INCIDENT AND COMPLAINT SUMMARIES FOR FOURTH QUARTER 2017*

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Regulatory Services Division
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* Any complaint and/or incidents involving hospitals on or after August 30, 1999 are not releasable under the Texas Public Information Act & the Health and Safety Code Chapter 241.051(d). These summaries will not appear in this report.

Copies of this report are available on the internet at http://www.dshs.state.tx.us/radiation/incident.shtm

Incident and Complaint Summaries
4th Quarter 2017

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Incidents Opened Fourth Quarter 2017

I - 9514 - Medical Waste at Landfill - Methodist Healthcare System of San Antonio LTD LLP - San Antonio, Texas

On October 2, 2017, the Agency received notice from a landfill operator that waste containing Iodine-131, a medical isotope, was coming from a licensee's facility. The licensee investigation determined that a temporary contracted housekeeper in one of its clinics did not follow procedures for scanning the waste and compact dumpsters before it left the facility. Additionally, the investigation found a hand wand was not being used properly and appeared to be not functioning. The batteries were found depleted. Instrument restored to working order and training was conducted with all environmental services staff. This is a category four violation which was not cited due to compliance with regulations for the past six months or previous. No violations cited.

File closed.

I - 9515 - Radiography Source Disconnect - Acuren Inspection Inc. - Midland, Texas

On October 2, 2017, the Agency was notified by the licensee that one of its radiography crews had experienced a source disconnect while working at a field site. The radiography crew was using a QSA 880D exposure device containing a 75 curie iridium-192 source. The radiographers had completed a shot and as they approached the exposure device their alarming rate meters alarmed. The radiographers retreated to the end of the crank out device and attempted to retract the source. The source could not be retracted. The radiographers contacted their radiation safety officer (RSO) who responded to the scene. The RSO was able to drive the source into the collimator and place shielding over the source. The RSO inspected the drive cable and found that the drive cable had pulled out of the drive cable connector to the source pigtail. The RSO connected a new crank out device to the source and was able to retract the source into the fully shielded position in the camera. The RSO stated he inspected the drive cable at the connection and it appeared the cable had been stretched. The RSO stated the connector had obvious crimp marks on it. The RSO stated the equipment would be returned to the manufacturer for inspection. No individual received an overexposure due to this event. The manufacturer determined that the cable age and maintenance history had caused the failure. No violations were cited.

File closed.

Incidents Opened Fourth Quarter 2017

I -9516 - Regulatory Violations - Texas Department State Health Services - Austin - Texas

On October 10, 2017, the Agency had an alarm system breach at 1135 CST. Security called the radiation control program stating the alarm to the source room was alarming. A person went down to the room to check it out. The person checked the door and it was locked, turned off the alarm system by entering the code, and called the security company and provided information to stop law enforcement from responding to the location. The postal service technician was next door and the person asked her who opened the door. Tech stated the contractors asked her to open the door and she went to building operations office and obtained the key and opened the door for the contractors. She stated that when the alarm went off, she closed the door immediately and she informed the security guard. That is when the radiation program received the call to go down there. An investigator from the program stayed with the contractors and set the alarm when they were finished. A complete investigation was conducted to determine any theft or suspicious activity. This was not the case. Agency personnel had set off the alarm by not understanding they did not have unescorted access to the room. Radiation safety Officer for the license conducted two staff briefings updating building operations personnel on the security of the room and the door was re-keyed to prevent recurrence. No violations were cited.

File closed.

I - 9517 - Nuclear Pharmacy Error- GE Healthcare - Dallas, Texas

On October 25, 2017, the Agency was notified by the licensee that an irregularity had occurred in the assay of radiopharmaceutical dispensed by its facility. As per the facilities license condition, notification was submitted for September 26, 2017, when a Tc99m MAG 3 dose was distributed to a Hospital, upon assay the customer reported the order labeled as 1,.5 mCi calibrated for 10am was only reading .75mCi at 10 am. Upon investigation, it was postulated that because the dose was drawn exactly six hours prior to the dose calibration time, the pharmacy tech drawing the dose incorrectly read the current activity displayed on the dose calibrator instead of the calculated decayed activity at calibration time. The employee has been retrained to pay close attention to the dose calibrator read outs when assaying doses. The facility was offered a new dose but decided the concentration was sufficient to proceed with the test for the patient. No violations were cited.

File closed.

I - 9518 - Nuclear Pharmacy Error- GE Healthcare - Temple, Texas

On October 25, 2017, the Agency was notified by the licensee of an irregularity in the assay of a radiopharmaceutical. A hospital that received the dose for the licensee found the Tc99m MUGA assay to be 22 mCi instead of the 30 mCi on the label. Additionally, the pharmacist did not scan the barcode, so they were not able to confirm the identity of the product. The employee has been retrained to scan the bar code on every product and to make a standard solution with a barcode for all Sodium Pertechnetate doses that are issued. No violations were cited.

File closed.

Incidents Opened Fourth Quarter 2017

I-9519 - Gauge Shutter Failure - Westlake Longview Corporation - Longview, Texas

On November 6, 2017 the Agency received a report from the licensee stating the shutter on a Ronan model SA1 gauge, containing a 50 millicurie cesium-137 source, failed to open. The shutter was closed for maintenance on a hopper. The cotter pin on the handle was broken allowing the handle to turn without operating the shutter. On November 6, 2017, a service company repaired the gauge. No licensee employee received any exposure as a result of this event. No violations were cited.

File closed.

I - 9520 - Gauge Shutter Failure - ExxonMobil Chemical Company - Baytown, Texas

On November 10, 2017, the Agency was notified by the licensee's service provider that during routine test of an Ohmart Vega model SHD-45 nuclear gauge, the shutter failed to close. Open is the normal operation position. The gauge contains a 250 millicurie (original activity) cesium-137 source. The service provider stated the gauge is not an exposure risk to any individual. The investigation into this event is ongoing.

File open.

I - 9521 - Pharmacy Error - GE HealthCare - Houston, Texas

On November 1, 2017, the Agency was notified by the licensee of an irregularity in the assay of a radiopharmaceutical. A hospital that received the dose for the licensee found the Tc99m MUGA assay to be 23 mCi for Myoview on the label. Additionally, the pharmacist did not scan the barcode, so they were not able to confirm the identity of the product. All employees have been retrained to scan the bar code on every product and to make a standard solution with a barcode for all Sodium Pertechnetate doses that are issued. No violations were cited.

File closed.

Incidents Opened Fourth Quarter 2017

I-9522 - Device Leaking Radioactive Material - Chevron Phillips Chemical Company LP - Baytown, Texas

On November 17, 2017, a licensee reported after the removal of nuclear gauge one of its vessels that post survey of the area indicated radiation readings on 250 microrem per hour. The area was isolated and the hole was taped over with clear plastic. On November 21, 2017, the Agency conducted an onsite investigation and determined that the radionuclide was Cesium-137 indicating that the gauge had leaked. Contamination surveys around the barrier and floor indicated that there was no spread of contamination. A contractor was hired to decon the area. They used gel and grinding to remove most of the contamination. Two areas exceeded the 5000 dpm/100 cm2 release criteria after grinding. Approval was given to post a sign stating "Caution Fixed Radioactive Contamination, Radiological Controls Required to Work on Surface." The surface is not accessible when the gauge is installed. The manufacturer of the gauge reported that the leak test indicated .064 uCi on the outside of the gauge. The gauge was packaged for disposal as radioactive waste. No violations were cited.

File closed.

I - 9523 - Badge Overexposure - Interteck Asset Integrity Management Inc. - Waco, Texas

On November 28, 2017, the Agency was contacted by the licensee's radiation safety officer (RSO) who reported the OSL badge reading for one of their radiographer trainees was reported to read 62 rem. The Agency performed an on-site investigation on December 6, 2017. The investigation did not find an explanation for the exposure. The RSO stated the individual had provided a blood sample that had been sent to Radiation Emergency Assistance Center/Training Site (REAC/TS) for analysis. On December 18, 2017, the licensee reported the results of the blood test indicated the sample was normal indicating the individual did not receive the reported dose. The RSO stated that based on his investigation and the results of the blood sample the dose was to the badge only. The licensee assigned the individual a dose of 356 millirem for the exposure period. No violations were cited.

File closed.

I - 9524 - Radioactive Material Involved In A Fire - ExxonMobil Oil Corporation - Beaumont, Texas

On November 30, 2017, the Agency was notified by the licensee's consultant that two nuclear gauges were involved in a fire on November 28, 2017. The investigation into this event is on going.

File open.

Incidents Opened Fourth Quarter 2017

I - 9525 - Badge Overexposure - Christus Santo Rosa Hospital Alamo Heights - San Antonio, Texas

On December 1, 2017, the Agency was notified by the licensee's radiation safety officer that they had received a report from their dosimetry processor that one of their employees had received 6.440 rem for the July through September, 2017 exposure period. The RSO stated they believe that the exposure was to the badge only based on interviews with the individual. The RSO stated the individual had not conducted fluoroscopy work during the exposure period. The RSO stated during the interview the individual stated they had lost their badge for a two week period and it was found near a x-ray room. The individual was assigned a dose of 32 millirem for the period which is an average of the last 5 quarters. No violations were cited.

File closed.

I - 9526 - Regulatory Violation - Lewis Petro Properties, Inc. - Encinal, Texas

On December 5, 2017, the licensee reported to the Agency that on December 3, 3017, during a routine monthly gauge inspection, one of its technicians had found damage to the lead on the shutter assembly of one of its Thermo Fisher Scientific Model 5190 densitometers mounted on a frac trailer. The licensee removed the trailer/device from service. On December 4, 2017, the licensee contacted the manufacturer to ask if the licensee could replace the shutter assembly and the manufacturer's employee erroneously told the licensee it could. The licensee replaced the one-piece, slide-type shutter assembly with a new one and notified the Agency as directed by the manufacturer's employee. The Agency contacted the manufacturer's radiation safety officer (RSO) for the license involved and its corporate RSO concerning the misinformation given to the licensee. From the licensee's initial written report, the Agency learned that technicians had swapped the damaged shutter with one on a back-up trailer on December 3rd and informed the licensee later that evening. On December 13, 2017, the licensee notified the Agency that one of its technicians had found that the shutter that had been swapped from the back-up trailer was now also damaged similarly to the other. The damage consists of breakage around the outside bolt hole on the two, of six, lead plates closest to the slide bar. Based on manufacturer's device information, description of the technicians' actions, and surveys performed by the licensee which showed no increased radiation levels from the damaged shutters, exposure would have not exceeded any regulatory limit. Though damaged, the shutters were still fully operational. An investigation into this event is ongoing.

File open.

I - 9527 - Stolen X-ray Device - Aker Subsea, Inc. - Houston, Texas

On December 19, 2017, the registrant notified the Agency that one of its x-ray fluorescence devices, an Oxford XMET 5100, had been removed from the facility by a former employee without the registrant's permission and was allegedly sold. An investigation into this event is ongoing.

File open.

Incidents Opened Fourth Quarter 2017

I - 9528 - Lost Source of Radioactive Material - Versa Integrity Group Inc. - Grove, Texas

On December 29, 2017, the Agency was notified by the licensee's corporate radiation safety officer (CRSO) who reported a lost radiography camera. The CRSO stated one of the licensee's radiographers had removed from storage and placed a QA model D880 exposure device containing a 40.9 curie iridium-192 .source on the tailgate of their truck. The radiographer did not lock the device in the transfer case and drove off with the device still on the tailgate. On December 29, 2017, at 1528 hours the gauge was reported as found. The investigation into this event is ongoing.

File open.

Incidents Opened in a Previous Quarter and Closed in Fourth Quarter 2017

I - 9396 - Loss of Control of Radioactive Material - Texas DSHS - Austin, Texas

On April 31, 2016, the Agency discovered it had lost control of a smoke detector containing an 80 microcurie americium-241 source. The source was out of the Agency's control for less than an hour and was found at the back entrance of the Agency's facility. The investigation found that the source had been stored on a cart that was used that morning to move a large piece of equipment from a vehicle to its normal storage location. The source fell off the cart just outside the building entrance. An Agency employee saw the material and contacted a member of the Incident Investigation Program, who retrieved the source. The source was surveyed and the dose rates did not pose a risk of exposure to any person. A procedure for controlling radioactive material was developed in response to the event.

File closed.

I - 9508 - Unable to Retract Radiography Source - IRISNDT Inc. - Houston, Texas

On September 8, 2017, the Agency was notified by the licensee's radiation safety officer (RSO) that one of their crews had experienced a source disconnect on September 7, 2017 at a field site. The crew was using a SPEC 150 exposure device containing a 92 curie iridium – 192 source. The radiographers had completed an exposure and attempted to retract the source. The RSO stated the radiographers could not get the lock on the camera to trip. As they approached the camera the radiographers noted the dose rate reading on their dose rate meter was pegged so they retreated to the area where they operated the crank out device and called the RSO. The RSO drove to the location and performed the source recovery. The RSO placed shielding over the source which was located in the collimator and removed the guide tube from the camera. The RSO found the drive cable sticking through the front of the camera. He disconnected the crank out device from the rear of the camera and found the drive cable had gone completely through the camera. The RSO found that the drive cable broken in two inside the drive cable housing about 18 feet from the source. The RSO manually retracted the source into the camera by pulling on the drive cable. The source was returned to its fully shielded position. The licensee sent the drive cable assembly to the manufacturer for inspection. No over exposure or exposure to a member of the general public occurred as a result of this event. The manufacturer was unable to determine the cause for the failure. No violations were cited.

File closed.

Incidents Opened in a Previous Quarter and Closed in Fourth Quarter 2017

I - 9509 - Gauge Shutter Failure - BASF Corporation - Bishop, Texas

On September 12, 2017, the Agency was notified by the licensee's radiation safety officer (RSO) that during routine inspections, three Berthold nuclear gauges were found with shutters stuck in the open position. On September 19, 2017, the service company repaired all three gauges. They were able to exercise shutters on all three devices by applying lubricant in appropriate areas and allowing it to sit for a period of time to free up the shutter on/off mechanism, locking latch as well as keying mechanism. All gauges were returned to service. No violations were cited.

File closed.

I - 9510 - Potential Theft of Radioactive Material - American Piping Inspection - Midland, Texas

On September 15, 2017, the Agency was notified by the licensee's radiation safety officer (RSO) that an event involving two radiography crew's had occurred. The two crews left field sites in west Texas with the intention of driving to their home site office in La Porte, Texas turning in their trucks and cameras and quitting their jobs. The Midland office directed the two crews to turn in their trucks to the Midland office, however, the radiographers decided to continue to drive the trucks to La Porte. The licensee notified local law enforcement which resulted in stopping the trucks and arresting one radiographer. An investigation by the Agency and the Licensee's RSO determined that the radiographers had no intention of stealing the two radioactive iridium-192 sources in the cameras or the trucks. The radiographers intended to quit their job due to dissatisfaction in pay and were all four terminated that day by the licensee. No violations were cited.

File closed.

I - 9511 - Gauge Shutter Failure - Solvay Specialty Polymers USA LLC - Orange, Texas

On September 22, 2017, the Agency was notified by the licensee that the shutter on a Ronan SA1-F37 gauge containing a 500 millicuire (original activity) cesium - 137 source would not open. The manufacturer repaired the gauge on September 26, 2017. The manufacturer reported the failure was due to a buildup of debis in the operating arm area. The licensee stated they were increasing the inspection frequency to quarterly to prevent recurrence of the event. One level IV violation was identified in the investigation, but was not cited.

File closed.

Incidents Opened in a Previous Quarter and Closed in Fourth Quarter 2017

I - 9512 - Regulatory Violation -Security Issues - Diamond G Inspection, Houston - Texas

On September 22, 1017, the Agency was notified by the licensee's radiation safety officer (RSO) that an unusual event had occurred at their facility. The RSO stated that while he was working on his computer, he noted that the display for 16 security cameras went blank. The RSO determined that their computer system had been hacked. On site investigation completed on October 4, 2017 confirmed the system was breached from the video surveillance company and down linked into the radiography company's video feed communication line. The breach was directly targeted to the company supplying the video surveillance. The vault security system has a separate communication system and the security plan is not stored on the computer system. Upgrades in firewalls and alerting system have been completed as well as password changes to prevent a recurrence. The security system has back up power from batteries and a generator. There was no breach in the camera security system. No violations were cited.

File closed.

I - 9513 - Improper Disposal - Southwest Research Institute - San Antonio, Texas

On September 25, 2017, the licensee radiation safety officer (RSO) reported to the Agency that the contents of four 55-gallon barrels of engine oil that contained low levels of cobalt-60 contamination had been collected and disposed of by their regular oil recycler during its pickup of non-contaminated oil. The individual managing the disposal of two drums of diesel exhaust fluids was asked if the four drums containing the cobalt were to be disposed of and he stated they were. Both individuals involved had not been trained in the handling radioactive waste. The licensee stated all four drums did have radioactive material labels on them. The RSO stated the dose rates on the drums were undistinguishable from background levels. The licensee provided sample results for the oil completed when the drums were placed into storage. The activities (decay corrected) would have been less than the release limits for discharge to sanitary systems and were far below the levels which required reporting under our rules. The licensee has added additional labels to drums containing radioactive materials and will store these drums in a segregated location. The RSO stated additional training on the proper handling of fluids containing radioactive material will be provided to individuals who handle any waste fluids. One non-cited violation was identified during the investigation of this event.

File closed.

Complaints Opened Fourth Quarter 2017

C - 2771 - Inadequate Credentialing - Texas Municipal Power Agency - Anderson, Texas

On October 4, 2017, the Agency received a complaint alleging the licensee intends to place a person in the position of radiation safety officer (RSO) who is not qualified. On November 8, 2017, the Agency was informed that the licensee no longer intended to replace the RSO. No violations were cited.

File closed.

C - 2772 - Regulatory Violations - Medical Facility - Plano, Texas

On October 19, 2017, the Agency received a complaint regarding a mammography imaging facility not having the previous patient record for the complainant. An investigation was conducted at the facility on November 15, 2017 and the facility had a Purchase Agreement and a Medical Records Custody Agreement for the previous facility records. The complainant records were searched for in the electronic system. She was the first patient seen that day and a search for other patients seen that day produced their records although not the complainants. The previous day records were searched and all found. A selection of dates used produced those patient's records. It was believed that the complainant's record had been corrupt in electronic format and was not saved into the system. Unfortunate event to lose a record, although the facility had completed the purchase of the past records. The complainant was able to obtain her records from another facility to complete an image comparison. No violations were cited.

File closed.

C - 2773 - Regulatory Violation - Viascan of Las Colinas - Irving, Texas

On October 20, 2017, the Agency received a complaint that the registrant was continuing to perform self referred cardiac scans which violated the Emergency Order issued to the registrant on October 13, 2017. The registrant was in litigation with this Agency at the time of the complaint so it was decided that the investigation of the complaint would be delayed until the results of the litigation were known. The litigation was completed on November 29, 2017. The resulting Mediated Agreed Order allows the registrant to continue performing self-referred studies with some limitations. The complaint was substantiated, but no violation was cited due to the results of the mediation.

File closed.

Complaints Opened Fourth Quarter 2017

C - 2776 - Failure to Ensure Equipment Performance Evaluation - Siemens Medical Solutions USA Inc - Cary, North Carolina

On November 6, 2017, the Agency received a complaint that the registrant was providing installation and service for radiation-producing machines without providing or ensuring the required equipment performance evaluation within 30 days. An investigation into this event is ongoing.

File open.

C - 2777 - Failure to Ensure Equipment Performance Evaluation - Philips Electronics North America Corp - Andover, Massachussets

On November 6, 2017, the Agency received a complaint that the registrant was providing installation and service for radiation-producing machines without providing or ensuring the required equipment performance evaluation within 30 days. An investigation into this event is ongoing.

File open.

C - 2778 - Failure to Ensure Equipment Performance Evaluation - GE Healthcare Inc - Arlington, Texas

On November 6, 2017, the Agency received a complaint that the registrant was providing installation and service for radiation-producing machines without providing or ensuring the required equipment performance evaluation within 30 days. An investigation into this event is ongoing.

File open.

C - 2779 - Failure to Ensure Equipment Performance Evaluation - BC Technical Inc - West Jordan, Utah

On November 6, 2017, the Agency received a complaint that the registrant was providing installation and service for radiation-producing machines without providing or ensuring the required equipment performance evaluation within 30 days. An investigation into this event is ongoing.

File open.

Complaints Opened Fourth Quarter 2017

C - 2780 - Failure to Ensure Equipment Performance Evaluation - Toshiba Medical Systems Inc - Tustin, California

On November 6, 2017, the Agency received a complaint that the registrant was providing installation and service for radiation-producing machines without providing or ensuring the required equipment performance evaluation within 30 days. An investigation into this event is ongoing.

File open.

C - 2781 - Improper Disposal - ISO-TEX DIAGNOSTICS INCORPORATED - Friendswood, Texas

On November 8, 2017, the Agency was notified by Texas Commission on Environmental Quality (TCEQ) that they had received an allegation that a licensee was disposing of potentially contaminated material without performing contamination survey. The investigation into this event is ongoing.

File open.

C -2782 _ Regulatory Violations - Century Inspection INC, Longview, Texas

On November 22, 2017, the Agency received an anonymous complaint about a licensee conducting multiple regulatory violations including employees knowingly exposing other employees to x-ray radiation, failing to put up and monitor barricades, and not wearing film badges. The Agency conducted an onsite investigation on December 6, 2017 and found items of non-compliance. The items of non- compliance were addressed by the radiation safety officer while the investigator was on site and immediately afterwards employees were retrained in safety aspects. The complaint was substantiated. Three violations were cited.

File closed.

C - 2783 - Unfiltered X-ray Tube - Mansfield Smiles and Orthodonics PC - Mansfield, Texas

On November 27, 2017, the Agency received a complaint stating that a registrant was operating a dental x-ray device without the appropriate filters in place. The complaint stated that they could see the red glow of the x-ray tube anode every time an x-ray was taken. An Agency inspector performed an inspection at the facility on November 27, 2017. The inspector found that the x-ray tube was built using a glass filter. This is the reason the glow from the energized anode could be seen. The machine was tested by the inspector and functioned properly. The complaint could not be substantiated. No violations were cited.

File closed.

Complaints Opened Fourth Quarter 2017

C - 2784 - Veterinary Regulatory Violations - Gulf Coast Veterinary Specialists - Houston, Texas

On November 29, 2017, the Agency received an anonymous complaint against a registration including unsafe practices, not wearing badges, and not sure the facility is registered. On December 14, 2017, the Agency conducted an investigation. The facility was properly registered, equipment performance evaluations were completed at the new location, and proper personnel and area dosimetry were used. The complaint could not be substantiated. No violations were cited.

File closed.

C - 2785 - Regulatory Violations - Bonded Inspections, Inc - Dallas, Texas

On December 14, 2017, the Agency received a complaint alleging that a registrant employee was performing radiography without proper barriers, control, or transport of a radioactive source. An investigation into this event is ongoing.

File open.

Complaints Opened in a Previous Quarter and Closed in Fourth Quarter 2017

C - 2759 - Monitoring Not Provided - Community Portable X-ray LLC - Plano, Texas

On August 8, 2017, the Agency received a complaint that the registrant was not providing personnel monitoring and that x-ray equipment was in disrepair. Prior to an onsite investigation the complainant reported that the equipment had been repaired and he had received dosimetry. On September 26, 2017, the Agency conducted an onsite investigation. Dosimetry records were reviewed and it was determined that the complainant conducted x-rays for over 5 months without dosimetry. The Agency recommended that the facility keep extra badges so they are assigned as soon as an employee starts. The complaint was substantiated. One violation was cited.

File closed.

C - 2762 - Radiation Exposure to Cancer Patients -Medical Facility- Woodlands, Texas

On August 21, 2017, the Agency received a complaint from a physician alleging they had treated six patients for wounds that would not heal after treatments for skin cancer. The investigation into this event was difficult at best to determine if any of the six patients had received higher than normal dosage of radiation to treat cancer. No medical records were provided, thus it could not be determined that the levels of radiation caused the patients wound to stop healing. The doctor originating the complaint was informed to speak with the Medical Review Board to file a detailed complaint and patient history to the Board. At this time this complaint could not be substantiated. No violations were cited.

File closed.

C - 2763 - Transportation Violation - QSA Global - Houston, Texas

On August 22, 2017, the Agency received an allegation from the State of Washington's Office of Radiation Protection stating that two Texas licensees had shipped sources to licensees in its state and the shipping documents did not include a no-later-than date and time. Due to Hurricane Harvey, the Agency delayed its investigations at both licensee's locations until September 27, 2017. The investigation at the first licensee location found that the licensee had already been investigated in another of it locations outside of the State of Texas and had corrected the issue. The investigation at the second licensee's location found that it was not including the information on the shipping documents as required. On September 29, 2017, the licensee provided the Agency with a copy of the new template for its shipping document which showed the information added to the document. One violation was cited.

File closed.

Complaints Opened in a Previous Quarter and Closed in Fourth Quarter 2017

C - 2766 - Laser Registration 302 - Women Want Moore - Austin, Texas

On August 23, 2017, the Agency received a complaint alleging a facility was performing laser treatments without registration from this Agency. This file has been refered to the Texas Department of Licensing and Registration.

File closed.

C - 2769 - Laser Hair Removal Burn - Sigma Laser Med Spa - Farmers Branch, Texas

On September 26, 2017, the Agency received a complaint of a burn received from a Laser Hair Removal (LHR) treatment. The complainant stated that the setting of the LHR machine was twice the required amount and that she will have permanent scarring from the treatment. On October 10,2017, a joint investigation with Texas Department of Licensing and Regulation (TDLR) was conducted on site. The Agency determined that the burn was not caused by improper setting of the machine nor was there any gross negligence during the LHR treatment. The Agency did determine that the facility did not report the injury to DSHS or the FDA. Additionally, the facility was not registered to conduct LHR or Laser tattoo removal. The complaint was not substantiated. Four LHR violations were turned over to TDLR for investigation. One violation was cited for DSHS.

File closed.

C - 2770 - Unregistered Laser Equipment - Waco Electrolysis Center - Waco, Texas

On September 29, 2017, the Agency received a complaint alleging an individual may be removing tattoos using a laser with out registration. The Agency contacted the owner of the facility and they stated there were no laser devices at there business and that they where not aware of anytime a laser had been used at their business. The Agency contacted the individual the allegation was made against. They stated they do not own or use a laser. A review of the business's web site did not find any indications of any type of laser service offered. The web site states their method of hair removal is the alternative to laser hair removal. The complaint could not be substantiated.

File closed.

C - 2774 - Regulatory Violations - Rio Grande Urology PA - El Paso, Texas

On October 27, 2017, the Agency received an anonymous complaint about a clinic reporting that the registrant conducts multiple unnecessary x-rays on patients including over seventy on one patient on one day. On November 16, 2017, the Agency conducted an onsite investigation. The x-rays conducted for the treatment process, which is common in 95 percent of the patients, requires a large field. The registrant explained the process to the Agency. The Agency recommended some additional communication with the patients on the required x-ray protocols. No violation was cited.

File closed.