

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III 2443 WARRENVILLE RD. SUITE 210 LISLE, IL 60532-4352

July 7, 2016

Mr. Richard Hodges, Director Ohio Department of Health 246 North High Street Columbus, OH 43215

Dear Mr. Hodges:

A periodic meeting with you and your staff was held on June 7, 2016. The purpose of the meeting was to review and discuss the status of Ohio's Agreement State Program. The U.S. Nuclear Regulatory Commission (NRC) was represented by Jack Giessner and me.

I have completed and enclosed a general meeting summary, including any specific actions that will be taken as a result of the meeting.

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 630-829-9661 or email to <u>James.Lynch@nrc.gov</u> to discuss your comments.

Sincerely,

/RA/

James L. Lynch State Agreements Officer Division of Nuclear Materials Safety

Enclosure: Periodic Meeting Summary

AGREEMENT STATE PERIODIC MEETING SUMMARY WITH THE OHIO DEPARTMENT OF HEALTH

NRC Attendees	Ohio Attendees
Jack Giessner, Division Director	Richard Hodges, Director
Jim Lynch, Regional State Agreements Officer	Gene Phillips, Chief, Bureau of Environmental Health and Radiation Control
	Rebecca Fugitt, Assistant Chief, Bureau of Environmental Health and Radiation Control
	Mike Snee, Administrator
	Steve James, Health Physics Supervisor,
	David Lipp, Health Physics Supervisor,

DATE OF MEETING: June 7, 2016

DISCUSSION:

Richard Hodges was appointed by Governor John Kasich as Director of the Ohio Department of Health in August 2014. Ohio has approximately 600 specific licensees. The State Liaison Officer position is located in another agency, the Ohio Emergency Management Agency.

The Agreement State Program is administered by the Bureau of Environmental Health and Radiation Protection (the Bureau), within ODH, led by Gene Phillips. The Bureau has three program areas, the Radiological Health and Safety Program, the X-ray Program, and the Agreement State Program, each led by an Administrator position.

The State's last IMPEP review was conducted in December 2013. The review team found Ohio's performance to be satisfactory for all performance indicators reviewed. The review team made no recommendations and identified a good practice for the incident evaluation program entitled "Bureau Medical Event Review Team." Accordingly, the review team recommended, and the Management Review Board agreed, that the Ohio Agreement State Program was adequate to protect public health and safety, and compatible with NRC's program.

Program Strengths:

Since its Agreement in 1999, Ohio has had a very strong, competent radiation control program. The Bureau provides excellent support to NRC and other Agreement States with their thorough evaluation of proposed regulations and procedures.

Ohio has been a leader in response to the radiological security concerns which face the country.

Program Weaknesses:

Vacancies in key management positions have resulted in increased workloads for supervisors and staff personnel.

A Department-wide cutback in out-of-State travel has kept personnel from attending national meetings and participating in the IMPEP process. A State manager was scheduled to serve as an instructor for the 2016 IMPEP training class, but had to cancel due to travel cutbacks. Additionally, a staff member scheduled to attend the training was similarly recalled. The annual Organization of Agreement States and Conference of Radiation Control Program Directors meetings are also not being supported.

Feedback on NRC's Program:

State managers indicated that they appreciated the good relationship and communication that they have with NRC Region III. They were also appreciative of NRC's funding for Agreement State training.

Program Reorganizations:

In January 2015, the Ohio Department of Health, which houses the Ohio Agreement State Program, reorganized. The former Bureau of Radiation Protection is now part of the Bureau of Environmental Health and Radiation Protection. As a result of the reorganization, a new Division Director and Bureau Chief were named to lead the program.

Staffing and Training:

Ohio's program has experienced a significant amount of turnover in recent months. The Agreement State Administrator position has been vacant since February 2016. The State plans to fill the position later this year. The Nuclear Materials Services Supervisor position, vacated recently, will likely be combined with the vacant Medical Supervisor position. Additionally, one Health Physicist position is vacant, and is currently posted.

Materials Inspection Program:

Ohio inspection frequencies are identical to those found in NRC's Inspection Manual Chapter (IMC) 2800. According to program managers, no inspections are currently overdue with respect to IMC 2800 priorities.

New licensees are inspected within 12 months of license issuance (usually within the first 6 months), regardless of whether the licensee has received radioactive material. Reciprocity

inspections are performed in accordance with the frequencies identified in NRC Manual Chapter 1220. Reciprocity inspections are being performed for approximately 30 to 40 percent of candidate licensees, according to the program managers.

Materials Licensing Program:

Ohio does not have any significant backlog of licensing actions. Pre-licensing visits are performed for all applicants unless they already have an NRC or Agreement State license. Ohio is aware of national concerns about inappropriate issuance of materials licenses.

Regulations and Legislative Changes:

Ohio's regulations are up-to-date and compatible with the NRC's regulations. During the review period, approximately 15 regulation packages were submitted by the State and approved by the NRC. Two minor comments on rule packages were made by the NRC which have not yet been resolved. Ohio asked for one of the comments to be rescinded, which is currently under consideration.

Ohio was one of the first Agreement States to adopt 10 CFR 37 equivalent regulations, adopting the rules in October 2014, significantly ahead of the March 2016 deadline. The Program provided excellent leadership for other Agreement States, sharing checklists and other tools developed during outreach to Ohio licensees.

Response to Incidents and Allegations:

The Bureau continues to be sensitive to notifications of incidents and allegations. Incidents are quickly reviewed for their effect on public health and safety. Approximately 30 NRC reportable incidents were reported since the last IMPEP review. Staff is dispatched to perform on-site investigations when necessary. All of the events were reported to the NRC, and were entered into, and updated, within NMED. Several reportable incidents were recently reported late to the NRC Headquarters Operations Center. Program managers explained that the late reports were due to a heavy workload and a misunderstanding of reporting requirements. The NRC representatives emphasized the 24-hour reporting requirement identified in SA-300 "Reporting Material Events."

Very good communication with Region III was noted during event response. The program managers have placed emphasis on maintaining an effective response to incidents and allegations.

The OAS proposed reactive inspection teams comprised of staff from both Agreement States and the NRC for event response was discussed. The RSAO indicated to the State that this issue is currently being discussed by OAS and NMSS. More information will be coming to the Agreement States in 2016.

During the 2013 IMPEP review, the team identified a good practice for the State's "Bureau Medical Event Review Team (BMERT)." This team involves managers from the Nuclear Materials Safety, Technical Support, and X-Ray Sections. BMERT evaluates incidents and allegations involving medical events or other potential exposure events. Participation by both radioactive material and x-ray program representatives allows the Bureau a comprehensive

view of radiation uses in the State. The process has resulted in the identification of crosscutting issues amongst the represented sections who regulate the same licensees, but different activities such as linear accelerators and brachytherapy. The BMERT also tracks escalated enforcement and allegation cases.

The NRC referred four allegations to Ohio since the last IMPEP review. All of the allegations were promptly investigated and closed.

Significant Events and Generic Implications:

The Bureau responded to a significant contamination incident and two abnormal occurrences (AOs) since the last IMPEP review.

In February 2016, scrap material was received at several Ohio recycling facilities which contained damaged radium sources and resulting contamination. The handling of the material caused personnel contamination and significant facility contamination. Ohio issued orders to the owner of the facilities, coordinated with State and Federal agencies, and performed extensive surveys of businesses, homes, vehicles and workers. The Bureau did an outstanding job of identifying potential radiation hazards and aggressively investigated the incident to protect public health and safety.

In January 2014, a medical event occurred at the Cleveland Clinic Foundation. The patient was treated with yttrium-90 microspheres for colorectal cancer. Shunting caused an unplanned dose to the patient's duodenum. The incident was included in the Fiscal Year 2014 AO report.

In July 2015, a medical event occurred at University Hospitals of Cleveland. The patient was treated with yttrium-90 microspheres for liver cancer. The microspheres were instead delivered to the patient's small bowel. The incident was included in the Fiscal Year 2015 AO report.

In each instance described above, the response performed by the State was comprehensive in its scope and aggressive in its response time.

Large, Complicated, or Unusual Authorizations for use of Radioactive Materials:

Ohio continues with the decommissioning of a former cobalt-60 manufacturing facility, Advanced Medical Systems. The facility has extensive contamination and is prohibited from releasing untested water into the municipal water treatment system. The Bureau's efforts over the last two decades has resulted in the disposal of sources that had been stored in the facility with a significant reduction in source term. The State is working with the U.S. Environmental Protection Agency to see if the Federal government can assist with the decommissioning of this facility. (Note: Since this Periodic Meeting, the Bureau reported that vandalism at the AMS facility has resulted in a major response to ensure that contamination is not released from the facility.)

Sealed Sources and Devices:

Ohio has an active SS&D program, with no backlogs noted. The Medical Supervisor, the primary SS&D reviewer, recently left the program. Additional staff members are being trained to ensure that adequate expertise is maintained for SS&D evaluation.

Current State Initiatives:

The Republican National Convention is scheduled for July 2016 in Cleveland. The Bureau will provide security technical support to law enforcement agencies.

Out-of-State travel is an issue for the program. Program managers stated that out-of-State travel, even if paid for by the NRC, is closely monitored and may not be done depending on Bureau travel prioritization, unless it is required. Training courses, needed for qualification of staff, are being allowed. NRC was encouraged to promote more online communications so that travel is not necessary.

Current NRC Initiatives:

NRC's effort to analyze historical uses of radium sources was discussed with Bureau managers. NRC plans to provide specific information about the project to Agreement States in July 2016.

CONCLUSION:

The Ohio Agreement State Program remains a very strong radiation control program. Recent losses in key management positions have challenged the entire program. The training level for staff members is on target.

The NRC representatives expressed concern that Ohio, a leader in the National Materials Program, has not been prioritizing some efforts that require out-of-State travel. Ohio managers acknowledged the concern and will evaluate the Department's position on out-of-State travel.

NRC staff recommends that the next IMPEP review to be held, as currently scheduled, in late 2018.