TCEQ REGULATORY GUIDANCE
Waste Permits Division
RG-001 ● Revised August 2016

Texas Regulations on Medical Waste

This is a regulatory guide to assist generators of medical waste, transporters of untreated medical waste, and operators of medical-waste treatment facilities or mobile treatment units. This guidance is based on rules pertaining to medical waste that became effective May 26, 2016, contained in Title 30, Texas Administrative Code, Chapter 326. Permits and registrations issued to medical-waste treatment and transfer facilities that existed before May 26, 2016, remain valid for two years from that date, or until a final decision is made on a timely filed new application for an existing authorization to comply with Chapter 326, whichever is later. The executive director is authorized to extend that deadline based on an authorized entity making a request supported by good cause. Registrations by rule for transporters and mobile treatment units, subject to annual renewal, remain in effect and must renew under this chapter. Notifications that existed before May 26, 2016, remain valid and are subject to these rules.

Abbreviations

- ***CFR***—Code of Federal Regulations.
- ***DSHS***—Texas Department of State Health Services.
- ***mL***—milliliter(s).
- ***MSW***—municipal solid waste.
- ***TAC***—Texas Administrative Code. "30 TAC *xx.yy*" is short for "Title 30, Texas Administrative Code, Chapter *xx*, Section *yy*."

Definitions

Medical waste: Defined in 30 TAC 326.3(23). Includes "special waste from health care–related facilities" as used by the DSHS and "regulated medical waste" as defined in 49 CFR 173.134(a)(5). Note that the TCEQ's use of "medical" is equivalent to "health care–related" as used by the DSHS.

Special waste: As defined in 30 TAC 330.3(148), includes **untreated** medical waste. Treated medical waste may be sent for disposal in an MSW Type I landfill provided a shipping document, including a statement that the waste has been treated, accompanies the shipment as referenced under 30 TAC 326.75(r).

Special waste from health care–related facilities: As defined in 25 TAC 1.132(44), identifies five categories of waste that are regulated:

1. Waste from animals that have been intentionally exposed to pathogens.
2. **Bulk** blood, bulk human-blood products, and bulk human bodily fluids.
3. Microbiological waste.

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4. Pathological waste.
5. Sharps.

Bulk: A containerized aggregate volume of 100 mL or more [25 TAC 1.132(7)]. A volumetric standard for identifying waste items that are not medical waste but are used in a health-care setting: examining gloves, tongue depressors, clean scrubs, etc. The term also provides for accumulation of waste. Waste may become regulated as medical waste, for example, if small amounts of blood are commingled in a container and eventually reach 100 mL in volume.

On-site: As defined in 30 TAC 326.3(29), applies to management of medical waste on property owned or effectively controlled by one entity and within 75 miles of the point of generation or at an affiliated facility. The provision allows for management of medical waste within 75 miles by a parent hospital. Waste may be transported to a storage area at a parent hospital for on-site treatment or for pickup and transport off-site to an authorized treatment facility. The provision also allows for management of medical waste between contiguous hospitals that share a waste-management system; it does not require the hospitals to be owned or effectively controlled by one entity.

Affiliated facility: As defined in 30 TAC 326.3(2), a health care–related facility that generates a medical waste that is routinely stored, processed, or disposed on a shared basis in an integrated medical-waste management unit owned, operated by a hospital, and located within a contiguous health-care complex.

Requirements for Generators of Medical Waste

Generators of medical waste that ship their waste off-site for treatment are required to package and label it properly as specified in 30 TAC 326.17, 326.19, and 326.21 before its transportation off-site. The following options are available to comply with the container weight requirements.

Generators may record the weight or volume on the manifest for reporting and calculation of fees.

- If the generator chooses to use weight, the generator may have the transporter weigh each container for the generator and note the weight on the container label before transportation off-site, **or**
- Transporters must give the generator a written or electronic statement of total weight or volume of the containers collected within 45 days of shipment.

The TCEQ does not require the use of certified scales to weigh medical-waste containers. The accuracy of general-use scales is appropriate for the records that must be kept. Subsection 30 TAC 326.19(a) requires that the bags containing medical waste be placed in a rigid container that is leak resistant, **impervious to moisture**, strong enough to prevent tearing and bursting under normal use and handling, and sealed to prevent leakage or as otherwise required by the U.S. Department of Transportation under 49 CFR 173.134 and 49 CFR 173.196, which address infectious substances. To clarify, the TCEQ does not construe "impervious to moisture" to eliminate the use of cardboard boxes designed for medical waste, but intends to set a standard for medical-waste containers that do not conform to 49 CFR 173.134. Most commercially purchased cardboard containers for medical waste do meet the CFR requirements.

Generators are required to obtain a signed shipping receipt from a registered transporter, maintain records of all shipments of untreated medical waste sent off-site for three years after the date of shipment, and make the records available for inspection by the TCEQ. Generators should also obtain a receipt from the medical-waste treatment facility certifying that the waste has been properly treated as required by 30 TAC 326.75(e)(7)(D) and must also maintain these records and make them available for TCEQ inspection upon request.

Generators that treat their own medical waste on-site are required to notify the TCEQ of the operation as specified in 30 TAC 326.39 and 326.41 and are also required to maintain records of the amount of each load of medical waste treated. **All** such generators must maintain records including the date of treatment, the amount of waste treated, and the name of the person performing the treatment. Generators of **more than 50 pounds of medical waste per month**—large-quantity generators (LQGs)—must also maintain records documenting the testing of microorganism-reduction performance or parameter monitoring of the treatment unit. Record-keeping requirements for LQGs are specified in 30 TAC 326.41(b).

Requirements for Transporters of Untreated Medical Waste

Generators of **less than 50 pounds of medical waste per month** (small-quantity generators) may transport their own untreated medical waste without being subject to the transporter requirements specified in 30 TAC 326.31(b).

LQGs and transporters of untreated medical waste who are not the generator of the waste may obtain a registration by rule as specified in 30 TAC 326.53 **only** after they supply the TCEQ with the information required by the rule. The agency also requires transporters to pay an annual registration fee to maintain their authorization to transport.

Transporters are required to use transport units that meet the requirements of 30 TAC 326.53(b)(6). As required by 326.53(b)(6)(A), the cargo compartment must have a floor and sides made of an impervious, nonporous material in order to allow disinfection of the surfaces of the cargo area should containers leak or if the unit will be used to transport other items as specified in 30 TAC 326.53(b)(7).

For putrescible or biohazardous untreated medical waste, maintaining a temperature of 45 degrees Fahrenheit or less during pre-collection storage is optional. (Pre-collection storage is storage by the generator, normally on the generator's premises, before initial collection.) Such medical waste in more than 72 hours post-collection storage must be maintained at 45 degrees Fahrenheit or lower. There are two types of post-collection storage as defined under 30 TAC 326.3(53). Post-collection storage by a **transporter** occurs while the medical waste is in transit. Post-collection storage by a **processor** occurs at a processing facility while the waste is awaiting processing or transfer to another storage, disposal, or recovery facility.

Transporters, like generators, are required to maintain records of all shipments of untreated medical waste for the most recent three years and must make the records available to the TCEQ for inspection as specified in 30 TAC 326.53(b)(8).

Transporters may only transfer loads of untreated medical waste at an authorized facility unless a transportation unit malfunctions or is involved in a traffic accident. If a vehicle breakdown or accident occurs, a transporter may transfer the load to an operational transportation unit but must notify the TCEQ by the end of the next working day if there is an accident and within five working days if there is a vehicle malfunction, as specified in 30 TAC 326.53(b)(18) and (19). Update to the transporter's registration by rule is required when the new unit or units are placed in medical-waste transport service for more than five days.

Transporters of waste within Texas when the transportation neither originates nor terminates in Texas must follow 30 TAC 326.53(b)(16).

Transporters must summarize, in a report to the TCEQ, all their activities for the preceding calendar year. The report must be submitted no later than March 1 of the following year. The report must contain all the information specified in 30 TAC 326.89(d).

Requirements for Operators of Mobile On-Site Treatment Units

Operators of mobile on-site treatment units who are not the generator of the waste may obtain a registration by rule as specified in 30 TAC 326.55(a) only after supplying the information required by that rule to the TCEQ as part of registration by rule. The TCEQ requires operators of mobile on-site treatment units to estimate the costs for waste removal and disposal as well as equipment decontamination for each treatment unit. Once the TCEQ accepts the estimate, the operator is required to provide financial assurance based on the accepted estimate. Cost estimates must represent the worst-case scenario based on a third party removing the largest volume of waste and decontaminating all treatment units.

According to 30 TAC 326.55(b)(10), operators of mobile on-site treatment units must document to the generator the integrity of the mobile treatment unit and associated cargo compartments as specified in 30 TAC 326.55(b)(6), as well as provide a statement to the generator that the medical waste was treated using an approved method as specified in 25 TAC 1.136. Operators of mobile treatment units are also required to maintain records of all medical waste treated as specified in 30 TAC 326.55(b)(8).

Operators of mobile treatment units may not transport untreated medical waste unless they are registered as a transporter as discussed previously in this document. If an operator of a mobile treatment unit is also a registered transporter, then all the transporter rules apply. Paragraph 30 TAC 326.53(b)(11) requires shipment of untreated medical waste to a facility that is authorized to accept the waste. An operator of a mobile treatment unit is not permitted to transport untreated medical waste to a central office, treat the waste at that location, and then transport the treated waste to an MSW landfill.

Operators of mobile treatment units must summarize, in a report to the TCEQ, all their activities in each calendar year no later than March 1 of the following year. The report must contain all the information specified in 30 TAC 326.55(b)(8).

Requirements for Operators of MSW Type V Medical-Waste Treatment Facilities

Operators of medical-waste treatment facilities are required to obtain a registration, rather than a permit to operate the facility, as specified in 30 TAC 326.61(a).

Operators of treatment facilities must maintain records of all treated waste similar to the records required of operators of mobile treatment units. The required records are specified in 30 TAC 326.71(j) and include either microorganism-reduction performance testing or parameter monitoring. If chemicals or reagents are used in treatment, the operator must also maintain records of the effective treatment strength of all reagents and chemicals. All documents must be maintained for three years.

Operators of treatment facilities shall only accept waste that is accompanied by a shipping document that indicates their facility as the receiving facility as specified in 30 TAC 326.75(e)(7). The operator is also required to sign the shipping document, give a copy of the document to the transporter, retain a copy for the facility records, and within 45 days send a copy of the document to the generator of the waste including a statement that the medical waste has been treated using an approved method as specified in 25 TAC 1.136.

Regulatory References

DSHS rules: 25 TAC 1.131–1.137.

TCEQ rules: 30 TAC Chapters 326 and 330.

For more information or answers to questions about management of medical waste, please contact our Municipal Solid Waste Permits Section at 512-239-2335 or e-mail us at <mswper@tceq.texas.gov>.