



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PA 19406-2713

July 29, 2014

Matthew McKinley, Administrator
Radiation Health Program
Cabinet for Health & Family Services
275 East Main Street, HS1C-A
Frankfort, KY 40621-0001

Dear Mr. McKinley:

A periodic meeting with you and your staff was held on July 9, 2014. The purpose of this meeting was to review and discuss the status of the Kentucky Agreement State Program. The U.S. Nuclear Regulatory Commission (NRC) was represented by James Clifford, Duncan White, and me.

I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions. A Management Review Board (MRB) meeting to discuss the outcome of the periodic meeting has been scheduled for September 23, 2014 at 1:00pm. Call in information for the MRB has been provided in a separate transmission.

If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at (610) 337-5214 or via e-mail at Monica.Ford@nrc.gov to discuss your concerns.

Sincerely,

/RA/

Monica Lynn Ford
Regional State Agreements Officer
Division of Nuclear Materials Safety
U.S. NRC Region I

Enclosure:
Periodic Meeting Summary for Kentucky

cc w/encl.: Curt Pendergrass, Supervisor
Radioactive Materials Section

July 29, 2014

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SUNSI Review Complete: MLF (Reviewer's Initials) ML14210A556
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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
KENTUCKY CABINET OF HEALTH AND FAMILY SERVICES
RADIATION HEALTH PROGRAM

DATE OF MEETING: July 9, 2014

Nuclear Regulatory Commission (NRC) Attendees	Kentucky Cabinet of Health and Family Services Attendees
Monica Ford, Regional State Agreements Officer, Region I	Matthew McKinley, Administrator, Radiation Health Program
James Clifford, Division Director, Region I	Curt Pendergrass, Supervisor, Radioactive Materials Section
Duncan White, Branch Chief, Office of Federal and State Materials and Environmental Management Programs (FSME)	Kraig Humbaugh, Senior Deputy Commissioner, Department for Public Health (exit only)
	Allyson Taylor, Policy Advisor, Office of the Commissioner, Department for Public Health (exit only)
	Kathy Fowler, Division Director, Division of Public Health Protection and Safety (exit only)

DISCUSSION:

During the 2012 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 the performance indicators Technical Staffing and Training, Technical Quality of Licensing, Technical Quality of Inspections, Technical Quality of Incidents and Allegations, and Sealed Source and Device Evaluation Program; satisfactory but needs improvement for the performance indicator Compatibility Requirements; and unsatisfactory for the performance indicator Status of Materials Inspection Program. On September 6, 2012, 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 NRC's program. The MRB added one recommendation to the final IMPEP report. 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 two years from the June 2012 IMPEP review. DPH provided their response to the final IMPEP report in a letter dated October 18, 2012.

TOPICS COVERED DURING THE MEETING INCLUDED:

Program Strengths

The Program noted two strengths. Program management stated that program staff go above and beyond to figure out better ways to do things and are constantly working together to look for ways to improve the Program. This leads to good staff morale and camaraderie. The Program also noted that managerial support for the Program is excellent at all levels of management.

Program Challenges

Program management stated that one of the Program's challenges is their end licensing product database. The database is very old and is a DOS based system. The Program is unable to do any type of watermark or headers, including security markings, on its licenses. The Program is working on developing a new database in order to address the issues with the current database. Another challenge is the Program's fee structure. Currently the Program charges approximately 10 percent of NRC's fees from the 2008/2009 timeframe. The fees also go into a general fund which can be used by anyone in the Department for Public Health. The Program's regulation promulgation process is a third challenge for the Program. The process can be very lengthy and often causes rules to be promulgated outside of the three year timeframe allowed by the NRC. The Program is considering changing their rules to adopt NRC's regulations by reference. This would alleviate the lengthy rule promulgation process once the adoption by reference is in place.

Feedback on the NRC's Program

The Program commented that both the overall relationship and communications with the NRC are good. The Program also expressed its appreciation for the NRC training classes. The Program did make one suggestion regarding NRC's implementation of Agreement State adoption of NRC rule changes. The Program stated that the way NRC rolls out its changes to regulations, which currently are issued one rule at a time, can be frustrating and cumbersome for the States to deal with. It can also make it difficult for a State to keep their regulations current. The Program suggested a more structured approach to regulations which might include FSME issuing all rule changes that happened in a six or twelve month period as one document and requiring the States to adopt those regulations within three years. The Program also suggested that NRC could formalize a holistic approach to regulations in a policy statement that would outline the rule adoption process for the Agreement States.

Agreement State Program Staffing and Training

At the time of the IMPEP review, the Program was composed of one program administrator, one supervisor, and seven technical staff positions (one of which was on military deployment and not scheduled to return until December 2013 and two of which were vacant). Since the IMPEP review the Program hired two new technical staff members to fill the vacant positions identified during the IMPEP review and the individual on military deployment has returned. The Program also had an additional staff member leave the Program in July 2013 and subsequently hired another new staff member in December 2013 to fill that program vacancy. At the time of the Periodic meeting the Program is fully staffed. The three new staff members are currently working on their qualifications to become qualified license reviewers and inspectors. Since joining the Program, one new staff member has become fully qualified in industrial inspections and is now working on becoming qualified to perform medical inspections, the second new staff member is almost fully qualified in industrial inspections, with the exception of industrial radiography inspections, and will begin working on becoming qualified in medical inspections once the industrial qualifications are completed, and the third new staff member is working on becoming a qualified inspector for medical inspections, however is not currently qualified to perform any types of inspections since they have only been with the program approximately seven months. All of the new staff have qualification journals to use as they progress through

their qualifications. The Program will ensure that the qualification journal has, at a minimum, the same requirements as NRC's Inspection Manual Chapter 1248 "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."

The Program continues to support staff training and utilizes the NRC training courses when available. The Program is hopeful that two of their new staff will be able to attend the S-201 course in the next NRC fiscal year. The Program also hosted a Sealed Source and Device Evaluation Training workshop in March 2014.

Organization

The Program is administered by the Radiation Health Branch, which is located within the Department for Public Health. The Department for Public Health is part of the Cabinet for Health and Family Services.

Program Budget/Funding

The Program currently charges around ten percent of NRC's fees from the 2008/2009 time frame. The fees go into a general fund which can be used to fund any program in the Department of Public Health. The Program is looking at changing its fee structure so that each modality would be charged a fee. This would require the Program to separate out each license based on modality so that fees are charged appropriately.

Licensing and Inspection Programs

The Program currently has approximately 398 specific licenses. The Program has completed 1509 licensing actions since the last IMPEP review. At the time of the periodic meeting there were 32 pending licensing actions in house. The longest action has been in house since December 2013 (a new license). The Program has been working with the new licensee to obtain additional information that was needed before the license can be issued. The average turnaround time for a licensing action is 43 days. All completed licensing actions undergo a three step process: initial review, peer review, and supervisor review before being signed by the program administrator and then issued.

The IMPEP review found that the Program completed 41 percent of its priority 1, 2, and 3 and initial inspections overdue during the review period. Since the IMPEP review the Program has conducted one inspection overdue which was an initial inspection. This inspection was overdue at the time of the IMPEP review. Based on the number of inspections completed since the IMPEP, the Program is calculating that they have completed 1.53 percent of Priority 1, 2, and 3 and initial inspections overdue. The Program's inspection frequencies are the same as NRC's inspection frequencies as listed in Inspection Manual Chapter 2800. As mentioned above one initial inspection was completed greater than one year from license issuance since the IMPEP review. Program management stated that the Program has inspected greater than the required 20 percent of candidate licensees for reciprocity in calendar year 2013 and to date in calendar year 2014. The Program's policy is to issue inspection findings to their licensee's within 30 days from the date of the inspection. The Program performed supervisory accompaniments for its entire staff in 2012 and 2013. The Program has two supervisory inspection accompaniments left to complete in 2014.

The 2012 IMPEP review generated one recommendation for this performance indicator. The recommendation is listed below along with the status.

Recommendation 1: The MRB recommends that the Branch perform a self-assessment to determine the effectiveness of its oversight of the inspection program and that the results of this self-assessment be reviewed as part of the periodic meeting.

Status: The Program submitted the self-assessment and the resulting programmatic changes to the NRC on July 3 and 7, 2014. All of these documents were discussed with the Program during the periodic meeting. The changes put in place by the Program will help to identify and prevent circumstances in the future that would cause program management to be unaware of the extent of the actual backlog of inspections that may be occurring as the Program responds to an unusual event. Along with updating several procedures the Program also put a new inspection tracking database into place. This new database allows for simplified tracking of inspection metrics and removes the uncertainty that resulted from the transition of one previous database to another during the timeframe covered by the previous IMPEP review. This transition between databases made it difficult for the Program to compile continuous data during the 2008-2012 timeframe and therefore the Program struggled to complete certain data dependent sections of the IMPEP questionnaire making them unaware of the overall impact of the performance of overdue inspections.

Regulations and Legislative Changes

The Branch is designated as the Commonwealth's radiation control agency. No legislation affecting the Program was passed since the last IMPEP review and the Program is not subject to sunset requirements.

When the Program promulgates a rule they must first send the draft changes to the Cabinet for Health and Family Services for comment. Then once those comments are incorporated the draft changes go to the Legislative Review Committee for comment. Lastly the rules go to a subcommittee in the Legislature for approval for public comment. Then once public comments are received the regulations must go through the entire process again before becoming final. This process can take several years to complete.

The Program stated that given the number of issues they are having in regards to adopting regulations they are in the process of exploring adopting applicable sections of NRC's Title 10 Code of Federal Regulations (CFR) by reference. The Program stated that they plan to address 10 CFR Part 37 this way and hope to get it to the Cabinet by the end of calendar year 2014. The Program believes that they will be able to get this regulation promulgated in final before the March 2016 deadline, however if they determine they will not meet the deadline the Program will implement adoption of 10 CFR Part 37 by license condition.

Six NRC regulations are overdue for implementation:

- "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;

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

Event Reporting

The Program has had eight reportable events since the IMPEP review. All reportable events have been reported to the NRC accordingly and appropriate follow-up through NMED has occurred. The Program stated that all staff is aware of event reporting criteria.

Response to Incidents and Allegations

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. The Program continues to be sensitive to allegations. The Program has received one allegation and one additional concern, involving items being sold on eBay, for action since the IMPEP.

Sealed Source and Device Evaluation (SS&D)

There have been no changes in the SS&D program since the IMPEP. The Commonwealth has one device manufacturer with 12 active SS&D registrations. The Program has completed two amendments to active registries since the IMPEP review and the Program has no pending actions at the time of this meeting. The last action received, an amendment, was completed and the revised sheet was issued on August 16, 2013. The Program has two qualified SS&D reviewers. The Program is working to qualify one more individual to perform SS&D reviews. This individual is learning the process as SS&D requests come in. The Program hosted the SS&D Workshop in March 2014.

Low-Level Radioactive Waste Disposal (LLRW) Program

Kentucky's LLRW program consists of oversight at one facility; the Maxey Flats site (Site), which is located in eastern Kentucky. The Program stated during the periodic meeting that they were having difficulty maintaining a regulatory posture at the Site.

The Site operated a commercial LLRW disposal facility from May 1963 through December 1977. The site was added to the National Priorities list in 1986, a record of decision was issued in 1991, and a consent decree was entered in 1995. The consent decree in Section I Part C states "Pursuant to the requirements of the AEA, the Site is owned by the Commonwealth of Kentucky ("Commonwealth"). The Commonwealth, through the Cabinet for Human Resources, exercises regulatory authority over the Site pursuant to its status as an "Agreement State" under the AEA and the Kentucky Cabinet for Natural Resources and Environmental Protection is the current licensee of the Site."¹ The site is currently in the Final Closure Period.

The Program maintains a license for the Site which is issued to the Kentucky Energy and Environment Cabinet. The license for this site authorizes possession and activities associated with maintenance related to the closed LLRW disposal site. It is important to note that the Cabinet for Health and Family Services is designated as the radiation control agency for the Commonwealth of Kentucky in Kentucky Revised Statute (KRS) 211.842. KRS 211.842 goes on further to state "(2) The Cabinet for Health and Family Services shall issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation. (3) The Cabinet for Health and Family Services shall develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, nonionizing, and electronic product radiation. (4) The cabinet or its duly authorized representative may enter at a reasonable time upon the property of a licensee, registrant, or other person where sources of ionizing, nonionizing, or electronic product radiation are reasonably believed to be located for the purpose of determining whether or not such licensee, registrant, or other person is in compliance with or in violation of the provisions of KRS 211.842 to 211.852 and administrative regulations promulgated hereunder, and the owner, occupant, or person in charge of the property shall permit entry and inspection; provided, that entry into areas under the jurisdiction of an agency of the federal government or its duly designated representative shall be only upon permission of the agency or its representative." KRS 211.846 then states "The Cabinet for Health and Family Services shall monitor radioactive waste material sites in Kentucky for the protection of the public health, safety, and welfare. The Finance and Administration Cabinet and the Cabinet for Health and Family Services shall cooperate and coordinate their activities in the leasing, regulation, monitoring, and control of radioactive waste material burial sites." The Program, per KRS and as delegated by the Cabinet for Health and Family Services, has the lead for licensing activities for this Site as well as determining whether or not the licensee is in compliance with or in violation of the KRS and administrative regulations promulgated as a result of the KRS. The Program is continuing to work on bringing about a resolution regarding the potential regulatory issues associated with this Site.

¹ The Cabinet for Human Resources is now known as the Cabinet for Health and Family Services and the Cabinet for Natural Resources and Environmental Protection is now known as the Energy and Environment Cabinet.

CONCLUSIONS:

The Program continues to be an effective and well maintained Agreement State program. Since the last IMPEP three new technical staff members have joined the Program filling the two vacancies noted at the time of the last IMPEP review and the one created by the departure of a current staff member in July 2013. The Program has no inspections of priority 1, 2, and 3 overdue by more than 25 percent of their inspection due date and has completed one initial inspection overdue since the last IMPEP review. The Program has a minimal licensing backlog and has six regulations overdue for adoption. The Program has taken action to complete the one open recommendation from the 2012 IMPEP review. Based on the above, NRC staff recommends that the Kentucky Agreement State Program be removed from monitoring and that the next IMPEP review be conducted as scheduled in June 2016.