GENERAL PRINCIPLES OF USP <800> 2

2.1 Where did the information in <800> come from?

Information about risks to personnel from hazardous drugs (HDs) has been in the medical literature since the 1970s. ASHP's first guidance on handling HDs was published in 1985 as the *Technical Assistance Bulletin on Handling Cytotoxic Drugs in Hospitals.*[1] Revisions to that document were published in 1990[2] and 2006.[3] A new revision is anticipated in early 2018. The National Institute for Occupational Safety and Health (NIOSH) published the *Alert* on *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* in 2004.[4] The *Alert* included a list of HDs, which was updated in 2010, 2012, 2014, and 2016.[5] The ASHP and NIOSH documents form the core of the information in <800>. The Occupational Safety and Health Administration (OSHA) information on controlling occupational exposure to HDs,[6] other professional organizational guidance (e.g., from the Oncology Nursing Society), scientific publications,[7] and best practices that have evolved since these documents were published have also been incorporated into <800>.

2.2 Why is the term *entity* used? Why not just call it a pharmacy?

<800> applies to many more healthcare settings than pharmacies. Physician offices, clinics, veterinary offices, and many other locations handle HDs. When you see the term *entity* in <800>, apply it to your setting.

2.3 What is the source for the list of HDs?

The NIOSH list of antineoplastic and other HDs[5] is the hazardous drug list used in <800>.

2.4 Do we need to include drugs on the EPA hazard list that aren't on the NIOSH list?

No. The NIOSH list includes drugs that are hazardous to personnel; it's the focus of <800>. The Environmental Protection Agency (EPA) hazardous materials list includes drugs and other substances that are hazardous to the environment. That is not the focus of <800>. Some drugs appear on both lists, so compliance with both <800> (for protecting personnel) and the EPA (for protecting the environment) needs to be addressed.

2.5 Can we add agents that aren't on the NIOSH list to our own facility list?

Yes, but there is no requirement to do so.

2.6 Are beta-lactam antibiotics addressed in <800>?

No, because they are not on the NIOSH list of HDs. However, you can include agents other than those listed on the NIOSH list in your policies if you choose to.

2.7 When must I comply with <800>?

<800> is official and federally enforceable on December 1, 2019. However, states or other regulatory agencies, accreditation organizations, and entity policy may require compliance before that date. This is all about limiting occupational exposure, so the sooner compliance is achieved, the safer your workplace will be.

2.8 Is there a distinction between *must* and *should* in the text of <800>?

Yes. *Must* is used for a requirement; *should* is used for a recommendation.

2.9 What are the major differences between <800> and the 2008 version of USP <795> and <797>?

Major differences include the following:

- ***Scope.*** <795> and <797> deal with receipt, compounding, and storage up to the point of administration. The scope of <800> spans more activities because its intent is to protect all healthcare workers. <800> includes protection of healthcare workers from the time the HD is received, through and including administration of the HD and disposal of HD waste.
- ***Elimination of the "low use" exemption.*** <797> allowed placement of a biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) in a positive pressure room, provided only a low volume of HDs was compounded. This is not allowed by <800>. All HD compounding must occur in a negative pressure room.
- ***Requirement to compound nonsterile HDs in a negative pressure room.*** USP <795> *Pharmaceutical Compounding—Nonsterile Preparations* provides general guidance for compounding nonsterile HDs but does not specify required elements. <800> includes requirements for compounding nonsterile HDs.
- ***Requirement for use of closed system drug-transfer devices (CSTDs) when administering antineoplastic agents.*** The scope of <795> and <797> stops when administration of the drug begins. The scope of <800> is greater and includes requirements for worker protection through administration and disposal of the HD. CSTDs provide protection for those individuals who administer HDs and are required by <800> when the dosage form allows their use.

2.10 What containment strategies are included in <800>?

There are three major containment strategies: engineering controls, personal protective equipment, and work practices.

2.11 Not all HDs are antineoplastics. How much volume is needed to invest in a negative pressure room? We compound a very low volume of HDs (1-2 items a week). Does this require a whole negative room?

There is no "low use" exemption in <800>, and it will be removed from <797> so the two chapters are in synch. If you compound any active pharmaceutical ingredients (APIs) on the NIOSH list or any antineoplastics, you need the proper facilities. The two options in <800>