USP <800> and Environmental Monitoring Webinar Q&A

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
Phone: 405-271-1144 • Fax: 405-271-1174 • www.arlok.com

1. **How long do we keep reports of testing/sampling?**

   The recommendation is to follow the document storage procedures specified in your quality manuals and standard operating procedures. Our laboratory stores reports for five years.

   USP <800> states "The entity shall establish policies and procedures to ensure that compounding and dispensing records meet the requirement of this chapter, chapters 795 and 797, entity policy, and federal and state laws and regulations. Activities that shall be documented include but are not limited to the acquisition, preparation, and dispensing of a compounded HD, personnel training, and the use and maintenance of equipment and supplies. These records shall be available for review by the applicable authorities. Policies and procedures shall be reviewed at least annually by the compounding supervisor, and the review shall be documented. Revisions in forms or records shall be made as needed and communicated to all compounding personnel."

2. **We are working on our configuration...can refrigerated HD be stored in the negative pressure clean room suite? Can non-sterile HD compounding occur in the same room as the HD storage?**

   Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD active pharmaceutical ingredient (API) must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.

   Separate rooms, containment secondary engineering control (C-SECs), are required for sterile, nonsterile, HD and non-HD compounding with two exceptions:

   (1) Per section 5.3 Compounding, for entities that compound both nonsterile and sterile HDs, the respective containment primary engineering control (C- PECs) must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process; and

   (2) Per section 5.3.2 Sterile Compounding, a biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.
   http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

3. **The slide on "Storage (5.2)" makes it appear that storage of HDs has to be in a negative pressure room. Is this true, even if there is no compounding being done? We anticipate simple packaging into bubble pack card or Rx vials and some tablet splitting. Thank you**

   If you are manipulating antineoplastic agents—even oral tablets—you need to do this in the proper facility. Manipulation of HDs that aren't antineoplastic may be described in your Assessment of Risk. <800> permits use of the biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) in your sterile negative pressure compounding room for occasional nonsterile use, as long as the stipulations listed in <800> are followed. If you do this routinely, you need to have the proper equipment for nonsterile HD compounding/repackaging.
   Kienle, Patricia "The Chapter <800> Answer Book", American Society of Health-System Pharmacists

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
Phone: 405-271-1144 • Fax: 405-271-1174 • www.arlok.com

4. **Are there commercially available surface sample wipes available? Can you recommend a kit to perform surface wipe sampling for reproductive HDs (i.e. estradiol, progesterone, testosterone)?**

   There are several kits currently on the market for USP <800> surface wipe sampling. We recommend verifying that the supplier has done the appropriate method development / validation to qualify their kit as being able to detect Group 1 – 3 HDs.

5. **If the only hazardous drugs we compound with are non-sterile steroid hormones (estradiol, estriol, testosterone, progesterone etc) is sample wipe sampling required?**

   Estradiol, estriol, and progesterone are classified drugs in Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG). Testosterone is a classified drug in Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects.
   https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

   USP <800> recommends but does not require the performance of environmental wipe sampling.
   http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

6. **Since USP 800 states that surface testing "should" be conducted, it would be my option since it does not state "shall" that a pharmacy is not required to do this. Do you agree? It may be best practice but not required by USP 800. Is wipe sampling mandatory or best practice?**

   Wipe sampling is best practice. Environmental wipe sampling for HD surface residue should be performed to verify containment. Contamination in any amount indicates a lack of containment. Wipe sampling kits need to be evaluated to ensure they are appropriate for HDs used by the entity. If contamination is found, the chapter states that the designated person must identify, document, and contain the cause of contamination. Such action may include reevaluating work practices, re-training personnel, performing thorough deactivation, decontamination, cleaning, and improving engineering controls. Repeat the wipe sampling to validate that the deactivation/ decontamination and cleaning steps have been effective.
   http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

   Although described in <800> as a "SHOULD" versus a "MUST," some form of environmental wipe sampling (EWS) in the opinion of the Hazardous Drug Consensus Statement (HDCS) is STRONGLY recommended. An entity cannot assess its success in controlling environmental contamination if it cannot in some way measure the extent of such contamination. A sampling program can not only detect shortcomings, it could reveal "overkill" in which the entity is wasting time and resources treating contamination that does not exist.
   http://compoundingtoday.com/Compliance/HDCS_Consensus_Statement.pdf

   The Hazardous Drug Consensus Statement (HDCS) was developed by the Hazardous Drug Consensus Group (HDCG). This group is a joint effort of the Accreditation Commission for Health Care/Pharmacy Compounding Accreditation Board (ACHC/PCAB) and the International Academy of Compounding Pharmacists (IACP). The group consists of a number of experts from a wide range of backgrounds who have extensive experience in the handling of hazardous drugs.

7. **Do you feel that air sampling is necessary or optional?**

   <800> provides information on handling HDs and must be used in conjunction with <797> for sterile compounding. According to <797>, an appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning.

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
Phone: 405-271-1144 • Fax: 405-271-1174 • www.arlok.com

8. Can ARL help with strategies for wipe sampling that were discussed?

ARL can assist in developing a robust wipe testing sampling program. For more information, contact ARL's Business Development info@arlok.com or 405-271-1144.

9. What is the best way to contain and send a sample of a wipe before sending it to an analytical lab?

Most companies provide six wipes (swabs) with instructions for use and vials for shipping.

Suggested areas for wipe sampling include inside the biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI), pass-through chambers, surfaces near the BSC or CACI, the floor underneath the front of the C-PEC, areas immediately outside the negative pressure room, and areas where patients are administered antineoplastics.
Kienle, Patricia "The Chapter <800> Answer Book", American Society of Health-System Pharmacists

10. For non-sterile, do we still need to do the disinfection step?

"Disinfection" is of course a critical process for sterile compounding and a desirable one even for nonsterile compounding.
http://compoundingtoday.com/Compliance/HDCS_Consensus_Statement.pdf

11. Can the same product be used for more than one cleaning step? You mentioned peroxide could be used for deactivation and decontamination.

There are commercially available sodium dichloroisocyanurate (NaDCC) products that will deactivate many HDs, not degrade surfaces, and act as an effective disinfectant.

Household nonsterile 3% hydrogen peroxide solution is an inexpensive but very effective oxidizing and disinfecting agent.

Since there are commercially available sterile hydrogen peroxide / peracetic acid combinations that deactivate many HDs and act as effective disinfectants, they are a reasonable one-step process for the sterile compounder.

Ultimately, the effectiveness of deactivation and physical cleaning will rely on environmental surface sampling or ultraviolet light validation.
http://compoundingtoday.com/Compliance/HDCS_Consensus_Statement.pdf

12. If we plan on doing our EM in house, do we need to do our own kit quality sampling- or can we rely on information from the kit manufacturer?

ARL recommend verifying in house and manufacturer kits through appropriate method development/validation to qualify kits as being able to detect Group 1 – 3 HDs.

13. If we use approved agents for deactivation and decontamination, is the spike study a must or can surface wipes be sent to ARL for testing (hormones)?

The spike study is a procedure performed by the outsourced laboratory. The purposeful addition of HD's to the swab (spike study) is intended to demonstrate the extraction efficiency of the laboratory procedure. If recovery percentages are low, the laboratory should evaluate alternative extraction methods.

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
Phone: 405-271-1144 • Fax: 405-271-1174 • www.arlok.com

14. From the standpoint of retail pharmacies that is handling finished dosage forms and not compounding any HD, what impact will <800> have in that setting?

<800> is designed to protect healthcare workers from unintentional exposure to drugs that are hazardous to personnel. Most unintentional exposure comes from touching, inhaling, or ingesting these agents. <800> lists potential opportunities for exposure including receipt, transport, dispensing, compounding, mixing, manipulating dosage forms (e.g., crushing or splitting tablets or opening capsules), administering, cleaning up spills, and handling waste.

All healthcare personnel must comply with USP <800>. This includes anyone who handles hazardous drugs (HDs)—personnel involved in receiving, storage, compounding, transporting, administering, disposal, or spill cleanup. This includes pharmacies of any type, physician offices and clinics, veterinarian offices, and any other healthcare setting where HDs are handled.
Kienle, Patricia "The Chapter <800> Answer Book", American Society of Health-System Pharmacists

To view webinar recording, visit: *http://acainfo.org/education/webinars/*.