Department of State Health Services (DSHS) First Quarter 2019
Program Report to the Texas Radiation Advisory Board (TRAB)
Consumer Protection Division

June 28, 2019

Business Filing and Verification Section

Radioactive Material Unit – Karl Von Ahn, Manager

We have finished updating the General License Acknowledgements (GLA) so that there is only one location of use per GLA certificate.

We have been and continue to work on developing a paperless system of processing and storing licensing and other documents on an internal SharePoint site. In addition to creating an electronic filing system, internal procedures and business rules are being created and amended.

We are resuming updating rule guides and application guides for office and public use. The documents require a substantial rewrite, and must now meet the DSHS report document formatting. The guide updating process is currently a lower priority than the internal paperless system development.

Vanessa Danese participated in the NRC's IMPEP review of the Arkansas' agreement state program.

Staff participated in the Combined Functional Drill at South Texas Project Nuclear Power Plant in Bay City.

Radiation Machine Source Unit – Jo Turkette, Manager

The U.S. Food and Drug Administration (FDA) conducted an annual performance evaluation of the DSHS Mammography States as Certifiers (SAC) program for the period of July 1, 2017 through June 30, 2018. The evaluation is based on the following:

- Issuance of interim notices within the required timeframes.
- Issuance of MQSA certificates within the required timeframes.
- Certificate information file return and data transmissions through the Mammography Program Reporting Inspection System (MPRIS) in required timeframes.
- Facility appeals of CA certification decisions
- Inspection activities
- Compliance actions
- Consumer and Facility Complaints
- Texas Certifying Agency (CA) policy and procedures

FDA concluded that the State of Texas is fulfilling its CA responsibilities.

Radiation Surveillance Section-Radiation Unit

Radioactive Materials Inspection Group – Eric Skotak, Manager

The Radioactive Materials Group (Inspections) has mailed the annual request for alternate emergency contact information to select licensees along the Texas Gulf Coast. We are collecting this information to assist in contacting licensees during and after an emergency such as a hurricane. For our RAM Group's July staff meeting we are attending the American Association of Physicists in Medicine annual meeting in San Antonio.

Mammography and Remote Inspections Group – Trae Windham, Manager

The Mammography Inspections Group has moved into year three of the Enhancing Quality Using the Inspection Process (EQUIP) initiative, this means that repeat violations are now a possibility. Repeat violations will result in a random 2 case Additional Mammography Review (AMR) at

minimum. The EQUIP initiative was brought forth by the FDA in 2016 in response to a rise in accreditation failures due to poor image quality.

The Mammography Inspections Group has reviewed the FDA's proposed Mammography Quality Standards Act (MQSA) regulation changes presented to Congress recently and has no comments to submit. Preliminary talks concerning changes to the Texas Administrative Code 289.230 have been initiated within the group in preparation to align the agency's regulation with the proposed federal changes.

The remote inspections program is continuing its work on an updated procedure manual that will enable senior reviewers to train new hires more efficiently. It will also bring the manual in-line with the current regulations, and policies.

The Remote Inspection Program has added a new reviewer in May. This brings the Remote Inspections Group into a fully staffed status.

X-Ray Group – Shannon Quinn, Manager

Lisa Bruedigan attended the 51st Annual Meeting of the Conference of Radiation Control Program Directors in Anchorage, Alaska, May 6th – 9th, 2019.

A few highlights covered during the meeting include:

- Updates from:
  - The US Nuclear Regulatory Commission (NRC)
  - The US Food and Drug Administration
  - The US Environmental Protection Agency
  - The Centers for Disease Control and Prevention
  - The International Atomic Energy Agency
- Training on current medical x-ray issues by the American Association of Physicists in Medicine
- Updates on:
  - Patient shielding
  - Dose management in pediatric CT
  - The Nationwide Evaluation of X-ray Trends
  - Medical isotopes and radiopharmaceuticals
  - Emergency response protective actions and communication during radiation emergencies
  - Integrating the Radiological Operations Support Specialist (ROSS)

Ms. Bruedigan also participated in a panel discussion with staff from the NRC and the US Department of Energy titled Americium: the Unknown Disposal Challenge. The panel discussed the ongoing issue of no pathways for US licensees to dispose of radioactive waste that has been deemed as foreign waste. This includes sources that were legally purchased from a foreign entity and used for their intended purpose in the US, yet when the source is no longer useful and should be disposed of, there is no disposal pathway.

Joann Harthcock, manager of X-Ray Group South, has left the agency for the private sector. The position will be posted in July.

Five inspectors completed the second phase of training, which included training on CT and fluoroscopy inspections. Three are in Region 6, one is in Region 11, and one is in Region 7.

One inspector transferred from Region 4 to Region 7 in April but resigned in June. One inspector transferred from Region 3 to Region 4 in April.

Environmental Monitoring Group – Bob Free, Manager

Incident Investigations:

On May 9, 2019, the Agency was notified by an industrial facility that a worker had received radiation burns on fingers on both hands while conducting maintenance on an x-ray machine on April 18, 2019. The facility used a Rigaku Supermini 200 XRF machine to analyze the elements in catalyst used in the oil and gas industry. The machine was not registered with the Agency. The worker conducted internal maintenance with an improper procedure resulting in his hands exposed to a 50 kV x-ray tube for approximately two minutes. A dose in excess of 2000 rad was received. The worker has significant injuries to 6 fingers. The worker is receiving medical treatment and REAC/TS is providing consultation to the physicians. Violations for both the industrial facility and the service provider have been identified. An investigation into the incident is ongoing.

On March 14, 2019, the Agency was notified by the licensee's radiation safety office (RSO) that a therapy event had occurred. A patient was scheduled for three fractions using a high dose rate afterloader containing a 6.8 curie iridium - 192 source. Multiple catheter positions were to be used. On March 14, 2019, prior to the third fraction, the licensee determined that one of the insertion position was set at 1293 mm instead of 1500 mm resulting in the patient receiving 50% of the prescribed dose (350 cGrays) to

the target tissue for each of the first two fractions. The third fraction was not administered. The RSO stated that the technician had seen the wrong position had been entered into the treatment plan and had changed it but failed to hit the enter key. Therefore, the treatment plan was not corrected. The RSO stated that a new treatment plan would be created to correct the error and insure the intended area received the correct dose. The RSO stated the patient would not experience any long-term effects from the error.

On March 1, 2019, the Agency was notified by the registrant of an event that had been discovered on February 28, 2019. The registrant reported a patient was to receive 3,000 cGray to a treatment site in 5 fractions. Prior to treatment and during the first three treatments, the tumor area was obscured by adjacent loops of bowel in the vicinity. Prior to the fourth treatment, the bowel was no longer obscuring the lesion and it was discovered that the lesion was, in fact, moving. The decision was made to treat the visualized lesion for the fourth fraction. Re-simulation was done prior to the fifth fraction and confirmed the lesion had moved so the fifth fraction was made to the actual lesion. Using prior and current imaging, it was confirmed the lesion had received only a portion of the prescribed dose during the first three fractions. The patient received an additional fraction to the lesion to insure the prescribed dose was delivered. Both the patient and the physician were notified of the error. The registrant stated the patient would not experience any adverse effects from the error. The registrant now requires additional imaging techniques in cases where the target tissue cannot be identified through normal methods.

Since February 2019, there have been three events in which radioactive tracer material has been identified in waste coming into landfills in Odessa and San Antonio. The tracer materials, used during fracking operations, were iridium-192, scandium-46, and antimony-124 bound in a ceramic "sand" varying in size from 200-2000 microns. Companies licensed for tracer material place it into the frack sand in a non-licensed company's pumping equipment. The surveys conducted after completion are not identifying all contamination in the pumping equipment. As a result, pump company vehicles are being serviced after these jobs and residual contamination is being transferred to wash bays, mechanics work areas and adjacent areas of the pumping company sites. Levels identified by DSHS staff have been low, and did not represent a significant hazard. However, some contamination exceeded release limits and the pump companies are not licensed to possess the radioactive material. The agency is continuing its investigation of these occurrences to determine the appropriate regulatory action.

South Texas Project:

The Emergency Response Planner for the South Texas Project, Rae Walker, took another position within the Agency as the Operations Team Lead & Intelligence Analyst for the DSHS Response and Recovery Unit.

DSHS Radiological Emergency Response Team (RERT) members will participate in a Combined functional drill on June 12, 2019 in support of South Texas Project (STP) and Matagorda County exercise participants.

Comanche Peak:

Meridian/Bosque County has been added as a new Reception Center location for the Comanche Peak Nuclear Plant (CP). The new Reception Center (RC) in Meridian TX is at the Meridian High School located at 500 Yellow Jacket Dr. Meridian TX 76665. CP has worked with Bosque County on writing a Radiological Response Plan for the RC and have provided the radiological detection equipment. CP and DSHS have participated in radiological training on:

April 25th, 2019 - Intro to Radiation/Equipment use and setup
May 4th, 2019 - Walkthrough #1/Practice
May 25th, 2019 - Walkthrough #2/Practice
June 15th, 2019 - Walkthrough #3/Practice

The Response Plan and Training were developed in preparation for a FEMA Evaluated RC exercise scheduled for Thursday, July 25th, 2019.

A FEMA Evaluated MS-1 Medical drill is scheduled for Wednesday, September 25th, 2019 at the Texas Health Cleburne Hospital.

In addition, DSHS and Comanche Peak will be participating in a FEMA Evaluated Plume Phase exercise. The Dress Rehearsal is scheduled for Wednesday, October 2nd, 2019 and the FEMA Evaluation is scheduled for Wednesday, November 6th, 2019.

Waste Isolation Pilot Plant:

In February, WIPP staff participated in the North Texas Council of Government Dirty Bomb exercise in Arlington, Texas. Representatives from State and Federal agencies participated as well as various local Fire Departments.

In March, the Smith County/City of Tyler WIPP Tabletop Exercise was conducted at the Smith County Fire Marshall Office. Participation was very good with approximately 22 Emergency Response individuals attending. In addition, 26 radiological detection instruments were updated throughout the county.

In April, WIPP staff attended and participated in the Radiological Transportation Symposium in Pearl, Mississippi. The symposium reviewed and discussed the different types of radiological materials commonly transported through the state routes that are used and the organizations that provides transportation oversite.

During the week of April 1 – 5, 2019, WIPP program staff attended and participated in the 2019 National Radiological Emergency Preparedness Conference in Orlando, Florida.

During the week of April 15 – 18, 2019, the program staff attended the 2019 Texas Emergency Management Conference in San Antonio, Texas. In addition, the staff provided and staffed the WIPP display booth in the conference exhibit hall next to the WIPP transport vehicle.

Pantex:

During the week of April 15 – 18, 2019, the program staff attended the 2019 Texas Emergency Management Conference in San Antonio, Texas

DSHS participated in a national level exercise hosted by Pantex in April. Participants include the Department of Defense, Department of Energy (DOE), FBI, EPA and several other government entities.

The After-Action Report and Improvement Plan are currently in the process of being written for DSHS' participation in the NUWAIX exercise in April.

DSHS continues to support local emergency responders who are trained to respond to events at Pantex Plant.

Environmental samples (soil, water and vegetation) from the area around the Pantex plant were taken and were sent for analysis. These samples are taken to satisfy requirements in the AIP grant from the Department of Energy.

Compliance Section

Environmental and Radiation Control Unit – Alyson Henry

From February 2019 – May 2019, the Compliance Section issued 173 Orders against individuals and companies that were found to have violated the Texas Regulations for Control of Radiation (25 Texas Administrative Code §§289.201 – 302). These Orders have resulted in the assessment of $238,215.00 in administrative penalties. 44 X-ray registrations and 3 Laser registrations were revoked as a result of failing to terminate or timely notify the Department of changes that would render the information contained in the certificate of registration inaccurate. These facilities are typically no longer in business. 1 Industrial Radiographer certification was revoked by an Agreed Order.

On January 31, 2019, the State Office of Administrative Hearings (SOAH) Administrative Law Judges (ALJs) issued a Proposal for Decision (PFD) on a case heard before SOAH on November 7, 2018. The PFD affirmed that the Department's evidence failed to establish that Respondent caused, suffered, allowed, or permitted a registrant to violate the Texas Regulations for Control of Radiation and determined that Respondent is not subject to the assessment of administrative penalties. The closure of this case is pending the issuance of a Final Order by the DSHS Commissioner.

Policy, Standards, and Quality Assurance Section

Radiation Unit – Brian Vamvakias, Manager

The following proposed x-ray rule was presented at the TRAB meeting on September 28, 2018. TRAB recommended forwarding of the rule for approval by the Health and Human Services Executive Council.

The proposed x-ray rule packet includes:

§289.232 concerning radiation control regulations for dental radiation machines

- The new adoption dental rule text will be posted in the June 21, 2019, issue of the *Texas Register.* The rule will become effective on June 25, 2019. The rule will be uploaded to the Radiation website on or before June 25, 2019.

The revision of Regulatory Guide 4.4, *GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR DENTAL RADIATION MACHINES* has been revised and will be uploaded to the Radiation website on or before June 25, 2019, along with the new rule.

The revision of Regulatory Guide 4.3, *GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR THE HEALING ARTS OF MEDICINE, PODIATRY, AND CHIROPRACTIC* is complete. Special thanks to the Surveillance Section, X-Ray Group, for their efforts in making the necessary updates. The new guide will be uploaded to the Radiation website in the near future.

Upcoming rules:

- §289.233, Radiation Control Regulations for Radiation Machines used in Veterinary Medicine will be the next x-ray rule to be revised.
- At this time, the next Nuclear Regulatory Commission required changes to radioactive material rules will include:
  - §289.201, General Provisions for Radioactive Material
  - §289.202, Standards for Protection Against Radiation from Radioactive Materials
  - §289.251, Exemptions, General Licenses, and General License Acknowledgements
  - §289.252, Licensing of Radioactive Material