



WASTE MANAGEMENT OF HAZARDOUS DRUGS

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PURPOSE. This technical information paper (TIP) provides disposal guidance for National Institute for Occupational Safety and Health (NIOSH) listed Hazardous Drugs (HD). 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; some of these drugs are identified as HD by NIOSH. Waste examples include partially used or expired HDs, and items previously 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 seem daunting 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 avenue 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 U.S. Army Technical Bulletin-Medical 515 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.

Contaminated Items. 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.

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. 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 the only controlled substance found on the 2016 NIOSH HD list.

The DEA differentiates between waste inventory/stock drugs and waste non-inventory drugs.

- Inventory/stock drugs are strictly regulated 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, AR 40-3 and AR 40-61 or turned in to a registered DEA reverse distributor. The Defense Logistics Agency's (DLA) pharmaceutical returns vendor is a DEA registered reverse distributor.
- Non-inventory drugs are leftover drugs that have been taken out of the inventory to be dispensed to a patient. Waste *non-inventory drugs*, e.g., "wastage", may be generated if a patient doesn't take the entire dosage of the drug; some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, etc. Pharmaceutical wastage is not as strictly regulated by the DEA but must still be properly managed to prevent diversion under AR 40-3.

Hazardous Drug. 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. A complete listing of HDs is published by NIOSH at <https://www.cdc.gov/niosh/docs/2016-161/default.html>. This list is updated and republished approximately every 2 years.

Hazardous Waste. The 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. A waste becomes a HW if listed or meets the RCRA characteristic of ignitability, reactivity, corrosivity, or toxicity. There are four RCRA HW lists, only two of which include some HDs:

- P-List (acutely toxic commercial chemical products, some of which are HDs)
- U-List (commercial chemical products, some of which are HDs)
- F-List (mostly manufacturing and industrial process wastes)
- K-List (mostly specific industry process wastes)

To avoid potential confusion between terms, NIOSH drugs will be referred to as "NIOSH HD" and drugs classified as HW by the EPA will be referred to as "RCRA-HW" drugs from here on. 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. State and local HW governance may be more stringent than the Federal RCRA requirements and must be followed as well.

HD Waste Container. Waste containers must be sealable, leak and puncture proof.

NIOSH HDs. These drugs are toxic and may pose a risk to healthcare workers, and in some cases, to patients. 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 RCRA-HW when they are no longer needed and must be managed and disposed meeting certain regulatory requirements.

Table 1 lists the NIOSH HDs from the 2016 list 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, or toxic per EPA parameters). Contact the ESEO/installation environmental office for assistance in determining if there are facility specific requirements.

Table 1. 2016 NIOSH HDs that are also 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	Cytoxan, 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%)

Non-retrievable. The condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

Pharmaceutical Returns Program. A reverse distribution program for unneeded pharmaceuticals. The DLA manages the contract with the company servicing Department of Defense (DOD) medical facilities. The pharmaceutical returns company accepts expired/unneeded pharmaceuticals and contacts drug manufactures 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, medication 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.

The RCRA empty container definition **does not** apply to containers that held P-listed RCRA-HW drugs. The EPA defines P-listed RCRA-HW drugs as acutely toxic to human health and the environment. Empty containers which held P-listed RCRA-HW drugs must also be managed as HW unless they are triple rinsed with an approved rinsate (liquid); the rinsate must then be collected as P-Listed RCRA-HW.

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, check with the Environmental Science and Engineering Officer (ESEO) or supporting installation environmental office for specifics.

The RCRA-HW information provided in this paper is very basic. Detailed RCRA-HW management requirements are outside the scope of this TIP; contact the facility ESEO 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 product.

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. Unused NIOSH HDs include drugs that were hydrated with saline or dextrose for delivery purposes but were not used.

Used Drug. Used drugs include residues contained in dispensing devices (tubing, syringe, IV bag, other administration set) that have been physically introduced to a patient.

Disposal Procedures for NIOSH HD

- *Unused Drugs.* Turn in unopened (the manufacturer's seal must be intact) drugs through the pharmaceutical returns vendor for potential monetary credit.
- *Used Drugs.* Dispose of used drugs or drugs not eligible for the pharmaceutical returns program (such as partial containers of drugs) by following facility procedures or into the NIOSH HD waste container.
- *Empty Containers.* Dispose of empty vials, containers, IV bags and tubing, ampules, dispensing cups, etc. into the NIOSH HD waste container.
- *Syringes.*
 - Dispose of all used syringes (empty or partially full) following facility procedures or into the NIOSH HD waste container.
 - Unused, preloaded by the manufacturer syringes may be turned in through the pharmaceutical returns program.
- *Spill Residue.* Dispose of drug spill residue and contaminated cleaning materials following facility procedures or into the NIOSH HD waste container.

Disposal Procedures for NIOSH HDs that are a DEA Controlled Substance

Note, testosterone is the only controlled substance found on the 2016 NIOSH HD list.

- *Inventory/Stock Drugs.* Turn in all inventory/stock HD controlled substances to the DLA pharmaceutical returns vendor for potential monetary credit. This includes unopened drugs, partially full containers of drugs, and single dropped pills.
- *Non-Inventory Drugs ("Wastage").* Discard non-inventory HD controlled substances following the requirements of AR 40-3 for witnessed destruction. This includes containers/tubes of partially dispensed drugs, and single dropped pills.
- *Empty Containers.* Dispose of empty vials, containers, IV bags and tubing, ampules, dispensing cups, etc. into the NIOSH HD waste container.
- *Syringes.*
 - Empty: dispose of empty used syringes into the NIOSH HD waste container.
 - Partially used: expend the contents of partially used syringes following the requirements of AR 40-3 for witnessed destruction; discard the empty syringe in the NIOSH HD waste container.
 - Unused and preloaded: turn in unused syringes that were preloaded by the manufacturer to the DLA pharmaceutical returns vendor for potential monetary credit.
- *Spill Residue.* Dispose of HD spill residue and contaminated cleaning materials into the NIOSH HD waste container.
- *NIOSH HD that are a DEA controlled substance and a RCRA-HW.*
 - Some gel forms of testosterone may have a low flashpoint and meet the definition of a RCRA-HW for ignitability.

- In states that do not permit turning in RCRA-HW drugs to a pharmaceutical returns company, manage the drugs as RCRA-HW and dispose them through the DLA Disposition Services.¹ Special arrangements may need to be made with the DLA Disposition Services to ensure the HW treatment facility is both RCRA permitted and DEA registered to accept this waste.

Disposal Procedures for RCRA-HW Drugs

For each of the following scenarios described in this section contact the ESEO or installation environmental office for HW management procedures.

- *Unused Drugs.*
 - Some states permit the return of unneeded or expired RCRA-HW drugs, still in the original untampered container, to a pharmaceutical returns company. Verify with the ESEO or installation environmental office that your state allows the return of RCRA-HW drugs.¹
 - In states that do not permit turning in RCRA-HW drugs to a pharmaceutical returns company, manage the drugs as RCRA-HW and dispose them through the DLA Disposition Services.¹
- *Used Drugs.* Used, partially full vials or containers, and single pills must be managed as HW and disposed through the DLA Disposition Services.
- *Empty Containers.*
 - Dispose of empty containers that held P-listed RCRA-HW drugs as HW through the DLA Disposition Services.
 - Dispose of all other RCRA empty containers into the NIOSH HD waste container.
- *Syringes.*
 - Dispose of all used syringes, empty or partially full, following facility procedures or into the NIOSH HD waste container.
 - Manage full, unused syringes through the pharmaceutical returns vendor in states that allow turning in RCRA-HW drugs to such a company.
 - Manage full, unused syringes as RCRA-HW and dispose of them through DLA Disposition Services in states that do not allow turning in RCRA-HW drugs to a returns vendor company.
- *Spill Residue.*
 - Spill residue and material used to clean up P-listed RCRA-HW drug spills must be collected as a HW and disposed through DLA Disposition Services.
 - Dispose of non-P listed RCRA-HW drug spill residue and contaminated cleaning materials into the NIOSH HD waste container.

¹ The U.S. Army Public Health Center Fact Sheet # 37-041-1017, *Classification of Waste Pharmaceuticals*, lists states that do not allow turn in of RCRA HW drugs to a return vendor company. Due to potential regulatory changes always check with the ESEO or installation environmental office for the most recent state and local requirements.

- *NIOSH HD that are a DEA controlled substance and a RCRA-HW.*
 - Some gel forms of testosterone may have a low flashpoint and meet the definition of a RCRA-HW for ignitability.
 - In states that do not permit turning in RCRA-HW drugs to a pharmaceutical returns company, manage the drugs as RCRA-HW and a DEA controlled substance and dispose them through the DLA Disposition Services.¹ Special arrangements may need to be made with the DLA Disposition Services to ensure the HW treatment facility is both RCRA permitted and DEA registered to accept this waste.

Management Procedures for Contaminated Linen

- Place reusable linen contaminated with HDs or body fluids from patients that received HDs within the past 48 hours into an impervious, specially marked/color coded laundry bag.
- 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.*
 - Containers must be sealable, leak and puncture proof, and are typically yellow in color. Chemotherapy waste containers meeting these requirements may be used as NIOSH HD waste containers. A regulated medical waste (RMW) container meeting these requirements may be used as long as the outside of the container meets the marking and labeling requirement described below.
 - 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 provided by the RMW disposal contractor.
 - Always store NIOSH HD waste containers awaiting disposal in a secure area (that is, in a locked area or 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 ESEO/installation environmental office for facility specific requirements.

Waste Container Labeling and Marking

- *NIOSH HDs.* Label or mark the outside of the waste collection container and the DOT shipping container, generally provided by the RMW disposal contractor, with the following words:

Regulated Medical Waste, UN3291 Chemotherapy Waste Incineration Required
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- *RCRA-HW Drugs.* Follow the facility's HW management plan's labeling and marking requirements. Contact the ESEO or installation environmental office for assistance.

CONCLUSION

The U.S. Army Medical Command treatment and research facilities generate a variety of NIOSH HDs and drug related wastes. Disposal of wastes must be done in a manner 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.

The facility ESEO or installation environmental office can assist with determining proper waste management and disposal procedures. The Military Item Disposal Instruction database provides methods of destruction for the disposal of hazardous and non-hazardous items used within the DOD. This database is available online at: <http://usaphcapps.amedd.army.mil/MIDI/>. Facilities can also contact the APHC Environmental Health Sciences Division to request a free pharmaceutical formulary review to identify drugs requiring special waste management. To request this service call (commercial) 410-436-3651, (DSN) 584-3651, or send an email to usarmy.apg.medcom-phc.mbx.midi@mail.mil.

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Appendix A

References

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AR 40-61, Medical Logistics Policies.

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