TECHNICAL INFORMATION PAPER

APHC U.S. ARMY PUBLIC HEALTH CENTER

CONUS MANAGEMENT OF PHARMACEUTICAL WASTAGE CONTAINERS

TECHNICAL INFORMATION PAPER NO. 37-069-0217

PURPOSE. To identify the proper management of commercial containers used for "pharmaceutical wastage".

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

POINTS OF MAJOR INTEREST AND FACTS.

BACKGROUND

Pharmaceutical wastage containers such as the Cactus® SMART SINK® are designed to accept specific types of pharmaceuticals as an alternative to using a sink, toilet, or waste bin when unneeded pharmaceuticals are typically "wasted" or destroyed. The primary purpose is to eliminate the negative impact to the environment and to prevent the unauthorized use of unused or waste drugs.

NOTE: Pharmaceutical wastage containers are not Drug Enforcement Administration (DEA) approved for controlled substance destruction of inventory but are intended only for "pharmaceutical wastage"—partials remaining of dispensed after it was used on a patient.

Pharmaceutical wastage containers such as the Cactus SMART SINK system are designed to be placed at the "point of use" for pharmaceuticals. Typical locations include nursing stations, near drug dispensing machines (e.g., Pyxis™ medication dispensing station), procedural rooms, or next to sharps containers so that unused drugs can be disposed of prior to disposal of the syringes or vials (Cactus LLC, 2013).

In utilizing the pharmaceutical wastage containers, liquid waste is dispensed into a cartridge consisting of an absorbent material containing a proprietary mixture of denaturants and deterrents (e.g., ipecac and quinine to induce vomiting and make unpalatable) used to convert the liquid waste into a semi-solid, non-palatable state. Solid pharmaceutical wastage is disposed of through a pill maze and patch slot containing a proprietary mixture of the denaturants and deterrents. One liter of water must be added to the "solid" cartridge prior to adding the initial drug waste to ensure the pharmaceuticals are rendered unrecoverable (Cactus LLC, 2013).

Approved for public release; distribution unlimited.

Use of trademarked name(s) does not imply endorsement by the U.S. Army but is intended only to assist in identification of a specific product.

NOTE: Failure to use pharmaceutical wastage containers such as the Cactus SMART SINK system strictly according to manufacturer's instructions may not render DEA controlled-substance pharmaceutical wastage unrecoverable and unusable as required by DEA Title 21 Code of Federal Regulations (CFR) 1300-1321.

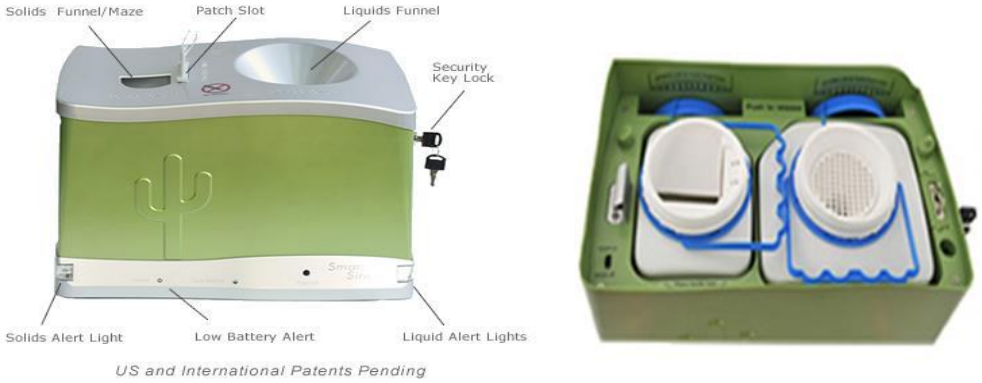

Figure. Cactus SMART SINK system (Cactus LLC, 2013)

WASTE DEFINITIONS

a. DEA Controlled Substances. A controlled substance is a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of Title 21 U.S. Code (USC) Controlled Substances Act. These schedules are updated annually.

b. Chemotherapy Waste. Items such as unused chemotherapy pharmaceuticals, and needles, containers and syringes, gowns, gloves, and tubing that contained chemotherapeutic pharmaceuticals or were exposed to chemotherapeutic pharmaceuticals during the treatment of patients. Chemotherapy waste does not include hazardous waste regulated by the Environmental Protection Agency (EPA).

c. National Institute for Occupational Safety and Health (NIOSH) Hazardous Drug. The NIOSH definition of hazardous drugs is based on a definition originally developed in 1990 by the American Society of Hospital Pharmacists (ASHP 1990), currently known as the American Society of Health-System Pharmacists. The 1990 ASHP definition of hazardous drugs was revised by the NIOSH Working Group on Hazardous Drugs. Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

The NIOSH list of hazardous drugs is updated biannually on the Web site http://www.cdc.gov/niosh/topics/hazdrug/(DHHS, NIOSH. 2016). The NIOSH hazardous drugs list also includes chemotherapy wastes not regulated by the EPA as hazardous wastes. NIOSH drug wastes not regulated by the EPA are disposed of with the chemotherapy waste.

d. Pharmaceutical. The proposed EPA definition of pharmaceutical is "any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals."

e. Pharmaceutical Reverse Distributor. Pharmaceutical reverse distributor is an entity that helps healthcare facilities calculate and receive credit from pharmaceutical manufacturers when healthcare facilities have "viable" pharmaceuticals, which are defined as any unused and/or unopened pharmaceuticals that can be returned for monetary credit.

f. Pharmaceutical Waste. Pharmaceutical waste includes all expired, unused, contaminated or discontinued drugs (also known as medicines or chemicals) that can no longer be used for humans or animals.

g. Pharmaceutical Wastage. Drug amounts/partials remaining in a dispensing device (i.e., syringe, used patch, and so forth) after it was used on a patient. Wastage does not included DEA-controlled inventory amounts that must be deemed unretrievable.

h. Resource Conservation and Recovery Act (RCRA) Hazardous Waste Pharmaceutical. A pharmaceutical waste is a RCRA hazardous waste if it meets a listing or exhibits a characteristic described in Title 40 of the CFR Part 261

Subpart C and D. Medical waste generators must identify these listed or characteristic hazardous wastes and manage them accordingly. All hazardous wastes need to be separated, properly packaged and labeled, and disposed of according to Federal, state, and local regulations.

Waste pharmaceuticals may be RCRA hazardous waste if they exhibit one or more of the four characteristics of hazardous waste: ignitability, corrosivity, reactivity, and toxicity. For example, solutions containing more than 24 percent alcohol exhibit the ignitability characteristic. Pharmaceuticals exhibiting the corrosivity characteristic are generally limited to compounding chemicals, including strong acids such as glacial acetic acid and strong bases, such as sodium hydroxide. Depending on the concentration in different pharmaceutical preparations, pharmaceuticals may also exhibit the toxicity characteristic because of the use of substances such as arsenic (D004), barium (D005), cadmium (D006), chloroform (D022), chromium (D007), lindane (D013), m-cresol (D024), mercury (D009), selenium (D010), and silver (D011).

Listed wastes appear on one of four lists of hazardous waste (F, K, P and U). There are approximately 30 commercial chemical products listed on the P and U hazardous waste lists that have pharmaceutical uses. As the P and U lists are based on chemical designations, this number does not completely represent the total number of brand name pharmaceuticals that may actually be listed hazardous wastes. For example, the following chemotherapy drugs: Cytoxan®, Neosar, and Procytox, are all designated as a U058 hazardous waste for cyclophosamide. P- and U-listed chemotherapy waste must be managed as RCRA hazardous waste or as nonhazardous chemotherapy waste, depending on remaining amounts and whether the drug was a P- or U-listed waste.

WASTE MANAGEMENT

To prevent regulatory noncompliance, the types of waste that are accepted by the pharmaceutical wastage container should be identified by the medical treatment facility (MTF) in a standing operating procedure (SOP) prior to utilizing the device. Containers used to collect pharmaceutical wastage must be managed according to Federal, state, and local regulations to include: EPA RCRA Title 40 CFR 260-271; DEA Title 21 CFR 1300-1321, Department of Transportation, AR 200-1, and Supply Bulletin (SB) 8-75-11. States may permit disposal of the device as solid waste or require shipment to an approved treatment facility such as incineration.

NOTE: The EPA published the proposed rule for Management Standards for Hazardous Waste Pharmaceuticals on September 25, 2015. Under the proposed rule, hazardous waste pharmaceuticals would be managed under the new 40 CFR 266,

Subpart P. Currently, the proposed rule has not been finalized. Ensure the MTF staff handling pharmaceutical waste are knowledgeable of the most current management and disposal requirements.

Disposal Through Pharmaceutical Reverse Distributor

Consult state regulations prior to disposal through Reverse Distributor. In certain states, pharmaceutical wastage containers, such as the Cactus SMART SINK system, may not be considered acceptable technology for the disposal of DEA-controlled substances wastage. Therefore, any transference from one DEA Registrant (e.g., the MTF) to another (e.g., the Reverse Distributor) would be subject to DEA regulations.

As stated above, pharmaceutical wastage containers are only intended for the disposal of dispensed waste pharmaceuticals remaining after patient treatment to include liquids, tablets, capsules, and/or patches that are frequently disposed of in a sink, toilet, sharps container, or garbage.

EPA RCRA Hazardous Waste

Waste generators are required to characterize all wastes as hazardous or nonhazardous according to the EPA regulations. The APHC conducted a pilot Cactus Sink waste characterization study at one MTF to evaluate the Cactus Sink waste stream. A limited, preliminary analysis of select Cactus SMART SINK system devices did not determine the presence of RCRA hazardous constituents when used according to the manufacturer's instructions. Analytical tests of the new, unused Cactus SMART SINK system cartridges also did not indicate the presence of RCRA characteristic hazardous constituents.

NOTE: Do not place RCRA hazardous waste pharmaceuticals into the pharmaceutical wastage container. Commingling of a RCRA hazardous waste pharmaceutical will render the entire container contents a RCRA hazardous waste. Additionally, do not place chemotherapy waste pharmaceuticals into pharmaceutical wastage containers. Manage "product", "trace" and "bulk" chemotherapy waste according to Federal, state, local, and MTF SOPs (i.e., (1) RCRA hazardous chemotherapy waste = hazardous waste container; (2) RCRA non-hazardous chemotherapy waste = yellow bucket; or (3) pharmaceutical reverse distributor for viable chemotherapy pharmaceuticals).

Pharmaceutical wastage container management SOPs, policy, analytical test results and/or other documentation identifying procedures used to prevent comingling of pharmaceutical wastage with RCRA pharmaceutical waste should be readily accessible to regulators.

Common RCRA pharmaceutical hazardous wastes include, but are not limited to:

- Erythromycin Gel 2%
- Texacort Solution 1%
- Taxol Injection
- Flexible Collodion
- Potassium Permanganate
- Glacial acetic acid with pH less than or equal to 2
- Sodium hydroxide with pH greater than or equal to 12.5
- Primatene Aerosol
- Clindamycin Phosphate
- Hand Sanitizer
- Insulin
- Thimerosal preserved vaccines

Toxicity Characteristic D-Listed Drug Formulation Example

Chemical	Concentration (mg/l)	Waste Code	Drug Formulations Containing Chemical
Arsenic	5.0	D004	Arsenic trioxide (also P012); Carbasone; Glycobiarosol; Thiacetarsamide
Barium	100	D005	Barium Sulfate
Cadmium	1	D006	Multiple mineral preparations
Chromium	5	D007	Multiple mineral preparations
Lindane	0.4	D013	Treatment of lice, scabies
Cresol	200	D024	Preservative in human insulin
Mercury	0.2	D009	Vaccines with thimerosal, eye, ear preparations
Selenium	1.0	D010	Dandruff shampoo, multiple mineral preparations
Silver	5.0	D011	Silver sulfadiazine cream

DEA Controlled Substances

Prior to utilizing pharmaceutical wastage containers, such as the Cactus SMART SINK system, the MTF should develop a SOP that provides a detailed list of the proper use

and management of the containers to prevent noncompliance with Federal, state, local, and Department of Defense laws and regulations.

A list of the questions while evaluating the pharmaceutical wastage device include but are not limited to: (1) Are pharmaceutical wastage devices secured to the wall/floor by an outer container in a manner as to prevent theft or tampering? (2) Does the pharmaceutical wastage device physically or chemically render the drug wastage unrecoverable and unpalatable? (3) Can contents be removed from the openings? (4) What procedures are in place to prevent comingling of RCRA hazardous and NIOSH hazardous pharmaceutical wastage? (5) Is waste characterization documentation available upon regulatory request for review? The SOP should clarify the difference between drugs eligible for wastage in the device versus drugs that require DEA inventory destruction. Types of drug wastage staff could put in the device include residuals remaining in syringes after injections, used pain patches, and pills spit out by patients.

NOTE: Routine review of hazardous and controlled substances lists is required to maintain Federal, state and local regulatory compliance, as DEA and NIOSH drug lists are regularly updated.

POINT OF CONTACT

For additional information, contact the APHC Environmental Health and Sciences Division at 410-436-3651.

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Prepared By: APHC Environmental Health and Sciences Division

APPENDIX A

References

Cactus, LLC. 2013. Cactus® SMART SINK® Instruction Manual. Cactus, LLC 1031 Le Grand Blvd. Charleston, SC 29492. April 2013. www.cactusLLC.net

DEA. Drug Enforcement Administration (DEA). Title 21 CFR 1300-1321.

DHHS (NIOSH). Department of Health and Human Services. Publication Number 2016−161. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016.

DOT. Department of Transportation. Title 49 CFR 172.

EPA. Environmental Protection Agency. Medical Waste. https://www.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals

EPA. Environmental Protection Agency. Title 40 CFR Part 260-271.