



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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May 14, 2020

Ms. Angela Leek, Chief
Bureau of Radiological Health
Iowa Department of Public Health
Lucas State Office Building, 5th Floor
321 East 12th Street
Des Moines, IA 50319

Dear Ms. Leek:

A periodic meeting with Iowa was conducted via Skype on April 13, 2020. The purpose of this meeting was to review and discuss the implementation of Iowa's Agreement State Program. The Nuclear Regulatory Commission (NRC) was represented by David Pelton, Director, Division of Nuclear Materials Safety; Christine Lipa, Deputy Division Director, Division of Nuclear Materials Safety; and Darren Piccirillo, Regional State Agreements Officer from NRC's Region III Office.

We have completed and enclosed a general meeting summary. If you feel that our comments or conclusions do not accurately summarize the meeting discussion, please contact me at (630) 829-9661, or via email at Darren.Piccirillo@nrc.gov to discuss your comments.

Sincerely,

/RA/

Darren W. Piccirillo
Regional State Agreements Officer

Enclosure:
Periodic Meeting Summary for Iowa

Letter to Angela Leek from Darren Piccirillo dated May 14, 2020.

SUBJECT: Iowa FY20 IMPEP Periodic Meeting Summary

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

PERIODIC MEETING WITH THE STATE OF IOWA

TYPE OF OVERSIGHT: NONE

April 13, 2020

PERIODIC MEETING PARTICIPANTS

NRC

- David Pelton: Director, DNMS, NRC Region III
- Christine Lipa: Deputy Director, DNMS, NRC Region III
- Darren Piccirillo: RSAO, NRC Region III

State of Iowa

- Gerd Clabaugh, Director, Department of Public Health
- Angela Leek, Chief, Bureau of Radiological Health
- Randal Dahlin, Health Physicist, Bureau of Radiological Health
- Stuart Jordan, Health Physicist, Bureau of Radiological Health
- Derek Elling, Health Physicist, Bureau of Radiological Health

Iowa Periodic Meeting Summary

1.0 INTRODUCTION

This report presents the results of the periodic meeting held between the U.S. Nuclear Regulatory Commission (NRC) and the State of Iowa. The meeting was held remotely via Skype on April 13, 2020 and was conducted in accordance with NMSS Procedure SA-116 "Periodic Meetings between IMPEP Reviews," dated June 3, 2009.

The Iowa Agreement State Program is administered by the Bureau of Radiological Health (the Bureau) which is located within the Division of Acute Disease Prevention, Emergency Response, and Environmental Health (the Division). The Division is part of the Department of Public Health (the Department). At the time of the Periodic meeting, the Iowa Agreement State Program regulated approximately 142 specific radioactive materials licensees authorizing the possession and use of radioactive materials. The review focused on the Iowa Agreement State Program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Iowa.

The Bureau is fee funded. On September 18, 2019, a fee increase went into effect for all specific radioactive material licensees and general license registrants. This fee increase is expected to keep the program on solid financial footing for the next several years. It is anticipated that these fees will be reviewed periodically to assess the need for adjustments.

The Bureau last underwent an Integrated Materials Performance Evaluation Program (IMPEP) review from August 8-10, 2017 (ML12310A146). A Management Review Board (MRB) meeting to discuss the outcome of the IMPEP review was held on October 24, 2017.

During the October 24, 2017, MRB meeting, the Iowa Agreement State Program's performance was found to be satisfactory for all indicators reviewed. The team made no new recommendations and there were no open recommendations from the previous review for the team to consider. Accordingly, the team recommended, and the MRB agreed, that the Iowa Agreement State Program is adequate to protect public health and safety and compatible with the NRC's program. The team recommended, and the MRB agreed, that the next IMPEP review will take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

2.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC Regional Office and Agreement State radioactive materials programs during an IMPEP review. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

2.1 Technical Staffing and Training (2017 IMPEP Rating: Satisfactory)

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The Bureau when fully staffed is comprised of 3.2 full time equivalents. Iowa has three staff members in the radioactive materials program, with oversight of the program delegated to the Bureau Chief. Since the last Iowa IMPEP, which ended on August 10, 2017, the Bureau has hired one new Health Physicist (HP). This new staff member started employment with the Bureau on September 1, 2017. The HP has completed all “core” NRC courses, in addition to several “non-core” courses. The HP is fully qualified to perform all licensing and inspection types for Iowa licensees.

The Bureau will have one staff member on a one-year military deployment beginning in June 2020. Due to a light inspection year compared to previous years, it is not anticipated that Iowa will require outside assistance to complete inspections within the timeframes outlined in Inspection Manual Chapter (IMC) 2800.

The Bureau has a training and qualification program equivalent to the requirements in IMC 1248. There has been no change to the Iowa training program since the last IMPEP. Each staff member tracks their own continuing education requirements of 24 hours every 2 years. Staff members are provided opportunities to fulfill this requirement.

2.2 Status of the Materials Inspection Program (2017 IMPEP Rating: Satisfactory)

The Bureau’s inspection frequencies are the same as, and for some licensees, more frequent than the NRC’s inspection frequencies identified in IMC 2800. Iowa has historically inspected some license categories on a more frequent basis than the NRC. These include broadscope licensees, HDR licensees, and nuclear pharmacy licensees that the Bureau typically inspects on an annual basis. Due to the COVID-19 pandemic, the Iowa State University (ISU) academic broadscope license inspection was cancelled for 2020. ISU was last inspected in April 2019, so the Bureau will still fall within the guidelines of IMC 2800 for this licensee.

At the time of the Periodic meeting, the Bureau performed a total of 78 Priority 1, 2, and 3 inspections since the 2017 IMPEP. No inspections were currently overdue, and none had been performed overdue since the 2017 IMPEP review.

The Bureau reported that there are currently no in-state travel restrictions and no stay-at-home orders due to the Coronavirus (COVID-19) pandemic. All inspections have been postponed through the end of April and remain within Iowa's normal operational frequencies. Even if conditions would require Iowa to further delay or cease travel for inspections, the Bureau should not have an issue with due dates until after July 1, 2020. The Bureau indicated that they will re-evaluate inspection status at the end of April.

The Bureau reported that in 2018 they performed inspections on a total of 33 percent of candidate licensees coming into Iowa under reciprocity. From 2019 to date, they performed 20 percent of reciprocity inspections. The changes to IMC 2800 were discussed with the Bureau to ensure they were aware that the 20 percent annual goal for conducting reciprocity inspections as previously identified in IMC 1220 would no longer be used. The Bureau indicated that while they may not be required to meet the 20 percent goal in the future, they will continue to attempt reaching the 20 percent goal for conducting

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reciprocity inspections because they believe those inspections are important to their program.

Inspection findings are routinely sent to licensees within 30 days of the inspection exit.

2.3 Technical Quality of Inspections (2017 IMPEP Rating: Satisfactory)

The Bureau uses inspection procedures that are consistent with the inspection guidance outlined in IMC 2800. The inspectors provide proposed inspection results, findings or violations to the licensee at the exit meeting. All inspection findings and/or violations are brought back to the office where a peer review is performed by a second inspector. Both inspectors sign the inspection report, and then the lead inspector signs out the final letter that is issued to the licensee.

A total of 10 inspector accompaniments were performed since the 2017 IMPEP. Inspector accompaniments are completed by the program Bureau Chief annually for each qualified inspector. Non-qualified inspectors are accompanied by a qualified inspector on all inspections until the individual is qualified.

2.4 Technical Quality of Licensing Actions (2017 IMPEP Rating: Satisfactory)

The Bureau had approximately 142 specific licensees at the time of the periodic meeting. The inspection staff also performs all licensing actions. Since the 2017 IMPEP review, the Bureau completed 185 licensing actions, which includes: 93 license amendments, 71 license renewals, 3 new license applications, and 18 license terminations.

The Bureau has one new portable gauge license that received a lengthy deficiency letter related to their application. Iowa is awaiting the applicant's response to the items in that letter, so the timing and/or need for a pre-licensing site visit is not known at this time. Currently, there are two licenses under timely renewal, which Iowa refers to as a Deemed Timely letter. Generally, Iowa rarely has licensees operating under Deemed Timely letters.

All license renewals go through the Bureau's pre-licensing guidance process which is based on NRC's NUREG-1556 Series guidance. All new licenses go through the pre-licensing process and if the licensee is an unknown entity, they will receive a pre-licensing site visit. Any new applicant, or existing licensee, requesting radioactive material in quantities of concern must implement all requirements of Iowa Administrative Code 641-Chapter 37(136C) (10 CFR Part 37) and be inspected by the Bureau prior to any new license or license amendment being issued.

2.5 Technical Quality of Incident and Allegation Activities (2017 IMPEP Rating: Satisfactory)

The Iowa Agreement State program has procedures and processes in place to maintain effective responses to incidents and allegations. When an event is reported to the state, the Bureau evaluates each event to determine if it may involve generic concerns or issues,

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or could have a significant impact on public health and safety, security, and/or the environment, and then decides on the appropriate response. That response can range anywhere from responding immediately to reviewing the event during the next inspection. When an event is determined to have high health and safety significance, inspectors are dispatched to respond immediately.

Since the 2017 IMPEP review, the Bureau reported a total of 3 events to the HOO and NMED database. One of the events involving a potential underdose of a Y-90 Therasphere treatment at the University of Iowa Hospital, was reported to the HOO on May 24, 2019. After discussions with NRC Region III staff, it was determined that no detectable amount of Y-90 was administered to the patient, therefore, no dose was delivered to the patient. The event was then appropriately retracted by the Bureau on May 30, 2019. At the time of the periodic meeting, all events were closed in NMED.

When an event is received requiring reporting to the NRC's Headquarters Operations Officer (HOO), those events are identified and HOO reporting is performed within the required timeframe and in accordance with the guidance found in SA-300.

No allegations were referred to Iowa from NRC, and no allegations were received by Iowa since the 2017 IMPEP. The State indicated that when allegations are received, they are reviewed and investigated by the Bureau, concerned individuals are notified of the actions taken, and allegeders' identities are protected whenever possible in accordance with state law.

3.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State Programs: (1) Compatibility Requirements, (2) Sealed Source and Device (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal (LLRW) Program, and (4) Uranium Recovery (UR) Program. The NRC's Agreement with Iowa does not relinquish regulatory authority for SS&D, LLRW, or UR; therefore, only the non-common performance indicator Compatibility Requirements applies.

3.1 Compatibility Requirements (2017 IMPEP Rating: Satisfactory)

Iowa's administrative rulemaking process takes approximately 6 months to 1 year from drafting to finalizing a rule. Each rule is filed with the Office of the Administrative Rules Coordinator which indexes and publishes the rule in the Iowa Administrative Bulletin, after which the rule becomes effective in 35 days. There are no changes to Iowa's rulemaking process, and there were no legislative changes affecting the program since the 2017 IMPEP. Iowa's rules and regulations are not subject to "sunset" laws.

At the time of the 2017 IMPEP review no amendments were overdue. Iowa has initiated a rule change package to address the following NRC Regulation Amendment Tracking Sheet packages (2018-1, 2018-2, 2018-3, 2019-1, and 2019-2). The final adopted and filed rules incorporating NRC comments are scheduled to be voted on by the State Board of Health in May. Once adopted, Iowa will be compatible with all NRC RATS packages.

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4.0 SUMMARY

The Iowa Bureau of Radiological Health continues to be an effective and well managed Agreement State program. There are no program vacancies at this time. The Bureau is effectively managing its licensing and inspection activities, even in the face of the COVID-19 pandemic. The Bureau will respond to events as appropriate, and they currently have no overdue regulation amendments. Based on the information discussed during the Periodic Meeting, NRC staff recommends that the next IMPEP review for the Iowa Bureau of Radiological Health be conducted as scheduled in 2022. The Bureau did not request a Special MRB.