accompanied annually by the Unit Supervisor.

Current NRC Initiatives:

NRC staff discussed ongoing initiatives with the Minnesota representatives. These included pre-licensing guidance, national source tracking, web based licensing, safety culture, and generally licensed devices.

CONCLUSIONS:

The Minnesota Agreement State Program remains a strong, stable program with excellent management support. Staffing has remained consistent since the Agreement and the training level for staff members is on target. The State has established innovative outreach programs to physicists, radiographers and neighboring Agreement States. Minnesota managers indicated that they will continue to support the IMPEP program, which they view as a valuable process.

Schedule for the Next IMPEP Review:

NRC staff recommends that the next IMPEP review to be held, as currently scheduled, in late 2011.

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR  
MARYLAND DEPARTMENT OF THE ENVIRONMENT  
AIR & RADIATION MANAGEMENT ADMINISTRATION  
RADIOLOGICAL HEALTH PROGRAM

DATE OF MEETING: November 4, 2009

<b>NRC Attendees</b>	<b>Maryland Radiological Health Program Attendees</b>
Donna Janda, Region I RSAO	Roland Fletcher, Manager, Radiological Health Program
Michelle Beardsley, FSME	Raymond Manley, Chief, RAM Licensing & Compliance Division
	Alan Jacobson, Supervisor, RAM Inspection Section
	Barbara Park, Supervisor, RAM Licensing Section

**DISCUSSION:**

In August 2007, the Integrated Materials Performance Evaluation Program (IMPEP) review team found the Maryland Department of the Environment (MDE) Agreement State Program's (the Program) performance to be satisfactory for all performance indicators. No recommendations were made by the review team regarding the Program. On November 14, 2007, the Management Review Board (MRB) met to consider the IMPEP review team's proposed findings regarding the Program. The MRB found the Program adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately four years and that a periodic meeting be held in approximately two years from the date of the IMPEP.

This summary describes that periodic meeting.

**TOPICS COVERED DURING THE MEETING INCLUDED:**

**Program Strengths**

A well-trained, stable, and experienced staff is a major strength of the Program. An additional strength was implementation of increased security requirements including Increased Controls inspections, fingerprinting, and the National Source Tracking System. The Program receives good management and administrative support. In addition, the Program staff routinely reviews IMPEP reports from other States to identify items for possible future use by the Maryland program. Since the most recent IMPEP, MDE implemented a department-wide enforcement program which allows for the collection of civil penalties. The Program staff believes this new policy will encourage licensees to be more accountable regarding program performance.

### Program Weaknesses

The Program identified a potential weakness in their handling of bankruptcies involving materials licensees. The Program managers and licensing section developed a flowchart which provides direction on handling bankruptcies.

In addition, the Program staff identified a potential weakness in communicating issues involving a State of Maryland materials licensee to the NRC and other Agreement States. The Program Manager indicated that the State intends to share more detailed information on root cause analysis and generic implications when reporting future events involving this particular licensee. In addition the Program is working on entering event information for all Maryland materials licensees into NMED in a more timely manner.

### Feedback on the NRC's Program

The Program staff commented that the overall relationship with the NRC is good. In particular, the Program noted that the NRC funding of training is appreciated.

The Program staff also discussed the challenges faced by NRC and Agreement States with implementation of the National Source Tracking System and future implementation of Web-Based Licensing.

The Program noted that dealing with the Tc-99m shortage and resulting exemption was a resource drain on the licensing staff due to the large number of licensing amendment requests to address.

### Agreement State Program Staffing and Training

Since the August 2007 IMPEP, the Program hired two technical staff members, one each in the inspection and licensing areas, who are undergoing qualification training. The Program is now fully staffed with nine full-time staff members, including managers and one contractor. This staffing level does not include administrative support staff. The Program has one license reviewer in a contractor position which currently cannot be converted to a permanent State position due to budget constraints. The MDE recently performed a staffing analysis to determine adequacy of the Program's staffing level and determined that approximately 11 full-time equivalent (FTE) technical staff and five FTE program support staff are needed to effectively manage the radioactive materials program. This analysis has been submitted to senior MDE management for review.

Support for staff training exists in the Program. The Program staff welcomed the NRC's revised policy on funding training for Agreement States. Program staff members attend NRC and other training courses and seek alternate resources for training such as in-house and on-the-job training.

### Organization

The Program is administered by the Radioactive Materials Licensing and Compliance Division, which consists of the Inspection Section and Licensing Section. The Division is headed by a full-time Division Chief. Each Section has three full-time technical staff and a Section Head.

### Program Budget/Funding

The State has experienced a significant budget shortfall and implemented staff furloughs over the last two years. The Program Manager stated that the radioactive materials program, which is fee-based with occasional State funding, is adequately funded at this time. License fees have not been increased since 2004. A new fee package proposing a 70-75% fee increase is under management review.

### Inspection/Licensing Programs

The Program has approximately 625 radioactive materials licenses. The Program's inspection frequencies are at least as frequent as NRC's. The Program has completed all 60 Priority 5 inspections which were overdue at the time of the August 2007 IMPEP. No inspections were overdue at the time of this meeting. The Program maintains a database to monitor inspection scheduling and tracking. Management is aware of the importance of inspection program schedules. The Program has completed the first round of IC inspections and continues to conduct IC inspections in conjunction with the routine safety inspection.

The Program maintains a database for tracking licensing actions and did not have a licensing backlog at the time of this meeting. The Program staff developed a procedure to handle license abandonments. The Program issues Notices of Violations to licensees who abandon their licenses. The Program staff noted that they have difficulty at times locating some of these licensees. The Program has been conducting pre-licensing site visits since 1996. The staff will not issue a license if the information gathered during the pre-licensing visit does not match the information provided in the license application.

### Regulations

Since the August 2007 IMPEP, the State submitted ten final regulation packages and two legally binding requirements to NRC for a compatibility review to address the following amendments:

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendment (65 FR 63750), that was due for Agreement State implementation on January 8, 2004.
- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298), that was due for Agreement State implementation on April 5, 2005.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State implementation on October 24, 2005.
- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendment (68 FR 57327), that was due for Agreement State implementation on December 3, 2006.
- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 1, 2007.

- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR Part 30 amendment (70 FR 2001), that was due for Agreement State implementation on July 11, 2008.
- “Medical Use of Byproduct Material – Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2005.
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005), that was due for Agreement State implementation on March 27, 2009.
- “National Source Tracking System – Serialization Requirements,” 10 CFR Part 32 with reference to Part 20 Appendix E amendment (71 FR 65685), that was due for Agreement State implementation on February 6, 2007.
- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65685, 72 FR 59162), that was due for Agreement State implementation on January 31, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.
- “Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material,” NRC Order EA-07-305 (72 FR 70901), that was due for Agreement State implementation by June 5, 2008.

The State will need to address the following NRC amendments in the future:

- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.
- “Occupational Dose Records, Labeling, Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.
- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Part 35 (74 FR 33901), that is due for Agreement State adoption by September 28, 2012.

### Event Reporting

The Program has reported 12 events to the NRC since the 2007 IMPEP review. Follow up and closure information for all events reported by the Program are included in the State's NMED entries.

### Response to Incidents and Allegations

The Program continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for the potential effect on public health and safety. Staff is dispatched to perform onsite investigations when necessary. No allegations were referred from NRC to the Program since the 2007 IMPEP review.

### Significant Events and Generic Implications

The Program reported several significant events since the 2007 IMPEP review. One event involved a manufacturer with 14 incidents involving high dose rate remote (HDR) afterloader units at various locations across the nation. The State performed independent root cause analyses on the incidents to identify any generic implications. Another significant event involved an individual receiving an extremity overexposure during a teletherapy source exchange at a hospital in Brazil. The State provided valuable support to NRC on coordination of information exchange with Brazil and the International Atomic Energy Agency.

### Sealed Source and Device Evaluation Program

Since the August 2007 IMPEP, the Program has issued one new SS&D certificate to an HDR manufacturer and one amendment.

### Current State Initiatives

The Program staff discussed several initiatives, including State representation on the Southern States Energy Board; increasing knowledge of the National Source Tracking System; participation on NRC/OAS/CRCPD conference calls; and continued actions to address issues related to disposal of sources from a licensed manufacturing facility.

### Emerging Technologies

Topics discussed included positron emission mammography and the use of portable gauges which do not contain radioactive material.

### Large, Complicated, or Unusual Authorizations for Use of Radioactive Material

The Program staff has received inquiries from licensees regarding use of depleted uranium/yellowcake.

### State's Mechanisms to Evaluate Performance

The State has created a tracking system to follow all escalated enforcement actions from beginning to end. In addition, all training, licensing, and inspection information is tracked on Program databases. Program managers review monthly reports on inspections, violations, and pre-licensing visits. Supervisors perform inspection accompaniments of all materials inspectors. The Program licensing staff meets once to twice per month to review the status of licensing actions. Evaluation plans for new personnel are reviewed every six months and updated as needed.

### Current NRC Initiatives

NRC staff discussed ongoing initiatives with the Program staff. These included pre-licensing guidance, fingerprinting orders, national source tracking, web-based licensing, generally-licensed devices, working group prioritization activities, blending of low level radioactive waste, Part 37 rulemaking, safety culture, FSME management changes, and enhancements to the FSME website.

### Summary

The Maryland radioactive materials program continues to be a strong, stable Agreement State program. The Program staff is experienced and well trained. The Program staff has experienced several mandatory furlough days in the past year due to State budget issues. With the increased focus on the safety and security of radioactive material, adequate program resources have become much more critical and the State is closely monitoring the need to increase staffing when necessary. In addition, the Program has drafted a new fee package which is currently under management review.

NRC staff recommends that the next IMPEP review should be conducted as scheduled in FY 2011 (tentatively August 2011).

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR  
NEW HAMPSHIRE DEPARTMENT OF HEALTH AND HUMAN SERVICES  
RADIOLOGICAL HEALTH SECTION

DATE OF MEETING: October 16, 2009

<b>NRC Attendees</b>	<b>New Hampshire Radiological Health Section Attendees</b>
Donna Janda, Region I RSAO	Dennis O'Dowd, Administrator
Monica Orendi, FSME	Twila Kenna, Manager, Radioactive Materials Program

DISCUSSION:

In September 2008, the Integrated Materials Performance Evaluation Program (IMPEP) review team found the New Hampshire Department of Health and Human Services (DHHS) Agreement State Program's (the Program) performance to be satisfactory for six performance indicators and satisfactory, but needs improvement, for the indicator Compatibility Requirements. One recommendation was made by the review team regarding the Program. On December 5, 2008, the Management Review Board (MRB) met to consider the IMPEP review team's proposed findings regarding the Program. The MRB found the Program adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately four years and that a periodic meeting be held in approximately one year from the date of the IMPEP.

This summary describes that periodic meeting.

The status of the State's actions to address the open recommendation follows:

1. The review team recommends that the State develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility.

Current status: The State has submitted seven regulation packages to NRC for review since the September 2008 IMPEP. Four of these packages were under review at the time of this meeting. The State has not developed a formal action plan to address this recommendation; however, the State has made significant progress on addressing overdue regulations through the use of legally binding license conditions to meet compatibility requirements. In addition, the Program has received approval for two new staff positions, one of which will be dedicated to rulemaking activities. The Program is currently seeking funding for the new positions.

This recommendation remains open and should be evaluated at the next IMPEP review.

TOPICS COVERED DURING THE MEETING INCLUDED:Program Strengths

A well-trained, stable, and experienced staff is a major strength of the Program. The Program has also been very successful in training junior technical staff. An additional strength was meeting all of the licensing and inspection Program goals during implementation of increased security requirements including Increased Controls inspections, fingerprinting, and implementation of the National Source Tracking System. The Program receives good management and administrative support. The Program Administrator noted that the Radiation Advisory Committee is also very supportive of the Program.

Program Weaknesses

The Program Administrator identified the State's rulemaking process as a weakness due to the resource commitments needed to maintain up-to-date regulations. The Program Administrator noted that once the new staff position dedicated to rulemaking is funded, this weakness should be alleviated. The staff noted that the Program's website needs to be updated but IT staff support is limited at this time.

Feedback on the NRC's Program

The Program staff commented that the overall relationship with the NRC is good. In particular, the Program noted that the NRC funding of training is appreciated.

Agreement State Program Staffing and Training

Since the September 2008 IMPEP, the Program has had no changes in personnel and has been fully staffed. The Program, which is headed by the Program Administrator, has two Program Managers and four technical staff. One Program Manager is dedicated to the Radioactive Materials Program and the other is dedicated to the Radiation Machines Program. The Program has received approval for two new technical positions, one of which will also be responsible for rulemaking activities; however, due to current budget constraints the positions have not been filled.

Support for staff training exists in the Program. DHHS welcomed the NRC's revised policy on funding training for Agreement States. Program staff members attend NRC and other training courses and seek alternate resources for training such as in-house and on-the-job training. The Program also takes advantage of training opportunities with neighboring Agreement States.

Organization

The Program is administered by the Radiological Health Section (the Section), which is part of the Division of Public Health Services in the Department of Health and Human Services. In addition to the Program activities, the Section is responsible for radiation-producing machines and radiological emergency response activities. Due to budget issues, a proposed change to the Program's organization has been put on hold.

### Program Budget/Funding

The Program Administrator stated that fees from radioactive materials licensees are placed into a dedicated fund which adequately funds the Program. The Program also receives fees from utilities and x-ray registrants located in the State.

### Inspection/Licensing Programs

The Program has approximately 80 radioactive materials licenses. The Program's inspection frequencies are at least as frequent as NRC's. No inspections were overdue at the time of this meeting. The Program maintains a database to monitor inspection scheduling and tracking. Management is aware of the importance of inspection program schedules. The Program has completed the first round of IC inspections and continues to conduct IC inspections in conjunction with the routine safety inspection.

The Program maintains a database for tracking licensing actions and did not have a licensing backlog at the time of this meeting. The Program is aware of the requirement for "pre-licensing" visits. The Program hand delivers all new licenses and will not issue a license if the information gathered during the pre-licensing visit does not match the information provided in the license application.

### Regulations

Since the September 2008 IMPEP, the State submitted one final regulation package, one proposed regulation package, and five legally binding requirements to NRC for a compatibility review to address the following amendments:

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715), that was due for Agreement State implementation on July 1, 1996.
- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendment (62 FR 4120), that was due for Agreement State implementation on May 29, 2000.
- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," 10 CFR Part 35 amendment (63 FR 37059), that was due for Agreement State implementation on July 1, 2001.
- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendment (68 FR 57327), that was due for Agreement State implementation on December 3, 2006.
- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 1, 2007.

- “National Source Tracking System – Serialization Requirements,” 10 CFR Part 32 with reference to Part 20 Appendix E amendment (71 FR 65685), that was due for Agreement State implementation on February 6, 2007.
- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65685, 72 FR 59162), that was due for Agreement State implementation on January 31, 2009.

The following amendments are overdue, one of which is significantly beyond three years from the effective date:

- “Medical Use of Byproduct Material,” 10 CFR parts 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State implementation on October 24, 2005.
- “Medical Use of Byproduct Material – Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008.
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005), that was due for Agreement State implementation on March 27, 2009.

According to the Program Administrator, the first two regulation packages described above have been drafted and will be submitted to NRC for review as soon as possible.

The State will need to address the following NRC amendments in the future:

- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.
- “Occupational Dose Records, Labeling, Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.
- “Medical Use of Byproduct material – Authorized User Clarification,” 10 CFR Part 35 (74 FR 33901), that is due for Agreement State adoption by September 28, 2012.

### Event Reporting

The Program has reported one event to the NRC since the 2008 IMPEP review. Follow up and closure information for all events reported by the Program are included in the State's NMED entries.

### Response to Incidents and Allegations

The Program continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for the potential effect on public health and safety. Staff is dispatched to perform onsite investigations when necessary. No allegations were referred from NRC to the Program since the 2008 IMPEP review.

### Significant Events and Generic Implications

The Program reported that no significant events have occurred since the 2008 IMPEP review. No generic implications have been identified.

### Current State Initiatives

The Program developed a formal plan and initiated a seven-year period for full renewals of materials licenses.

### Emerging Technologies

One licensee has started using electronic brachytherapy treatments in place of high dose rate remote afterloader treatments.

### Large, Complicated, or Unusual Authorizations for Use of Radioactive Material

DHHS has received a license application for a veterinary equine medical and surgical center. In addition, the Program has received an application for a new radiography license which will need to incorporate Increased Controls requirements prior to license issuance. The Program has not received any unusual requests for use of radioactive materials.

### State's Mechanisms to Evaluate Performance

All training, licensing, and inspection information is tracked on Program databases. All documents created by the radioactive materials staff are audited by the Program management. All licenses are signed by the Program Administrator. Supervisors perform inspection accompaniments of all materials inspectors. The Program holds biweekly staff meetings and monthly updates on the status of inspections and licensing actions.

Current NRC Initiatives

NRC staff discussed ongoing initiatives with the DHHS staff. These included pre-licensing guidance, fingerprinting orders, national source tracking, web-based licensing, generally-licensed devices, safety culture, FSME management changes, and enhancements to the FSME website.

Summary

The New Hampshire radioactive materials program continues to be a strong, stable Agreement State program. The Program staff is experienced and well trained. The Program has stable funding; however, overall State budget issues continue to be a concern. With the increased focus on the safety and security of radioactive material, program resources have become much more critical and the State is closely monitoring the need to increase staffing when necessary.

NRC staff recommends that the next IMPEP review should be conducted as scheduled in FY 2012 (tentatively September 2012).

AGREEMENT STATE ORIENTATION MEETING SUMMARY FOR VIRGINIA DEPARTMENT  
OF HEALTH (VADH)

DATE OF MEETING: January 20, 2010

<b>NRC Attendees</b>	<b>VADH</b>
John Kinneman, Director, Division of Nuclear Materials Safety, Region I	Diane Helentjaris, MD, MPH, Deputy Director, Office of Epidemiology
James Kottan, Region I RSAO	Leslie Foldesi, CHP, Director, Division of Radiological Health
Monica Orendi, Health Physicist, FSME	Michael Welling, Assistant Director, Radioactive Materials
Carmen Rivera , FSME	

**DISCUSSION:**

Virginia became the 36<sup>th</sup> Agreement State on March 31, 2009. The Agreement discontinued NRC regulatory authority in the Commonwealth for: a) byproduct materials as defined in Section 11e.(1), 11e.(3), and 11e.(4) of the Act; b) source materials; and c) special nuclear materials not sufficient to form a critical mass. The Agreement does not cover safety evaluations of sealed sources and devices or regulation of 11e.(2) byproduct material resulting from the extraction or concentration or source material from ore processed primarily for its source material content or its management or disposal

FSME Procedure SA-118, *Orientation Meetings for New Agreement States*, requires that orientation meetings with new Agreement States take place approximately nine months after the signing of the agreement. The orientation meeting serves as a forum to hold discussions, to exchange information, to identify areas of concern during the initial implementation for the new Agreement State program, and to assess IMPEP review planning. The orientation meeting is not a formal evaluation.

The Virginia Agreement State Program is located in the Division of Radiological Health of the Office of Epidemiology within the Virginia Department of Health under the Deputy Commissioner for Public Health.

This summary describes Virginia's orientation meeting.

**TOPICS COVERED DURING THE MEETING INCLUDED:**

**Program Strengths**

An experienced and well trained staff is the strength of the Program. There is a good working relationship among staff and management. Two staff work from home in various parts of the Commonwealth. This allows program coverage of the entire Commonwealth on short notice if

required. There is support for training from Program and Office management. Office and Program management have a clear vision for the Program. The program has a good mix of staff with respect to new hires and experienced staff.

#### Management Support of the Agreement State Program

There is support for the Program from Division and Office management. Recently the Office has been focused on H1N1 pandemic issues. This has resulted in some loss of senior management attention to the program. However the program has been able to adequately function under the direction of the Division Director.

#### Feedback on the NRC's Program

The Assistant Director commented that both the overall relationship and communication with the NRC are good and welcomed the NRC funding of training. The Assistant Director also stated that the National Source Tracking System (NSTS) is cumbersome to use, and most licensees are entering data into the system via paper, rather than electronically. One member of the Program has access to the NSTS system, with one additional staff in the process of applying for access.

#### Agreement State Program Staffing and Training

The Program is fully staffed. Six FTE are allotted to the Program. This consists of the Assistant Director, four Radiation Safety Specialists, an administrative assistant and fiscal support technician. Future Program plans call for the addition of an additional Radiation Safety Specialist.

Support for staff training exists in the Program. Virginia welcomed the NRC's revised policy on funding training for Agreement States. Program staff has attended NRC and other training courses, including the NRC's Security Systems and Principles Course. The Program plans are for staff to attend six NRC training courses in 2010. The Assistant Director noted that other activities that are not specifically training, such as attendance at professional organization meetings, also provide valuable opportunities for knowledge sharing.

#### Materials Inspection Program

The Program's inspection frequencies are at least as frequent as NRC's. At the time of the Agreement, NRC Region I provided an approximate three-month "cushion" of completed inspections to allow Virginia time to concentrate on structuring its Program without concern about the need to immediately conduct inspections. No inspections were overdue, and there is no inspection backlog. Virginia has performed 51 inspections since becoming an Agreement State. The Program maintains a data base for tracking inspection activities. Approximately 80 inspections are due within the next six months. Of these inspections, six are Priority 1 inspections, 10 are Priority 2 inspections, and 20 are Priority 3 inspections.

The Program has conducted eight reciprocity inspections of 44 candidate licensees that have entered the Commonwealth. The Assistant Director is conducting inspection accompaniments on at least an annual basis. The Program maintains a sufficient number and variety of

calibrated radiological survey instrumentation for use during inspections. Additionally, the Program has access to both a mobile radioanalytical laboratory and the Commonwealth's fixed radioanalytical laboratory for sample analyses.

### Licensing

No licensing backlog exists. The Program has approximately 425 active radioactive materials licenses. At the time of this meeting approximately 46 licensing actions were being processed, and six applications for new licenses were in process. All medical licenses have been merged to include NARM, and new licenses have been issued to these licensees. Pre-licensing visits are conducted.

### Regulations and Legislative Changes

There have not been any legislative changes or proposals that have affected the Program.

Virginia has no regulations that are overdue. The Virginia regulations are fully compatible with the NRC's.

### Program Budget/Funding

The Virginia Agreement State Program is 100 percent funded by the fees charged to licensees by the Program. At the present time the Program is adequately funded. Fees are placed into a restricted account that is available only to the Program

### Financial Assurance

The Commonwealth has ten licensees that require financial assurance. Of these ten, six are Commonwealth Universities. The Program is working with the Attorney General's Office to convert the beneficiary on the financial instruments from NRC to the Commonwealth of Virginia, and to obtain financial assurance for the Commonwealth institutions.

### Event Reporting

The Program communicates reportable incidents to the NRC Operations Center and Region I when appropriate in a prompt manner. Since Virginia became an Agreement State, four events were reported to the NRC.

### Response to Incidents and Allegations

The Program is sensitive to notifications of incidents and allegations. The Assistant Director stated that incidents are quickly reviewed for their effect on public health and safety, and staff is dispatched to perform onsite investigations when necessary. The Program is aware of the need to maintain an effective response to incidents and allegations. No allegations have been received by the Program since becoming an Agreement State.

General Licensing Program

Virginia has an active program for generally licensed devices. The Program has contacted the generally licensed device users within the Commonwealth. There are approximately 3100 total general licensees in the Commonwealth. Approximately 180 generally licensed devices are subject to fees by the Commonwealth. The Program plans to work with general licensees to establish an accurate and accountable inventory list for general licensed devices in Virginia

Security

The current security climate and potential future security measures were discussed in detail, including discussions on fingerprinting requirements and security of self-shielded irradiators. The Program is aware of relevant security issues.

The Program has completed the initial round of inspections of licensees subject to the Increased Controls Order. Subsequent inspections are conducted in conjunction with routine safety inspections.

CONCLUSIONS:

The Virginia Agreement State Program appears to be a capable, stable Agreement State program. Staffing has remained consistent since the implementation of the Agreement, and the training and experience level for the staff is good. Management support for the Program is also good.

NRC staff recommends that the initial IMPEP review should be conducted as scheduled in early FY 2011 (tentatively October 2010).

**Agenda for Management Review Board Meeting  
March 25, 2010, 2:00 p.m. - 4:00 p.m. EST, TWFN-2-B5**

1. Announcement of Public Meeting to all attendees and request for identification of any members of the public participating in this meeting.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other representatives participating remotely.
3. Discussion of Periodic Meetings:
  - a. NRC Region III  
(November 9-10, 2009) – ML093490392 – Lewis/Xu
  - b. Minnesota  
(October 15, 2009) – ML093100259 – Lynch/McCraw
  - c. Maryland  
(November 4, 2009) – ML100550121 – Janda/Beardsley
  - d. New Hampshire  
(October 16, 2009) – ML10054131 – Janda/Orendi
4. Discussion of Orientation Meeting:

Virginia  
(January 20, 2010) -- ML100541986 – Kottan/Orendi/Rivera
5. Adjournment

Invitees:	Martin Virgilio, FSME	Robert Lewis, FSME
	Bradley Jones, OGC	Donna Janda, Region I
	Charles Miller, FSME	James Kottan, Region I
	Marc Dapas, Region I	Jim Lynch, Region III
	Jared Thompson, OAS	Aaron McCraw, FSME
	Mark Satorius, Region III	Monica Orendi, FSME
	George Johns, MN	Shirley XU, FSME
	Roland Fletcher, MD	Michelle Beardsley, FSME
	Dennis O'Dowd, NH	Karen Meyer, FSME
	Dr. Diane Helentjaris, VA	Terrence Reis, FSME
	Mike Franovich, OEDO	Duncan White, FSME