

December 21, 2010

MEMORANDUM TO: Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Bradley W. Jones, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

Cynthia Pederson, Deputy Regional Administrator
Region III

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

SUBJECT: JANUARY 25, 2011 SPECIAL MRB MEETING

A Special Management Review Board (MRB) meeting to discuss the results of periodic meetings held with the Tennessee, Oregon, and California Agreement State Programs has been scheduled for **Tuesday January 25, 2011 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 1-3).

In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for this meeting is enclosed (Enclosure 4).

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

Enclosures:
As stated

cc w/ encl.: Gibb Vinson, Illinois
Organization of Agreement States
Liaison to the MRB

MRB Members

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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH

DATE OF MEETING: July 28, 2010

NRC Attendees	Tennessee Division of Radiological Health Attendees
John Kinneman, Region I, Director, DNMS	Debra Shults, Acting Director
Donna Janda, Region I RSAO	Johnny Graves, Manager, Licensing, Registration, and Planning
Michelle Beardsley, FSME , Health Physicist	Billy Freeman, Manager, Inspection and Enforcement
	Beth Murphy, Supervisor, Standards Development
	Eddie Nanney, Health Physicist

DISCUSSION:

In April 2008, the Integrated Materials Performance Evaluation Program (IMPEP) review team found the Tennessee Department of Environment and Conservation (DEC) Agreement State Program's (the Program) performance to be satisfactory for four performance indicators and satisfactory, but needs improvement, for the indicators Technical Staffing and Training, Compatibility Requirements, and Sealed Source and Device Evaluation Program. Four recommendations were made by the review team regarding the Program. On July 15, 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, but needs improvement, 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.

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

1. The review team recommends that the State evaluate the Division's projected staffing level and take appropriate action to ensure that the Division has adequate resources to achieve its primary objective of protecting public health, safety, and security.

Current status: Since the 2008 IMPEP review, six employees left the Division and three employees were hired by the Division. The Program Director recently retired and has returned to the Program as a 120-day rehired annuitant. The Deputy Director is currently serving as the Acting Program Director. The Program currently has 37 individuals with various degrees of involvement in the radioactive materials program, including 27 inspectors, five license reviewers, and one contractor. The Division expects the freeze to be lifted in the near future on two of the five open positions which were frozen at the time of the 2008 IMPEP review. Although still understaffed, the Program is not experiencing any backlogs in licensing or inspection activities.

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

The review team recommends that the State develop a method to document clearly that an inspector or license reviewer is qualified or approved to perform inspections or licensing actions of the different license types upon completion of specified training.

Current Status: The Program has implemented the use of training records for each inspector to document qualification/approval for the different types of licenses after completion of training courses and supervisory accompaniments. Copies of these records are maintained in the Central Office as well as the Regional Office in which the inspector is based. In addition, the Central Office maintains records for license reviewer qualifications, including documentation of training courses and on-the-job training for license reviewers for the different types of licensing actions.

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

2. The review team recommends that the State review the training policy to ensure that it meets current and future needs of the staff and revise the policy, as appropriate, to include on-the-job training and security training.

Current Status: The Program's current training policy includes on-the-job training and security training to address current and future needs of the staff. Both license reviewers and inspectors have attended the NRC security training course.

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

3. The review team recommends that the State establish a means to ensure evaluations are conducted with thoroughness; consistency with ANSI standards and NUREG-1556, Volume 3; and adherence to existing guidance in product evaluations.

Current Status: In order to ensure thoroughness and consistency with ANSI standards and existing guidance, the Program's SS&D reviewers use a review checklist based on the checklist found in NUREG-1556, Volume 3, for all SS&D licensing actions.

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 senior staff with 10 years or more of experience is a major strength of the Program. According to Program management, the technical staff has developed unique skill sets in licensing and inspection of the State's complex waste processing licensees and in external communications for dealing with media and public interest in the Bulk Survey for Release program, waste processing and blending issues, and the Nuclear Fuel Services site. The Program receives good management and administrative support.

Program Weaknesses

Program management identified low salaries and the absence of pay raises for the past 3 years as a weakness of the Program because of the difficulty in retaining technical staff once they are

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trained. In addition, field inspection staff members do not directly report to the Central Office. Instead they report to Field Office Directors, which makes it difficult to maintain a sense of rapport within the Division's radioactive materials program.

Feedback on the NRC's Program

The Program staff commented that the overall relationship with the NRC is good. The Program appreciates NRC funding of qualification training courses. The Program staff noted that because NRC sponsors only one or two medical courses each calendar year, it can be difficult for State staff to be accepted into the courses due to the limited number of spaces available. In addition, the Program would appreciate more emphasis on regulation of radioactive material and health physics implications of medical modalities in the medical courses.

Agreement State Program Staffing and Training

Program staffing, turnover and vacancies are discussed in Recommendation 1 above.

Support for staff training exists in the Program. New technical staff members are currently in the qualification process and attending NRC courses as available. 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 Division of Radiological Health (the Division), which is part of the Department of the Environment and Conservation. The Division is comprised of the Office of the Director and four Sections: Administrative, Inspection and Enforcement, Licensing/Registration/Policy Services, and Technical Services sections. Inspection, enforcement and incident response activities are conducted primarily through four field offices located in Nashville, Chattanooga, Memphis, and Knoxville. All other Program activities are conducted primarily through the Central Office in Nashville.

Program Budget/Funding

Fees from radioactive materials licensees are placed into the Environmental Protection Fund (EPF). Licensee fees have not been increased since 2001 and cannot be raised if program funding is cut. The State legislature has taken approximately one half of the carryover funds from the 2007-2008 fiscal year and it is unknown if the carryover funds from the 2008-2009 fiscal year will be decreased. The Program is attempting to raise licensee fees by approximately 20%. Rulemaking and public hearings have been held on the issue but the Program cannot move forward until it is known if the EPF will be decreased.

Inspection/Licensing Programs

The Program has approximately 600 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. Inspections which were overdue at the time of the 2008 IMPEP have been completed. 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 increased controls (IC) inspections and continues to conduct IC inspections in conjunction with the routine safety inspection.

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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 issues licenses with a ten-year renewal requirement.

Regulations

Since the April 2008 IMPEP, the State submitted eight final regulation packages and two proposed regulation packages to NRC for a compatibility review to address the following amendments:

- The 30.35 portion of “Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites],” 10 CFR Parts 30 and 40 amendment (58 FR 39628), that was due for Agreement State implementation on October 25, 1996.
- The 30.35 portion of “Clarification of Decommissioning Funding Requirements,” 10 CFR Parts 30, 40, and 70 amendment (60 FR 38235), that was due for Agreement State implementation on November 24, 1998.
- The 30.35 portion of “Termination or Transfer of Licensed Activities: Recordkeeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendment (61 FR 24669), that was due for Agreement State implementation on June 17, 1999.
- “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.
- “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.
- “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.
- “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.
- “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.

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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 communicates reportable incidents to the NRC Operations Center and Region I when appropriate in a prompt manner. The Program has reported five events to the NRC since the 2008 IMPEP review.

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 members are dispatched to perform onsite investigations when necessary. The Program is aware of the need to maintain an effective response to incidents and allegations and has procedures in place to ensure appropriate follow up action is taken. The Program conducts investigations of allegations received by the Program and follows up with the concerned individuals regarding the outcome of the investigations.

Significant Events and Generic Implications

The Program staff and NRC discussed one significant event involving a Tennessee licensee which occurred at a South Carolina hospital in December 2009. The event involved the rupture of a sealed source resulting in the contamination of several areas in the Radiation Oncology Department at the hospital and in the vehicle of an employee of the TN licensee who packaged the source. Both Tennessee and South Carolina have conducted follow up investigations.

The Program is currently evaluating possible generic implications from several recent events in other jurisdictions involving stuck shutters on fixed gauges distributed by a Tennessee licensee. Subsequent to this meeting, the Program has been working with FSME to determine if any future actions regarding this issue are warranted.

Sealed Source and Device Evaluation Program

Since the 2008 IMPEP review, the program has received one new application and five amendment requests for SS&D certificates. The Program has five individuals who perform SS&D evaluations.

Tennessee Periodic Meeting Summary

Current State Initiatives

The Bulk Survey for Release Program is being revised to ensure consistency in the modalities between the four licensees in this State Program.

Emerging Technologies

The Program noted that an amendment which was introduced in the State Senate to ban blending of radioactive waste did not pass in Committee. The State has not received any requests to license blending activities.

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

Since the 2008 IMPEP review, the Program has licensed activities involving pyrolysis of non-resin products and processing of steam generators.

State's Mechanisms to Evaluate Performance

The Program tracks inspection due dates on a Program database. Program management reviews the inspection due list on a monthly basis to ensure timeliness of inspections. Program managers review inspection reports. Field Office managers hold staff meetings on a quarterly basis.

Certain licensing actions are reviewed by Program managers. Licensing actions signed by junior reviewers receive several levels of review before the license is issued. If a licensing action is not worked on within 60 days of receipt of the action, the fee is returned to the applicant/licensee.

The Division holds a 2-3 day annual staff meeting for both Central Office and Field Office staff to discuss items of mutual importance and to conduct training sessions as needed.

Summary

The Tennessee radioactive materials program continues to be a strong, stable Agreement State program. The Program staff is experienced and well-trained. 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 April 2012).

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE
OREGON HEALTH AUTHORITY

DATE OF MEETING: SEPTEMBER 21, 2010

NRC Attendees	
Randy Erickson, RSAO	
Charles Cain, Deputy Director, DNMS	

Oregon Attendees	
Terry Lindsey, RPS Special Projects	Kevin Siebert, Health Physicist-Inspections
David Howe, Acting Section Manager	Justin Spence, Health Physicist-Inspections
Todd Carpenter, Licensing Manager	Daryl Leon, Health Physicist-Inspections
Bonny Wright, Medical Physicist	Nancy Curry, Office Specialist
Sylvia Martin, Health Physicist-Licensing	

DISCUSSION:

At the time of the 2009 IMPEP review, the Oregon Agreement State Program was administered by the Radiation Protection Services Section (Section) in the Division of Public Health (Division) which was part of the Oregon Department of Human Services. The most recent legislative session in 2009 moved the Division and ultimately the Section to the Oregon Health Authority. This transition is anticipated to be completed by June 30, 2011.

The 2009 IMPEP Review was conducted the week of August 24-27, 2009. The review team found Oregon's performance to be satisfactory for three performance indicators and satisfactory, but needs improvement for three other indicators. The team closed three open recommendations and opened three new recommendations; and, recommended that the Oregon Program be found adequate to protect public health and safety, but needs improvement, and is compatible with NRC's program.

The team recommended that the Program remain on monitoring with a periodic meeting to be held in one year. The team also recommended that the next full IMPEP review be held in four years, but the Program requested that the next review take place in three years to not conflict with the 2011 and 2013 sessions of the Oregon Legislature.

Following the August 2009 program review NRC held two Monitoring calls with the Section. The first call was held on March 16, 2010 where the Section reported they had completed one of the three recommendations involving development and implementation of a procedure for the control of sensitive or security-related information that provides guidance to identify, mark, handle, and protect such information. The second call was held on June 16, 2010 where the Section reported they were still working on the remaining recommendations involving staff

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qualifications; and, the timely entry of information into NMED.

The following is a status summary of the three recommendations that were identified in the 2009 Oregon final IMPEP report:

- The review team recommends the State develop and use a documented formal qualification program (including refresher training) for inspection and licensing staff that would include journals that clearly indicate each individual's training and qualification including oral and/or written evaluation of their understanding of regulations and guidance documents.

Current Status: The Section developed a Training Policy Statement which clarifies their commitment to proper training and development of the technical staff. Additionally, they developed a comprehensive qualification program utilizing a three phased approach. Manual Chapter 1246 was used as a guide during development, and their program closely mirrors NRC's required classroom training and inspection requirements. As candidates move through the training program, trainers and supervisors sign off on their progress. When candidates have completed the training requirements and have received enough inspection related experience to operate independently, they are reviewed by management who then signs their qualification documentation.

This recommendation should be verified and closed at the next IMPEP review.

- The review team recommends that the State develop and implement a procedure for the control of sensitive or security-related information that provides guidance to identify, mark, handle, and protect such information.

Current Status: The Section developed a protocol entitled, "Sensitive Unclassified Non-Safeguards Information (SUNSI)" which was developed using the guidance found in RIS 2005-31. The Section implemented their SUNSI program and staff now utilizes the protocol to more consistently identify, mark, handle and properly protect sensitive or security-related information. The protocol is now applied to all documents, either incoming or staff generated, to appropriately handle documents determined to be sensitive.

This recommendation should be verified and closed at the next IMPEP review.

- The review team recommends that the Section implement a process to ensure all required information is submitted to NMED and to also promote timely completion of NMED entries.

The Program in conjunction with Idaho National Laboratory provided NMED training to the staff on May 11, 2010. Concurrent with that training, NRC Region IV provided SA-300 training. During that training, discussions were held regarding appropriate and timely reporting to the Headquarters Operations Officer in addition to NMED, and the requirements associated with each type of reporting. The Program has also developed a protocol regarding events which includes timely NMED data entry and follow-up to ensure NMED data is properly submitted. Additionally, the incidents are now reviewed during monthly staff meetings. As closing information is gathered, it goes through two levels of management evaluation prior to being sent to NMED for closure.

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This recommendation should be verified and closed at the next IMPEP review.

Other topics covered at the meeting included.

Program Strengths: The Oregon Program is a relatively stable program with most of the technical staff having been with the Program for several years. These individuals came to the Program from diverse health physics backgrounds which only serve to bolster the cohesive nature in which the inspectors work together. Staff is supportive of each other and work together to achieve maximum success for the program.

Program Weaknesses: The Section identified one main area that continues to stress the Program, with that being in the area of unfunded NRC requirements. Managers noted that to date, the Program has been able to conduct increased control inspections, issue fingerprinting license conditions, implement pre-licensing guidance; and, keep up with the requirements of the National Source Tracking System, mainly because RPS personnel have been able to be flexible and prioritize regulatory projects. Although the RML program was successful in securing recent fee increases, this may not continue to be the case in the future.

The Section also noted difficulties with navigating NRC's public website as a hindrance to efficiently locating guidance documents. Specifically, the Program noted that the search function of the website does not function as easily as other public and government websites.

Feedback on NRC's program as identified by the State, including identification of any action that should be considered by NRC:

The Section expressed concern about how the IMPEP process worked for them during the 2009 review. Their concerns were focused on the specific recommendation requiring the development and implementation of what the Section believed to be an NRC style qualification journal. The specifics of their concern can be found in ADAMS under ML102710098.

The Section also expressed their appreciation for NRC's continued funding of Agreement State staff training.

Staffing and training:

The Oregon Program is a moderate sized program with 21 staff members. Most of the technical staff has both primary and secondary responsibilities within the Program. However, the majority of their time is spent within their main program area. At the time of the 2009 IMPEP review, the Program had 5.25 full-time equivalents in the technical program areas, now they are up to 7.5 full-time equivalents. They plan to ask for 2 additional staff during the next legislative session. The entire process for securing additional staff can take up to 6 years to complete.

The technical staff has been very stable with no turnover since 2001. While Section management completely turned over in 2007 due to the retirement of several individuals,

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it has been stable since that time. However, the current Program Manager announced his retirement effective January 31, 2011, and a nationwide search for a replacement is currently underway.

The Section reported that they have been able to get staff into training courses and have even hosted courses. The most recent course they hosted was NRC's Transportation Course which was approximately two years ago. The Section reported that several of their staff, including some of the senior staff, failed the class. This was discussed with the Section who stated that they discussed this in detail with FSME senior management at the time. The Section reported that none of the staff who failed the course actually required it for qualification at the time so specific alternatives for training were discussed.

Program reorganizations:

The Section reported that the 2009 Oregon legislative session passed House Bill 2009 which resulted in the Public Health Division being transferred to a new agency named the Oregon Health Authority. Administrative and Information Technology services will remain a shared expense between the two departments. The change is being phased in over a two year period and is anticipated to be completed by June 30, 2011. The Section views this as a positive change with more access to the legislature.

The Section believes that additional organizational changes are likely to occur as the Department moves towards a more "lean" organization structure.

Changes in Program budget/funding:

The Department has not experienced significant problems with budgeting or funding in regards to the materials program. The Department is 85 percent fee funded. The most recent change to the Section's funding increased on September 1, 2010 when the Radioactive Materials Licensing fees were approved for a 20 percent fee increase. The Program reported that this funding level is sufficient to operate the Program at current levels.

The Section also reported that the Section has lost one FTE equivalent over the last three years due to reductions in CDC federal grant appropriations. This loss of funding has had to be absorbed by the Section to continue to provide an emergency response function.

Materials Inspection Program:

The Department reported that they currently have no overdue inspections. Routine inspections are generally performed by the due date. Initial inspections are generally performed within 12 months of issuance. The Section continues to inspect Increased Controls inspections in conjunction with routine inspections.

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Regulations and Legislative changes:

The Department reported that they are currently up to date on all regulations. There are three regulation packages that will come due by the end of 2010. These include:

- “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. [RPS has already submitted this rule package as final rule for NRC review]
- “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.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that is due for Agreement State adoption by October 29, 2010.

Event reporting, including follow-up and closure information in NMED.

The Section reported that all NMED information with the exception of three open items is currently up to date.

Response to incidents and allegations.

The Section maintains sensitivity 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 Section Manager and staff have placed a high emphasis on maintaining an effective response to incidents and allegations.

Status of allegations and concerns referred by the NRC for action.

No allegations were referred by NRC to the Section since the 2009 IMPEP review.

Significant events and generic implications.

The Section reported multiple examples of fixed gauge failures at Oregon industrial plants which they believe may be related to improper installation or maintenance failures. The Section plans to escalate follow-up inspections from a five-year frequency, to a one or two year frequency to ensure that these issues are addressed.

Current State Initiatives.

The Department plans to initiate a funding proposal in the 2011 legislative session to fund NRC’s requirements placed upon the program. They are also seeking funding to build a comprehensive environmental health program within the Public Health Division of the Oregon Health Authority. Additionally, Oregon is in the final phase of the CRCPD SCATR source disposal program.

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Emerging Technologies.

None noted. The Section reported they recently updated their administrative rules to be compatible with 10 CFR.1000 rule on emerging technologies.

Large, complicated, or unusual authorizations for use of radioactive materials.

None noted. However, the Section did note that an ORAU contractor recently submitted a FOIA request related to the NIOSH Dose Reconstruction Project for an Oregon licensee. This effort took about 40 staff hours as they reviewed approximately 20,000 pages of records.

State's mechanisms to evaluate performance.

Section managers use a combination of internal audits of the program, the use of databases to track work and evaluate performance, accompaniments of inspectors to evaluate training and performance, and also conducts routine staff meetings to review the status of the licensing and inspection programs, regulation compatibility, protocol development, and incident reviews as a means to evaluate the Section's overall performance.

Current NRC initiatives:

NRC staff discussed ongoing initiatives with the Office. This included pre-licensing guidance, fingerprint orders, national source tracking, web-based licensing, generally licensed devices, safety culture, Part 37; and, revisions of NuReg 1556 series, IMC 1246 and IMC 2800.

Summary:

The Section appears to have spent a significant amount of time and effort to address the three recommendations identified during the 2009 IMPEP review. A Training Policy Statement has been developed, formal qualification journals have been developed and implemented, procedures to properly handle and mark sensitive documents have been developed and implemented, and a process for timely submission of NMED documents has been developed and implemented. The Section believes they have sufficiently demonstrated a period of sustained performance. The Section reports that sensitive documents are now being marked and handled appropriately, and NMED data is being closed out in a timely manner. While qualification journals have been developed for the technical staff, current technical staff has been with the program a minimum of nine years and have been fully qualified for several years. The newly developed qualification journals will be used for all new staff joining the Section.

For those reasons it is recommended that the Management Review Board consider removing the Oregon Program from Monitoring.

Oregon Periodic Meeting Summary

Schedule for the next IMPEP review:

It is recommended that the next IMPEP review to be held in two years (2012) to accommodate Oregon's request to not conflict with the 2011 and 2013 legislative sessions.

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DATE OF MEETING: OCTOBER 13, 2010

NRC Attendees	California Attendees
Randy Erickson, RSAO	Robert Schlag, Division Chief
Janine Katanic, FSME	Gary Butner, Branch Chief
	Gonzalo Perez, Senior Health Physicist
	John Fassell, Senior Health Physicist
	Phillip Scott, Health Physicist
	Ron Rogus, Health Physicist
	Steve Hsu, Health Physicist

DISCUSSION:

The Radiological Health Branch (the Branch), located within the Division of Food, Drug, and Radiation Safety (the Division), administers the California Agreement State Program. The Division is a part of the Department of Public Health (the Department).

The previous IMPEP review was conducted the week of March 31 – April 4, 2008. At the conclusion of the review the team found California's performance to be satisfactory for six performance indicators and unsatisfactory for the performance indicator Compatibility Requirements. The review team made two recommendations regarding Branch performance and identified one good practice. Accordingly, the review team recommended and the MRB agreed that the California Program is adequate to protect public health and safety and not compatible with NRC's program. The MRB also concluded that the period of Heightened Oversight should end and a period of Monitoring should be initiated. Additionally, the MRB agreed with the team's recommendation that the next full IMPEP review should take place in four years and that a Periodic Meeting be held within one year.

The initial Periodic Meeting was held on April 29, 2009 (ML091480762). This Periodic Meeting covers the period from April 30, 2009 through October 13, 2010. The meeting was conducted in lieu of a scheduled Monitoring call with the Branch and therefore includes additional specific details of the Branch's progress on completing each of the recommendations from the 2008 follow-up IMPEP review.

The proposed status of the recommendations from the 2008 California final IMPEP report is summarized below.

- The review team recommends that the State reevaluate its justification for inspecting HDR licensees on a 3-year interval and demonstrate that the health, safety, and security of HDR devices are not compromised. (Section 3.2)

Status on April 29, 2009: The Branch has changed the frequency of HDR inspections from a 3-year interval to a 2-year interval to be compatible with NRC's frequency.

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This recommendation should be verified and closed at the next IMPEP review.

- The review team recommends that the Branch develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 4.1.2)

Status on April 29, 2009: The Department recognized that the rulemaking process in place at the time of the 2008 IMPEP review was inefficient and needed revision. In response to that need, the Department hired a consulting firm to assess the rulemaking process and make recommendations on how to improve it within the confines of state law. The consulting firm made recommendations to the Department, and in December 2008 the Branch in coordination with the Office of Regulations, drafted an Action Plan to streamline the Branch's rulemaking process. Additionally, they implemented a team approach to development and promulgation of regulations and are now just beginning to follow the Action Plan. More time will be needed to fully evaluate the effectiveness of this approach.

Current Status: The Department reported they continue to make progress on the regulation backlog. California processes rule packages by "Parts", such as Part 20 or Part 35, instead of by amendments containing several smaller parts similar to the manner in which NRC promulgates rules. This method of rule promulgation gives the impression that the California program remains seriously behind on regulation development, when in fact they continue to steadily implement regulations. The Branch completed and filed Part 35 regulations (including some subsequent amendments) with the California Secretary of State on the date of the meeting. They will become effective on January 1, 2011. The Branch also reported that the Department's new rule development and promulgation process is working well. The process hasn't significantly reduced the amount of time it takes to promulgate new rules, but it has brought efficiencies to the process that have helped the Branch, primarily in the area of concurrent processing of rule packages. This recommendation remains open and should be evaluated at the next IMPEP review.

Other topics covered at the meeting included.

Program Strengths: The California Program is a large and busy program with a highly motivated staff that at the time of the meeting had responsibility for 1913 specific materials licensees. Management support to the Branch is outstanding and access to senior management is unencumbered. Senior managers have offices on the same floor as the Branch. The close physical location allows easy access to both Branch and Division management and allows managers to be more intimately involved in staff activities.

While the Branch continues to experience minor staff losses, they have been very successful in filling positions with talented individuals bolstering the Branch's already broad knowledge base. The Branch has successfully integrated the added workload associated with Increased Controls, as well as fingerprinting and NSTS requirements. Staff members work well together providing a high level of customer service to their

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licensees, and Branch management has worked diligently to ensure that a proper balance is achieved within the Branch.

Program Weaknesses: The Branch was previously a strong supporter of staff involvement in NRC working groups and participation on IMPEP teams; however, due to the state's economic downturn and the high negative visibility associated with sending staff out of state to participate in these activities, senior management has restricted travel for both. Additionally, for approximately the last year, staff has been restricted from traveling out of state to attend NRC training courses. Because of this, Region IV has coordinated with TTC to bring the licensing and inspection procedures courses to California. Additionally, furloughs have now been in place for over a year and continue for the staff at the rate of three days per month.

Feedback on NRC's Program:

The Branch discussed issues associated with environmental remediation of several Department of Defense facilities located in California, but the majority of the Branch's concerns are focused on clean-up activities at the former Treasure Island Naval Station (Treasure Island), a Base Realignment and Closure (BRAC) site undergoing decommissioning. The Branch discussed their concerns about jurisdiction of Treasure Island both prior to and during the Periodic Meeting. The Branch has experienced difficulty in determining who (the State, the NRC or someone else) is responsible for oversight of ongoing environmental remediation activities involving byproduct materials at the site, and has also experienced difficulties in obtaining access to the site.

Subsequent to the meeting, Region IV staff was able to confirm with the Navy Master Materials License (MML) Project Manager that NRC has no jurisdiction on the site at this time. This is because the only material identified at Treasure Island thus far has been radium, and due to current NRC policy regarding military use. This was conveyed to the Branch telephonically on October 20, 2010. The Branch reported that on October 27, 2010, staff members from the Branch would be provided escorted access to the site by members of the Naval Radiological Affairs Support Office (RASO) and BRAC so that the Branch could perform independent radiological surveys.

The Branch expressed their concerns about requests by the Domestic Nuclear Detection Office (DNDO) for access to licensee information contained in the Branch's licensee database. DNDO provided the Branch with a Memorandum of Understanding (MOU) detailing the access needed. As of the date of the meeting, the Branch has not responded to DNDO's request. They are uncomfortable providing specific licensee information to anyone outside of direct coordination with, or working through NRC.

Staffing and training:

The California Program is a large program which is divided into several program areas. The Branch has an average of 150 total staff members with approximately one third of those being associated with the radioactive materials program. At the time of the meeting, the Branch reported they were fully staffed but anticipated losing one licensing reviewer in the near future. In addition to hiring experienced staff, the Branch also aggressively

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recruits from local universities, and continue to do so. The Branch continues to assess their staffing needs which are in part, dependent on additional requirements placed upon them by NRC.

The status of Agreement State staff members who fail NRC core training courses was discussed. Branch managers indicated it is their policy to provide other forms of remedial training whenever this might occur. They discussed one staff member who recently failed NRC's "Transportation of Radioactive Materials" course (H-308). They worked with this individual, providing alternate methods of training until they were satisfied the individual was sufficiently capable of understanding and applying DOT regulations.

Program reorganizations:

The Branch has not been subject to reorganization since the last meeting. A change in the Governor's office will occur with the upcoming election, but this is not expected to result in Department reorganization. Since the last meeting, the Branch rotated the individuals occupying the positions of Chief of the Radioactive Materials Inspection, Compliance and Enforcement Section, and Chief of the Strategic Planning and Quality Assurance Section to each other's position.

Changes in Program budget/funding:

The Branch has not experienced any problems with budgeting or funding. The Branch is fee funded. The FY11 budget has been passed by the legislature. The only issue that has affected the Branch irrespective of their funding levels is the overriding requirement that all state government offices close three days per month which has had a net effect of an approximate 15 percent pay cut to all employees.

Materials Inspection Program:

The Branch reported that they currently have no overdue inspections. Routine inspections are generally performed by the due date, but occasionally inspections are performed within the allowed +25 percent window. Initial inspections are typically performed within 12 months of issuance. They continue to inspect reciprocity licensees and have not had difficulty performing inspections on at least 20 percent of candidate reciprocity licensees.

The Branch initially identified 140 licensees who were required to implement Increased Controls (IC). At the time of the meeting, the Branch reported they currently have 138 IC licensees. At the time of the 2008 IMPEP review, the Branch still had 12 of these inspections to perform but during the April 2009 meeting reported that all IC inspections had been completed. Also during that meeting the Branch noted that all but three licensees had completed the fingerprinting implementation. All fingerprinting requirements have now been implemented. IC inspections are now performed in conjunction with routine health and safety inspections. Fingerprinting and NSTS requirements are also reviewed at the time of inspection.

Increased Controls/Fingerprinting files are locked in uniquely keyed file cabinets and are not subject to release under FOIA.

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The Branch reported they have developed and implemented a formal procedure on how they address pre-licensing guidance requirements including pre-licensing visits. At the time of the April 2009 meeting, the Branch stated that only new IC licensees received a site visit. During this meeting the Branch stated that all new licensees now receive a pre-licensing visit. Additionally, a non-IC licensee who requests an increase in license authorization that now subjects them to IC requirements also receives a pre-licensing visit, even though the Branch has a relationship with the licensee.

Regulations and Legislative changes:

During the 2008 follow-up IMPEP review, the Branch was found to not be compatible with NRC's program due to large number of overdue amendments. The period of Heightened Oversight was terminated and a period of Monitoring was initiated. Over the successive months, quarterly calls with the Branch were conducted to update NRC on the Branch's progress towards compatibility with NRC's program. The most recent Monitoring call with the Branch took place on June 9, 2010 (ML101660110). At the time of that call, the Branch reported on the remaining 11 out of the original 13 outstanding amendments.

During the Periodic Meeting, the Branch confirmed that on October 13, 2010, Part 35 (medical) regulations had been adopted and had been filed with the Secretary of State. These regulations will become effective for licensees on January 1, 2011, and licensee workshops for Part 35 are scheduled for early December 2010 in both northern and southern California. The adoption of Part 35 resulted in the completion of three amendments and the partial completion of four additional amendments. The remaining eight amendments continue to work their way through the rulemaking process.

The incompatibility of legislation found in Section 115261 of California's "Health and Safety Code – Radiation Control Law" to NRC's 10 CFR Part 61 with regards to low-level radioactive waste disposal was also discussed with the Branch. This incompatibility was initially noted in an amendment submission to NRC on June 25, 2007. At that time, NRC notified the Branch that their statute was more restrictive than 10 CFR 61.41, and therefore did not meet the Compatibility "A" designation assigned to the rule. To date this compatibility issue has not been resolved. On November 3, 2010, the Branch notified NRC by telephone and email that they will be requesting additional time to resolve the issue due to the upcoming change in administration following the 2010 elections (ML103140535).

As noted in the Discussion section of this summary, a scheduled Monitoring meeting with the Branch was held in conjunction with the Periodic Meeting, and therefore this section includes additional specific details of the Branch's status of overdue amendments.

- "Quality Management Program and Misadministration," 10 CFR Part 35 amendment (56 FR 34104), that was due for Agreement State implementation on January 27, 1995.

Status: This amendment has been completed. It was adopted on October 13, 2010.

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- “Timeliness in Decommissioning of Materials Facilities,” 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026), that was due for Agreement State implementation on August 15, 1997.

Status: This amendment remains open. This amendment is tied to the amendment, “Radiological Criteria for License Termination,” noted below.

- “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (60 FR 48623), that was due for Agreement State implementation on October 20, 1998.

Status: This amendment has been completed. The Part 20 portion of this amendment was adopted on September 10, 1998. The Part 35 portion of this amendment was adopted on October 13, 2010.

- “Recognition of Agreement State Licenses in Areas under Exclusive Federal Jurisdiction within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662), that was due for Agreement State implementation on February 27, 2000.

Status: This amendment remains open. The Branch has completed the 45-day public comment period. Based on comments received, they are about to place the amendment out for an additional 15-day comment period.

- “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120), that was due for Agreement State implementation on May 29, 2000.

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010.

- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that was due for Agreement State implementation on August 20, 2000.

Status: This amendment remains open. The 10 CFR Part 20 portion of the regulation was adopted and then challenged in State court by “The Committee to Bridge the Gap, et al.” The challenge was successful, and the “Radiological Criteria for License Termination” portion of the regulation was repealed on August 8, 2002. The Branch is currently terminating licenses on a case-by-case basis.

- “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 35, and 36 amendments (63 FR 39777 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001.

Status: This amendment remains open. The Part 35 portion of this amendment was

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adopted on October 13, 2010. The Part 36 portion of this amendment was completed by License Condition. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010.

- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Part 30, 31, and 32 amendments (65 FR 79162), that was due for Agreement State implementation on February 16, 2004.

Status: This amendment remains open. The Branch has completed the 45-day public comment period. Based on comments received, they are about to place the amendment out for an additional 15-day comment period.

- “Medical Use of Byproduct Material,” 10 CFR Parts 20, 32, and 35 amendments (67 FR 20250), that was due for Agreement State implementation on October 24, 2005.

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010.

- “Medical Use of Byproduct Materials - Recognition of Specialty Boards - Part 35,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008.

Status: This amendment has been completed. It was adopted on October 13, 2010.

- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that is due for Agreement State implementation by March 27, 2009.

Status: This amendment remains open. The Part 35 portion of this amendment was adopted on October 13, 2010. The Part 20 portion of this amendment has been filed with the Office of Administrative Law for review. The review has a deadline of November 23, 2010. Changes for Parts 30, 40 and 70 are compatibility Category D so they are not being addressed. Change to Part 32 is already addressed through the licensing review process.

Event reporting, including follow-up and closure information in NMED.

Between the date of the 2008 IMPEP review and the April 2009 Periodic Meeting, the Branch had reported 129 events to NMED, with 72 remaining open. The majority of those events were landfill radiation monitor alarm trips. Between the April 2009 meeting and October 13, 2010, the Branch reported 143 events to NMED, with 56 remaining open. The Branch continues to monitor open events and closes them as rapidly as possible. Their goal for event closure is 120 days from the date of the event.

Response to incidents and allegations.

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The Branch continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for their affect on public health and safety. Incidents are evaluated for safety significance and staff is dispatched to perform onsite investigations whenever possible. The Branch has taken the position that if they demonstrate responsiveness to incidents and allegations, no matter how trivial they might be, licensees and individuals will realize that reporting incidents and allegations should be important to them as well.

Status of allegations and concerns referred by the NRC for action.

The Branch continues to process allegations as they are received. In addition to allegations received by the Branch directly, since the 2009 Periodic Meeting, NRC has referred two allegations to the Branch. One did not require a response to NRC; the other was immediately investigated by the Branch and a response to NRC was generated within a week. The Branch continues to be sensitive to issues of identity protection regarding alleged.

Significant events and generic implications.

While the Branch continues to monitor several significant events, they reported that no new significant events have originated following the 2008 IMPEP review. One specific issue noted was the Branch's tracking of radioactive materials being sold on Ebay.

Current State Initiatives.

The Branch noted that furloughs continue. No specific end date has been identified.

The Branch also noted they continue to work with RASO and BRAC on the environmental remediation of various former military installations within the State. Specifically, the Branch is concerned with clean-up of Treasure Island, and to a lesser extent Hunter's Point.

Emerging Technologies.

Nothing specific noted.

Large, complicated, or unusual authorizations for use of radioactive materials.

Nothing specific noted.

State's mechanisms to evaluate performance.

Branch managers review performance reports involving licensing actions, inspections performed, incidents reported, and reports reviewed.

Inspector accompaniments are also performed to ensure they are performing at the expected level.

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Current NRC initiatives:

NRC staff discussed ongoing NRC initiatives with the Branch. These included in part, NRC's draft safety culture policy statement, web based licensing, NSTS, the NUREG 1556 revision process, the revisions to IMC 2800, the proposed Part 37 and accompanying guidance document, and potential changes to Part 20.

Summary:

The Branch appears to have spent a significant amount of time and effort to correct the issues that were initially facing them. While the rulemaking process in California continues to be a cumbersome and sometimes difficult regulatory process, the Branch has taken advantage of some of the recent changes in the process that allow for concurrent streaming of regulations which allows them to get regulatory packages out sooner. While the Branch has completed several amendments and partially closed others, they still have several to complete. It is recommended that the Management Review Board consider continuing the period of Monitoring for the California Program until the next IMPEP review.

Schedule for the next IMPEP review:

It is recommended that the next IMPEP review to be held on schedule in April 2012.

**Agenda for Management Review Board Meeting
January 25, 2011, 2:00 p.m. – 4:00 p.m. EST, T-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, NRC staff members, State representatives, and other participants.
3. Discussion of Periodic Meetings:

California
 (October 13, 2010) – ML103140660 – Erickson / Katanic

Oregon
 (September 21, 2010) – ML102730132 – Erickson / Cain

Tennessee
 (July 28, 2010) – ML103000173 – Janda / Beardsley
4. Adjournment

Invitees:	Michael Weber, OEDO	Donna Janda, Region I
	Bradley Jones, OGC	Monica Orendi, Region I
	Charles Miller, FSME	Randy Erickson, Region IV
	Cindy Pederson, Region III	Janine Katanic, FSME
	Gibb Vinson, IL	Duncan White, FSME
	Gary Butner, CA	Michelle Beardsley, FSME
	David Howe, OR	Karen Meyer, FSME
	Debra Shults, TN	Kathryn Brock, OEDO
	Rob Lewis, FSME	
	Terry Reis, FSME	