August 1, 2005

Clyde Bolton, Director
Division of Public Health Protection & Safety
Department of Public Health
275 East Main Street
Mail Stop HS 2E-D
Frankfort, KY 40621-0001

Dear Mr. Bolton:

A periodic meeting with Kentucky was held on July 14, 2005. The purpose of this meeting was to review and discuss the status of Kentucky’s Agreement State program. Our October 26, 2004 letter to William D. Hacker, M.D., Commissioner, indicates that a periodic meeting should take place in July 2005 due to the performance of the program during the July 19-23, 2004, IMPEP review. Specific topics discussed at the meeting included staffing, the program’s progress on the seven recommendations made during the 2004 IMPEP review, and impact to the performance of the program due to loss of the Radiation Health Branch Manager that occurred on May 31, 2005.

I have completed and enclosed a general meeting summary. It was noted during the meeting that the program’s overall performance has declined since the 2004 IMPEP review. In particular, the program’s performance has declined with respect to two of the performance indicators, “Technical Staffing and Training” and “Status of Materials Inspection Program”. Performance with regard to the remaining indicators has not changed over the last year.

As discussed with you and Dr. Hacker during the meeting, it appears that staffing changes, namely loss of an experienced staff member, a newly-hired staff, and the Radiation Health Branch Manager, as well as staffing shortages, has caused lack of progress in addressing the recommendations. The recommendations from the 2004 review, many of which are contingent upon the program hiring additional staff, remain open. It was noted that both you and Dr. Hacker expressed your commitment to getting the program up to its full staffing level in order to improve program performance.

This meeting will be discussed at a future Management Review Board meeting.
C. Bolton  
Division of Public Health Protection & Safety

If you feel that my conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at 610-337-5358 or email to sam9@nrc.gov to discuss your concerns.

Thank you and your staff for the exchange of information.

Sincerely,

Original signed by Duncan White

Sheri Minnick  
Regional State Agreements Officer  
Division of Nuclear Materials Safety

Enclosure: As stated

cc w/enclosure:  
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OFFICIAL RECORD COPY
AGREEMENT STATE PERIODIC MEETING SUMMARY FOR KENTUCKY

DATE OF MEETING: July 14, 2005

ATTENDEES:

NRC
Sheri Minnick, RSAO, Region I

STATE
William D. Hacker, M.D., Commissioner
Clyde Bolton, Director, Division of Public Health Protection & Safety
Matthew McKinley, Supervisor, Radioactive Materials Section
Rick Horky, Radioactive Materials Section
Robert Gresham, Radioactive Materials Section
Angela Britton, Radioactive Materials Section
Curt Pendergrass, Radioactive Materials Section

BACKGROUND:

During the July 2004 IMPEP review, the review team found Kentucky’s performance to be satisfactory for five performance indicators and satisfactory, but needs improvement, for three performance indicators. Seven recommendations were made by the IMPEP team. Accordingly, the review team recommended and the MRB agreed with the finding that the Kentucky Agreement State program is adequate to protect public health and safety and compatible with NRC’s program. The team considered a finding of adequate, but needs improvement, but noted that the Branch identified a number of needed improvements, developed and in some cases implemented action plans to correct specific performance issues and has been approved to expand the Section’s staff. To monitor the Commonwealth’s program progress with regard to their action plans, the MRB directed staff to conduct the periodic management meeting one year after the IMPEP review.

DISCUSSION:

A meeting was held with the Kentucky representatives on July 14, 2005. The topics listed in NRC letter dated May 18, 2005 (ML051390076), to the Director were discussed. Details for each area are discussed below.

CURRENT STATUS OF PERFORMANCE INDICATORS:

Technical Staffing and Training

Status during July 2004 IMPEP review:

The review team considered a finding of satisfactory, but needs improvement, for this indicator based on the complete turnover of staff and the number of identified weaknesses. However, the review team notes that the Branch identified a number of needed improvements, developed and in some cases implemented action plans to
correct specific performance issues. In addition, the Branch continued to perform the core inspection and licensing functions and has recently received authorization to fill one vacant position and to add two new positions. The review team concluded that the Branch has an adequate plan to sufficiently staff the Section and make the necessary improvements to the program. Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

Current Status:

The Radiation Health Branch is located in the Department for Public Health offices in Frankfort. The Branch Manager is responsible for the Radioactive Materials Section, Radiation Producing Machines Section, and the Radiation/Environmental Monitoring Section. The position reports to the Director, Division of Public Health Protections & Safety. The Branch Manager left the program on May 31, 2005. The Director stated that the Division will be interviewing two internal candidates and expects to select a candidate to fill the position during the week of July 18, 2005. As of July 25, 2005, the Director reported that a candidate for the position has been selected and the decision to hire has been formally approved by the Cabinet.

The Radioactive Materials Section Supervisor (Supervisor) is primarily responsible for materials licensing and compliance activities. At the time of the July 2004 IMPEP, there were five technical staff members in the Section. The Section had one vacancy (separate from the 2.5 FTE discussed below), which the Branch had been given authority to fill, in the midst of a hiring freeze. An applicant was selected, however the individual resigned shortly thereafter. The vacancy has been reposted. Since that time, one member of the staff was activated to military duty in May 2005 and date of return to the program in unknown at this time. Currently two staff members are fully qualified and two newer staff members will soon be interim qualified. The most experienced staff member has been with the program since 2001.

The Director stated that he has been working hard at trying to make progress in the staffing levels of the Division. He expressed his commitment to increased staffing of the Radioactive Materials Section. He received authorization to add 2.5 FTE for activities under the Agreement State program and is awaiting the approval to hire. On July 11, 2005, an exemption request to the Commissioner was submitted by the Director in order to fill the 2.5 funded positions. Two FTE will be utilized for licensing and inspection. Improvements to the SS&D program are planned through the additional 0.5 FTE. The Division has also received approval for 2 FTE overhire positions. The Director expressed that he is placing importance on recruiting and potential salary upgrade efforts, in order to combat the lack of staffing in the current program.

**Status of Materials Inspection Program**

Status during July 2004 IMPEP review:
Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

Current Status:

The Branch’s inspection priorities are generally the same as those listed in NRC Manual Chapter (MC) 2800, with some being more restrictive. At the time of the last IMPEP, there were 10 core licenses currently overdue by more than 25 percent of the NRC inspection frequency. A current query of the database shows that the Branch has approximately 20 core licenses currently overdue by more than 25 percent and a number of initial inspections that have not been completed within one year. The Supervisor stated that, if he can fill the additional 2 funded positions, he expects the Section to get caught up on the overdue inspections within one year.

Technical Quality of Inspections

Status during July 2004 IMPEP review:

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

Current Status:

Based on discussions with staff, there has been no change in the technical quality of inspections since the IMPEP review. Only qualified inspectors are performing inspections. Two members of the staff will soon be interim qualified and will be performing lower priority inspections.

Technical Quality of Licensing Actions

Status during July 2004 IMPEP review:

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

Current Status:

Based on discussions with staff, there has been no change in the technical quality of licensing actions since the IMPEP review. Only qualified license reviewers are performing licensing actions.

Technical Quality of Incident and Allegation Activities

Status during July 2004 IMPEP review:
Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Technical Response to Incident and Allegation Activities, be found satisfactory, but needs improvement.

Current Status:

Four incidents occurred since the last IMPEP. Initial responses to the incidents appeared to be prompt with the level of effort commensurate with the health and safety significance. Follow-up of the events included investigations and gaining corrective actions from the licensees. The Section dispatched inspectors for on-site investigations when appropriate.

The Supervisor uses the program’s procedures for documenting responses to incidents and allegations. A training class was conducted for staff on the proper documentation of incidents and allegations as well as a booklet that includes NRC guidance and the Branch’s policy. During the past year, four event reports were submitted to the Nuclear Materials Events Database (NMED). Upon review, it appears that reports are being submitted appropriately but subsequent follow-up reports are not being made. NRC has requested additional information for three of the four events because the record is not complete. All four events will remain open in NMED until the State requests them to be closed.

No allegations were referred to Kentucky since the last IMPEP. No allegations were reviewed during this meeting.

Compatibility Requirements

Status during July 2004 IMPEP review:

Based on IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

Current Status:

In September 2004, the Branch submitted proposed revisions to their regulations for “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995. The NRC performed a review and is awaiting a final, amended version based upon three comments that were identified.

The Branch currently has the following five overdue NRC amendments, work on which will be delayed until additional staffing is obtained:

1. “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998.


5. “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. The Branch has amended the appropriate licenses with license conditions compatible with the requirements in 10 CFR 32.52 (a) and (b). The Branch has not adopted the remainder of the amendment.

Sealed Source and Device (SS&D) Evaluation Program

Status during July 2004 IMPEP review:

Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory, but needs improvement.

Current Status:

The Branch’s sole manufacturer is Ronan Engineering. After considering turning the SS&D program back to the NRC, Kentucky decided not to relinquish the program. The Supervisor stated that they currently have no pending technical changes for this manufacturer and there are only minor amendment requests to the registration certificates that his staff can handle. No pending requests were reviewed during the meeting.

The Division has received approval to fund 0.5 FTE to perform this function. After training and qualification, this individual will be tasked with terminating Ohmart’s old registries since they no longer manufacture in Kentucky, develop a registration certificate evaluation and document format consistent with NUREG-1556, Volume 3, and develop license conditions to require Ronan to report defects, deviations, or non-conformance of safety related system, structures or components. In the interim, the Section plans to send two staff members to the NRC’s SS&D training workshop.

Low-Level Radioactive Waste (LLRW) Disposal Program

Status during July 2004 IMPEP review:
Based on the IMPEP evaluation criteria, the review team recommends that Kentucky’s performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, be found satisfactory.

Current Status:

No change in status was identified.

ACTION ON JULY 2004 IMPEP RECOMMENDATIONS:

1. Recommendation:

The review team recommends that the Branch upgrade their database so that all relevant licensee data are incorporated and maintained to ensure that inspections can be scheduled and performed in accordance with the requirements of MC 2800. Specifically, initial inspection due dates were not entered, and thus a large number of initial inspections were overdue.

Status:

The Supervisor is working towards a permanent upgrade to the database and expects completion of this recommendation by December 2005. Until this is completed, information needed so that initial inspections can be scheduled in accordance with MC 2800, is being entered manually.

In addition to needed database upgrades with regard to initial inspections of new licensees, the database needs to be upgraded for other licensees. Specifically, it was noted that the current database does not list inspection priorities (intervals) for many licensees. For example, the Supervisor provided a report from a recent query of the database in order to provide a list of all licensees with currently due inspections. The report headings are: license number, name, next inspection date, priority, program code, and location. The report lists 35 licensees without inspection priorities. The blank fields in the database make it difficult to quickly determine if a licensee is overdue for an inspection. The blank fields also raise questions as to the validity of the next inspection date, since it appears that it is being manually entered, rather than automatically determined by the inspection interval. A review of casework files would be needed in able to determine if the next inspection date is correct for these licensees.

This recommendation remains open.

2. Recommendation:

The review team recommends that the Branch identify those licensees who require financial assurance and take appropriate action to have them comply with the Commonwealth’s decommissioning and financial assurance requirements.

Status:
The Section has created a reference document to assist staff in determining the need for financial assurance. They plan to add this item to the licensing checklists. Although expected to be completed in the 2nd quarter of 2005, based upon lack of staffing, an evaluation of which licensees need financial assurance has not yet been completed. The State expects to have this completed by the fourth quarter 2005.

This recommendation remains open.

3. Recommendation:

The review team recommends that the Branch document incident and allegation responses in accordance with its procedures and provide training on their procedures to all technical staff.

Status:

The Supervisor has been directed to use the procedures for documenting responses to incidents and allegations. A training class was conducted for staff on the proper documentation of incidents and allegations as well as a booklet that includes NRC guidance and the Branch’s policy. During the past year, four event reports were submitted to NMED. Upon review, it appears that reports are being submitted appropriately but subsequent follow-up reports are not being made. INEL has requested additional information for three of the four events because the record is not complete. All four events will remain open in NMED until the State requests them to be closed.

This recommendation remains open.

4-7. Recommendations:

The review team recommends that the Branch establish, implement and document a training program for SS&D reviewers.

The review team recommends that the registration certificate evaluation criteria and document format be consistent with NUREG-1556, Volume 3.

The review team recommends that the Branch review and determine the status of SS&D registrations issued to non-Kentucky manufacturers and take appropriate action to either update or inactivate the registration certificates.

The review team recommends that the Branch implement an enforceable mechanism (e.g., rule or license condition) to have the manufacturers report defects, deviations or non-conformance of safety-related systems, structures, or components and document follow up actions.

Status on 4-7:
The Branch’s sole manufacturer is Ronan Engineering. After considering turning the SS&D program back to the NRC, a decision was made not to relinquish the program. The Supervisor stated that they currently have no pending technical changes for this manufacturer and there are only minor amendment requests to the registration certificates that his staff can handle.

They have received approval to fund 0.5 FTE to perform this function. After training and qualification, this individual will be tasked with terminating Ohmart’s old registries since they no longer manufactured in Kentucky, develop a registration certificate evaluation and document format consistent with NUREG 1556, Volume 3, and develop license conditions to require Ronan to report defects, deviations, or non-conformance of safety related system, structures or components. In the interim, they plan to send two staff members to the SS&D training workshop.

These recommendations remain open.

CONCLUSION:

The Program’s performance has declined with respect to two of the performance indicators, namely “Technical Staffing and Training” and “Status of Materials Inspection Program”. Additional improvement is still needed in the performance indicators of “SS&D Evaluation Program”, “Compatibility Requirements” and “Technical Quality of Incidents & Allegations”. These indicators were found “Satisfactory, but Needs Improvement” during the 2004 IMPEP review.

As discussed with the Director and the Commissioner during the meeting, it appears that staffing changes, namely loss of an experienced staff member, a newly-hired staff, and the Radiation Health Branch Manager, as well as staffing shortages, has caused lack of progress in recommendations made during the 2004 IMPEP review. All of the recommendations, many of which are contingent upon the program hiring additional staff, remain open.