

KENTUCKY DEPARTMENT FOR PUBLIC HEALTH
QUARTERLY MONITORING CONFERENCE CALL
February 29, 2012

Nuclear Regulatory Commission Attendees	Kentucky Department for Public Health Attendees
Raymond Lorson, Director, DNMS, Region I	Matthew McKinley, Radiation Control Program Administrator
Monica Orendi, RSAO, Region I	Curt Pendergrass, Radiation Health Supervisor
Donna Janda, Region I	Michele Greenwell, Radiation Health Specialist III
Michelle Beardsley, FSME	Marissa Vega Velez, Radiation Health Specialist II
Lisa Dimmick, FSME	
Rachel Browder, Region IV	

BACKGROUND

During the 2008 Integrated Materials Performance Evaluation Program (IMPEP) review of the Kentucky Agreement State Program (the Program), the review team found the Commonwealth's performance satisfactory for five performance indicators and satisfactory, but needs improvement, for three performance indicators. Six recommendations were made by the IMPEP review team. On October 28, 2008, the Management Review Board (MRB) met to consider the proposed final IMPEP report. The MRB found the Program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB directed that Kentucky continue to remain in monitoring status, that calls between the Kentucky Department for Public Health (DPH) and NRC staffs continue to be conducted quarterly, and that a Periodic Meeting take place approximately one year from the 2008 IMPEP review. DPH provided their response to the IMPEP findings in a letter dated December 8, 2008 with an additional response provided in an e-mail dated January 30, 2009. NRC acknowledged DPH's responses in a letter dated February 3, 2009. NRC staff concluded that the DPH responses are addressing the recommendations in the IMPEP report in a reasonable and realistic manner. NRC staff review noted that action had been taken on all recommendations. The tasks, milestones, and assignments for completing final action on the recommendations appeared reasonable and achievable.

On September 15, 2009 a Periodic Meeting was held with DPH. Subsequent to this Periodic Meeting, the MRB met on January 7, 2010 to consider the findings of the Periodic Meeting. The MRB directed that the Commonwealth remain on monitoring and that calls between DPH and NRC continue to be conducted quarterly. Another Periodic Meeting was held with DPH on February 10, 2011. Subsequent to this Periodic Meeting, the MRB met on April 5, 2011 to consider the findings of the Periodic Meeting. The MRB again directed that the Commonwealth remain on monitoring and that calls between DPH and NRC continue to be conducted quarterly. This is the third quarterly conference call with DPH since the April 5, 2011 MRB.

DISCUSSION OF PROGRAM STATUS

Mr. McKinley and Mr. Pendergrass led the discussion of the Commonwealth's status for each of the IMPEP performance indicators.

Technical Staffing and Training (2008 IMPEP finding: Satisfactory)

Since the last quarterly call the Section has lost two staff members and will be losing a third staff

member to retirement in March 2012. Paperwork is currently in the governor's office which if approved will allow DPH to post two of the vacant positions. The Section also has a void in one staff position due to a current staff member being deployed with the National Guard. The Program expects this individual to be deployed for at least another 20 months. The Program continues to support staff training and utilizes NRC training courses when available. Kentucky is working with the NRC in an effort to hold the inspection procedures course at their offices.

Status of the Materials Inspection Program (2008 IMPEP finding: Satisfactory but Needs Improvement)

For part of the review period Kentucky's inspection frequencies were more restrictive than NRC inspection frequencies in some instances. As of the start of 2012 Kentucky has adopted inspection frequencies equivalent to NRC's inspection frequencies. Mr. Pendergrass stated that the number of overdue inspections has been trending downward since July, 2011. At the time of the call Mr. Pendergrass stated that five inspections were currently overdue (no Priority 1 inspections overdue). The Section continues to perform reciprocity inspections and is timely with their initial inspections. Mr. McKinley stated that the Radioactive Materials Section continues to focus on completing and documenting inspections within the required time.

Technical Quality of Inspections (2008 IMPEP finding: Satisfactory bur Needs Improvement)

The 2008 IMPEP review team generated three recommendations for this performance indicator. These recommendations are listed below along with their current status.

Recommendation 1: The review team recommends that the Commonwealth revise its inspection procedures to require documentation of the closure of any previous violation, verification of corrective actions, and evaluation of preventative measures implemented by the licensee both in the inspection documentation and during the exit with the licensee.

Status: This revision has been made and staff has had initial and refresher training on the subject matter.

Recommendation 2: The review team recommends that the Commonwealth discuss previous inspection findings, corrective actions, and any potential violations with the licensee during inspections.

Status: This has become the first topic of discussion when entrancing with a licensee. The inspector discusses previous items of non-compliance, looks at program audits, and has discussions with staff during the inspection to identify any other problems the licensee may have had.

Recommendation 3: The review team recommends that the Commonwealth use its own calibrated radiological survey equipment to perform independent confirmatory surveys during inspections.

Status: This is the Section's current practice. This recommendation was implemented very quickly after it was made. The last incidence occurred in June 2008.

Kentucky has completed actions with respect to all three recommendations. The Program continues to provide continuing training to inspectors. Inspections are being adequately documented. Annual inspector accompaniments are ongoing.

Technical Quality of Licensing (2008 IMPEP finding: Satisfactory)

The 2008 IMPEP review team generated two recommendations for this performance indicator. These recommendations are listed below along with their current status.

Recommendation 4: The review team recommends that the Commonwealth develop and implement a reliable mechanism to identify when a license is in need of a comprehensive renewal, identify these licenses, and develop and implement a plan to perform these renewals.

Status: Mr. Pendergrass stated that letters to licensees whose licenses hadn't been amended in their entirety within the last five years had been sent out. Fifty-three amendment in entirety requests were sent out in 2011 with 29 of those still in process. Kentucky stated that some licensees are slow to respond since the license does not expire; however Kentucky can issue Notices of Violation if there is no response from the licensee within 30 days. The Section had been working on these amendments in entirety, however given the upcoming IMPEP, the Section has put these on hold to concentrate on other incoming licensing actions (i.e.: amendments, new license requests). The Section instituted a tracking system to ensure proper tracking of comprehensive license renewals.

Recommendation 5: The review team recommends that the Commonwealth integrate the pre-licensing requirements of FSME 07-026 into their licensing program and reevaluate new licenses issued since September 2007 for implementation of these requirements.

Status: The Program has implemented NRC's pre-licensing guidance and developed a checklist to screen new licensing actions. Staff has received initial and refresher training on the subject matter. The Program has gone back through their files to ensure that all previous new licenses issued during the review period were evaluated based on the pre-licensing criteria.

Kentucky has completed actions with respect to both recommendations. The Program has a working inventory of approximately 100 to 200 licensing actions currently on the books. These range from amendments to new licenses to termination requests to amendments in entirety. The Program has seen an increase in the number of licensing actions related to new applications being received (primarily due to consolidation of medical facilities). The longest licensing action has been pending for approximately 1 year. The Section is aware of the maximum possession limit criteria for licenses and is working to amend their licenses appropriately.

Technical Quality of Incidents and Allegations (2008 IMPEP finding: Satisfactory)

The Program is aware of the need to maintain an effective response to incidents and allegations. Incidents are quickly reviewed for their effect on public health and safety and staff is dispatched to perform onsite investigations when necessary. The Program appropriately communicates reportable incidents to the NRC Operations Center and Region I. Since the last Periodic Meeting in February 2011, the Program has received Nuclear Materials Events Database (NMED)/ SA-300 training and has installed the NMED software onto their computers, which the Program stated is running smoothly and helping the Program to better track incidents that come in. The Program continues to be sensitive to allegations. The Program has received one allegation since the February 2011 Periodic Meeting and is following the procedures currently in place for the handling and follow-up of this allegation.

Compatibility Requirements (2008 IMPEP finding: Satisfactory but Needs Improvement)

Kentucky continues to move forward in this area. The 2008 IMPEP review team noted the

progress the Program made to address overdue regulations. Mr. McKinley stated that Kentucky is continuing to focus attention on bringing the Commonwealth up to date with regulation development.

Nineteen NRC regulations are overdue for implementation:

- “Low-Level Waste Shipment Manifest Information and Reporting,” 10 CFR Parts 20 and 61 (60 FR 15649 and 60 FR 25983), that was due for Agreement State implementation on March 1, 1998. (RATS ID 1995-3)
- “Clarification of Decommissioning Funding Requirements,” 10 CFR Parts 30, 40, and 70 (60 FR 38235), that was due for Agreement State implementation on November 24, 1998. (RATS ID 1995-6)
- “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20 and 35 (60 FR 48623), that was due for Agreement State implementation on October 20, 1998. (RATS ID 1995-7)
- “10 CFR Part 71: Compatibility with the International Atomic Energy Agency,” 10 CFR Part 71 (60 FR 50248 and 61 FR 28724), that was due for Agreement State implementation on April 1, 1999. (RATS ID 1996-1)
- “Minor Corrections, Clarifying Changes and a Minor Policy Change,” 10 CFR Parts 20, 35, and 36 (63 FR 39777 and 63 FR 45393), that was due for Agreement State implementation on October 26, 2001. (RATS ID 1998-5)
- “Transfer for Disposal and Manifests: Minor Technical Conforming Amendment,” 10 CFR Part 20 (63 FR 50127), that was due for Agreement State implementation on November 20, 2001. (RATS ID 1998-6)
- “Respiratory Protection and Controls to Restrict Internal Exposure,” 10 CFR Part 20 (64 FR 54543 and 64 FR 55524), that was due for Agreement State implementation on February 2, 2003. (RATS ID 1999-3)
- “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 (65 FR 20337), that was due for Agreement State implementation on May 17, 2003. (RATS ID 2000-1)
- “New Dosimetry Technology,” 10 CFR Parts 34, 36, and 39 (65 FR 63749), that was due for Agreement State implementation on January 8, 2004. (RATS ID 2000-2)
- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, and 32 (65 FR 79162), that was due for Agreement State implementation on February 16, 2004. (RATS ID 2001-1)
- “Revision of the Skin Dose Limit,” 10 CFR Part 20 (67 FR 16298), that was due for Agreement State implementation on April 5, 2005. (RATS ID 2002-1)
- “Medical Use of Byproduct Material,” 10 CFR Parts 20, 32, and 35 (67 FR 20250), that was due for Agreement State implementation on October 24, 2005. (RATS ID 2002-2)
- “Financial Assurance for Materials Licensees,” 10 CFR Parts 30, 40, and 70 (68 FR

57327), that was due for Agreement State implementation on December 3, 2006. (RATS ID 2003-1)

- “Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments,” 10 CFR Part 71 (69 FR 3697), that was due for Agreement State implementation on October 1, 2007. (RATS ID 2004-1)
- “Medical Use of Byproduct Materials - Recognition of Specialty Boards - Part 35,” 10 CFR Part 35 (70 FR 16336 and 71 FR 1926), that was due for Agreement State implementation on April 29, 2008. (RATS ID 2005-2)
- “Security Requirements for Portable Gauges Containing Byproduct Material,” 10 CFR Part 30 (70 FR 2001), that was due for Agreement State implementation on October 1, 2007. (RATS ID 2005-1)
- “Minor Amendments,” 10 CFR Parts 20, 30, 32, 35, 40, and 70 (71 FR 15005), that was due for Agreement State implementation on March 27, 2009. (RATS ID 2006-1)
- “Medical Use of Byproduct Material - Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 (72 FR 45147, 54207) that was due for Agreement State implementation on October 29, 2010. (RATS ID 2007-1)
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 (72 FR 68043) that was due for Agreement State implementation on February 15, 2011. (RATS ID 2008-1)

Kentucky submitted 12 regulation amendment changes to the NRC for final review in January 2012. Once Kentucky receives NRC’s response regarding the review of their final regulations, the Section plans to work on one RATS ID per month until they have completed all rule changes needed for compatibility.

Sealed Source and Device (SS&D) Evaluation Program (2008 IMPEP finding: Satisfactory)

There have been no changes in the SS&D program since the February 2011 Periodic Meeting. The 2008 IMPEP review team generated one recommendation for this performance indicator. This recommendation is listed below along with its current status.

Recommendation 6: The review team recommends that the Commonwealth develop and implement a mechanism to verify the implementation of the approved quality assurance and quality control program.

Status: This recommendation was implemented within a few days of the 2008 IMPEP as Kentucky only has one licensee that falls into this category. Kentucky added this item to their inspection form to assure that inspectors verified these elements for SS&D manufacturers.

Kentucky currently has two qualified SS&D reviewers one of whom who will be retiring in March. The retiring individual did all of the Section’s SS&D work. Since learning of this individual’s impending retirement, Kentucky is working to qualify at least one more individual to perform SS&D reviews. Several of the Section staff has attended the SS&D workshop. The amount of incidents in NMED related to SS&D’s manufactured by the one SS&D licensee in Kentucky was discussed. The Section agreed to look at these incidents in NMED to determine if there was an underlying issue with device from this licensee.

Low-Level Radioactive Waste Disposal (LLRW) Program (2008 IMPEP finding: Satisfactory)

Kentucky's LLRW program consists of oversight at one facility, the Maxey Flats site, which is located in eastern Kentucky. The site operated a commercial LLRW disposal facility from May 1963 through December 1977. The license for this site authorizes maintenance activities related to the closed LLRW disposal site. Since the facility is closed and has no on-site activity or operations, the activities at the site are limited to a radiological environmental monitoring program consisting of soil, surface water, and ground water monitoring. This site has been an ongoing issue and the Program may request NRC assistance in the future for site closure discussions.

Our Lady of Bellefonte (OLBH)/ Highlands Regional Medical Events

The Section gave an update as to the status of Kentucky's ongoing investigation into several prostate brachytherapy medical events related to one particular Authorized User (AU) working at two separate hospitals. Kentucky has received some of the information that they requested from their licensees. Currently OLBH has hired a contractor to analyze the patient data. Once the contractor has finished their analysis they will provide this information to Kentucky for review. Currently OLBH has terminated their prostate brachytherapy program and Highlands Regional has temporarily suspended their program while they look for a new AU to perform the procedure. Kentucky continues to investigate these events and will provide NRC with updates as more information is received. The Section is hopeful that a resolution and close out of both these cases will be achieved by April 2012.

Conclusion

Kentucky's program continues to improve. Kentucky has been responsive to the recommendations that were made during the 2008 IMPEP review. The Section is currently operating with one unfilled staff position due to a military deployment. Twelve final overdue regulations were submitted for NRC review. NRC is in the process of reviewing the final regulations and hopes to have a response to Kentucky no later than March 2012.