



TIP No. 005-0223

Waste Management of Hazardous Drugs

PURPOSE. This technical information paper (TIP) provides disposal guidance for National Institute for Occupational Safety and Health (NIOSH)-listed Hazardous Drugs (HD) based on federal requirements. Proper disposal procedures are essential to protect workers from exposure to HDs.

REFERENCES. See Appendix A for a list of reference information.

POINTS OF MAJOR INTEREST AND FACTS

Background

Healthcare workers generate various wastes by preparing and administering drugs; NIOSH identifies some of these drugs as HDs. Waste examples include partially used or expired HDs, and items in contact with HDs such as empty containers, IV bags and tubing, wipes, needles and syringes, gloves, and spill clean-up materials.

Disposing of these wastes may be confusing at times, but it doesn't have to be. NIOSH HDs and the items in contact with these drugs must be disposed in dedicated waste containers to protect workers. Certain HD wastes require a different method of disposal because they are also regulated as a hazardous waste (HW) under federal and state law.

Anyone handling HD-contaminated items and wastes must use personal protective equipment and follow work practices outlined in their respective medical treatment facility (MTF) and military Service manuals to reduce or eliminate exposure to HDs.

Terms Used and Explanations

Chemotherapy Waste. Includes antineoplastic drug waste, drug residuals, and items contaminated with these drugs. All chemotherapy drugs are NIOSH- listed HDs and must be managed in a manner to limit human exposure.

Controlled Substances. The Drug Enforcement Administration (DEA) regulates the management of drugs that have a potential for abuse and the likelihood of causing dependence when abused (P.L. 91-513). Controlled substances are divided into five schedules, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Testosterone is both a DEA Controlled Substance and a NIOSH HD.

The DEA differentiates between waste inventory/stock drugs and pharmaceutical wastage. Management of any NIOSH HD must comply with regulations and classifications listed below.

Waste inventory/stock drugs are strictly regulated (controlled) and must be destroyed to render the pharmaceutical non-retrievable (see this definition below) following the requirements of Title 21 Code of Federal Regulations (CFR) Part 1317 (21 CFR 1317), or turned in to a registered

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DEA reverse distributor. The DLA pharmaceutical returns vendor is a DEA registered reverse distributor.

Pharmaceutical wastage is the remaining amount of a drug that has been taken out of the controlled inventory and dispensed to a patient. Specifically, wastage may be generated if a patient doesn't take the entire dosage of the drug; if some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, etc. The DEA does not require pharmaceutical wastage to be recorded and tracked; however, it must still be properly managed to prevent diversion. Check the facility's and the Service-specific requirements for diversion prevention procedures.

Defense Logistics Agency (DLA). Manages the Department of Defense (DoD) pharmaceutical returns contract (DLA Troop Support) and specific waste disposal contracts (DLA Disposition Services). Wastes that cannot be discarded into the environment are generally turned in to DLA, by way of the supporting installation environmental office, for proper treatment and/or disposal by a commercial waste contractor .

Hazardous Waste. The U.S. Environmental Protection Agency (EPA) defines and regulates HW under Title 40 CFR Part 261, also known as the *Resource Conservation and Recovery Act* (RCRA) Subtitle C (PL 94-580). A waste becomes a HW if it is "listed" or meets the RCRA characteristic of ignitability, reactivity, corrosivity, or toxicity. There are four RCRA HW lists, only two of which include NIOSH HDs:

- P-List (acutely toxic commercial chemical products, some of which are NIOSH HDs)
- U-List (commercial chemical products, some of which are NIOSH HDs)

To avoid potential confusion between terms, NIOSH "hazardous drugs" will be referred to as "NIOSH HD." NIOSH HD drugs that are classified as HW by the EPA will be referred to as "RCRA HW." Table 1 lists NIOSH HDs that are regulated as RCRA HW and the corresponding EPA HW number (#). RCRA HW drugs have specific accumulation and labeling requirements under the Federal regulations. State and local HW governance may be more stringent than the Federal RCRA requirements. In such cases, the more stringent requirement must be followed.

Table 1 lists the NIOSH HDs that are also found on the EPA HW lists (P- and U-listed) when they become a waste. All other waste NIOSH HDs must be evaluated on an individual basis to determine if they are *characteristic* RCRA HW (corrosive, ignitable, reactive, or toxic per EPA parameters). Contact the facility environmental officer or supporting installation environmental office for assistance.

Table 1. 2016 NIOSH HDs that are RCRA-HW Drugs*

Chemical Name	Brand Name	EPA HW#
Arsenic trioxide	Trisenox	P012
Azaserine	Azaserine (usually in research)	U015
Chlorambucil	Leukeran	U035
Chlornaphazine	Chlornaphazine (usually in research)	U026
Cyclophosphamide	Cytosan, CTX, Neosar	U058
Daunorubicin	Cerubidine, Daunomycin	U059
Diethylstilbestrol	DES, Stilboestrol (veterinary use)	U089
Melphalan	Alkeran, L-PAM	U150
Mitomycin	Mitomycin, Mutamycin	U010
Streptozocin	Streptozotocin, Zanosar	U206
Uracil Mustard	Uracil mustard	U237
Warfarin	Coumadin	P001 (>0.3%) U248 (<0.3%)

Note: * 2016 is the current version at the time of publication of this document.

HD Waste Containers. These containers are frequently identified as chemotherapy waste containers. They must be sealable, leak- and puncture-proof. Chemotherapy waste containers meeting these requirements may be used as NIOSH HD waste containers.

NIOSH-HD. Hazardous drugs, as defined by NIOSH, exhibit one or more of the following six characteristics in humans or animals: (1) carcinogenicity, (2) teratogenicity or other developmental toxicity, (3) reproductive toxicity, (4) organ toxicity at low doses, (5) genotoxicity, or (6) new drugs that mimic existing hazardous drugs in structure or toxicity.

These drugs require safe handling procedures and engineering controls to limit human exposure. The NIOSH HD list includes chemotherapy, antiviral, hormones, and bioengineered drugs. Some of these drugs, and some items in contact with the drugs, become a HW when they are no longer needed; they must be managed and disposed according to specific regulatory requirements. The *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* (NIOSH 2016) is located at <https://www.cdc.gov/>. The list is updated every few years; as of this writing, the 2016 NIOSH HD list is the current version.

Non-retrievable. The DEA defines non-retrievable” as the condition or state to which a controlled substance is rendered following a process that permanently alters that controlled substance’s physical or chemical condition or state through irreversible means, thereby rendering the controlled substance unavailable and unusable.

Pharmaceutical Returns Program. A reverse distribution process for unwanted pharmaceuticals. The DLA manages the contract with the companies servicing DoD MTFs. A pharmaceutical returns company accepts certain expired/unwanted pharmaceuticals and

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contacts drug manufacturers on behalf of a facility to solicit monetary credit. Facilities use these credits toward purchasing new drugs.

RCRA Empty Containers. Containers (drug vials and bottles, IV bags and tubing, drug dispensing cups, etc.) from which all contents of a RCRA HW drug were removed using commonly employed practices and (1) no more than 1 inch of residue remains on the bottom of the container, or (2) no more than 3% by volume of the total capacity of the container remains; whichever is less. RCRA empty containers that held NIOSH HD drugs are trace waste.

The RCRA empty container definition **does not** apply to containers that held P-listed RCRA-HW drugs in states that have **not** adopted the EPA HW pharmaceuticals rule, *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine* (EPA 2016). In states that have **not** adopted the rule, these empty containers must be managed as HW unless they are triple rinsed with an approved rinsate; the rinsate must then be collected as P-Listed RCRA-HW.

The EPA maintains an online map that shows which states have adopted the HW pharmaceuticals rule: <https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>.

RCRA-HW Drug. A waste drug that is an EPA characteristic HW or is found on one of the EPA HW lists. RCRA HW drugs have specific accumulation and disposal requirements. State and local regulations may have additional RCRA HW requirements.

The RCRA HW information provided in this paper is basic. Detailed RCRA-HW management requirements are outside the scope of this TIP; contact the facility environmental manager or supporting installation environmental office for more information. The reference section of this TIP lists several RCRA-HW resources.

Rinsate. Liquid that effectively removes the residue of a material from a container. Depending on the type of residue to be removed, the liquid may be water or a chemical solvent.

Trace Waste. Items contaminated with droplets or minor splashes of HDs such as containers, surfaces, gloves, gowns, masks, gauze pads, alcohol wipes, chucks/absorbent pads, certain soiled linens, and hood filters. In containers, the residue must be less than 3% by volume of the container. Single pills are not trace waste.

Unused Drug. An unused drug is a product that is still in its original container or dispensing instrument (syringe, IV bag, other administration set) and was not physically connected to or used on a patient. Expired drugs are unused drugs. Note, unused NIOSH HDs drugs that were hydrated with saline or dextrose for delivery purposes, but were not used, fall under the category "Used Drugs."

Used Drug. Includes single/loose pills, pills that were repackaged and are no longer in their original container, and residues greater than 3% by volume remaining in a container. Drugs that were hydrated with saline or dextrose and not connected to a patient (IV) fall into this category

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as well. These drugs are not eligible for reverse distribution and have to be properly disposed as described in Tables 2–4.

Table 2. Disposal Procedures for NIOSH HDs

Disposal Procedures for NIOSH HDs	
Trace Waste	Dispose into the NIOSH HD waste container.
Unused Drugs	Turn in to the pharmaceutical returns vendor.
Used Drugs	Dispose of used drugs through DLA or commercial contractor.
Syringes	<ul style="list-style-type: none"> Dispose of used syringes (empty or partially full) into the NIOSH HD waste container. Turn in unused syringes, preloaded with medication by the manufacturer, to the pharmaceutical returns vendor.
Spill Residue	Dispose into the NIOSH HD waste container.

Table 3. Disposal Procedures for NIOSH HDs that are DEA Controlled Substances*

Disposal Procedures for NIOSH HDs that are DEA Controlled Substances*	
Trace Waste	Dispose into the NIOSH HD waste container.
Inventory/Stock	Turn in to the pharmaceutical returns vendor.
Wastage	Discard following requirements for witnessed destruction. Commercial wastage devices may be used.
Syringes	<ul style="list-style-type: none"> Empty: Dispose into the NIOSH HD waste container. Partially full: Expend contents following requirements for witnessed destruction. Discard empty syringes in the NIOSH HD waste container. Unused and preloaded by manufacturer: Turn in to the pharmaceutical returns vendor.
Spill Residue	Dispose into the NIOSH HD waste container.

Note: *Testosterone is the only controlled substance on the 2016 NIOSH HD list.

Table 4. Disposal Procedures for RCRA HW Drugs*

Disposal Procedures for RCRA HW Drugs*	
Trace Waste	<ul style="list-style-type: none"> State has <u>not</u> adopted the EPA HW pharmaceuticals rule: Dispose of waste contaminated with a P-listed RCRA-HW drug as HW. State <u>has</u> adopted the EPA HW pharmaceutical rule: Dispose empty containers into the NIOSH HD container as trace waste.
Unused Drugs	Turn in to the pharmaceutical returns vendor.
Used Drugs	Manage as HW.
Syringes	<ul style="list-style-type: none"> Dispose empty and partially full syringes into the NIOSH HD waste container. Turn in unused syringes, preloaded by the manufacturer, to the pharmaceutical returns vendor.
Spill Residue	<ul style="list-style-type: none"> Dispose residue and materials used to clean up <u>P-listed RCRA-HW drug as a HW</u>. Dispose non-P listed RCRA-HW residue into the NIOSH HD waste container.

Note: *Some gel forms of testosterone with a low flashpoint may meet the definition of a RCRA-HW for ignitability.

Management Procedures for Linen Contaminated with HD

- Place reusable linen contaminated with HD residuals or body fluids from patients that received HDs within the past 48 hours into an impervious, specially marked/color coded laundry bag. Follow facility procedures for marking/color code requirements.
- Transport the contaminated linen to the laundry facility in a closed container and wash separately from other laundry.
- Discard disposable linen contaminated with HDs or body fluids from patients that received HDs within the past 48 hours into the NIOSH HD waste container.

Waste Container Management

- *For NIOSH HDs:*
 - Keep exterior surfaces of the NIOSH HD waste containers free of contamination as much as possible. If exterior surfaces become contaminated, wipe the outside of the container with the designated decontamination agent, followed by a germicidal detergent. Adhere to the manufacturer's recommended concentrations and contact times; place the contaminated wipes and gloves into the NIOSH HD waste container.
 - Place the NIOSH HD waste containers in an approved U.S. Department of Transportation (DOT) shipping container, generally provided by the RMW disposal contractor (P.L. 93-633).
 - Always store NIOSH HD waste containers awaiting disposal in a secure area (that is, in a locked area or area limited to authorized personnel only).
- *For RCRA-HW Drugs:* Containers must be sealable, leak-proof, and compatible with the waste being collected. Follow the facility's HW management requirements, or contact the environmental manager/installation environmental office for facility-specific requirements.

Container Labeling and Marking

- *NIOSH HDs Waste Container:* Label or mark the outside of the waste collection container with the following words:

Chemotherapy Waste
Incineration Required

- *NIOSH HDs Shipping Container:* Label or mark the outside of the DOT shipping container with the following words in addition to the required DOT markings:

Regulated Medical Waste, UN3291
Chemotherapy Waste
Incineration Required

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- *RCRA-HW Container*: Follow the facility's HW labeling and marking requirements. Contact the environmental manager/installation environmental office for assistance.

CONCLUSION

The Defense Health Agency medical treatment and research facilities generate a variety of NIOSH HDs and drug-related wastes. Disposal of wastes must be done in such a manner as to protect all healthcare workers. Some waste NIOSH HDs and related wastes are regulated as HW by federal and state regulations and have specific collection and disposal requirements.

ASSISTANCE

The facility environmental manager and the installation environmental office can assist with determining proper waste management and disposal procedures.

Personnel may also contact the DCPH-A Environmental Health Sciences Division at 410-436-3651 or DSN 584-3651. To request a free pharmaceutical formulary review to identify drugs requiring special waste management submit a *Mission Service* request at <https://phc.amedd.army.mil/Pages/Contact.aspx> and selecting *Waste Management* in the menu.

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Appendix A

References

- Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH). 2016. DHHS (NIOSH) Publication Number 2016-161, *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016*.
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- U.S. Environmental Protection Agency. 2016. *Management of Hazardous Waste Pharmaceuticals*. <https://www.epa.gov/hwgenerators/management-hazardous-waste-pharmaceuticals> (page last updated January 25, 2023).