TECHNICAL INFORMATION PAPER

APHC U.S. ARMY PUBLIC HEALTH CENTER

HAZARDOUS DRUGS: SURFACE DEACTIVATION, DECONTAMINATION AND CLEANING STANDARD OPERATING PROCEDURE GUIDE TECHNICAL INFORMATION PAPER NO. 55-085-1017

PURPOSE

This Technical Information Paper (TIP) provides guidance on the proper method to remove hazardous drugs (HD) from work surfaces within both sterile and non-sterile areas of Department of Defense medical treatment facilities (MTF). This TIP is a guide to develop a location specific Hazardous Drug Surface Deactivation, Decontamination and Cleaning (DDC) Standard Operation Procedure (SOP).

BACKGROUND

Surface contamination from HD presents itself anywhere HD has been within the MTF. This surface contamination poses a threat of unintended exposure to anyone who may encounter that surface, unless proper DDC takes place. Unintentional contamination with HD can occur at locations due to the transfer of HD from the exterior of containers, HD dust settling, and transfer from other contaminated items. There are other locations contaminated because they come into direct contact with HD, such as counting trays. Therefore it is critical that thorough and effective DDC occurs to minimize lingering surface contamination and thereby minimize the risk of exposure to the workforce.

SOP COMPONENTS

General Statements

Each MTF is required to develop a DDC SOP, unique to the MTF. The following information is guidance only; development of an SOP must be in accordance with SOP guidelines for the specific MTF. Additionally it is at the discretion of the MTF to determine who will carry out the functions of the DDC SOP.

Requirements

Locations. Routine implementation of DDC SOP must occur on all surfaces that have the potential for contact with any HD. Surfaces include but are not limited to:

- Storage shelves
- Secondary storage containers
- HD compounding engineering controls (i.e., Biological Safety Cabinets, Compounding Aseptic Containment Isolators)
- HD counting locations

Frequency. Installation Industrial Hygiene (IH) staff and Hazardous Drug Officer (HDO), in coordination with pharmacy staff and Infection Control Officer (ICO), must determine the frequency the DDC SOP is executed, based on HD use volume and throughput at the specific MTF. Implementation of DDC is dependent on specific location volume of dispensing HD. If HD dispensing occurs daily, at a minimum DDC must occur daily. If HD dispensing occurs less than daily, DDC must occur when dispensing occurs. If HD is located in multiple locations within the MTF, do not generalize frequency of DDC SOP execution.

During sterile compounding, DDC is required to occur within the primary engineering control (biological safety cabinet (BSC) or compounding aseptic containment isolator), between all differing HD compounding sessions. Additionally DDC must occur any time a spill occurs, when there has been a gap in compounding, and before and after certification or maintenance.

Training. Training will occur for all personnel responsible for execution of the DDC SOP prior to independent DDC. The DDC training is the responsibility of the HDO or the IH associated with HD, or the designee of the MTF. This training is to include implementation of the DDC SOP, HD safe work practices (including proper personal protective equipment (PPE) garbing/donning and hand hygiene), and other requirements associated with HD DDC specific to the MTF.

Personal Protective Equipment. All personnel who execute the DDC SOP must wear appropriate PPE, resistant to the cleaning agents used. At a minimum this requirement includes two pairs of HD resistant gloves and an impermeable disposable gown. When execution of DDC in aseptic locations occurs, additional PPE is required. Follow proper garbing as required by the MTF (including shoe covers, head cover and surgical masks). Personnel conducting DDC of a spill may be required to use respiratory protection; those personnel are required to be medically evaluated for respirator use and enrolled in a respiratory protection program prior to using a respirator.

Materials. All materials required by the DDC SOP must be approved for MTF use. The DDC SOP must include information on proper storage and disposal of all DDC agents used. Reusable materials prescribed by the DDC SOP must be included in the SOP for proper DDC. All expendable materials used in the DDC SOP must be appropriate for MTF use (e.g., non-shedding wiping materials). The following list of DDC agents are for reference only; request specific agents from HD manufacturer.

- Deactivation Agent: Agent must be either an approved EPA-registered oxidizer or an approved specific HD label listed deactivation agent (e.g., sodium hypochlorite, peroxides).
- Decontamination Agent: Agent that allows for removal of residual HD contamination. These include, but are not limited to, sterile alcohol, peroxides, sterile water, and sodium hypochlorite.
- Disinfection agent: Antimicrobial agent, from either MTF approved antimicrobial agent list or EPA List A antimicrobial.

Records. The DDC SOP must include requirements for recordkeeping for the following topics: training, annual SOP update, and site completion of SOP.

Keep training records for individuals who will implement the DDC SOP in compliance with MTF records requirements.

Review and update of the DDC SOP must occur annually. The SOP should be updated more frequently if major changes occur outside of the annual review. These changes include: use of new HD, changes in HD handling process, changes in engineering controls (i.e., BSC, Isolators, "Clean Rooms"), and any other major changes as determined by the MTF HD staff. Keep proper records when review and update of the SOP occurs.

The SOP must include a requirement for a DDC completion log. The DDC completion log needs to include a record of the date, time, and personnel responsible for completing the DDC. It should be specific to location and not generalized to the MTF. The inclusion of each step of DDC, with simplified instructions, is recommended but not required for DDC completion log. See figure 1 for a DDC completion log example.

Example Army Community Hospital
Pediatric Oncology Pharmacy – Sterile Compounding Isolator

Date	Deactivation (Wet surface with 5% NaClO)	10 Minute Contact Time	Neutralize (Wet surface with 5% Na2O3S2)	Decontaminate (Spray with IPA)	Clean (Scrub with Germicidal Detergent)	Disinfect (Wipe surface with Caviwipes)	Initials
29 Aug 17	X	X	X	X	X	X	JHL

FIGURE 1. Example DDC Completion Log

SOP PROCEDURES

The procedures in the DDC SOP are determined by the type of HD work that is done within each specific location of the MTF. All work with HD regarding work surface DDC are categorized into one of two situations, sterile work and non-sterile work. Sterile work with HD is defined as anything that the United States Pharmacopeia (USP) would consider sterile compounding. All other situations that relate to HD within the MTF are considered non-sterile work. This includes administration of HD to patients within an infusion clinic.

The process of work surface DDC as outlined by United States Pharmacopeia Convention Compounding Compendium Chapter 800 (USP <800>) is broken into three steps for non-sterile work and adds a fourth step for sterile work. The three common

procedural steps are deactivation, decontamination, and cleaning. The final step of DDC for a sterile work environment is disinfection. Employ the four procedural steps of sterile DDC for those reusable items that come into contact with HD but are not work surfaces, such as; counting spatulas, mortars, pestles, and other compounding equipment; however, the cleaning and disinfection of reusable items must take place apart from the DDC of HD surfaces and follow any additional guidelines for sterility imposed by the MTF.

The DDC SOP should indicate when DDC should take place. It should never take place while active HD manipulation is occurring. Additionally, if an item cannot be spot decontaminated (i.e., must be autoclaved or cleaned according to an MTF reusable equipment cleaning protocol), it must be removed from the area prior to DDC.

Deactivation. The goal of the deactivation step is to render any lingering HD either inactive or inert. By placing a strong oxidizer on the surface and letting the oxidizer degrade the HD, the surface can have all the HD deactivated. This process is time consuming, and if not allowed the proper time for contact, will result in incomplete deactivation of HD on the surface.

A large number of deactivating agents exist, although no one deactivation agent will be effective for all HD. The DDC SOP must address this limitation of deactivating agents and prescribe the MTF approved agent for use. Additionally the SOP must prescribe the approved method of application and contact time for the deactivation agent. If sodium hypochlorite is used to deactivate HD, a neutralizing agent, such as sodium thiosulfate, must be used. This neutralizer will reduce the likelihood of damage to surfaces by the sodium hypochlorite.

Note: Deactivation of all HD is not achievable. If the MTF location uses only HD that cannot be deactivated, remove the deactivation step and replace with a second iteration of decontamination.

Decontamination. The goal of the decontamination step is to neutralize and physically remove HD from the surface by transferring it to an absorbent disposable material. Select a decontamination agent with appropriate surface compatibility. Some decontamination agents will be incompatible with surfaces to be cleaned.

The DDC SOP must address what type of decontaminate is to be used. If the decontamination agent requires a prolonged contact time, the length of time must be prescribed in the SOP. Additionally, the method of application of the decontaminating agent, as well as proper disposal, must be addressed.

Cleaning. The cleaning step is used to remove HD residue as well as other contaminants from the surfaces of the work spaces and tools used in the HD dispensing process by the use of germicidal detergents, surfactants and water. The cleaning associated with the DDC SOP must be separate from other cleanings that occur

throughout the workday. It must be done in conjunction with the remainder of the DDC SOP.

The DDC SOP must list the approved agent and method of cleaning. The cleaning agent must be an EPA List A antimicrobial or other MTF approved antimicrobial. Additionally there must be a description of how to appropriately clean and any sequence of events that must take place in order to consider the surface sufficiently cleaned.

Those items that have contacted HD and are not work surfaces must be cleaned in accordance with the MTF policy on cleaning re-usable medical devices.

Disinfection. Destruction of any microbial growth is the goal of the disinfection requirement of the DDC SOP. This step is required for SOPs that deal with items or surfaces used for sterile HD work. It is at the discretion of the MTF if the disinfection step will be required in the DDC SOP for non-sterile HD work.

The DDC SOP must list the approved disinfection agent to be used at the MTF location. The agent must be an EPA-registered disinfectant or sterile alcohol. Locations that must have the disinfection step performed must be listed clearly.

CONCLUSION

Effective DDC work will reduce the residual surface contamination by HD. This in turn will reduce worker exposure to HD. Locations of possible HD contamination vary across the Army medical system, and they vary within a given MTF. Therefore an effective DDC SOP must be created specifically for each location within a MTF that uses, dispenses, stores, or maintains HD.

The DDC SOP must be generated at the MTF under the cooperation of the HD associated IH, the HDO and ICO. This guide serves as a minimum requirement for compiling an MTF location specific SOP. For a more detailed explanation of the USP requirements for DDC please see USP <800> section 15 “Deactivating, Decontaminating, Cleaning, and Disinfecting.”

POINT OF CONTACT

For more information, contact the U.S. Army Public Health Center, Industrial Hygiene Field Services Division at commercial 410-436-3118 or DSN 584-3118.

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Dated: 7 May 2018

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ABBREVIATIONS

- APHC - United States Army Public Health Center
- BSC - Biological Safety Cabinet
- DDC - Deactivation, Decontamination and Cleaning
- EPA - United States Environmental Protection Agency
- HD - Hazardous Drugs
- HDO - Hazardous Drug Officer
- IH - Industrial Hygiene
- ICO - Infection Control Officer
- MTF - Medical Treatment Facility
- NIOSH - National Institute for Occupational Safety and Health
- OSHA - Occupational Safety and Health Administration
- PPE - Personal Protective Equipment
- SOP - Standard Operating Procedure
- TB MED 515 - Technical Bulletin Medical 515
- USP - United States Pharmacopeia Convention
- USP <800> - USP Compounding Compendium Chapter 800

TERMS

- Deactivation – To render a compound inactive or inert
- Decontamination – Removal of residue, specifically HD residue
- Cleaning – Removal of organic and inorganic compounds
- Disinfection – Destruction of microorganisms on a surface