



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
1600 EAST LAMAR BOULEVARD  
ARLINGTON, TEXAS 76011-4511

October 9, 2021

Dr. Charlotte Sullivan, Ed.D.  
Business Filing and Verification Section Director  
Consumer Protection Division  
Texas Department of State Health Services  
P.O. Box 149347, Mail Code 1986  
Austin, TX 78714-9347

SUBJECT: TEXAS DEPARTMENT OF STATE HEALTH SERVICE PERIODIC MEETING 2020

Dear Dr. Sullivan:

A periodic meeting with Texas Department of State Health Services was conducted on February 21, 2020. The purpose of this meeting was to review and discuss the implementation of Texas's Agreement State Program. The U.S. Nuclear Regulatory Commission (NRC) was represented by Mary Muesle, Director, Division of Nuclear Materials Safety, and Jacqueline D. Cook, Regional State Agreements Officer, from the NRC's Region IV office. Also attending was Patricia Silva, Chief, Materials Inspection Branch, also from the NRC Region IV office.

I have completed and enclosed a general meeting summary. If you feel that our comments, conclusions, or actions to be taken do not accurately summarize the meeting discussion or have any additional remarks about the meeting in general, please contact me at (817) 200-1132 or via email at [Jackie.Cook@nrc.gov](mailto:Jackie.Cook@nrc.gov) to discuss your concerns.

Sincerely,

 Signed by Cook, Jacqueline  
on 10/09/21

Jacqueline D. Cook  
Regional State Agreements Officer

Enclosure:  
Periodic Meeting Summary for Texas

SUBJECT: TEXAS DEPARTMENT OF STATE HEALTH SERVICE PERIODIC MEETING 2020  
DATED OCTOBER 9, 2021

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM  
PERIODIC MEETING WITH THE STATE OF TEXAS DEPARTMENT OF  
STATE HEALTH SERVICES (DSHS)  
TYPE OF OVERSIGHT: NONE

February 21, 2020

PERIODIC MEETING PARTICIPANTS

**NRC**

- Mary Muesle: Director, Division of Nuclear Materials Safety, NRC Region IV
- Patricia Silva: Chief, Materials Inspection Branch, NRC Region IV
- Jackie Cook: RSAO, NRC Region IV

**State of Texas Department of State Health Services (DSHS)**

- Karl Von Ahn: DSHS
- Greg Wilburn: DSHS
- Luis Morales: DSHS
- Bob Free: DSHS
- Eric Skotak: DSHS
- Jeff Wolfe: DSHS
- Janet Leubner: DSHS
- Brian Vamvakias: DSHS
- Stacey McLarty: DSHS
- Lisa Bruedigan: DSHS
- Charlotte Sullivan: DSHS

## 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 Texas (Department of State Health Services [DSHS]). The meeting was held on February 21, 2020 and was conducted in accordance with Nuclear Materials Safety and Safeguards (NMSS) Procedure SA-116, "Periodic Meetings between IMPEP Reviews," dated June 3, 2009.

The Texas Agreement State Program is comprised of staff located in three Divisions within two State Agencies: The Consumer Protection Division, the Radioactive Materials Division, and the Critical Infrastructure Division. The Consumer Protection Division is located in the Texas Department of State Health Services (the Department) and the Radioactive Materials Section (the Section) and the Critical Infrastructure Division (the Division) are in the Texas Commission on Environmental Quality (the Commission). This periodic meeting focused on the Department.

The meeting focused on the radioactive materials 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 Texas.

The Program's last Integrated Materials Performance Evaluation Program (IMPEP) review was from January 29-February 9, 2018. That report is in the NRC's Agencywide Documents Access and Management System under Accession Number [ML18120A324.A](#) Management Review Board (MRB) meeting to discuss the outcome of the IMPEP review was held on April 24, 2018.

During the April 24, 2018, MRB meeting, Texas's performance was found to be satisfactory for all indicators except Technical Quality of Licensing which was found to be satisfactory but needs improvement. The team recommended, and the MRB agreed, to two recommendations from the 2018 IMPEP review.

Accordingly, the team recommended, and the MRB agreed, that the Texas Agreement State Program be found adequate to protect public health and safety, and compatible with the NRC's program. Based on the results of the 2018 IMPEP review, the team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years with a periodic meeting to be held in approximately 2 years.

Below are the team's recommendations, as mentioned in the 2018 Final Texas IMPEP Report and as mentioned in this report, for evaluation and implementation by Texas:

1. Texas should develop and implement a plan to ensure that inspectors performing Yttrium-90 inspections get additional training in this area including accompanying experienced inspectors. (Section 2.3).
2. Texas should develop and implement an action plan to reduce the licensing renewal backlog. (Section 2.4).

## 2.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC's 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 (2018 IMPEP Rating: Satisfactory)

The Department is comprised of 14 inspector positions which is 13.25 full time equivalent (FTE), 9 of which are fully qualified, 5 are in training: 3 that are close to midway in training, and 2 are in early stages of training. There are nine radioactive material license reviewers which is 9 FTE, five are fully qualified and four are partially trained. During this meeting, there were no vacancies.

Since the last IMPEP review, there have been 5 inspector and 3 license reviewer positions vacated and filled. Two individuals retired, one transferred within the Department, and five left the Department for external jobs. The positions were filled within 2.5 to 7 months.

The Department has a training and qualification program that is consistent with NRC's Inspection Manual Chapter (IMC) 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs."

### 2.2 Status of the Materials Inspection Program (2018 IMPEP Rating: Satisfactory)

Since the last IMPEP review, out of 701 total routine inspections performed, 4 (0.6%) were inspected overdue. The Department performed 192 initial inspections and 2 (1%) were inspected overdue.

At the time of this meeting, there were no inspections overdue.

In 2018, the Department inspected 7 of the 18 (39%) eligible companies coming into Texas under reciprocity. In 2019, they inspected 12 of the 32 (38%) eligible companies under reciprocity.

Between February 10, 2018 and February 21, 2020, there were 33 letters sent to the licensee more than 30 days after the inspection date. It appears that the primary causes for the late letters were:

- Inspectors did not submit the report to Policy, Standards and Quality Assurance (PSQA) within 16 days for 25 of the letters.
- PSQA inspection report reviewers did not send the letter to the licensee within 14 days for 8 of the letters. Administrative errors occurred when preparing the reports for review for several of the letters.
- The requirement for timely submission of reports and letters to meet the 30-day deadline was discussed with the inspectors and reviewers and the following actions are being implemented:

- The surveillance manager modified the inspectors self-scheduling of inspections process and added an alert feature in the system when a site is within 6 months of being overdue, and a 2<sup>nd</sup> alert when the site is within 3 months of being overdue. The manager reviews the inspection due list every week or two and contact inspectors directly, as needed, to communicate the need for an inspection in short order.
- The PSQA manager is now reviewing reports from the database weekly to track the dates for notice of violation (NOV) and non-NOV letters, and following up with the reviewers, as needed. Additionally, the reviewers have reviewed reports in the database and cleaned up as much missing or erroneous dates, as possible.
- The Department expects fewer administrative errors for processing routine inspection reports now that they are using an automated system for submitting inspection reports. This system allows for more standardized language and will result in fewer clerical errors.

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### 2.3 Technical Quality of Inspections (2018 IMPEP Rating: Satisfactory)

All supervisory accompaniments of fully qualified inspectors were performed and completed each year for 2018 and 2019. The Department is performing increased management inspection accompaniments with inspectors that were still in training and not fully qualified.

There has been a significant increase in the frequency and the number of required pre-licensing site visits.

**Recommendation 1:** Texas should develop and implement a plan to ensure that inspectors performing Yttrium-90 inspections get additional training in this area including accompanying experienced inspectors.

The Department addressed the above recommendation by sending additional information to all radioactive material inspectors immediately following the last IMPEP review in 2018. In addition, all inspectors completed additional training at the radioactive material staff meeting held during April 2-5, 2018.

### 2.4 Technical Quality of Licensing Actions (2018 IMPEP Rating: Satisfactory, but needs Improvement)

The Department had approximately 1,485 specific licensees at the time of this periodic meeting. The Department had performed 538 licensing actions since the last IMPEP review.

The following were large, complicated, or unusual authorizations for use of radioactive materials identified during this meeting:

- Manufacture and distribution licensee with research and development; thorium-228/radium-224 and lead-212 generators (since May 2016)
- Xcision gamma stereotactic radiosurgery (Gamma pod) – (since May/August 2018)

- Northstar Radiogenix 1.1 (since August 2019)
- Geranium/gallium-68 generator production (since March 2019)
- Multiyear decommissioning, various decommissioning plans (DP) and levels
- Device manufacturer multiyear decommissioning
- Denial of a new license (transfer of control) – failure to provide financial assurance (FA) – in decommissioning
- Americium -241 issues with FA, greater than Class C waste disposal

**Recommendation 2:** Texas should develop and implement an action plan to reduce the licensing renewal backlog.

The Department has addressed the above recommendation by taking the following actions:

- To implement and reduce backlog – they have been running a regular “aging application” list of open actions that are more than 120 days old for reviewers to highlight actions needed, take enforcement actions for non-responsive licensees (site visits by inspectors, license revocation, license renewal denial)
- The functions and duties of the support staff have been rewritten and are currently being trained to take on non-technical review duties from existing Health Physicists (HP) staff to “free up” time for technical licensing activities
- One HP II position description revised to focus on financial assurance, decommissioning cost estimate, decommissioning plan, complex licenses, and sealed source and device activities
- At the last IMPEP, the Department had 150 open renewal actions, 83 of the renewals were more than 1 year old. During this meeting, they had 77 open renewal actions, 33 of which are more than 1 year old. In addition, during this meeting, 118 new licenses and 215 license renewals were issued.

## 2.5 Technical Quality of Incident and Allegation Activities (2018 IMPEP Rating: Satisfactory)

Since the 2018 IMPEP review, all incidents in the Nuclear Materials Events Database (NMED) have been closed and completed except for those events for which there is no radioactive materials serial number. The NMED does not allow a file to be marked completed nor closed if any required information is missing, such as source serial numbers.

Since the 2018 IMPEP review, the NRC had referred 11 allegations to the department and 4 of them remain open.

## 3.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs:

(1) Legislation, Regulations and Other Program Elements, (2) Sealed Source and Device (SS&D) Evaluation Program, (3) Low-Level Radioactive Waste Disposal



(LLRW) Program, and (4) Uranium Recovery (UR) Program. In accordance with the NRC's Agreement with the Department, the Legislation, Regulations and Other Program Elements and SS&D are the non-common performance indicators applied to this meeting.

3.1 Legislation, Regulations and Other Program Elements  
(formerly Compatibility Requirements)  
(2018 IMPEP Rating: Satisfactory)

The Rules Coordination Office has a 10-month process that includes a public review of a draft version, proposed version, and final version. Comments are considered in the revision of the draft and proposed versions. Rule publication is coordinated with the Texas Register and the NRC office.

The Sections of the Texas Administrative Code (TAC) Chapter 289 of the Department's regulations that are affected by the recent regulation changes related to Medical Use of Byproduct Material are under review and a draft is being developed for internal review by Licensing and Surveillance staff.

As Regulation Amendment Tracking System Identification Numbers are published, a staff member dedicated to rule review determines the appropriate section in Texas regulations to amend and prepares a request to change the regulations. Texas regulations are changed and adopted within the 3-year adoption date.

A legislative bill (501.0125) affecting the program, "Release of Radioactive Substance to the Environment" was passed by the Legislature in 2019. This bill requires that a state agency is to immediately notify each political subdivision into which a radioactive substance was potentially released into the environment. This bill also modified the Texas Health and Safety Code to include this notification requirement but did not expressly require rulemaking as part of its implementation. Thus, it was not incorporated into the TAC, which is the equivalent to the Code of Federal Regulations. Only rulemaking to the TAC is sent to the NRC for a compatibility regulations review.

Please note that the Commission should submit any legislative changes that affect the Radiation Control Program to ensure that they are consistent with Federal statutes, regardless of whether it affects or adds to their regulations.

At the time of the periodic meeting, the following amendment (Regulation Amendment Tracking Sheet (RATS) Identification [ID]) was overdue:

- RATS ID 2015-4: "Miscellaneous Corrections," 10 CFR Parts 37 and 40 amendment (80 FR 45841) that was due for Agreement State adoption by September 2, 2018. The effective date that Texas finalized this RATS ID was September 24, 2018.
- RATS ID 2015-5: "Miscellaneous Corrections," 10 CFR Parts 19, 20, 30, 32, 37, 40, 61, 70, 71, and 150 amendment (80 FR 74974) that was due for Agreement State adoption by December 31, 2018, has been implemented timely by the Division. However, the Division recently resubmitted RATS ID 2015-4 and 2015-5 as part of a rule project that included RATS IDs 1993-1, 2007-2, 2007-3, 2011-2, 2012-4, 2013-2, 2015-3, 2015-4, and 2015-5 and revised 25 TAC

§289.251, §289.252, §289.253, §289.256, and §289.257 on June 30, 2021.

The adopted rules were published in the September 18, 2018 edition of the Texas Register. The rules became effective September 24, 2018.

3.2 Sealed Source and Device Evaluation (SS&D)

.....(2018 IMPEP review: Satisfactory)

- Technical Staffing and Training

The Department has three fully qualified SS&D reviewers. No vacancies existed at the time of the periodic meeting. In the near future when offered by the NRC, the Department is wanting to send two potential SS&D reviewers to the SS&D workshop.

- Technical Quality of Product Evaluation Program

Since the last IMPEP review, the Department has issued 4 new SS&D actions, 15 amendment SS&D actions, 25 inactivation SS&D actions, and 1 corrected error SS&D action.

- Evaluation of Defects and Incidents Regarding SS&Ds

Since the last IMPEP review, there was a manufacturing defect incident which occurred on May 15, 2018. This incident involved a custom device in which the source rod broke off external treads while being removed from the source well. The source manufacturer requested and was issued an amended SSD for the sealed source to be more robust.

4.0 SUMMARY

Within the scope of the periodic meeting, no programmatic concerns were noted at this time.

The Department has numerous current state initiatives being implemented to enhance the effectiveness and efficiency of the radioactive materials program.