USP <800> Update Webinar Questions and Answers

840 Research Parkway, Ste. 546 • Oklahoma City, Oklahoma • 73104
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Deactivation and Decontamination

1. **Any suggestions for good EPA approved deactivation/decontamination cleaning products?**

   USP <800> indicated an oxidizer such as Hydrogen Peroxide or Bleach to deactivate. A commercial product Peridox RTU is probably the most commonly used agent, and they provide a White Paper on drugs it deactivates.

2. **Do we need to decontaminate or deactivate a bagged product going from a negative pressure room through the pass-through?**

   If items are taken out of <800> room then yes, they need to be decontaminated.

3. **Do you know of any kits for surface wipe sampling? Does a protocol come with the kit?**

   ARL has a list of vendors, including Letco, for surface wipe sampling kits. The PDF also includes recommendations for sample collection. The kits on the market include items you may already have in your pharmacy: Chemo gloves and swabs are two key items. Check with your analytical lab to determine the swab needed for sampling. ARL and Letco recommend TexWipe Swab Part No TX714K for sample collection. This swab enhances absorbency, increases lifting, and captures small particles.

4. **Do you recommend a specific agent for deactivation/decontamination of the BSCs?**

   <800> recommends an oxidizer and mentions hydrogen peroxide or bleach. There is a commercial product Peridox and Peridox RTU that is peroxide based.

5. **Is over the counter hydrogen peroxide suitable for the deactivation for counters for USP <800>?**

   USP <800> does reference hydrogen peroxide as an example of an oxidizer to deactivate HDs. If you do use OTC H2O2 it would be highly advisable to conduct baseline validation that the H2O2 deactivated a known API such as Progesterone by doing a swab test of any area that was intentionally contaminated. Given industry trends to current Good Compounding Practices it may be more "expected" that one uses an agent that has preexisting documentation that it deactivates a range of APIs.

Hazardous Drugs

1. **Do you have any information on where compounding peptide injections fall with USP and NIOSH?**

   Compounding peptides just became quite complicated. As of Mar 23, 2020, pharmacies will not be able to compound peptides due to some new FDA policies. For now, a peptide would only have to be compounded under USP <800> conditions if it appears on the NIOSH Haz Drug List. The main one that comes to mind is HCG (on NIOSH list as chorionic gonadotropin).

2. **How should we handle drugs that have respiratory hazards per OSHA, but are not listed in any of the NIOSH tables? Should those be compounded in an 800 negative pressure room?**

   USP <800> provides for doing an assessment of risk to add drugs if deemed hazardous. If you do add it to your list, then handle as appropriate for the dosage form and include in your SOPs.

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Hazardous Drugs (continued)

3. Do you know of storing medications within a Boxpicker or Omnicell machine?

Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants. Packaging must maintain physical integrity, stability, sterility (if needed) during transport and storage. As long as the packaging protects the drugs from damage then storage in these should be fine. Do the assessment of risk and ensure SOPs reflect it has been done.

4. What are we supposed to do with compounded NIOSH drug waste(eg. unguator jar used to mix a cream with a NIOSH powder)? Would everything go in a yellow chemo bin or is there any way to deactivate it?

Yes - yellow chemo bucket or bag. Depending on the item, you can deactivate and decontaminate, but not necessarily required. If you do elect to deactivate/decontaminate make sure to add that into SOPs.

5. Do we have to handle Table 2 and Table 3 drugs in an HD room?

Yes, if working with APIs, crushing tablets, and/or opening capsules, HDs have to be handled in a "hood" in a negative pressure room until in final form ready to dispense.

6. If we do a risk assessment, can we decide that drugs in Group 2 and 3 be compounded in regular IV room (positive pressure)?

No. If you are compounding (doing any manipulation that potentially introduces HD into environment) the activity needs to be under negative pressure.

7. If we were to package Table 2 and 3 drugs (tabs/caps) in the HD room into prescription vials of our normal dispensing quantities, would we be able to clean the vials and put them into the normal area in order pull and put a label on to dispense? (with appropriate HD labeling of course)

Packaging finished drugs does not require an HD room unless these are end products of a compounding process. See USP 800 FAQs for general info about dispensing. Here are two links you can copy and paste into your web browser - one for the USP 800 FAQs - https://www.usp.org/sites/default/files/usp/document/our-work/compounding/faqs-usp-800.pdf and one that may allow you to download the chapter - http://go.usp.org/l/323321/2019-05-31/2dfgwl

8. Should all Table 2 and 3 NIOSH HD's be compounded and handled according to full USP 800 requirements same as antineoplastics?

Refer to USP <800> for specifics, but if the drug compounded is an API or a finished drug is manipulated in a way that creates dust or airborne particulates then It must be handled in a C-PEC/Hood that is located in a C-SEC/Neg pressure room. There are always some exceptions, but it is best to read the chapter thoroughly as well as the NIOSH Haz Drug list and ALL tables. This will allow one to align pharmacy specific practices with those noted in these documents.

9. Since HD's come packaged in their own plastic bag INSIDE a cardboard box, do we need to unpack the cardboard box in the 800 room, or just the plastic bag?

This is an operational decision. Refer to USP <800> section on Receiving, Storage, Transportation so you can determine how you want to proceed after doing the risk assessment.

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Hazardous Drugs (continued)

10. Are the requirements the same even if we are diluting bulk progesterone cream as making cream out of progesterone powder?

In general yes, USP <800> considers all manipulations hazardous until the preparation is in the final dosage form ready to dispense to the patient. There is an acknowledgment that once the API is "wet" certain manipulations may occur outside the C-PEC (hood), but a risk assessment must be done. Note that the manipulations are still carried out within the negative pressure room. See USP <800> FAQs - this can be found via a web search. Also, the details in the chapter so it is best to obtain the chapter to ensure full compliance.

11. What is the overall cost impact to make a compound for a patient?

Highly variable as there are several considerations. In general, traditional community pharmacies will invest between $50K and $100k to meet basic <800> facility design and equipment CapEx. RX volume and ROI tolerance will drive the additional cost to patient.

12. When dispensing a NIOSH drug to a patient in a final dosage form like a capsule, should we attach an auxiliary label stating it is a hazardous drug?

Yes - USP 800 provides detailed instructions on labeling. Once you have a copy of the chapter, review the section on labeling for those details.

13. Where do we find the list of Hazardous Drugs?

The newest list will be out Dec 2019. A web search of "NIOSH Haz Drug list" will return links to the CDC website and/or a downloadable PDF.

USP <800> General

1. How does USP 800 apply to non-compounding (commercially available) drugs? Ex: counting out drugs from stock bottles, such as spironolactone. Interpretations vary widely.

<800> indicates that a risk assessment be performed and incorporated into facility SOPs. For quick reference refer to the USP <800> FAQs - copy/paste this link into web browser - https://www.usp.org/sites/default/files/usp/document/our-work/compounding/faqs-usp-800.pdf

2. Do computer monitors, cameras, printers, etc need to be enclosed within the 800 space?

If they could come into contact with the Haz Drug - Yes. Essentially any equipment in the room must stay there. Some facilities are designing operations as much as possible to keep this equipment out of 800 room. It is recommended that staff be trained to avoid touching anything outside the C-PEC (hood) until final manipulations are done.

3. Where can we find a list of necessary items needed in compliance such as booties, gowns, cleaning fluids?

API suppliers may have a list, but you may not need everything on it or may need something they don't offer. The chapter and table 5 of the NIOSH Haz Drug list provide the best information on what is needed by each operation.

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USP <800> General (continued)

4. Gowning and garbing for counting tablets? What ones are there?

Gowning/garbing for counting finished dosage forms isn't specifically required. This would fall under the risk assessment outlined in USP <800> and placed in your SOPs. Some facilities may elect to require it while others may not. For example, a facility may decide that a table One drug (chemo) that is often broken/friable in original container is a candidate for handling with additional PPE such as gown and N95 mask. The chapter leaves this up to each facility and their respective process and drugs handled.

5. Which tablets/drugs require this?

Refer to the NIOSH Haz Drug lists, table 5 of NIOSH list for work processes requiring PPE, and USP 800. This info is available from a web search.

6. Do you have to get rid of your gowns and incinerate them even if there is no visual stuff?

All PPE that has come into contact with or potentially come into contact with an HD (especially HD Bulk powder) should be disposed of in a designated "chemo bucket" or chemo waste bag. Incineration is not required in USP 800. See USP 800 FAQs - copy/paste this link -
https://www.usp.org/sites/default/files/usp/document/our-work/compounding/faqs-usp-800.pdf

7. Do you recommend a separate corner of the pharmacy, separate tray/spatula to count those HD at the retail pharmacy?

Separate corner not necessarily needed. Separate tray and spatulas - Yes. Any equipment that comes in direct contact with a Haz Drug must be dedicated for that purpose. This is especially true when working with powders but would apply to finished drugs. <800> does provide for "assessment of risk" to determine exactly what suits a particular operation.

8. Does USP 800 require HVAC and hoods to be on emergency power?

It is implied by the operational requirements. The <800> room aka C-SEC must be kept negative to surrounding work spaces and be vented to the outside. If the hood(C-PEC) provides some or all of the venting to create a negative environment, then it must run continuously. If doing sterile Haz Drug compounding the C-PEC must run continuously.

9. Is there a free SOP anywhere?

You get what you pay for. If there is a free SOP, you will likely need to do a significant amount of work adapting it to your operation. A resource for a "non-denominational" SOP is Compounding Today. They do provide a sample page for some of the SOPs so you can see the format. Most of the API suppliers offer a suite of SOPs - not sure how many offer a sample page or pricing. Lastly, there are consultants that provide SOPs, and some may write customized SOPs specific to your setting, but those are likely the most expensive.

10. How would you handle inquiries from PBMs requiring compliance with 800 even though 800 is not enforceable at this time due to 795 and 797 being in appeals?

Refer them to the USP statement that the chapter is "informational" pending the appeals of USP 795 and 797.

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USP <800> General (continued)

11. If the new USP 797 and 795 implementation is delayed, is the Hazardous drug handling in old 797 and 795 is effective?

Correct, although USP still points to <800> as "Informational Guidance". Also, you will need to check with your state board of pharmacy as a few states have incorporated 800 into their rules and issued a "go live" date based on the original Dec 1st 2019 date from USP.

12. In Texas, does anyone have information on who we can contact that understands the HVAC requirements of <800>?

There is no HVAC info clearinghouse at state or national level that we've found.

13. Is plastic considered "non-porous?"

It depends on the plastic and nature of the drug. Plastic is commonly used for bulk powders and finished drugs from Pharma. They conduct container/closure tests to confirm that the plastic is suitable for intended use. Note for example that USP<800> states that the HD "should be received from supplier in impervious plastic…". If your question is whether plastic is non-porous relative to an HD dissolved in a liquid, it is possible that a solvent like alcohol could penetrate certain types of plastic and allow an HD to be transported through the plastic. For example, it is known that some drugs can adsorb into IV bags which by definition means the plastic is porous.

14. Does PPE used go into chemo bucket too?

Yes.

15. The 800 room must be externally vented to the outside of the building. Right? There is no wiggle room with venting.

Yes, room must be vented. If manipulating Table 2 or Table 3 drugs the hood can vent back into room IF DOUBLE HEPA filtered but room air still must be vented out of building.

16. USP 800 says that we need to separate HDs and non-HDs, does this have to be done in a completely separate room, or can they be stored in a separate area of the same space? For non-Sterile compounding for non-HDs is it enough to have a separate hood within the same room if the room meets requirements?

Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD 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). Nonantineoplastic reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.

17. What kind of training we need to do to our new hires and how often?

It varies depending on type of Haz Drug handling. You will need to refer to full chapter for details. This link may allow you to download the chapter otherwise contact USP and you can purchase the chapter. - http://go.usp.org/l/323321/2019-05-31/2dfgwl

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USP <800> General (continued)

18. **We are a small facility that doesn't dispense NIOSH Table 1 drugs. We do dispense Table 2 & 3 meds although limited. We currently do not have a negative pressure room. We do have a BSC in our positive pressure room (no longer allowed in USP 800). Would utilizing closed-system transfer devices in a laminar flow hood and excluding employees of reproductive age from handling these med meet the intent of USP 800 if we included these strategies in our risk assessments?**

    Are these finished drugs or compounded preparations? Most CSTD are for aqueous solutions such as reconstituted chemo drugs. Are you working with APIs (bulk substances), grinding/crushing tablets, opening capsules? If so, then those manipulations must take place in a "hood" of appropriate type inside a negative pressure room. If they are finished drugs that require no additional manipulation other than counting and repackaging, then no cabinets or negative pressure rooms are needed. USP has an excellent FAQ that addresses

19. **What should be done if your state has said they are not adopting 800?**

    As noted in webinar this is a workplace safety "standard", so oversight really falls to OSHA and related state agencies. Should a complaint be filed it most likely be handled by OSHA.

20. **Where can you find information on the specifications of PPE required? such as thickness of gloves requirement?**

    USP 800 and the NIOSH HazDrug list both provide specifications. There are no specs for glove thickness only that they meet ASTM 6978.

21. **My pharmacy does not have any employees, the pharmacy is owned and operated by two pharmacists, does OSHA have any jurisdiction?**

    To the best of my knowledge, OSHA has oversight of all workplace safety matters. One important thing to consider is that under the Drug Quality and Security Act, pharmacies must practice in accordance with applicable Federal and State law to keep "exemption" from full FDA oversight. It is unclear at this point, but FDA could use failure to comply with USP <800> as a reason to pull 503A exemption. Remember that all chapters under <1000> are enforceable. It is unlikely the FDA would do an <800> inspection but they could use this as a tool to pull exemption and inspect to cGMP standards.

22. **What is the link for the NIOSH Investigation of Oncology Clinic?**

    Here is the link: https://www.cdc.gov/niosh/hhe/reports/pdfs/2009-0148-3158.pdf

23. **What is the link to view the presentation on demand and slides?**

    On Demand Recording: https://youtu.be/dywaPVSGfdY
    Slides: http://bit.ly/USP800slides