TCEQ REGULATORY GUIDANCE



Waste Permits Division RG-001 • Revised September 2012

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 municipal solid waste that became effective March 27, 2006. Compliance with the subchapter on "Medical Waste Management" (30 TAC 330, Subchapter Y) was required by July 25, 2006. The 2006 rules substantially changed the requirements for managing medical waste, redefined management "on-site," and strengthened the recordkeeping requirements for all persons involved in the management of medical waste.

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 330.3(85). Includes "special waste from health care–related facilities" as used by 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: Under the 2006 rules, special waste no longer includes treated medical waste. As defined in 30 TAC 330.3(148), special waste only includes untreated medical waste. With the exception of nonencapsulated sharps and treated medical waste in whole red bags, no special handling is required prior to disposal in an MSW Type I landfill. Nonencapsulated sharps and treated medical waste in whole red bags 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.

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

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- 1. Waste from animals that have been intentionally exposed to pathogens.
- 2. Bulk blood, bulk human blood products, and bulk human body fluids.
- 3. Microbiological waste.
- 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 a provision 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 redefined in 30 TAC 330.1205(b), the 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 is management on-site. The revision 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. An affiliated facility means a health carerelated 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 or operated by a hospital, and located within a contiguous health-care complex. The revision also allows for management of medical waste between contiguous hospitals that share a wastemanagement system; it does not require the hospitals to be owned or effectively controlled by one entity. "Affiliated facility" was added to the definition to allow health-care complexes, or multiple contiguous hospitals, to offer a central area for storage or processing of medical waste (or both).

Requirements for Generators of Medical Waste

Generators of medical waste that ship their waste off-site for treatment are required to properly package and label it as specified in 30 TAC 330.1207(c) prior to transportation off-site. The following options are available to comply with the container weight requirements.

- Generators may weigh each individual container of medical waste and record the weight on the container label, **or**
- transporters may record the total number of containers on the shipping documents as long as the transporter supplies to the generator a written or electronic statement of total container weight within 45 days of shipment.

In addition, 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. MSW rule 30 TAC 330.1207(c)(2) requires the placement of 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. 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 following 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 330.219(h)(4) 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 330.11(f) 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 and method of treatment, the amount of waste treated, and the name of the person performing the treatment. Generators of **more than 50 lbs of medical waste per month** must also maintain records documenting the testing of pathogen-reduction performance or parameter monitoring of the treatment unit. Record-keeping requirements are specified in 30 TAC 330.1219(a)(2–3).

Requirements for Transporters of Untreated Medical Waste

Generators of **less than 50 lbs of medical waste per month** may transport their own untreated medical waste without being subject to the transporter requirements specified in 30 TAC 330.1211. Generators of **more than 50 lbs of medical waste per month** may transport their own waste but shall comply with 30 TAC 330.1211(d) through (l) and must notify the TCEQ as specified in 30 TAC 330.1211(a)(2).

Transporters of untreated medical waste who are not the generator of the waste may obtain a registration by rule as specified in 30 TAC 330.9(l) **only** after they supply the TCEQ with the information required by 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 330.1211(c). As required by 330.1211(c)(2)(D), 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 330.1211(d).

The rules also require the refrigeration, at 45°F or colder, of any medical waste held longer than 72 hours after pickup from the point of generation as specified in 30 TAC 330.1209(b).

Transporters, like generators, are required to maintain records of all shipments of untreated medical waste for the past three years and must make the records available to the TCEQ for inspection as specified in 30 TAC 330.1211(h).

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 for an accident and within five working days for a vehicle malfunction as specified in 30 TAC 330.1213(1-2).

Transporters of untreated medical waste into or out of Texas must follow all applicable MSW rules for such transport as specified in 30 TAC 330.1215.

Transporters 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 330.1211(m).

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 330.9(m) only after supplying the information required by the cited rule to the TCEQ as part of the registration process. The TCEQ is now requiring operators of mobile on-site treatment units to estimate the costs for waste removal and equipment decontamination for each treatment unit. Once 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.

Operators of mobile treatment units are required to issue a receipt to the generator containing the information specified in 30 TAC 330.1219(a)(3). This information concerns either testing of pathogen-reduction performance or parameter monitoring and includes a statement from the operator that the medical waste has been 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 330.1221(g).

Operators of mobile treatment units may not transport untreated medical waste unless 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. **30** TAC **330.1211(j)** 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 a 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 330.1221(g).

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

Under the 2006 rules, 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 330.9(n).

Operators of treatment facilities must maintain records of all waste treated similar to the records required of operators of mobile treatment units. The required records are specified in 30 TAC 330.1219(a)(3) and include either pathogen-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 330.219(h). 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 supply 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 1.131–137.

TCEQ rules: 30 TAC 330.

For additional information or questions regarding management of medical waste, please contact the Municipal Solid Waste Permits Section of the TCEQ at 512-239-2335 or e-mail us at <mswper@tceq.texas.gov>.