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December 5, 2016

MEMORANDUM TO: Marc L. Dapas, Director
Office of Nuclear Material Safety
and Safeguards

Mary B. Spencer, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Pamela J. Henderson, Deputy Director
Division of Material Safety, State, Tribal, and
Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Darrell J. Roberts, Deputy Regional Administrator
NRC Region III

FROM: Lisa C. Dimmick, Senior Health Physicist */RA/*
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Division of Material Safety, State, Tribal,
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Office of Nuclear Material Safety and Safeguards

SUBJECT: MINUTES: OCTOBER 20, 2016 KENTUCKY
MANAGEMENT REVIEW BOARD MEETING

Enclosed are the minutes of the Management Review Board (MRB) meeting held on October 20, 2016, for the Kentucky Agreement State program. If you have comments or questions, please contact me at (301) 415-0694.

Enclosure:
MRB Meeting Minutes

cc: BJ Smith, MS
Organization of Agreement States
Liaison to the MRB

Management Review Board Members

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MINUTES: MANAGEMENT REVIEW BOARD MEETING OF KENTUCKY
October 20, 2016

The attendees were as follows:

In person at U.S. Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland:

Marc Dapas, MRB Chair, NMSS
Mary Spencer, MRB Member, OGC
Pam Henderson, MRB Member, NMSS
Jim Lynch, Team Leader, RIII
Vince Holahan, NMSS

Lisa Dimmick, NMSS
Paul Michalak, NMSS
Duncan White, NMSS
Curt Pendergrass, KY
David Spackman, NMSS

By videoconference:

Darrell Roberts, MRB Member, Region III
Jackie Cook, Team Member, Region IV
Donna Janda, Team Member, Region I

Joe Nick, Region I
Monica Ford, Region I
Kathy Modes, Team Member, NMSS

By telephone:

BJ Smith, MRB Member, MS, OAS
Dwight Shearer, Team Member, PA
Lizette Roldan-Otero, NMSS

Ron Parsons, Team Member, TN
Matt McKinley, KY

1. Convention. Ms. Lisa Dimmick convened the meeting at 1:00 p.m. (ET). She noted that this Management Review Board (MRB) meeting was open to the public. Ms. Dimmick then transferred the lead to Mr. Marc Dapas, Chair of the MRB. Introductions of the attendees were conducted.
2. Kentucky IMPEP Review. Mr. Jim Lynch, Team Leader, led the presentation of the Kentucky Integrated Materials Performance Evaluation Program (IMPEP) review results to the MRB. He summarized the review and the team's findings for the eight indicators reviewed. The on-site review was conducted by a review team composed of technical staff members from the NRC and the Commonwealth of Pennsylvania and the State of Tennessee during the period of July 25–29, 2016. A draft report was issued to Kentucky for factual comment on August 31, 2016. Kentucky responded to the review team's findings by e-mail dated October 3, 2016. Mr. Lynch reported that the team found the Kentucky Agreement State Program satisfactory for seven of eight performance indicators reviewed. The Compatibility Requirements indicator was found unsatisfactory.
3. Common Performance Indicators.
 - a) Mr. Lynch reviewed and presented the common performance indicator, **Technical Staffing and Training**. His presentation corresponded to Section 3.1 of the proposed final IMPEP report. The Radiation Health Branch (Branch) is comprised of a manager, a supervisor, and seven staff members which equals approximately 8.2 full-time equivalents for the radioactive materials program. Currently, there are no vacancies, and the Branch is fully staffed. During the review period, one of the staff members left the program and three staff members

were hired, filling vacant positions. All of the staff members are fully qualified in licensing and inspection for either medical or industrial programs. Several staff members are undergoing qualifications for full qualification of all license types. Kentucky has a training and qualification manual compatible to IMC 1248. The review team also found that the Kentucky's training and qualification manual was compatible with NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

- b.) Mr. Dwight Shearer reviewed and presented the common performance indicator, **Status of Materials Inspection Program**. His presentation corresponded to Section 3.2 of the proposed final IMPEP report. Kentucky performed 203 Priority 1, 2, 3, and initial inspections during the review period. Kentucky conducted two percent of Priority 1, 2, 3, and initial inspections overdue. In 2012, this indicator was found unsatisfactory: 25 percent of inspections were conducted overdue. The 2012 MRB recommended that the Branch perform a self-assessment to determine the effectiveness of its oversight of the inspection program. The Branch implemented a new inspection tracking database allowing for simplified tracking of inspection metrics. The changes adopted by Kentucky allow managers to be aware of potential inspection backlogs. The review team determined that these efforts were effective in Kentucky's oversight of the materials inspection program. The review team recommended, and the MRB agreed, that this recommendation be closed. In 2016, the Branch performed a self-assessment and determined that it was incorrectly prioritizing service providers requesting reciprocity. A recalculation of reciprocity frequencies indicated that Kentucky performed only 13 percent of candidate reciprocity inspections in 2012, but had an inspection percentage above 20 percent for each of the last 3 years.

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

- c.) Mr. Shearer reviewed and presented the common performance indicator, **Technical Quality of Inspections**. His presentation corresponded to Section 3.3 of the proposed final IMPEP report. The review team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 29 materials inspections conducted during the review period. The casework reviewed included inspections conducted by nine current and former inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses. Review team members accompanied eight program inspectors in April and June 2016. The inspectors were adequately prepared and conducted performance-based inspections. Over the past two IMPEP

review periods, Kentucky developed a robust General License (GL) program for certain types of generally licensed devices, particularly fixed gauges. The GL program incorporates a tracking database, inspections, and fees. Inspections are performed at 5-year intervals.

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

- d.) Ms. Jackie Cook reviewed and presented the common performance indicator, **Technical Quality of Licensing Actions**. Her presentation corresponded to Section 3.4 of the proposed final IMPEP report. During the review period, Kentucky performed 2,856 radioactive materials licensing actions. The review team evaluated 27 of these actions. The licensing actions selected for review included six new applications, nine amendments, seven renewals (amendments in entirety), four terminations, and one bankruptcy filing. The review team evaluated casework which included the following license types and actions: broad scope academic, broad scope medical, medical diagnostic and therapy, other manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, self-shielded irradiators, well-logging, service providers, and bankruptcy. The casework sample represented work from nine license reviewers, including one former license reviewer. Terminated licensing actions were well documented, showing transfer to authorized recipients and final status surveys, as appropriate. All licensing actions undergo a peer review and management review by the Section Supervisor. The Branch performed a self-assessment of the pre-licensing program in response to the NRC's publication of Radiation Control Program Directors (RCPD)-15-010 in October 2015, entitled "The Importance of Using Pre-Licensing Guidance and Site Visits During the Licensing Process." The RCPD letter requested that the Agreement States conduct a self-assessment or audit of those licenses in which pre-licensing guidance was used and required. Kentucky performed a retroactive review of all pre-licensing actions to ensure that appropriate determinations had been made, in spite of the weaknesses identified in the process. Kentucky's pre-licensing review methods now incorporate the essential elements of the NRC's pre-licensing guidance to verify that an applicant will use requested radioactive materials as intended.

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

- e.) Ms. Donna Janda reviewed and presented the findings regarding the common performance indicator, **Technical Quality of Incident and Allegation Activities**. Her presentation corresponded to Section 3.5 of the proposed final IMPEP report. During the review period, Kentucky reported 25 incidents to the NRC. The review team evaluated 17 radioactive materials incidents which included 11 medical events and 6 damaged equipment events. The review team

also evaluated one potential overexposure event which Kentucky determined not to be an overexposure. The review team determined that the potential overexposure was correctly categorized by the Branch as non-reportable. Kentucky dispatched inspectors for onsite followup for nine of the cases reviewed. For the incidents that did not receive an onsite followup inspection, the review team determined that Kentucky conducted appropriate followup activities via telephone and/or e-mail to ensure that public health and safety were protected. Kentucky received six allegations during the review period. The review team evaluated all six allegations, including two allegations that the NRC referred to Kentucky during the review period. The review team evaluated the completed casework and determined that the Branch took prompt and appropriate action in response to the concerns raised. The concerned individuals were notified of the findings. The team found that the Branch adequately protected the concerned individuals' identity.

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

4. Non-Common Performance Indicators.

- a.) Ms. Janda reviewed and presented the non-common performance indicator, **Compatibility Requirements**. Her presentation corresponded to Section 4.1 of the proposed final IMPEP report. No legislation affecting the radiation control program was passed during the review period. The State's administrative rulemaking process takes approximately 12 months from drafting to finalizing a rule. During the review period, the Branch submitted one final regulation amendment and six proposed regulation amendments to the NRC for a compatibility review. The review team determined that during the review period, Kentucky did not meet all of the performance indicator objectives. Specifically, Kentucky had not adopted final regulations for 12 NRC amendments within the required 3-year timeframe. This represents an increase of seven overdue amendments since the 2012 IMPEP review. The review team considered making a formal recommendation to Kentucky for addressing the overdue regulations; however, because Kentucky has already developed a written plan and implemented a path forward to adopt all applicable NRC regulations by reference, the review team did not make a recommendation for this indicator. Kentucky started adoption by reference with 10 CFR Part 37 which was adopted timely and as a final regulation in February 2016. At the time of the team's review, Kentucky was in the process of adopting by reference specific tables from 10 CFR Parts 20 and 30. These regulations were finalized on August 17, 2016. The Branch intends to adopt all applicable NRC regulations by reference by June of 2018. The plan was shared with the review team at the time of its review. The Branch provided the plan in writing just prior to the October 20 MRB meeting. The MRB acknowledged the Branch's significant action to address the regulation backlog that has been accruing over time. The Branch's plan is

available in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML16298A199.

The review team found Kentucky's performance with respect to this indicator to be "unsatisfactory." The MRB agreed that Kentucky's performance met the criteria for an "unsatisfactory" rating for this indicator.

- b.) Mr. Ron Parsons reviewed and presented the non-common performance indicator, **Sealed Source and Device (SS&D) Evaluation Program**. His presentation corresponded to Section 4.2 of the proposed final IMPEP report. Kentucky currently has one device manufacturer who has 11 active SS&D registrations. Registrations clearly summarize the product evaluations and provide license reviewers with adequate information to license the possession and use of the products. Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. Overall, the review team determined that the product evaluations were thorough, complete, consistent, of acceptable quality, and adequately addressed the integrity of the product during use and under accident conditions. There were 31 events reported nationally over the review period for Kentucky's one device manufacturer. The review team determined that the Branch analyzed the events, reviewed the issues, and followed up on the incidents with the manufacturer, as appropriate. None of the events were related to manufacturing or design of the product.

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

- c.) Ms. Kathy Modes reviewed and presented the non-common performance indicator, **Low-level Radioactive Waste Disposal Program**. Her presentation corresponded to Section 4.2 of the proposed final IMPEP report. The review team noted that the Maxey Flats Disposal Site (MFDS) is a closed radioactive waste burial facility and the Final Closure Period is nearing completion. The review team noted that the Branch has conducted inspections biannually. The Branch shared the July 2014 inspection findings with the licensee, but has delayed issuance of the inspection report. In addition the Branch has not issued the renewal (amendment in its entirety) for the MFDS license. The review team discussed a rating of satisfactory versus satisfactory, but needs improvement for the indicator. However, the review team determined that this indicator should be found satisfactory with a recommendation. The Cabinet for Health and Family Services Cabinet is responsible for regulatory oversight of MFDS and the oversight is implemented by the Branch. The MRB noted that without issuance of inspection reports, there is no public visibility with respect to the results of the Branch's execution of its oversight responsibilities for MFDS in accordance with Kentucky's requirements. To ensure openness and transparency regarding the Branch's monitoring and oversight of MFDS, the team recommended, and the MRB agreed, that the Branch ensure timely and consistent issuance of licensing actions and inspection results for the MFDS.

The review team found Kentucky's performance with respect to this indicator to be "satisfactory." The MRB agreed that Kentucky's performance met the criteria for a "satisfactory" rating for this indicator.

5. MRB Consultation/Comments on Issuance of Report. The review team recommended, and the MRB agreed, that the Kentucky Agreement State Program be found adequate to protect public health and safety and not compatible with the NRC's program. The failure by Kentucky to adopt regulations, or other legally binding requirements, in a timely manner, creates a gap in the collective national effort to regulate radioactive materials, which led to the not compatible finding. The review team recommended, and the MRB agreed, the next IMPEP review take place in approximately 4 years with a periodic meeting mid-cycle. The final report may be found in the ADAMS using the Accession Number ML16299A197.
6. Precedents/Lessons Learned. None applicable to this review
7. Adjournment. The meeting was adjourned at approximately 2:45 p.m. (ET)