



Department of State Health Services (DSHS) Fourth Quarter 2016 Program Report to the Texas Radiation Advisory Board (TRAB)

December 9, 2016

Kathy Perkins, Assistant Commissioner

After 27+ years of working with the state, Kathy Perkins, Assistant Commissioner for the Division for Regulatory Services, retired effective November 30, 2016. She plans to take time to do something new and spend more time with her family. We thank Kathy for her professional dedication and commitment to DSHS.

We are pleased to announce that Jon Huss, our current Section Director for Environmental and Consumer Safety, has agreed to serve as Interim Assistant Commissioner for Regulatory Services effective December 1, 2016. Jon has been in hospital and public health administration for 31 years. Following 13 years in hospital administration, Jon joined legacy TDH as the Deputy Regional Director in Region 1. In the following years, Jon served in positions in Medicaid, Regional and Local Health Services and Region 7. He rejoined the Division for Regulatory Services in September 2013 as the Environmental and Consumer Safety Section Director, and is currently serving in that position where he oversees approximately 500 staff who are engaged in rules and policy development, quality assurance and compliance activities, and inspections in the areas of food, drug and meat safety; radiation control; and environmental safety.

Radiation Safety Licensing Branch

Radioactive Material Licensing Group

Licensing staff participated in a joint radioactive materials in-house training with the Inspection staff in October.

Radiation Inspections Group

X-Ray Inspection Group

- Due to the reporting software implemented in August 2014, the X-ray Inspections Group now has better capability to trend inspection data. The group has recently started looking at several ways to utilize this data to improve various aspects of the Radiation Control Program.
- In late November, one of the X-ray Group Managers will participate in a joint meeting with Medical Imaging & Technology Alliance (MITA), CRCPD, the Food & Drug Administration (FDA) and the American Association of Physicists in Medicine (AAPM) to discuss the FDA's proposal to adopt the International Electrical Commissions (IEC) standards in lieu of writing standards for the safe manufacture of x-ray units

Radioactive Materials (RAM) Inspections Group

- The Radioactive Materials Group (Inspections) in cooperation with the Licensing Group, is monitoring the construction of a new unshielded pool irradiator in Fort Worth.
- The Radioactive Materials Group (Inspections) 2016 staff meeting was held October 4–6, 2016.

Mammography and Remote Inspections Group

- The FDA is rolling out a new Mammography Quality Standards Act (MQSA) initiative, under the label EQUIP. EQUIP stands for Enhancing Quality Using the Inspection Program. The initiative was started due to the decline in clinical patient image quality observed through clinical image reviews conducted by the accrediting bodies. In too many cases, patient images submitted for review fail to meet the accrediting body's quality standards when, in the facility's opinion, they represent the facility's best work. EQUIP requires the establishment of a continuous image quality review process, a policy for dealing with poor patient image quality, and enhanced oversight by the lead interpreting physician. The FDA hopes this will reverse the trend of image quality failures, by focusing attention on clinical image quality, during the 3 year interval between the accrediting body's clinical image quality reviews. Being an FDA approved Certifying Agency, the state mammography inspection program will incorporate the same initiative elements into the state inspections. The initiative will start on January 1, 2017. No violations based on the initiative will be cited for the first year, in order to give everyone a chance to add acceptable elements to their quality control programs.

- Update on Tomosynthesis: No accrediting bodies have been approved to accredit the Tomosynthesis machines. The required accreditation can be accomplished only through a special provision from the FDA. Tomosynthesis, also known as 3D mammography, is still a very new and hot topic in mammography. Three major manufacturers, Hologic, Siemens and GE have all produced tomosynthesis capable machines. Tomosynthesis creates slice images of breast anatomy from a series of low dose radiographic images taken of the breast at various angles. These machines are responsible for a slight increase in total radiation dose for a mammogram, while they provide the ability to remove overlying tissue from view that sometimes obscures areas of clinical interest. The FDA and State face a challenge to regulate this new technology with regulations written prior to the emergence of the technology.
- Update on ACR QC manual: ACR has begun providing webinars on the QC manual and program. In August, the American College of Radiology (ACR) released a new quality control (QC) manual that includes a universal quality control program for full field digital mammography units. Until now, facilities were required to adopt the QC program recommended by the manufacturer of their digital mammography unit. The ACR's full field digital mammography QC program has been approved by the FDA as an alternative standard and facilities may start using it in July 2017.

Environmental Monitoring Group

Incident Investigations

- Decontamination efforts at the Thermo Process Instruments (Thermo) location in Sugarland are continuing. Efforts continue to focus on offsite areas. Very low activities of Cs-137 are being removed by Thermo contractors. DSHS is conducting verification surveys of remediated areas and collecting samples for analysis. Thermo and DSHS have been working closely with the City of Sugarland during this process.

Emergency Planning

South Texas Project (STP)

- A DSHS Radiological Emergency Planner is currently working with STP and Matagorda County in reviewing and updating plans and procedures in preparation to implement their new reception center that is in the process of being built. Matagorda County was awarded two FEMA dome shelters (one in Bay City and one in Tidehaven) and STP along with other local industries put forth money to modify part of the Bay City dome to include a decontamination facility for general population and emergency workers. This reception center will replace the Bay City reception center currently located at McAllister

Middle School which closed down a few years ago. The new Reception Center is projected to be completed fall of 2017.

Comanche Peak (CP)

- Comanche Peak and DSHS participated in a FEMA evaluated MS-1 medical drill at the Lake Granbury Medical Center on October 11th, 2016 and a Cleburne Reception Center Drill on October 12th, 2016. FEMA's final evaluation indicated that the participants demonstrated knowledge of their emergency response plans and procedures and adequately implemented them.
- Comanche Peak's next Plume Phase exercise will be in 2017. The Dress Rehearsal will be on July 12th, 2017 and the FEMA evaluated exercise will be on August 16th, 2017.

Waste Isolation Pilot Plant

- The Carlsbad Field Office continues to reevaluate the critical path schedule for reopening WIPP. December 2016 continues to be the target date for the restarting of operations. Transuranic Waste currently being stored on-site in the bay area will be the first drums of waste to be transferred to the underground storage facility. Shipments from sites throughout the nation are expected to begin in mid-2017.
- The Carlsbad Field Office has recently announced its intention to close the far south end of the WIPP underground. The decision to close this area is being made after balancing worker safety issues, overall issues related to rock bolting and ground control in contaminated areas, efficient use of resources, and the long-term integrity of the underground. This area is within the zone that was contaminated as a result of the February 2014 radiological release and is also the location of a series of recent rock falls.
- Recently, a total of six Radiological Emergency Response Training classes were provided to a total of 90 first responders at Fire Departments in Euless and in Big Spring, Texas.
- On October 5, 2016, WIPP program staff conducted a Radiological Transportation Tabletop exercise in Big Spring, Texas. Approximately 40 local officials and first responders from the City of Big Spring, Howard County, and the Scenic Medical Center in Big Spring participated in the exercise.
- On November 9, 2016, WIPP program staff members and the Department of Energy-Carlsbad Field Office conducted a Full-Scale Radiological Transportation Exercise in Big Spring, Texas. A total of 91 individuals participated in the exercise. A formal After-Action report will be developed and available by January 31, 2017.

Pantex

- The Department of Energy has approved the “Agreement in Principle” (AIP) contract for the federal contract years, 2017-2021.
- DSHS is currently in discussion with Pantex to create procedures for a new field team they are adding to their response to bridge the gap between an incident resulting in an offsite release and the arrival of state responders to the area.
- The Radiation Branch continues to participate, attend and support emergency exercises and drills as well as supporting environmental monitoring, sampling and radiological instrument maintenance and calibration.

Radiation Enforcement

- From September – October 2016, the Enforcement Unit issued 38 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 \$90,685.00 in administrative penalties.

Radiation Policy, Standards, and Quality Assurance Group

- No rules will be presented at the TRAB meeting on December 9, 2016.
- The draft radioactive materials rules (known as our "RAM 2016/2017" packet) includes:
 - §289.251 concerning exemptions, general licenses, and general license acknowledgements
 - §289.252 concerning licensing of radioactive material
 - §289.253 concerning radiation safety requirements for well logging service operations and tracer studies
 - §289.256 concerning medical and veterinary use of radioactive material
 - §289.257 concerning packaging and transportation of radioactive material
- We held an in-house staffing on August 31, 2016. We had anticipated presenting these rules to the TRAB as proposed rules at the Fourth Quarter 2016 meeting, however, management directive has determined that no rules will be processed until after the next legislative session. Now that time allows, we will continue to review the rules and post them on the web for public comment as draft rules in the near future. TRAB members will receive a notice via GovDelivery as well as a separate email containing the draft rules.