

Universal Waste and Hazardous Waste Management at Healthcare Facilities in Tennessee (To Include Pharmaceuticals)



Introduction:

Universal Waste and Hazardous Waste management requirements at healthcare facilities in Tennessee closely mirror the federal hazardous waste requirements promulgated by the U.S. Environmental Protection Agency (EPA). A recommended source of extensive guidance for dealing with waste management issues at healthcare facilities is the Healthcare Environmental Resource Center (HERC) at:

<http://www.hercenter.org/index.cfm>



It should be noted that patient safety and welfare, the safety of healthcare professionals and technicians, as well as environmental staff handling wastes, is a primary concern that cannot be compromised. Any environmental program must ensure patient and employee safety is not compromised. A good faith effort at an environmental waste management program, realizing occasional mishaps may occur, should help to eliminate or greatly reduce the chance of citations for substantial non-compliance and would be a significant mitigating factor if any violations were identified versus a facility that did not have a program. The Division's inspectors have been briefed to fully respect the sensitive and critical nature, as well as privacy issues, associated with healthcare facilities. However, the lack of a program would alert the inspector to the strong possibility of substantial environmental compliance issues.

Further guidance can also be found in EPA's August 26, 2010 draft, EPA-821-R-10-006 on Best Management for Unused Pharmaceuticals at Health Care Facilities:

<http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf>

It should be noted that a key difference is that Tennessee has a fee system on hazardous waste management that is potentially applicable to any hazardous waste generated at a healthcare facility. The hazardous waste fee requirements are found in Tennessee Rule 0400-12-01-.08:

<http://tn.gov/sos/rules/0400/0400-12/0400-12-01/0400-12-01.htm>

Tennessee's solid and hazardous waste regulations can be located here and can also be printed out:

<http://tn.gov/environment/solid-waste/index.shtml#regulations>

The Importance of a Viable Environmental Program

Violations of Tennessee's hazardous or solid waste laws and regulations, or failing to pay applicable environmental fees, can potentially lead to civil fines and/or criminal prosecution. These fines can potentially be substantial and knowing and willful violations, or a willful or substantially negligent disregard, of the state's environmental laws can potentially, if the violations are serious, lead to a felony conviction.



The lack of a viable environmental compliance program can obviously be used as evidence of a lack of intent to comply. Deliberate violations are much more serious than occasional inadvertent violations or oversights while the facility is in substantial compliance and has made a good faith effort to comply. Willful and knowing violations can potentially lead to criminal prosecution. Conversely, organizations and companies that have made a good faith effort at compliance are typically able to demonstrate violations were not intentional and their violations are typically of a more minor nature. Therefore, it is important that each healthcare facility or organization makes a good faith effort by having qualified environmental staff and/or contracts or support with a qualified environmental company(ies) to ensure compliance and to avoid the appearance of deliberate non-compliance or willful negligence. Many environmental and waste handling companies offer economical packages for compliance advice and support and/or may include such support as part of their waste handling package.



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Reverse Distribution for Unused and Unopened Pharmaceuticals:

Tennessee follows EPA's guidance on the reverse distribution process for unused pharmaceuticals that have not been sold or distributed, and are in the original packaging, that are returned by the healthcare

facility or retailer to the manufacturer under a legitimate reverse distribution system for evaluation, potential credits, and final disposition or resale or reuse.

Waste Management:

Besides pharmaceutical wastes, healthcare facilities may also have items like fluorescent lamps (bulbs), batteries, used oil, some types of maintenance waste, etc. that must be managed as hazardous or universal waste prior to being sent for recycling or disposal. Records and reporting are part of the required compliance requirements.

Medical wastes that are not hazardous waste are subject to regulation under Tennessee's solid waste regulations found at:

<http://tn.gov/sos/rules/0400/0400-11/0400-11-01.20130318.pdf>

Below are some examples of possible listed hazardous waste that healthcare facilities may generate.



P-list

If you are interested in reducing the hazardous waste generated in your facility, eliminating or finding substitutes for P-listed chemicals is a good place to start. A small quantity -- one kilogram -- of a P-listed waste can cause a facility to be classified as a "[large quantity generator](#)," and to have to comply with more stringent rules as a consequence.

The [P-list](#) includes about 239 different "acutely toxic" substances, listed under about 135 different waste codes. (Some codes cover several substances.) HERC has identified 15 of these that you might expect to find in a healthcare facility. They are listed below, along with their waste codes and typical uses associated with each. The CAS numbers for these compounds can be found in the official list at [40 CFR 216.33](#). The equivalent Tennessee regulation is found in Tennessee Rule 0400-12-01-.02(4)(d).

Please note that our short list is not meant to be exhaustive.

P-listed chemicals commonly found in healthcare facilities, Tennessee Rule 0400-12-01-.02(4)

Material	Code	Use
3-benzyl Chloride	P028	pharmaceutical manufacturing
Arsenic	P012	veterinary medicine, severe parasitic diseases
Arsenic Trioxide	P012	chemotherapy
Chloropropionitrile	P027	pharmaceutical synthesis
Cyanide Salts	P030	laboratory
Epinephrine ¹	P042	emergency allergy kits, certain types of glaucoma, eye surgery, cardiac arrest
Nicotine	P075	smoking cessation, nicotine patches , etc.
Nitroglycerin	P081	coronary vasodilator in angina treatment Individual doses, if not reactive, are not P081.
Phentermine ³	P046	appetite suppressant

Phenylmercuric acetate	P092	bactericide, pharmaceutical aid in contact lens solutions and nasal sprays
Physotigmine	P204	acholinergics (liberates/acts like acetylcholine)
Physotigmine Salicylate	P188	acholinergics (liberates/acts like acetylcholine)
Potassium Silver Cyanide	P099	bactericide
Sodium Azide ²	P105	chemical preservative in hospitals, laboratories
Strychnine	P108	veterinary tonic and stimulant

¹ Does not include epinephrine salts.

² **Special note on sodium azide (P105):** Sodium azide, found in *Enterococcus* agars, is also used in detonators and other explosives. An odorless white solid, it is a rapidly acting, potentially deadly chemical. It changes rapidly to a toxic gas with a pungent (sharp) odor when it is mixed with water or an acid, or when it comes into contact with certain metals (for example when it is poured into a drain pipe containing lead or copper). But the odor of the gas may not be sharp enough to give people sufficient warning of the danger. You should note that serious accidents have occurred in laboratory settings. In one case, when sodium azide was poured into a drain, it exploded and the toxic gas was inhaled.

³See [EPA 2/17/2012 memorandum](#) that clarifies the scope of the hazardous waste listing.

U-list

The [U-list](#) includes about 472 distinct materials, listed under about 247 different waste codes. (As with the P-list, the same code can refer to several different materials.) HERC has identified 66 of them that you might expect to find in a healthcare setting, and has listed them, along with their waste codes and typical uses, below. The CAS numbers for these compounds can be found in the official list at [40 CFR 216.33](#).

Our list is not meant to be exhaustive.

U-listed chemicals commonly found in healthcare facilities

Material	Code	Use
Acetone	U002	solvent in pharmaceutical formulations
Acetyl Chloride	U006	cholesterol testing
Acrylonitrile	U009	pharmaceutical manufacturing
Aniline	U012	pharmaceutical manufacturing
Azaserine	U015	antifungal, antineoplastic
Benzidine dichloride	U243	pathology laboratory
Bromoform	U225	sedative, hypnotic, antitussive
Cacodylic Acid	U136	dermatologic
Carbon Tetrachloride	U211	anthelmintic, pharmaceutical formulations
Chloral Hydrate	U034	cough syrups, sleeping pills
Chlorambucil	U035	chemotherapy
Chlornaphazin	U026	antineoplastic
Chloroform	U044	anesthetic
Creosote	U051	antiseptic, expectorant
Cresols	U052	antiseptics, disinfectants
Cyclophosphamide	U058	chemotherapy
Daunomycin	U059	chemotherapy
o-Dichlorobenzene	U070	germicides, pharmaceutical manufacturing
m-Dichlorobenzene	U071	germicides, pharmaceutical manufacturing
p-Dichlorobenzene	U072	germicides, pharmaceutical manufacturing

Diethylstilbestrol	U089	anticancer agent, contraceptive
Ethyl Acetate	U112	drug flavoring agent, topical anesthetic
Ethyl Carbamate	U238	antineoplastic
Ethyl Ether	U117	disinfectant, anesthetic
Ethylene Oxide	U115	high level sterilant for surgical instruments
Formaldehyde	U122	antiseptic, disinfectant, preservative
Formic Acid	U123	diuretic, heart and muscle treatment
Hexachloroethane	U131	anthelmintic (anti-worm treatment)
Hexachlorophene	U132	skin treatment (pHisoHex' , Septisol')
Hexachloropropene	U243	dialysis, pesticide (Septisol foam?) [note ref to Septisol as hexachlorophene -no hits on "hexachloropropene Septisol"]
Lindane	U129	scabicide
Melphalan	U150	chemotherapy
Maleic Anhydride	U147	pharmaceutical manufacture
Mercury	U151	preservatives (thimerosal), antiseptics (mercurochrome), devices (thermometers, sphygmomanometers, others)
Methanol	U154	solvent in pharmaceutical manufacture
Methylpyrilene	U155	antihistamine
Methylthiouracil	U164	thyroid inhibitor
Mitomycin	U010	chemotherapy
Naphthalene	U165	antiseptic, anthelmintic
N-butyl alcohol	U031	bactericide, pharmaceutical manufacture, pain control, anti-hemorrhagic
P-Chloro-m-Cresol	U039	antiseptic

Paraldehyde	U182	sedative, hypnotic
Phenacetin	U187	analgesic, antipyretic
Phenol	U188	antiseptic, anesthetic, antipruritic (relieves itching)
Reserpine	U200	hypertension, insanity, snakebite, cholera, horse tranquilizer
Resorcinol	U201	acne, dandruff treatment, intermediate in pharmaceutical synthesis
Saccharin	U202	sugar substitute, food preparation
Selenium sulfide	U205	shampoos
Streptozotocin	U206	chemotherapy
Tetrachloroethylene	U210	anthelmintic
Uracil mustard	U237	chemotherapy
Thiram	U244	antiseptic
Trichloroethylene	U228	inhalation anesthetic, pharmaceutical manufacture
Warfarin < 0.3%	U248	anticoagulant
2-Chloroethyl Vinyl Ether	U042	anesthetics and sedatives manufacture
3-Methylchloranthrene	U157	cancer research

Chemotherapy agents:

Some chemicals used to treat cancer patients during chemotherapy fall on either the U or P lists. These agents are often referred to by their brand names rather than the chemical designations appearing on the lists. For your convenience, HERC has compiled a [list of some common brand names, together with their chemical names and RCRA waste codes](#). Please note that since new products may be introduced at any time, the list may not include all brand names composed of RCRA listed chemicals.

⁸ Source: Healthcare Environmental Resources Center, Pharmaceutical Wastes in Health Care Facilities. Accessed online at: <http://www.hercenter.org/hazmat/pharma.cfm>

Hazardous Waste Characteristics

Tennessee Rule 0400-12-01-.02(3) [40 CFR 261. 21-24]

If it is determined that the waste pharmaceutical is not a listed hazardous waste, then the health care facility must determine if that waste pharmaceutical meets one of the hazardous waste characteristics. The generator of the waste can either use a standardized test method or apply general knowledge of the waste's properties in making this determination.



Examples of hazardous waste characteristics exhibited by pharmaceutical wastes, as well as other wastes, include the following examples. Generators should consult the actual regulations to get the exact limits and regulatory language.

Ignitability (D001): the presence of a flammable solvent is the most common reason pharmaceuticals meet this characteristic. For alcohol, the regulations set a threshold limit of 24% (i.e., if the formulation contains more than 24% alcohol, then the waste is considered hazardous waste). Strong oxidizers, such as silver nitrate and potassium permanganate, in pharmaceutical formulations may also meet the definition.

Corrosivity (D002): applies to strong acids ($\text{pH} \leq 2$) or strong bases ($\text{pH} \geq 12.5$). In pharmaceutical compounding, glacial acetic acid and concentrated sodium hydroxide might be used. Their wastes are corrosive (see above pH limits) and thus considered hazardous.

Reactivity (D003): nitroglycerin, a P-listed hazardous waste, would fall into this category if used in bulk. However, dosage forms typically do not exhibit characteristics of reactivity:

Toxicity (D004 to D043): The toxicity characteristic (TC) identifies wastes that are likely to leach concentrations of any one of 40 different toxic chemicals in amounts above the specified regulatory levels. Examples of TC chemicals/heavy metals that have pharmaceutical uses and their toxicity threshold levels are:

Arsenic (D004): 5.0 mg/L;

Barium (D005): 100.0 mg/L;

Cadmium (D006): 1.0 mg/L;

Chloroform (D022): 6.0 mg/L;

Chromium (D007): 5.0 mg/L;

m-Cresol (D024): 200 mg/L;

Lindane (D013): 0.4 mg/L;

Mercury (D009): 0.2 mg/L;

Selenium (D010): 1.0 mg/L;

Universal Waste Management In Tennessee



Universal waste is a specific subset of hazardous waste subject to less stringent management requirements than regular hazardous waste. Certain types of batteries, lamps (bulbs), pesticides, and mercury-containing equipment are potentially eligible for the less stringent universal waste requirements. In Tennessee, generators and handlers may elect to manage non-hazardous items in these categories as universal waste. For example, a non-hazardous battery can be managed as a universal waste battery in order to reduce the regulatory burden on trying to separate or identify non-hazardous waste materials from hazardous waste materials.

Universal waste management requirements in Tennessee closely mirror the federal universal waste management requirements. Questions and answers on universal waste management and issues can be found on RCRA Online at:

<http://www.epa.gov/epawaste/inforesources/online/index.htm>

More federal guidance on universal waste can be found at:

<http://www.epa.gov/epawaste/hazard/wastetypes/universal/>

A key difference between federal and state universal waste regulations is that Tennessee permits the utilization of lamp (bulb) crushers. Strict standards apply to operators of lamp crushers. Standards for lamp crushers are found at the end of Rule 0400-12-01-.12 in paragraph (8). Rule 0400-12-01-.12 is the last rule in Tennessee's Hazardous Waste Management Regulations.

<http://tn.gov/sos/rules/0400/0400-12/0400-12-01/0400-12-01.htm>

Another key difference from the federal regulations is that Tennessee universal waste destination facilities are subject to a state annual maintenance hazardous waste fee per Rule 0400-12-01-.08(4)(c).

Acknowledgements:

Much of the text for this web page has come from the HERC website or other EPA documents, to include EPA's August 26, 2010 draft, EPA-821-R-10-006, on Best Management for Unused Pharmaceuticals at Health Care Facilities.

Disclaimer:

This guidance is given as general comments on the regulations and waste management and cannot replace the actual pages of the regulations. In case of any conflict between this guidance and the regulations, the regulations would take priority over the information on this page.

Further Information:

For more information about Tennessee's Hazardous Waste Regulations Pertaining to Healthcare Facilities, please contact Robert Nakamoto by e-mail at Robert.Nakamoto@tn.gov or at 615-532-0868.