TEXAS Health and Human Services | Texas Department of State Health Services

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

June 24, 2022
Radiation Section

Licensing Unit – Karl Von Ahn, Manager

Staff continue to process licensing applications and participate in emergency response drills along with the associated training for the drills. The list of completed licensing actions is published in the Texas Register as required by 25 TAC §289.205(c)(1).

Licensing staff also participated in the Cobalt Magnet (CM22) weeklong disaster drill conducted in Austin the week of May 16, 2022.

The licensing application forms were revised to reflect the recent business realignment within the Consumer Protection Division and the Radiation Control Program. The application forms were formatted into fillable pdf (Adobe Acrobat) formats to enhance the electronic submission of application forms. These forms are available on the Radiation Control Program web page.

Now that we have updated our rules to be compatible with the current NRC rules, we have adopted the pdf fillable NRC application forms for medical user qualifications. These forms are used by institutions and training facilities nationally when documenting the training and experience of the medical user qualifications. It also ensures that our application and review processes match required national standards. This affects applications for medical Radiation Safety officers and Associate Radiation Safety officers, Authorized Medical Physicist and Ophthalmic Physicist, Authorized Nuclear Pharmacist, authorized users for diagnostic uses, authorized users for unsealed therapy, and authorized users for sealed source therapies. We have also generated a crosswalk between the cited NRC regulations and Texas rules for the convenience of Texas licensees.

Prior to officially adopting the NRC NUREG 1556 volume series licensing guidance documents, we will generate a crosswalk between NRC regulations and Texas rules. The NUREG 1556 series of documents provides extensive and detailed guidance for licensees in the license application process and can be hundreds of pages long. We will also identify any minor differences between the NRC guidance and our licensing practices.

Registration Unit – Jo Turkette, Manager

The staff is participating in several upcoming radiological emergency response exercise drills.

We continue to work on website updates and the new Enterprise Content Manager project.

Inspection Unit

Radioactive Materials Inspection Unit – Eric Skotak, Manager

The annual requests to provide updates for RSO emergency contact information were mailed to our licensees with sites along the Gulf Coast. This letter also included a reminder to make preparations for emergencies such as loss of power and evacuations during hurricanes and other potential disasters to maintain adequate protection of records and radioactive material at licensed facilities.

Mammography and X-Ray Unit – Trae Windham, Manager

DSHS Mammography Inspections program has initiated the State of Texas Physicist Verification initiative designed to verify a physicist's initial qualifications that make them eligible to conduct mammography physicist actions according to the federal Mammography Quality Standards Act and The State of Texas Mammography regulations.

One inspector has finished their FDA coursework for becoming a Mammography Quality Standards Act certified inspector and will aim to complete their field training requirements by July.

X-Ray and Remote Inspections Unit – Shannon Quinn and Stephanie Lopez, Managers

X-Ray-South is in the process of scheduling interviews to fill a vacant X-Ray/ Mammography inspector position in El Paso.

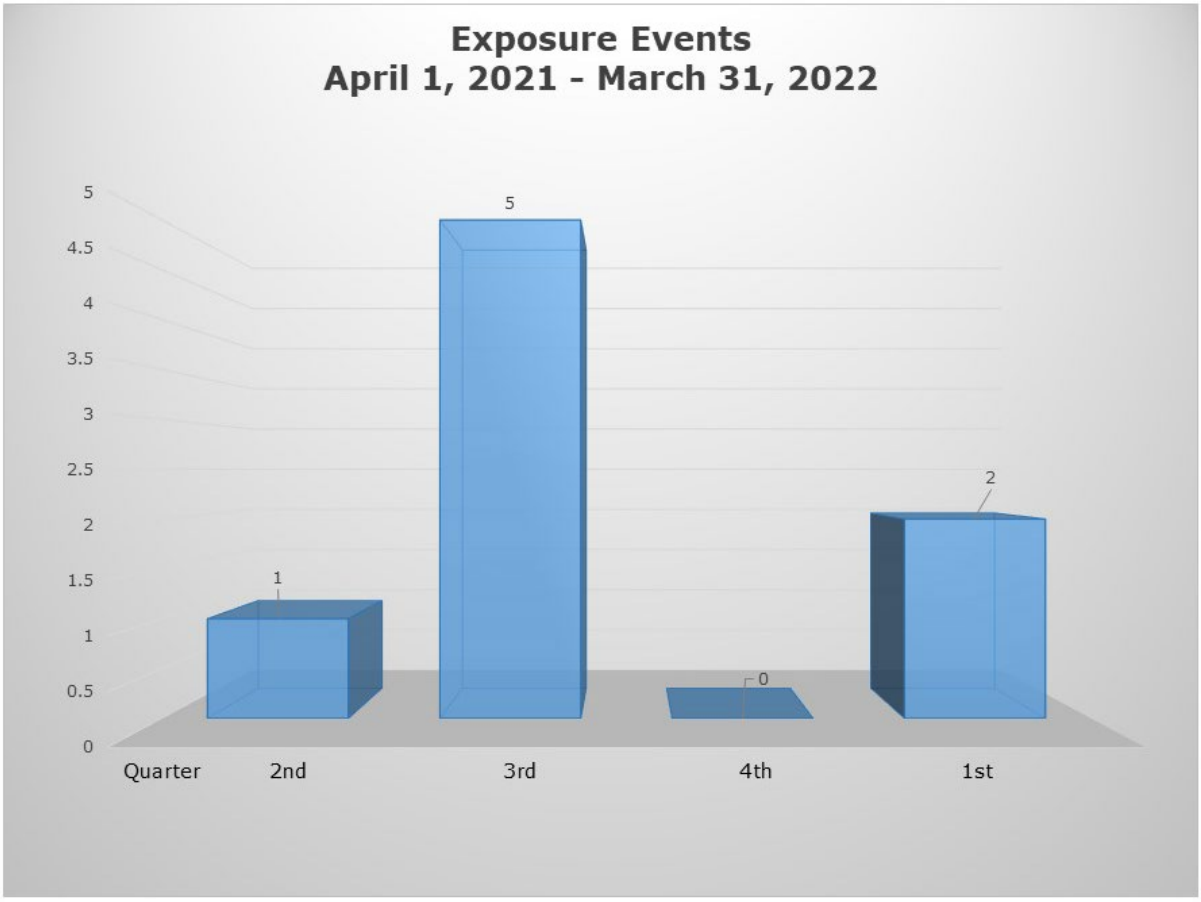
X-Ray-North has filled the vacant X-Ray inspector position in Arlington with an employee that transferred from San Antonio. The vacant San Antonio position was filled with an employee transfer from the Austin office. X-Ray-South is seeking applicants to fill the Austin office vacancy.
X-Ray Management and staff participated in the Cobalt Magnet 2022 exercise in May.

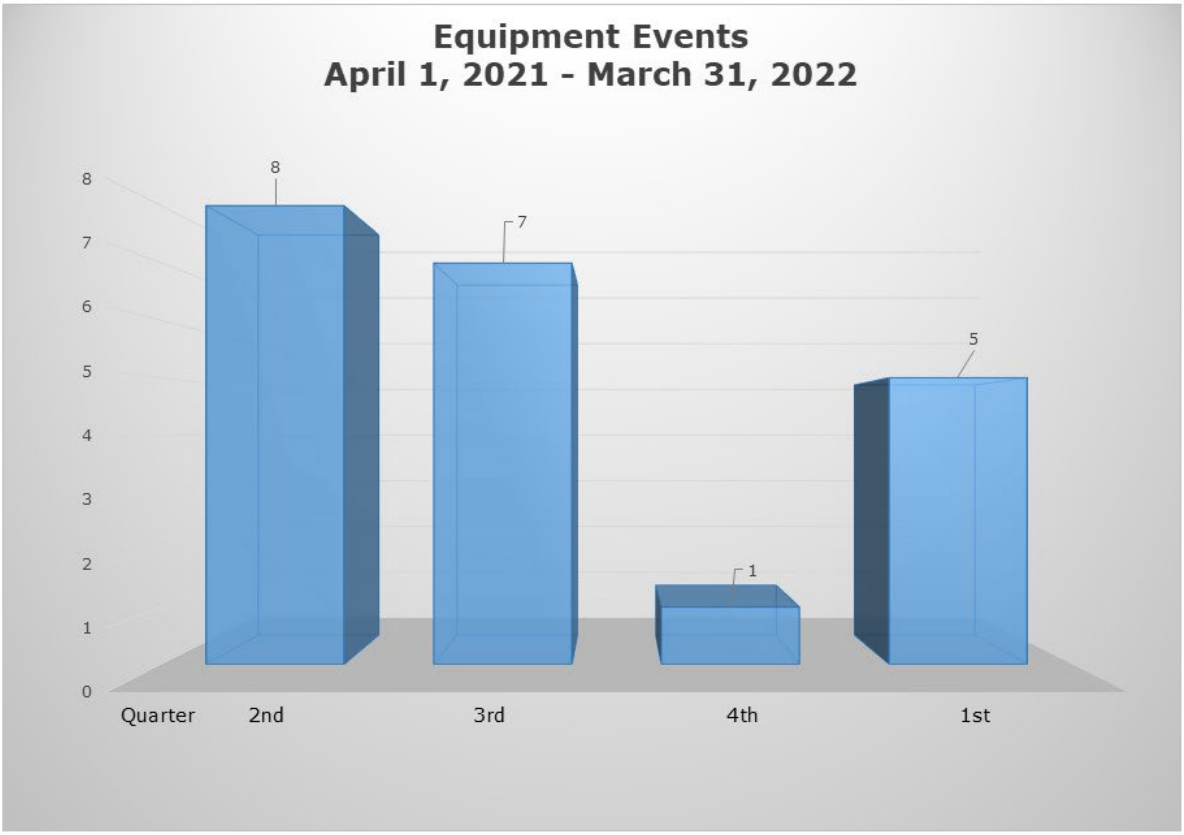
X-Ray Inspections Management & Radiation Section team members are preparing for the STP and Comanche Peak Power Plant dress rehearsals, which

are both scheduled in June to prepare for the graded exercises in July.

Environmental Monitoring Unit – Bob Free, Manager

Incident Investigations:
The graphs below reflect the numbers and categories of incidents received during this reporting period.




Equipment Events
April 1, 2021 - March 31, 2022
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Quarter
2nd
3rd
4th
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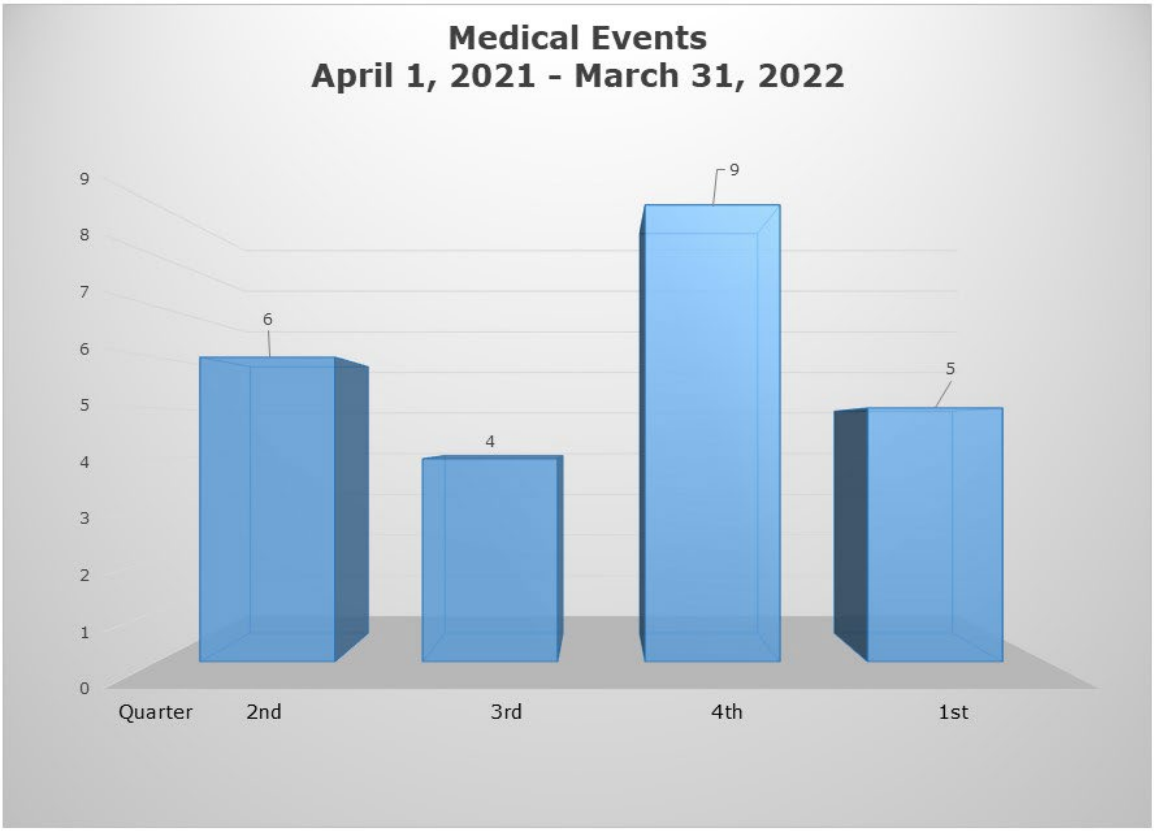
Medical Events
April 1, 2021 - March 31, 2022
6
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9
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Quarter
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3rd
4th
1st

Medical Event Summaries:

On April 7, 2021, the Agency was notified that a significant amount of Y-90 theraspheres leaked out of the connection between the tubing catheter and the patient catheter during a therapeutic procedure in which 24 mCi (a prescribed dose of 200 Gy) was to be delivered to the liver. The liquid was observed dripping out of the connection onto the towels and drapings. The dose to the skin was considered to be negligible. The dose to the liver was unknown but considered well below 80% of the prescribed dose. The procedure was repeated for the patient at a later date.

On April 14, 2021, the Agency received a report that a diagnostic procedure of 200 microcuries of iodine-123 was to be administered to the patient with the target organ as the thyroid. 150 millicuries of iodine-131 were instead administered, and the patient was allowed to leave. The patient was called back to the hospital and given Potassium Iodide (KI). The licensee spoke with the Radiation Emergency Assistance Center/Training Site (REAC/TS) team and confirmed that their course of treatment was the best given these circumstances. With the administration of KI, the actual dose to the thyroid is unknown, and the licensee doesn't feel an accurate estimate is possible due to the administration of KI. The most conservative estimate of dose provided by the Agency's Incident Investigator indicated that the thyroid likely received over 1200 rads. Interviews of the patient indicated there was no release of I-131 after discharge from the hospital. The patient remained at the licensee's facility for four days under iodine-131 administration safety protocols and then returned home. The licensee now requires two technologists to sign off before the administration of iodine. The licensee has also reported that the patient experienced the loss of taste and is on Synthroid medication.

On April 29, 2021, the Agency received a report of a medical event. On April 28, 2021, a gynecological treatment using a Varian VariSource iX device was performed. The device contained an iridium-192 source of 6.93 curies at the time of treatment. The licensee reported that after a treatment fraction the physicist discovered that a transfer tube of 125 centimeters (cm) was used instead of the 113 cm prescribed. The target tissue did not receive the prescribed dose of 600 centigray for the fraction. The licensee has removed all transfer tubes from the treatment room and will only use tubes of 125 cm in length for all treatments. The patient received additional treatment at the intended treatment site. Both the prescribing physician and the patient were notified of the event. The licensee stated the patient would not experience any adverse effects from the error.

On May 12, 2021, the Agency was notified that a medical event had occurred on May 10, 2021. The event involved a prostate seed treatment using cesium – 131 seeds. After the implant procedure, it was discovered that a large portion of the seeds had been implanted in the wrong location. The licensee reported the misplaced seeds were in fatty tissue and that it was unlikely the patient would experience any adverse effects. The prescribing physician was

made aware of the event and notified the patient. The licensee determined the tissue where most of the seeds were implanted received 115 Gy. The licensee's procedure was modified to include a timeout to verify the location of the prostate and bladder before seeds are implanted.

On July 9, 2021, the Agency was notified of a medical therapy event. A patient was scheduled for treatment to the thoracic spine (T-spine) and lumbar spine (L-spine). Each location had a separate prescription and plan, and the total dose and number of fractions were the same for each. The patient was set up for the prescribed T-spine treatment, but the L-spine prescription was pulled up on the treatment console. After the first of four fields in the L-spine prescription was administered, the setup error was identified. The patient was repositioned for the L-spine prescription, and the remaining three fields were treated. The treatment to the T-spine was also administered. The licensee identified the contributing factors: an insufficient review of treatment parameters during patient in-room setup; distracted work environment; lack of additional notation, citing multiple plans within the Record and Verify system; and inadequate communication among the treating team. Corrective actions to prevent recurrence include changes to procedures and review of event details and corrections with staff at the facility. The fraction doses for the remainder of the patient's treatment were adjusted, and the total treatment dose for the patient remained the same.

On August 31, 2021, the Agency received a notification from the Nuclear Regulatory Commission (NRC) stating that a Missouri supplier of radiopharmaceuticals had reported a misadministration that occurred with one of their products by a Texas licensee. The licensee contacted the Agency to report the event shortly after the Agency received the notification from the NRC. The treatment was an investigational study involving a novel radiolabeled targeted thorium conjugate (TTC) intended to deliver the radioisotope to epidermal growth factor receptor 2 (HER-2) antigen-expressing tumor tissue. The licensee stated that a patient was prescribed 0.0405 mCi of Th-227 (plus or minus 20 percent) tagged with antibody-chelator conjugate to affect the HER-2 antigen (Th-227 HER-2 TTC); however, on July 13, 2021, the patient was given 0.046 mCi of Th-227 tagged with antibody-chelator conjugate to target mesothelin (MSLN) antigen (Th-227 MSLN TTC). The licensee stated that some cancers that express HER-2 could also express MSLN, and it is possible that the radiopharmaceutical administered affected the intended sites. On August 31, 2021, the radiopharmaceutical manufacturer notified the licensee that during a routine retrospective document review performed on August 26, 2021, the manufacturer discovered a discrepancy and later confirmed that the product delivered to the licensee was Th-227 MSLN TTC and incorrectly labeled as Th-227 HER-2 TTC. The licensee stated that both drugs are processed the same in the body and that the estimated dose delivered to the liver, kidneys, red marrow, and small intestine is unavoidable and expected to be the same had the correct drug been administered. The licensee estimated the event resulted in approximately 6.09 Gy to the liver, 1.64 Gy to the small intestine, 1.74 Gy to the kidneys, and 0.853 Gy to the red marrow. The estimated organ doses were below the maximum tolerated doses as stated by the manufacturer. The

patient's laboratory results were monitored for six weeks, and the licensee had not noted any toxicities. The licensee does not expect any adverse effects on the patient. The physician and patient were notified. The licensee will suspend enrolling patients in the investigational study until the manufacturer can demonstrate appropriate corrective actions to reduce the likelihood of a recurrence.

On November 5, 2021, the Agency was notified that a patient being treated for multiple brain lesions received two treatments at the same location on the same day. The site was prescribed to receive one fraction one time. Instead, the individual received two treatments of 1800 cGy totaling 3600 cGy. Several plans were generated to treat multiple lesions. The planner and second person who reviewed the plan failed to notice the lesion was inadvertently prescribed into two unique plans instead of one plan. Training on the incident was held with all staff. The patient was notified, and there are no adverse effects expected from the increase in dose.

On November 9, 2021, the Agency was notified by the licensee that on November 8, 2021, the wrong patient was injected with 32.5 millicuries of Technicism -99m Sestamibi. The licensee's report stated the technician called a patient by their last name and escorted them to the treatment area. The technician injected the patient with the resting images. After one hour, the scan was performed. The front desk called the treatment area and asked how long it would be before a patient with the same last name would be treated. At this point, the technician realized the wrong patient had been injected. The patient and referring physician were notified of the error. The licensee stated no adverse effects would be experienced by the patient.

On November 10, 2021, the Agency received notification of a yttrium-90 TheraSphere administration error. An intended activity of 44.8 mCi (120 Gy) was to be inserted into the patient. Only 18.7 mCi was inserted. The remainder was still in the delivery system. The Radiation Safety Officer, RSO, reported the procedure was completed indicating there was no stoppage due to patient or other intervention. This was 41.6% of the prescribed activity inserted into the patient, which corresponded to a dose of 25 Gy. The target was a tumor in the liver. A survey of the room was done with no contamination found. After allowing the activity to decay to safe handling levels in the microsphere setup, the authorized user and radiation safety officer examined the setup, including the catheter. They found that the material had collected at the distal and proximal ends of the catheter but did not see any reason why. A manufacturer representative also examined the catheter and found that it was within the size requirements for the system. This representative did not find a cause either. The cause will be reported as unknown. The RSO has reported that when possible, they will try to flush the line more to prevent this from happening again.

On November 24, 2021, the Agency was notified that a medical event had occurred at its facility on November 23, 2021. A patient was being treated with SIRTEX SIR-spheres yttrium 90 microspheres. The order for the

treatment was 8.1 millicuries. Following the procedure, it was determined the patient had only received 6.3 millicuries. The licensee's investigation found higher than expected residual in the vial, and a member of the clinical group reported they noticed a blob of the spheres close to the vial septum before the dose delivery. The licensee contacted the manufacturer representative, who recommended gentle shaking of the vial before delivery for future cases when any sphere accumulation is observed. The Authorized User stated the dose delivered was enough radiation for an effective treatment. This procedure was one of two that were performed on the patient in sequence. There were no issues with the second procedure, which used a separate administration set and vial. The licensee will follow the manufacturer's recommendations to gently shake the vial.

On December 15, 2021, the Agency was notified of a therapy event. The caller stated that the wrong side of a patient's neck was treated with a linear accelerator. The patient received a full treatment of 45 gray over 25 fractions to the non-intended site. The registrant discovered the error after the intended lesion did not decrease in size. The patient and physician were notified on December 14, 2021, around noon, shortly after the discovery of the incident. The registrant stated that the cause was due to an improper assumption made by the radiation oncologist that was not confirmed prior to beginning the procedure. The registrant stated that procedures were amended to require verification with referring physician or radiologist when there is a question regarding the treatment site. The registrant does not expect an increased potential for toxicity due to this error and retreatment on the correct side.

On February 9, 2022, the Agency received a notification of a possible reportable medical event. A patient receiving a brain study was given 50 mCi of Tc-99m that was not mixed with the compounding drug to allow the material to cross the blood-brain barrier and accumulate in the tissue for imaging. The RSO submitted a dose estimate that demonstrated that the reportable dose limits of 5 rem whole body or 50 rem organ dose were not exceeded.

South Texas Project (STP):

DSHS held the midterm planning meeting for the upcoming STP exercise in July. Planning and training are currently underway for this event. DSHS has submitted the extent of play for this exercise for FEMA's review. DSHS gave training to the local hospital staff in Matagorda County to help prepare for their upcoming Medical Services Drill.

Comanche Peak Nuclear Power Plant (CP):

DSHS held the midterm planning meeting for the upcoming STP exercise in July. Planning and training are currently underway for this event. DSHS has submitted the extent of play for this exercise for FEMA's review. DSHS gave training to the local hospital staff in Matagorda County to help prepare for

their upcoming Medical Services Drill.

Waste Isolation Pilot Plant (WIPP):

The Department of Energy (DOE) has limited the shipments of transuranic waste through Texas to the WIPP site located southeast of Carlsbad, New Mexico. Shipments to WIPP are temporarily halted due to WIPP operational activities. Three waste shipments have been transported thru Texas to the WIPP site this year. Additional shipments are currently scheduled.

DSHS is currently choosing a new hosting site for a WIPP exercise. WIPP will be providing a roadshow in Fort Worth on June 20, 2022. The WIPP program will continue to provide emergency preparedness training for jurisdictions near the WIPP corridor. Also, a total of seventeen WIPP-related briefings were provided to local officials in Gregg, Smith, Tarrant, and Van Zandt counties.

The WIPP program for this period calibrated instruments provided to first responders in Hockley and Parker Counties. DPS instruments were also calibrated. An exchange of radiation detection equipment was done when training was performed in Marshall, Texas.

Pantex:

DSHS, along with other State and Federal partners, participated in the Pantex Full-Participation Exercise on March 30, 2022, in Amarillo, TX. Approximately 70 personnel participated. The Rad Responder (CBRNE) was fully implemented by DSHS in a full-scale exercise for the first time. Two new locations were also utilized during the exercise: the DSHS Staging Area building in Washburn, TX, and the DSHS sub-regional office in Amarillo.

Emergency Preparedness and Response:

The DOE national exercise Cobalt Magnet 22 (CM22), a one-week exercise, was completed in Austin on May 20, 2022. The exercise started with a classified search phase coordinated between the FBI, RAP region 4, and local law enforcement. On Tuesday, May 17, 2022, the exercise moved into the emergency response phase after the simulated detonation of a radiological dispersion device (RDD) at Camp Mabry. The full FRMAC was activated and set up in Austin, as well as the EPA aspect aircraft. The exercise was completed with a recovery discussion with federal, state, and local stakeholders.

This was the first time in a national exercise that the DOE and FEMA Incident Management Teams were integrated into a Cobalt Magnet Exercise. Coordination between all players improved daily. There were numerous issues identified in the exercise, and a full After Action Report (AAR) will be published in January 2023.

Highlights included the integration of the DOE fly-away lab at DSHS facilities. The DSHS main and mobile lab, as well as the University of Texas at Austin

and Texas A&M labs, received samples during the exercise. DSHS provided responder contamination monitoring for DOE and DSHS integrated field teams and supported DOE sample receipt. The 6th Civil Support Team provided decontamination for responders. Radresponder was used for logging all exposure readings and sample results during the exercise. All agencies have gained significant proficiency in the use of this critical tool for planning and responding to an exercise. DSHS used three Radiological Operations Support Specialists (ROSS) to gain experience working along with the DSHS Radiological Emergency Response Team.

Compliance Section

Environmental Health Unit – Alyson Henry

From March 2022 to April 2022, the Compliance Section issued 146 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 $272,480.00 in administrative penalties. 17 X-ray registrations and six (6) laser registrations were revoked during this period.

Operations Unit – Brian Vamvakias, Manager

RULES

- §289.252, §289.256, §289.257 - Medical Use of Radioactive Material (Project 21R035) went into effect on January 4, 2022.
- §289.229 Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices is currently under internal review and revision to incorporate comments received since the last revision in 2011. The goal is to have the draft put into the Rule Coordination Office process by September 2022.
- §289.301 Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices is currently under internal review to incorporate comments since the last revision in 2008 and also incorporate the latest laser safety guidance from the American National Standards Institute series, Z136.
- §289.253 Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies, §289.255 Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography, and §289.258 Licensing and Radiation Safety Requirements for Irradiators are being revised to incorporate NRC revisions to 10 CFR Parts 34, 36, and 39.