

The
CHAPTER
<800>
ANSWER
BOOK

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Any correspondence regarding this publication should be sent to the publisher, ASHP, 4500 East-West Highway, Suite 900, Bethesda, MD 20814, attention: Special Publishing.

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Editorial Project Manager: Ruth Bloom

Production Director: Johnna Hershey

Cover & Page Design: David Wade

Library of Congress Cataloging-in-Publication Data

Names: Kienle, Patricia C., author. | American Society of Health-System Pharmacists, issuing body.

Title: The chapter <800> answer book / Patricia C. Kienle.

Other titles: Guide to (work): United States pharmacopeia.

Description: Bethesda, MD : American Society of Health-System Pharmacists, [2017] | "Provides explanation of elements of USP Hazardous Drugs' Handling in Healthcare Settings and best practices to comply with the requirements and recommendations of the USP General Chapter"--Pref. | Includes bibliographical references and index.

Identifiers: LCCN 2016048833 | ISBN 9781585285730 (alk. paper)

Subjects: | MESH: Drug-Related Side Effects and Adverse Reactions--prevention & control | Hazardous Substances--standards | Occupational Exposure--prevention & control | Drug Compounding--standards

Classification: LCC RM302.5 | NLM WA 487.5.H4 | DDC 615.7/042--dc23

LC record available at <https://lcn.loc.gov/2016048833>

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ISBN: 978-1-58528-573-0

10 9 8 7 6 5 4 3 2

Corrections were incorporated, effective with this second printing, October 2017.

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Preface

The Chapter <800> Answer Book provides an explanation of elements of USP <800> *Hazardous Drugs—Handling in Healthcare Settings* and best practices to comply with the requirements and recommendations of the USP General Chapter.

The author is a member of the USP Compounding Expert Committee, but this publication is not endorsed by or affiliated with USP.

Comments in this book are related to USP <795> and <797> from *USP 39-NF 34*, 2016. Revisions to those documents must be considered when designing policies and practices.

Patricia C. Kienle

Introduction

USP <800> *Hazardous Drugs—Handling in Healthcare Settings*¹ was published in the First Supplement to *USP 39–NF 34* on February 1, 2016, with an extended official date of December 1, 2019. One erratum was published on April 15, 2016.² Pharmacies and other entities where handling hazardous drugs (HDs) occur should obtain a copy of the full document. It is available from the United States Pharmacopeial Convention (USP), either as a part of the full *USP–NF* or as part of the *USP Compounding Compendium*.

The USP is recognized in the Federal Food, Drug, and Cosmetic Act as an official compendium.³ Numbering of the chapters is significant: USP chapters numbered under <1000> are considered enforceable, and those numbered above <1000> are advisory or informational. Note that some regulatory agencies also consider those chapters above <1000> as requirements. USP uses the term *must* or *shall* when citing a requirement, but the term *should* is used when citing a recommendation.

USP is a standard-setting organization, not a regulatory or enforcement agency. Regulatory bodies (e.g., the Centers for Medicare & Medicaid Services [CMS], state boards of pharmacy, state departments of health) and accreditation organizations enforce USP standards and/or include them in their standards.

<800> is one of a number of compounding-related chapters in the *USP–NF*. It supplements but does not replace <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations*. Other related USP chapters are listed in the texts of <795>, <797>, and <800>.

References

1. United States Pharmacopeial Convention. General chapter <800> hazardous drugs—handling in healthcare settings. *USP 39–NF 34 First Supplement*; 2016.
2. United States Pharmacopeial Convention. <800> Hazardous drugs—handling in healthcare settings, errata. <http://www.usp.org/usp-nf/notices/hazardous-drugs-handling-healthcare-settings>.
3. United States Code, Title 21, §321, <http://uscode.house.gov/view.xhtml?req=%28official+compendium%29+AND+%28%28title%3A%2821%29%29%29&f=treesort&fq=true&num=0&hl=true&edition=prelim&granuleId=USC-prelim-title21-section321>. Accessed September 25, 2016.

Acknowledgments

Members of the USP Expert Panel on Hazardous Drugs devoted countless volunteer hours to discussion and development of practices that make patients and healthcare personnel safer. Many thanks to Thomas Connor, Melissa McDiarmid, Eric Kastango, Kenneth Mead, Martha Polovich, Luci Power, and James Wagner and to USP staff Emily Ann Meyer, Richard Schnatz, and Jeanne Sun.

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Acronyms

ACPH	air changes per hour
ADC	automated dispensing cabinet
API	active pharmaceutical ingredient
ASHP	American Society of Health-System Pharmacists
ASHRE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
ASTM	American Society for Testing and Materials
BSC	biological safety cabinet
C-PEC	containment primary engineering control
C-SCA	containment segregated compounding area
C-SEC	containment secondary engineering control
CACI	compounding aseptic containment isolator
CDC	Centers for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CMS	Centers for Medicare & Medicaid Services
CSP	compounded sterile preparation
CSTD	closed system drug-transfer device
CVE	containment ventilated enclosure
EPA	Environmental Protection Agency
FDA	U.S. Food and Drug Administration
HD	hazardous drug
HEPA	high-efficiency particulate air
HVAC	heating/ventilating/air conditioning
IPA	isopropyl alcohol
ISO	International Standards Organization
IV	intravenous
IVIG	intravenous immunoglobulin
LAFW	laminar airflow workbench
MAB	monoclonal antibody
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration

Acronyms (continued)

PAPR	powered air-purifying respirator
PEC	primary engineering control
PPE	personal protective equipment
SDS	safety data sheet (formerly called material safety data sheet [MSDS])
sIPA	sterile 70% isopropyl alcohol
TJC	The Joint Commission
UPS	uninterrupted power source
USP	United States Pharmacopeia
wc	water column

List of Questions

Chapter 1: USP <800> Availability

- 1.1 Where can I find the full text of USP <800>?
- 1.2 When will USP <800> become official?
- 1.3 I have heard there may be changes to <800> that will impact remodels. How can I find out quickly?

Chapter 2: General Principles of USP <800>

- 2.1 Where did the information in <800> come from?
- 2.2 Why is the term *entity* used? Why not just call it a pharmacy?
- 2.3 What is the source for the list of HDs?
- 2.4 Do we need to include drugs on the EPA hazard list that aren't on the NIOSH list?
- 2.5 Can we add agents that aren't on the NIOSH list to our own facility list?
- 2.6 Are beta-lactam antibiotics addressed in <800>?
- 2.7 When must I comply with <800>?
- 2.8 Is there a distinction between *must* and *should* in the text of <800>?
- 2.9 What are the major differences between <800> and the 2008 version of USP <795> and <797>?
- 2.10 What containment strategies are included in <800>?
- 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?
- 2.12 What are the area/facility requirements for nonsterile compounding of HDs? It sounds like USP <800> will require hoods for nonsterile compounding activities, but what if I'm just cutting tablets in half or packaging bulk tablets into unit doses?

Chapter 3: Contents of Sections of USP <800>

No questions

Chapter 4: Scope of USP <800>

- 4.1 **Why is <800> Necessary?**
 - 4.1-1 Who has to comply with <800>?
 - 4.1-2 What type of compounding does <800> cover?
 - 4.1-3 Does <800> replace <797>?
 - 4.1-4 Does <800> replace <795>?
 - 4.1-5 Do community or mail-order pharmacies have to comply with <800>? How about a private physician's office?
 - 4.1-6 Is a nursing station where HDs may be stored considered an "entity"?
 - 4.1-7 Does a nursing home have to comply with <800>?
 - 4.1-8 Who doesn't have to comply with <800>?
 - 4.1-9 Will USP chapters be enforced at pharmaceutical wholesalers?
 - 4.1-10 Is there any valid science behind <800>? Where can I find more information?
 - 4.1-11 We have never had anyone injured by handling chemo agents in our facility. Why is <800> needed?
 - 4.1-12 I've heard <800> referred to as a guideline and a standard. Which is correct? What's the difference?
 - 4.1-13 I have heard reference to a letter that The Joint Commission sent to hospital administrators concerning risks of HDs. Where can I get a copy of the letter?

List of Questions (continued)

4.2 Handling Hazardous Drugs

- 4.2-1 What is included in *handling*?
- 4.2-2 What does *manipulation of a dosage form* mean?
- 4.2-3 Does manipulation include manual repackaging from a bottle to a unit-dose package?
- 4.2-4 Does <800> apply in emergency situations?
- 4.2-5 What is meant by the “life cycle of a HD”?
- 4.2-6 The wording about HDs isn’t the same in Chapters <795>, <797>, and <800>. Which do I have to follow?

4.3 Regulations

- 4.3-1 Is <800> a regulation?
- 4.3-2 Can I select certain sections of <800> to be compliant with?
- 4.3-3 When will <800> go into effect?
- 4.3-4 Who will enforce <800> for compliance outside of pharmacy settings?
- 4.3-5 What is the difference between HDs and hazardous waste?

4.4 Personnel

- 4.4-1 Does <800> apply to the nurses in physician practices?
- 4.4-2 Our nurses mix chemo. Are they subject to <800> requirements?
- 4.4-3 Do environmental services personnel need to know about <800>?
- 4.4-4 Do pharmacy delivery drivers need to know about <800>?

4.5 Facilities

- 4.5-1 Why does <800> use the term *entity* to describe a pharmacy?
- 4.5-2 Does our outpatient pharmacy need to comply with <800>?
- 4.5-3 How does <800> apply to a patient’s home?
- 4.5-4 Do wholesalers have to follow <800>?

Chapter 5: Planning

5.1 Types of Exposure

- 5.1-1 How are healthcare personnel exposed to HDs?
- 5.1-2 What are the types of exposures addressed by USP <800>?
- 5.1-3 What are the best ways to protect against exposure to HDs?
- 5.1-4 What types of HDs need to be considered—nonsterile, sterile, chemo, or others?
- 5.1-5 Are final dosage forms safer than powders?
- 5.1-6 Why are manufacturers allowed to send us products that are contaminated?

5.2 NIOSH List of Hazardous Drugs

- 5.2-1 Where can I find a list of HDs?
- 5.2-2 Can I make my own list instead of using the NIOSH list?
- 5.2-3 Why is the NIOSH list used in <800>?
- 5.2-4 What is the definition of a HD?
- 5.2-5 What are the types of HDs?
- 5.2-6 What if I don’t agree with the NIOSH list? Can I eliminate some of the listed drugs from consideration at my organization?
- 5.2-7 When developing our hospital’s list of HDs, do we have to include all meds on the NIOSH list?
- 5.2-8 Why are drugs other than chemo agents included on the NIOSH list?
- 5.2-9 Since <800> was approved when the 2014 NIOSH list was available, will the 2014 list be the only one that’s used for <800>?

List of Questions (continued)

- 5.2-10 How often will the NIOSH list be updated?
- 5.2-11 How can I identify the HDs used in my organization?
- 5.2-12 How do I know if a drug that is new to the market is hazardous?
- 5.2-13 Why is the NIOSH list different from the list of hazardous medications we have from our waste hauler?
- 5.2-14 What is an *API*?
- 5.2-15 If I withdraw a med from a vial, is that an API because it isn't a finished dosage form until I mix it?
- 5.2-16 Based on NIOSH, should we change the labeling on drugs to hazardous/antineoplastic, hazardous/non-antineoplastic, and hazardous/reproductive?
- 5.2-17 Are all monoclonal antibodies (MABs) HDs?
- 5.2-18 MABs, with the exception of conjugated monoclonals, have been removed from the NIOSH list. How do you recommend monoclonals that have known teratogenic properties (i.e., rituximab, bevacizumab, cetuximab) be handled? Do these need to be prepared in a negative pressure environment? What about handling MABs for nursing?
- 5.2-19 Why do I need to handle megestrol as an antineoplastic? The only hazard information I see in the package insert is that it can cause malignant tumors in beagles taken for 7 years. How do you extrapolate this to a nurse pouring a liquid for a patient a few times each year who likely will not be touching it at all?
- 5.2-20 NIOSH lists drugs like finasteride and clonazepam in the same category. But I don't consider them the same risk. How would I know that handling should be different?
- 5.2-21 What about topical drugs such as diclofenac gel? It's not on the NIOSH list but definitely has the potential to affect the baby of a pregnant woman who handles it.
- 5.2-22 How are investigational drugs handled with respect to <800>? How should we classify investigational drugs, especially those in early clinical trials with limited safety data? It's often unclear from available information if they should be considered hazardous.
- 5.2-23 What are the options for investigational drug services that store HDs where sponsors require certain storage conditions? For instance, drugs must be stored in a limited access area within the investigational drug pharmacy.

Chapter 6: Assessment of Risk

- 6.1 What are my options to handle HDs?
- 6.2 What is a practical way to approach identifying the HDs I use that might be candidates for an Assessment of Risk?
- 6.3 Do I have to include all medications on the NIOSH list?
- 6.4 Our hospital decided not to include phenytoin and warfarin on our HD list. Is this OK?
- 6.5 What needs to be included in the Assessment of Risk?
- 6.6 Can I do an Assessment of Risk for an entire class of drugs (e.g., hormones) instead of each individual drug?
- 6.7 Is there a template I can use to list each drug and dosage form to determine if it's acceptable to be included in our Assessment of Risk?
- 6.8 Can non-antineoplastics and reproductive hazards be handled differently than antineoplastics?
- 6.9 Should all MABs be treated as hazardous?
- 6.10 Why is an Assessment of Risk allowed by <800> if all the drugs on the NIOSH list are hazardous?
- 6.11 When a HD is a final dosage form (e.g., tablet, capsule) and an Assessment of Risk has been performed, can this HD fall outside of the USP <800> regulation?

List of Questions (continued)

- 6.12 What antineoplastics don't have to be handled as HDs?
- 6.13 What about excluding "counting final dosage forms" when large quantity counting is performed?
- 6.14 How often do I need to review the Assessment of Risk?
- 6.15 Who needs to know that I did an Assessment of Risk?
- 6.16 What are some examples of alternative containment strategies?
- 6.17 Would the containment strategies be applied to drugs (e.g., megestrol oral suspension) if the patient receives less than the full size of the unit dose?
- 6.18 The NIOSH 2016 list of HDs says nurses must use double gloves for administration of anything on the HD list (even non-chemotherapy) except intact tablets or capsules. This seems excessive. Is this where the Assessment of Risk could be applied?
- 6.19 If I have to package methotrexate tablets, isn't the risk different for the tech who packages it versus the nurse who administers it?
- 6.20 Do I have to exclude packaging and counting in my Assessment of Risk?
- 6.21 What if I handle a non-antineoplastic HD but don't include it on my Assessment of Risk?
- 6.22 Can I do an Assessment of Risk for an entire class of drugs instead of listing each individual drug?

Chapter 7: Human Resources

7.1 Medical Surveillance

- 7.1-1 What does *medical surveillance* mean?
- 7.1-2 What department determines how this will work?
- 7.1-3 What types of medical surveillance will be required?
- 7.1-4 Should all employees have to sign lists acknowledging risk/NIOSH drug list?
- 7.1-5 Should pregnant or breast-feeding pharmacy technicians and pharmacists, or any employees trying to conceive, be removed from work duties of preparing chemo?
- 7.1-6 Should nurses who are pregnant or wish to become pregnant avoid taking care of patients who are on HDs due to administration and drug elimination in bodily fluids?

7.2 Designated Person

- 7.2-1 Who is the *designated person* mentioned in <800>?
- 7.2-2 Can the *designated person* be a committee instead of an individual?
- 7.2-3 Does the *designated person* need to be a pharmacist?
- 7.2-4 Does the *designated person* need to be a manager?
- 7.2-5 Is the *designated person* responsible for compliance with USP <800>?
- 7.2-6 Does oversight of handling HDs have to be the *designated person's* sole job responsibility?
- 7.2-7 Can the *designated person* be responsible for more than one site?
- 7.2-8 Where can the *designated person* obtain the necessary training for this job?
- 7.2-9 How much training does the *designated person* need to have?

7.3 Responsibilities of Compounding Personnel Training

- 7.3-1 What training is required to handle HDs?

7.4 Documenting Competence

- 7.4-1 What competence information has to be documented?
- 7.4-2 How often should training occur?
- 7.4-3 If we add a new drug similar to one we use, does that require full annual-type documentation?
- 7.4-4 Who needs to be trained on the hazards of HDs?
- 7.4-5 Do I still need to do the personnel training listed in <795>?
- 7.4-6 Do I still need to do the personnel training listed in <797>?

List of Questions (continued)

- 7.4-7 Does <800> require training separate from what we do for the hospital?
- 7.4-8 Do I need to teach my night nursing supervisors how to use the chemo hood?
- 7.5 Hazard Communication Plan**
- 7.5-1 What is a Hazard Communication Plan?
- 7.5-2 Whose responsibility is it to develop a Hazard Communication Plan?
- 7.5-3 Is a hazardous chemical the same thing as a HD?
- 7.5-4 Do all HDs require a Safety Data Sheet (SDS)?
- 7.5-5 What are the occupational exposure limits for HDs?
- 7.5-6 Do employees have to document that they know they are working with HDs?
- 7.5-7 Do both male and female employees need to document their acknowledgment of HDs?
- 7.5-8 Where can I get an example of an employee consent form regarding exposure to HDs?

Chapter 8: Personal Protective Equipment

8.1 General Information

- 8.1-1 What does <800> require for PPE?
- 8.1-2 What are the benefits of PPE?
- 8.1-3 Are all the components of PPE needed for every activity when handling HDs?
- 8.1-4 What does *donning* and *doffing* mean?
- 8.1-5 What does *hand hygiene* mean?
- 8.1-6 When gloves are mentioned in <800>, does that mean *chemo gloves*?
- 8.1-7 What PPE needs to be worn by receiving personnel?
- 8.1-8 What PPE needs to be worn by personnel who are transporting HDs?
- 8.1-9 What PPE needs to be worn by personnel who are packaging HDs?
- 8.1-10 What PPE needs to be worn by personnel who are compounding HDs?
- 8.1-11 Does the pharmacist checking the preparation compounded in the C-PEC need to wear all PPE if he or she is not touching anything, but just looking?
- 8.1-12 If a pharmacist completes the checking of a CSP in the anteroom, does he or she need to garb?
- 8.1-13 Is additional PPE required for personnel who are compounding from powders?
- 8.1-14 My CACI technical manual states that head/hair/shoe covers are not required when compounding. Does USP supersede that?
- 8.1-15 Should PPE be donned before entering the negative pressure lab?
- 8.1-16 Is it necessary for the compounding pharmacist to remove all PPE each time he or she steps out to answer the phone?
- 8.1-17 The compounding pharmacist does all the patient counseling when new prescriptions are picked up. Does the pharmacist have to remove all PPE each time during the day when counseling a patient?
- 8.1-18 Is an N95 respirator required when compounding HDs that could cause a respiratory risk?
- 8.1-19 How do PPE requirements differ between nonsterile and sterile compounding?
- 8.1-20 Do you have to wear PPE when transporting drugs to an infusion area?
- 8.1-21 What PPE needs to be worn by personnel who are administering HDs?
- 8.1-22 What PPE needs to be worn by personnel who are discarding HD trash?
- 8.1-23 What PPE does personnel need to wear when cleaning up a spill?
- 8.1-24 Can PPE be reused?
- 8.1-25 What is meant by “reused”? Can garb be reused if removed and then donned again when required to leave the area for just a few minutes? Or does it mean reused on a different day?
- 8.1-26 Is PPE required when using a compounding isolator?

List of Questions (continued)

- 8.1-27** <797> allows use of a gown throughout one shift. Does this apply when compounding HDs?
- 8.1-28** Does the pharmacist who is checking only items need to garb?
- 8.1-29** What is the proper order of donning and doffing PPE for compounding HDs in a cleanroom suite (positive pressure anteroom and negative pressure buffer room)?
- 8.1-30** What is the proper order of donning and doffing PPE for compounding HDs in a C-SCA?
- 8.1-31** What is the proper order of donning and doffing PPE for compounding HDs in a compounding room for nonsterile HD preparation?

8.2 Gloves

- 8.2-1** Do chemo gloves have to meet a particular standard?
- 8.2-2** How do I know if a glove is chemo-rated?
- 8.2-3** Is it OK for chemo gloves to be tested per ASTM D6978 and lab chemical tested per ASTM F739?
- 8.2-4** Do I have to wear chemo gloves when handling non-antineoplastic HDs?
- 8.2-5** Do sterile chemo gloves exist?
- 8.2-6** When must you use sterile gloves?
- 8.2-7** How do I sterilize chemo gloves?
- 8.2-8** Is double-gloving required?
- 8.2-9** Why do I need to wear two pairs of gloves?
- 8.2-10** How can you put on two pairs of gloves? They don't fit over each other.
- 8.2-11** Can the inner glove be a regular glove and the outer glove be a chemo glove?
- 8.2-12** Are chemo gloves required when working in a compounding isolator?
- 8.2-13** Do I need two pairs of chemo gloves if I'm working inside a CACI?
- 8.2-14** We use a CACI. Is the isolator glove considered to be the second pair of gloves, or do we need two pairs plus the isolator glove?
- 8.2-15** Do both pairs of chemo gloves need to be sterile?
- 8.2-16** Do both pairs of gloves need to be made of the same material?
- 8.2-17** How often do gloves need to be changed?
- 8.2-18** Where do I find the manufacturer's information about the glove permeability?
- 8.2-19** How do I find a glove that I can use with carmustine or thiotepa?

8.3 Gowns

- 8.3-1** Do chemo gowns have to meet a particular standard?
- 8.3-2** How do I know if a gown is chemo-rated?
- 8.3-3** What documentation exists concerning permeability of chemo gowns?
- 8.3-4** How do I know that a particular gown will resist permeability to HDs?
- 8.3-5** What is the difference between gowns we use for non-HDs and those used for chemo?
- 8.3-6** What are chemo gowns supposed to be made of?
- 8.3-7** How should chemo gowns be constructed?
- 8.3-8** In pharmacy, we have blue plastic gowns for mixing chemo. Our nurses wear yellow isolation gowns when they administer chemo. Is this OK?
- 8.3-9** Can I hang my gown in the anteroom for use later in the day?
- 8.3-10** <797> allows a gown to be removed, retained, and used throughout the work shift if it isn't soiled. Is this allowed by <800>?
- 8.3-11** Can gowns be re-worn during the day if a compounder must leave the HD compounding area? How should it be removed, stored, and re-donned?
- 8.3-12** Are washable gowns allowed?

List of Questions (continued)

- 8.3-13** If we use a reusable gown service and their cleaning procedures are sufficient, does that qualify as disposable?
- 8.3-14** How often do gowns need to be changed?
- 8.3-15** How long can I use a chemo gown—one compound, one batch, or all day?
- 8.3-16** Why do I have to change my gown every 2-3 hours?
- 8.3-17** Do I need to wear a regular gown under my chemo gown?
- 8.3-18** Do two gowns always need to be worn when compounding or is one chemo gown OK?
- 8.4 Hair Covers**
- 8.4-1** What is the difference between head and beard covers used for chemo and those used for non-HDs?
- 8.4-2** If personnel wear a head cover for religious or other reasons, is an additional hair cover necessary?
- 8.5 Shoe Covers**
- 8.5-1** What is the difference between shoe covers used for chemo and those used for non-HDs?
- 8.5-2** Can I use dedicated cleanroom shoes instead of shoe covers?
- 8.5-3** Why does <800> require two pairs of shoe covers?
- 8.5-4** Do nurses need to wear shoe covers when administering chemo?
- 8.6 Eye Protection**
- 8.6-1** What does *eye protection* mean?
- 8.6-2** Do I need goggles if I wear glasses?
- 8.6-3** When is eye protection needed?
- 8.6-4** I wear prescription eyeglasses. Does this qualify as eye protection?
- 8.6-5** I wear a face shield when I mix chemo. Is this proper eye protection?
- 8.6-6** Do I need eye protection when I'm mixing chemo?
- 8.6-7** Do I need eye protection when I'm cleaning the area inside a BSC or CACI?
- 8.6-8** Do I need eye protection when I'm cleaning HD areas outside a C-PEC?
- 8.6-9** Do I need eye protection when I'm cleaning up a spill?
- 8.7 Respiratory Protection**
- 8.7-1** What does *respiratory protection* mean?
- 8.7-2** What does an N95 respirator protect against?
- 8.7-3** Are there respirators that are better protection than N95?
- 8.7-4** When is respiratory protection needed?
- 8.7-5** Do I need respiratory protection when I'm working in a BSC or CACI?
- 8.7-6** Do surgical masks provide adequate respiratory protection?
- 8.7-7** Since the BSC and CACI provide respiratory protection, do I need to wear a regular mask for any HD compounding?
- 8.7-8** Do receiving personnel need to wear respiratory protection when unpacking HDs?
- 8.7-9** Do I have to wear a surgical mask when compounding?
- 8.7-10** Do I need to wear a respirator when I'm mixing chemo?
- 8.7-11** Can a surgical N95 respirator be used in place of a regular N95 respirator?
- 8.7-12** Does everyone who works with HDs need to be fit-tested for a N95 respirator?
- 8.7-13** My employer has never offered fit-testing of respirators. Can pharmacy staff fit-test each other?
- 8.7-14** Where can I find information about fit-testing of respirators?
- 8.7-15** Does each person handling HDs need his or her own N95 respirator?
- 8.7-16** Do I need respiratory protection when I'm cleaning up a spill?

List of Questions (continued)

Chapter 9: Receiving Personnel: Hazardous Drug Precautions

- 9.1 What training is required for receiving personnel?
- 9.2 Why is delivery and acceptance of HDs covered under <800>?
- 9.3 Where do I open the HDs I receive from suppliers?
- 9.4 How do I know if a container includes a HD?
- 9.5 Are suppliers required to label HD containers?
- 9.6 Do I need a designated room for unpacking? Does it have to be negative?
- 9.7 Should I unpack the wholesaler tote in the chemo room?
- 9.8 Won't I contaminate my C-SEC if I take the wrapped HDs into it?
- 9.9 Could we use a powder hood to open the packages?
- 9.10 What regulations do manufacturers have to control the hazardous residue on the outside of their products?
- 9.11 Do HD totes have to be delivered to the chemo room?
- 9.12 Would the individual taking the plastic-wrapped package into the buffer room have to be garbed?
- 9.13 How should the packages of HDs be taken into the chemo room?
- 9.14 Is there a requirement for pressure monitoring in the receiving area to demonstrate neutral or negative air?
- 9.15 How should I handle receipt of antineoplastics that will be dispensed without manipulation (e.g., unit-of-use methotrexate tablets)?
- 9.16 What PPE should be available to receiving personnel?
- 9.17 Do I need to wash my hands after I remove the chemo gloves I wear when receiving and stocking chemo agents?
- 9.18 How should damaged or broken HD containers be handled?
- 9.19 What happens if a damaged package needs to be opened?
- 9.20 We segregate antineoplastic deliveries from our wholesaler by using a unique PO number. Do non-antineoplastics (e.g., warfarin, estrogen, fluconazole) need to be in separate totes?
- 9.21 Will wholesalers designate hazardous items in their ordering system?
- 9.22 Do I have to receive HDs in a negative pressure area?
- 9.23 How can I identify HD containers when they come in from suppliers?
- 9.24 How should HDs be packaged by suppliers?
- 9.25 Where should HD shipments be received?
- 9.26 What garb needs to be worn by receiving personnel?
- 9.27 What is the ideal process for receiving HDs?
- 9.28 Should receiving personnel open up all the boxes of chemotherapy?
- 9.29 What should be done when broken or damaged HDs are received?

Chapter 10: Storage of Hazardous Drugs

- 10.1 What are the minimum storage requirements for the location of HD storage?
- 10.2 Am I required to store all HDs in a negative pressure room?
- 10.3 Where does <800> say that I have to keep two sets of inventory—one for nonsterile and one for sterile?
- 10.4 Are manufacturers required to clean the outer packaging of unit-dose/unit-of-use containers?
- 10.5 Why do HDs need to be stored in a negative room?
- 10.6 Can I store HDs in the negative pressure buffer room?
- 10.7 Can HD and non-HD APIs be stored in the same negative pressure room if they are separated?
- 10.8 Do all my non-chemo agents need to be in a negative room?

List of Questions (continued)

- 10.9** If I use an injection for nonsterile compounding, where do I store it?
- 10.10** What does *antineoplastic requiring only counting or packaging* mean?
- 10.11** Do I have to post a sign at the front door of the pharmacy stating that HDs are stored inside?
- 10.12** Do oral HDs have to be stored in a negative pressure room?
- 10.13** What examples of alternative containment strategies could we consider for oral antineoplastic agents to allow them to be stored with regular stock?
- 10.14** Can I store chemo with other stock?
- 10.15** Can hazardous and chemotherapy drugs be stored in the same area?
- 10.16** Can I store all my drugs (i.e., hazardous and non-hazardous) in a single negative pressure room?
- 10.17** Can I store nonsterile chemo drugs in my sterile chemo room?
- 10.18** I don't have room in my negative pressure buffer room to store stock. Can I use a vented flammable cabinet?
- 10.19** I have a negative pressure room with a negative pressure cabinet that is used to store all of our HD APIs. We keep other items in that cabinet that are not hazardous. Do we need to remove the non-HD items from there?
- 10.20** Where can I obtain a list of hazardous medications that release volatile vapors during storage?
- 10.21** Does USP <797> allow storage in the buffer area?
- 10.22** Where do I store HDs that require refrigeration?
- 10.23** What are my options for storing refrigerated HDs?
- 10.24** Does the refrigerator have to be a negative pressure refrigerator?
- 10.25** I have only one pharmacy refrigerator. Can I designate one shelf to store antineoplastics?
- 10.26** Can I store chemo vials in smooth-coated cardboard boxes in my negative pressure buffer room?
- 10.27** Can I store saline vials and other similar non-hazardous items in the negative pressure buffer room?
- 10.28** Would it be reasonable to store a limited number of oncology support (e.g., anti-emetics) medication to be stored alongside HD in a C-SCA where the compounding takes place? It sounds like this is prohibited.
- 10.29** Can I use a flammable cabinet to store my chemo?
- 10.30** Can HDs be stored in a negative pressure cabinet located in a neutral area?
- 10.31** Do I understand correctly that not only do chemo agents need to be compounded in a negative pressure room, but they also need to be stored there prior to use even if they are in a manufacturer's sealed box?
- 10.32** Would the separation of HDs and non-HDs include storage of large quantities in original packaging prior to unpacking for prescription packaging?
- 10.33** What are the recommendations regarding refrigerator placement for refrigerated antineoplastic HDs? USP <797> allows placement in a negative pressure buffer room; however, <800> recommendations indicate exhaust placement near the compressor and behind unit.
- 10.34** Can hazardous and chemotherapy drugs be stored in the same area?
- 10.35** Is it acceptable to store HDs in automated dispensing cabinets?
- 10.36** Is it acceptable to store HDs in carousels?
- 10.37** If the material is not volatile, why must negative pressure storage be used?
- 10.38** What are the storage area requirements for a nursing unit?
- 10.39** Can intact (unopened) HDs be stored in neutral/normal pressure areas in addition to negative pressure rooms?
- 10.40** We were compliant with <797> storage; it said "separate." Why does this now need to be negative?
- 10.41** How do you transport inventory that has been received into a negative pressure room?
- 10.42** Can I use a pneumatic tube to transport chemo items to our satellite pharmacy?

List of Questions (continued)

- 10.43** The only injectable antineoplastic we stock is methotrexate for ectopic pregnancy. How should this be stored?
- 10.44** <797> states that drugs are not to be stored in the buffer area or anteroom, so why does <800> allow for storage of drugs and refrigerators in the buffer room?
- 10.45** Does storage in a negative pressure room include both oral and injectable medications?
- 10.46** My workplace is a community pharmacy. Do I need a separate room for all HDs or just for the antineoplastics?
- 10.47** Does the area where I place HDs awaiting return to suppliers have to be separate from the regular HD storage area?

Chapter 11: Counting and Packaging Hazardous Drugs

- 11.1** Can I continue to package non-antineoplastics and reproductive hazards using automated packaging machines?
- 11.2** How should I package unit-dose solid oral antineoplastics?
- 11.3** If I buy only manufacturer unit-dose or unit-of-use packages, can I store the HDs—even antineoplastics—with my regular stock?
- 11.4** What would be an example of how a pharmacy could package unit-dose oral antineoplastic agents and be compliant with USP <800>?
- 11.5** What would be an example of how a community pharmacy should count out oral antineoplastic agents?

Chapter 12: Types of Engineering Controls

12.1 General Information

- 12.1-1** What are the types of engineering controls?
- 12.1-2** How do the PECs in <800> differ from those in <797>?
- 12.1-3** How do the SECs in <800> differ from those in <797>?
- 12.1-4** How do the supplemental engineering controls in <800> differ from those in <797>?
- 12.1-5** What is a *C-PEC*?
- 12.1-6** Do certain drugs require use of a CACI instead of a BSC?
- 12.1-7** What are the basic requirements for a BSC for sterile compounding?
- 12.1-8** What is a *containment ventilated enclosure*?
- 12.1-9** What additional items should be considered if my CVE will have redundant HEPA filters instead of being vented to the outside?
- 12.1-10** What is a *containment secondary engineering control*?
- 12.1-11** What is a *containment segregated compounding area*?
- 12.1-12** What is a *supplemental engineering control*?
- 12.1-13** Do HEPA filters stop gases?

12.2 Containment Primary Engineering Controls for Nonsterile Compounding

- 12.2-1** What is a *primary engineering control*?
- 12.2-2** Does nonsterile HD compounding require a C-PEC?
- 12.2-3** What types of C-PECs are compliant for compounding nonsterile HDs?
- 12.2-4** Does the C-PEC used for nonsterile compounding need to be vented to the outside?
- 12.2-5** What does *redundant HEPA filters in series* mean?
- 12.2-6** Can redundant HEPA filters in series be used instead of external venting if volatile agents are compounded?

List of Questions (continued)

- 12.2-7 Does the pre-filter count as one of the HEPA filters?
- 12.2-8 Can the C-PEC for nonsterile compounding be vented into another room instead of to the outside?
- 12.2-9 What should I look for when buying a powder hood or CVE?
- 12.2-10 I make only two or three nonsterile chemo preparations a year. Can I use my BSC in the sterile compounding room to do this?
- 12.2-11 What is *occasional* nonsterile compounding? At what point do I need a separate hood?
- 12.2-12 How should community pharmacies that dispense a large number of the drugs on the NIOSH list handle <800>?
- 12.2-13 The only antineoplastic agent I stock is methotrexate tablets. I need to count out tablets, and sometimes there is powder in the container. How does <800> deal with that situation?
- 12.2-14 The only risk I have is to package unit-dose methotrexate tabs. I don't have a BSC. Can I turn off my regular laminar air flow positive pressure hood and package them there?
- 12.2-15 How should we prepare single doses of HDs when we need to make an oral liquid from a tablet or capsule?
- 12.2-16 We currently use a non-externally vented CACI for preparation of oral HDs (i.e., drawing up pediatric liquid oral HD, compounding extemporaneous HD liquids from tablets). Per <800>, will this still be acceptable or will it need to be externally vented?
- 12.2-17 Can nonsterile compounds be prepared in a negative pressure room in a BSC?
- 12.2-18 It is my understanding that when USP <800> goes into effect that all chemicals considered hazardous need to be stored in a separate room, which contains a positive pressure powder hood vented to the outside and for which all compounding must be performed. Is this correct?
- 12.2-19 Does the powder hood need to have a filtration system in addition to venting outside or does venting out suffice?
- 12.2-20 Is there an industry guidance for testing/certification of a powder hood?
- 12.3 Containment Primary Engineering Controls for Sterile Compounding**
- 12.3-1 What is a *primary engineering control*?
- 12.3-2 What types of C-PECs are compliant for compounding sterile HDs?
- 12.3-3 Does the C-PEC used for sterile compounding need to be vented to the outside?
- 12.3-4 Can the C-PEC for sterile compounding be vented into another room instead of to the outside?
- 12.3-5 What should I look for when buying a C-PEC for sterile compounding?
- 12.3-6 I make only two or three sterile chemo preparations a year. Can I use my powder hood in the nonsterile compounding room to do this?
- 12.3-7 Are regular laminar air flow hoods acceptable for compounding with HDs under 800?
- 12.3-8 I use a positive pressure vertical laminar air flow hood for all CPSs. Will this still be allowed under <800>?
- 12.3-9 Do I need a separate BSC for non-antineoplastic HDs?
- 12.3-10 Can an acrylic glove box be used for preparation of HDs? It isn't negative pressure (there is no pressure differential), and it isn't vented.
- 12.3-11 Can I compound chemo and non-HDs in the same C-PEC?
- 12.3-12 My isolator manufacturer says I don't have to place my CACI in a negative pressure room. Is this compliant with <800>?
- 12.3-13 Can I compound non-hazardous CSPs in the anteroom?
- 12.3-14 Can I batch my chemo pre-meds in the anteroom of my negative pressure IV room?
- 12.3-15 Do isolators need to be vented to the outside if they have HEPA filters on the exhaust?
- 12.3-16 Can I place a regular hood in my negative pressure cleanroom to mix pre-meds?

List of Questions (continued)

- 12.3-17** USP <800> states that a LAFW cannot be used for compounding antineoplastic HDs. So, can a LAFW or CACI be used for compounding a non-antineoplastic HD?
- 12.3-18** Is it true that a CACI must now be installed in a segregated room? This was different from USP <797>, where if the CACI met certain air cleanliness requirements it could stand alone.
- 12.3-19** Must CACIs be located in a negative pressure room?
- 12.3-20** I have a CACI in a negative room, but it is not a cleanroom. Is this still OK with USP <800> requirements?
- 12.3-21** I have a CACI in a room that meets the requirements for a C-SCA. Can I still use the full BUDs listed in USP <797>?
- 12.3-22** Are BSCs obsolete? Do I need to get a CACI for my negative pressure cleanroom?
- 12.3-23** What does *class* of a BSC mean?
- 12.3-24** How are the types of Class II BSCs different?
- 12.3-25** I thought USP <797> required total exhaust BSCs.
- 12.3-26** I used to have a BSC that was a Class II, Type A2 unit. The exhaust was directly connected to the outside. Recently, my certifier told me I couldn't have this configuration and had to get either a new hood or change to what they term a *canopy* connection. Why?
- 12.3-27** How do I know that my BSC or CACI is working correctly?

Chapter 13: Closed System Drug-Transfer Devices

- 13.1** What is a *CSTD*?
- 13.2** Does <800> require the use of CSTDs for compounding HDs?
- 13.3** Do CSTDs have to be used when compounding in a CACI?
- 13.4** Does <800> require the use of CSTDs for administering HDs?
- 13.5** Do we need to use CSTDs for drugs such as chloramphenicol?
- 13.6** Is <800> requiring or recommending the use of CSTDs for more than just antineoplastic drugs?
- 13.7** Can I use a CSTD instead of a hood for occasional HD compounding?
- 13.8** USP <797> allows compounding an occasional HD in a BSC in a positive pressure room as long as a CSTD is used. Will this be acceptable under USP <800>?
- 13.9** Are CSTDs approved by the FDA?
- 13.10** Does the OMB code that some CSTD suppliers use mean that they are approved by the FDA?
- 13.11** How do I know if the CSTD we want to use actually works?
- 13.12** Can nursing use a different CSTD for administration than we do in the pharmacy for compounding?
- 13.13** <800> says "CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD."¹ I assume a CSTD could be physically incompatible because of physical dimensions, shape, composition, etc., but how could it be chemically incompatible?

Chapter 14: Design of Compounding Facilities

14.1 General Information

- 14.1-1** What are the minimum facility requirements for compounding HDs?
- 14.1-2** What is an *ACPH*?
- 14.1-3** What are the significant differences between USP <797> and USP <800> regarding requirements for negative pressure rooms and hoods?
- 14.1-4** Is there a way to look at the current (allowed by <797>) options versus the upcoming (allowed by <800>) options for placement of chemo hoods in different types of allowable rooms?
- 14.1-5** What does *fixed walls* mean?

List of Questions (continued)

- 14.1-6 Do the walls have to go from floor to ceiling?
- 14.1-7 Can I use plastic curtains or drapes to define the hazardous room?
- 14.1-8 Can I have a room with hard walls and use a plastic drape or strips for the doorway?
- 14.1-9 Can modular cleanrooms be used?
- 14.1-10 Must *fixed walls* be totally solid? Is a soft-wall system using a solid steel frame affixed to the floor and ceiling OK?
- 14.1-11 How much volume is needed to invest in a negative pressure room? We compound a very low volume of HDs, maybe one or two per week.
- 14.1-12 I have an ISO 7 positive pressure anteroom that opens up into two separate buffer rooms: one ISO 7 positive pressure room for non-hazardous sterile compounding and one ISO 7 negative pressure room for chemo compounding. The hoods and the rooms meet <797> requirements and are certified every 6 months. Do I have to build a new negative pressure cleanroom to meet <800>?
- 14.1-13 How do the PECs and the SECs differ from 797?
- 14.1-14 Do we need a separate room to do antineoplastic compounding?
- 14.1-15 Do I have to mix my chemo in a C-SCA?
- 14.1-16 Do nonsterile, non-antineoplastic, hazardous medications need to be compounded/prepared in a negative pressure environment?
- 14.1-17 We are in the process of building a pharmacy compounding room for nonsterile compounding only (no sterile compounding). Is it possible to compound both non-hazardous and hazardous mixtures in one compounding room?
- 14.1-18 What does *negative pressure* mean?
- 14.1-19 What does *separate* mean?
- 14.1-20 Can the negative pressure be greater than 0.03" wc?
- 14.1-21 Is there a requirement for pressure gauges?
- 14.1-22 What does *vented to the outside* mean?
- 14.1-23 What does *external venting* mean?
- 14.1-24 Does the external vent need to go to the roof?
- 14.1-25 Why is venting to the outside of the building needed?
- 14.1-26 What does a *classified room* mean?
- 14.1-27 What is *unclassified* space?
- 14.1-28 What ISO classification is required for a cleanroom?
- 14.1-29 What ISO classification is required for a C-SCA?
- 14.1-30 Can HDs be mixed outside a cleanroom?
- 14.1-31 I have a non-ISO 7 room with a CACI, 12 ACPH, and negative pressure. Will this environment be acceptable to compound HDs under <800>?
- 14.1-32 Is a negative pressure room required under <800>?
- 14.1-33 If I handle only HD liquids or semisolids where no particles, aerosols, or gases are produced, do I still need to compound those HDs in a negative room?
- 14.1-34 What constitutes a *low volume exemption* from <800> requirements?
- 14.1-35 Why did the allowance for *low volume* chemo sites that was allowed in <797> get removed from <800>?
- 14.1-36 Is it acceptable to prepare HDs in a BSC or CACI in a positive pressure cleanroom?
- 14.1-37 Do negative pressure rooms protect the employees in the room?
- 14.1-38 Are ACPH calculated using supply air or exhaust air?
- 14.1-39 If the HDs I use are not volatile, why do I need negative pressure and external venting?
- 14.1-40 Does *unclassified room* mean it doesn't meet <800> requirements?

List of Questions (continued)

- 14.1-41 Do I need an area for compounding nonsterile HDs?
- 14.1-42 *Occasional* nonsterile compounding is a subjective term. How many compounds are *occasional*?
- 14.1-43 Where does a sink need to be placed?
- 14.1-44 Can the sink be outside of the C-SCA?
- 14.1-45 Why does a sink need to be at least 1 meter away from the hood?
- 14.1-46 Can I turn off my hood when I am not using it?
- 14.1-47 Why is there a range for negative pressure?
- 14.1-48 Can the HD (negative) room be accessed through the positive pressure buffer room?
- 14.1-49 Can I have a pass-through between the positive pressure anteroom and the negative pressure buffer room?
- 14.1-50 Can I have a pass-through between the general pharmacy area and the negative pressure buffer room?
- 14.1-51 What are the requirements and recommendations for a pass-through chamber?
- 14.1-52 Can I have a pass-through refrigerator into the negative pressure buffer room?
- 14.1-53 Can I have a cart pass-through (a roll-up door) open into the negative pressure buffer room?
- 14.1-54 What kind of finishes do I need to use for floors, walls, and ceilings?
- 14.2 Certification of Primary and Secondary Engineering Controls**
- 14.2-1 How often does certification of the hoods and rooms need to occur?
- 14.2-2 What documents should my certifier reference on certification reports?
- 14.3 Anterooms**
- 14.3-1 What is the requirement for an anteroom?
- 14.3-2 Can I make both the anteroom and buffer room negative pressure?
- 14.3-3 Why does the anteroom to a chemo room need to be ISO 7 and not ISO 8?
- 14.3-4 Do negative rooms used only for compounding nonsterile HDs (no sterile compounding) require an anteroom?
- 14.3-5 Does a C-SCA require an anteroom?
- 14.4 Pre-Sterilization Areas for Weighing Powders**
- 14.4-1 Where should HD powders be weighed for preparation of sterile HD CSPs?
- 14.4-2 Can I weigh powders in a negative pressure anteroom?
- 14.5 Containment Secondary Engineering Controls**
- 14.5-1 What are *C-SEC*s?
- 14.5-2 How is a C-SEC in <800> different from a SEC for HDs as described in <797>?
- 14.5-3 What are the minimum requirements for a room/suite to compound HDs with the full BUDs allowed by <797>?
- 14.5-4 Does the exhaust air from a SEC room need to be HEPA filtered?
- 14.5-5 Can a negative pressure room be vented to the outside only through the BSC exhaust?
- 14.5-6 Can I use plastic curtains to separate the anteroom from the buffer room?
- 14.5-7 Does *fixed walls* mean I can't use a modular design?
- 14.5-8 Is a C-SCA different from a C-SEC?
- 14.5-9 What are the minimum requirements for a C-SCA, and what are the BUD limits?
- 14.5-10 Why would I choose to build a HD cleanroom instead of a C-SCA?
- 14.5-11 A segregated compounding area in <797> can be used only for low-risk preparations. Is that restriction also in <800>?
- 14.5-12 Can a negative room be too negative?
- 14.5-13 The door to my negative buffer room won't stay closed. Why does this happen?

List of Questions (continued)

- 14.5-14 I have a CACI in a room. Does the room itself need to be negative pressure, or is it enough if the CACI vents to the outside?
- 14.5-15 Do ceilings really need to be caulked in place under <800>?
- 14.5-16 Why do I need to place my CACI in a negative room if the manufacturer says I don't have to place it in ISO 7?
- 14.5-17 Do all HDs have to be compounded in a negative pressure room or just antineoplastic drugs?
- 14.5-18 Is there a statement in <800> about not compounding non-antineoplastic HDs in a negative pressure room?
- 14.5-19 Are there examples of designs for a C-SEC that I can use to explain the requirements?
- 14.5-20 Should the un-gowning area be inside the negative pressure room or outside of it?
- 14.5-21 Can a CVE used for non-hazardous compounding and a separate CVE used for hazardous compounding be in the same C-SCA?
- 14.6 Containment Segregated Compounding Area**
- 14.6-1 What is a C-SCA?
- 14.6-2 Can the C-SCA be an *area* and not a *room*?
- 14.6-3 What is the difference between a negative pressure cleanroom and a C-SCA?
- 14.6-4 Is a C-SCA in <797> the same as a C-SCA in <800>?
- 14.6-5 Does a C-SCA have to be negative pressure?
- 14.6-6 Does a C-SCA have to contain HEPA-filtered ceiling air?
- 14.6-7 Does a C-SCA require an anteroom?
- 14.6-8 How big does the perimeter in a C-SCA need to be?
- 14.6-9 What is the purpose of the perimeter in a C-SCA? What can be inside of the perimeter? What needs to be outside the perimeter?
- 14.6-10 Is there an example of a design for a C-SCA that I can use to explain the requirements?
- 14.6-11 Should the un-gowning area be inside the negative pressure room or outside of it?
- 14.7 Pass-Through Chambers**
- 14.7-1 What is a *pass-through chamber*?
- 14.7-2 Are there specific structural requirements for a pass-through?
- 14.7-3 How can I be sure a pass-through chamber isn't allowing particles into the chemo room?
- 14.7-4 Does a pass-through chamber into a chemo room need to be negative pressure?
- 14.7-5 Is a pass-through chamber the same as a pass-through window?
- 14.7-6 Is a pass-through chamber the same as what I have in my compounding isolator?
- 14.7-7 Is a pass-through chamber the same as a cart pass-through or a pass-through refrigerator?
- 14.7-8 Can I place a pass-through chamber between the main pharmacy and the chemo room?
- 14.7-9 Can I place a pass-through chamber between the anteroom and the chemo room?
- 14.7-10 Can I place a cart pass-through into the chemo room?
- 14.7-11 Can I place a pass-through refrigerator between the main pharmacy and the chemo room?
- 14.7-12 Can I place a pass-through refrigerator between the anteroom and the chemo room?
- 14.7-13 Can I place a pass-through refrigerator between a negative HD storage room and my negative buffer room?
- 14.8 Refrigerator and Freezer Placement**
- 14.8-1 Can I put a refrigerator or freezer in my negative cleanroom or C-SCA?
- 14.8-2 How can we put bulk storage and refrigerators in the buffer zone? I thought <797> was against it.
- 14.8-3 Are we allowed to have a refrigerator in the negative pressure room to store refrigerated antineoplastics?
- 14.8-4 Do I have to place a refrigerator in the compounding area?

List of Questions (continued)

- 14.8-5** Does USP <800> mention anything about a pass-through refrigerator for chemo?
- 14.9 Elimination of Low Volume Exemption from 2008 USP <797>**
- 14.9-1** I have been using the exemption in <797> for low volume of chemo preparations, so my chemo hood is in my regular buffer room. I don't see this listed in <800>. Has the requirement changed?
- 14.9-2** I compound only one or two chemos a week. I have only one IV room, and it's positive pressure. Why can't I continue to compound them in my IV room?
- 14.9-3** I cannot get approval to build a negative pressure cleanroom. What are my options?
- 14.10 Other Attributes for Designing a HD Compounding Area**
- 14.10-1** What type of sink do I need, and where should it be placed?
- 14.10-2** Can I put shelving in my cleanroom or C-SCA?
- 14.10-3** Can I put a refrigerator in my cleanroom or C-SCA?
- 14.10-4** Can I put a printer in my cleanroom or C-SCA?
- 14.10-5** What type of finishes for the floors, walls, and ceilings do I need?
- 14.10-6** Shouldn't all surfaces for HD compounding (sterile and nonsterile) be "smooth, impervious, free from cracks and crevices, and non-shedding"? Why is this listed only under Nonsterile Compounding in USP <800>?
- 14.10-7** Do I need to have the BSC, CACI, or room on emergency power?

Chapter 15: Compounding Hazardous Drugs

- 15.1** What type of policies should I have?
- 15.2** In 2006, ASHP published guidelines on handling HDs including a detailed process for decontaminating the final prepared CSP. Does <800> require use of the same steps?
- 15.3** What are good sources to review for developing policies?
- 15.4** What is an *API*?
- 15.5** Is it OK to compound non-HDs in the negative pressure hood and room?
- 15.6** Do nonsterile, non-antineoplastic hazardous medications need to be compounded and prepared in a negative pressure environment?
- 15.7** For non-antineoplastic hazardous oral solutions, does drawing up patient-specific doses from a bulk bottle need to be done in a negative pressure room?
- 15.8** If I need to crush tablets to make a solution, where do I do that?
- 15.9** Can I compound nonsterile HDs in an open room?
- 15.10** Do I have to package methotrexate tablets in a CVE?
- 15.11** Do I have to split methotrexate tablets in a CVE?
- 15.12** I mix about 200 grams of a hormone cream at one time but dispense it in 30-gram containers. After I make the 200 grams, can I store it outside the negative pressure area and place 30 grams in a container when I need to?
- 15.13** We have a compliant BSC in a compliant cleanroom for HDs. Once or twice a year, we need to weigh out HD APIs in our BSC. Is this OK?
- 15.14** Will USP <800> allow an exemption for nursing to draw up methotrexate in the emergency department?
- 15.15** When is a HD not a HD? When I dissolve it in liquid or add it to a cream or ointment, does it become non-hazardous?
- 15.16** When is a compounded topical cream able to leave the negative pressure area?
- 15.17** Is it OK to prepare HDs in the same Class II Type B2 BSC where biological preparations occur?
- 15.18** What is the best way to handle bacillus Calmette-Guérin?
- 15.19** Why do I have to doff garb in the chemo room?

List of Questions (continued)

- 15.20 Can the check of chemo items occur in the anteroom, or does it need to occur in the buffer room?
- 15.21 Why do I have to label non-chemo meds made in a BSC with PPE precautions?
- 15.22 Why do I need to use a plastic-backed preparation mat for compounding HDs?
- 15.23 Should the plastic-backed preparation mat be replaced each time the hood is cleaned?
- 15.24 Does the plastic-backed mat need to be sterile when used for sterile compounding?
- 15.25 Is it OK to spray alcohol?
- 15.26 How frequently should we change the spray bottles of cleaners?
- 15.27 How should alcohol be applied in the C-PEC if I can't use a spray?
- 15.28 Is it OK to use pre-saturated gauze to disinfect vials?
- 15.29 Are CSTDs required in an isolator?
- 15.30 Can corrugated cardboard be used in a negative pressure cleanroom?
- 15.31 Is there a disposable mortar and pestle that can be used for compounding HDs?
- 15.32 Can I use alcohol gel instead of washing my hands when I take off my gloves?
- 15.33 Do I have to record lot numbers for every chemo?
- 15.34 Is a different type of technique used for compounding HDs than used for regular compounding?
- 15.35 Does negative pressure technique have to be used if closed CSTDs are used for compounding?
- 15.36 What is the recommendation for HDs that are needed emergently (e.g., valproic acid, fosphenytoin)? Should they be compounded in the pharmacy's BSC rather than in the Emergency Department or intensive care unit?
- 15.37 If <800> requires compounding in negative pressure rooms, why is there a need to discuss compounding outside of the proper facility?

Chapter 16: Beyond-Use Dates

- 16.1 Why is there no BUD information in USP <800>?
- 16.2 How will a 12-hour BUD work if the drug needs to run longer than that?
- 16.3 We have a C-SCA and prepare HD pumps for home care patients. The infusion is started within 12 hours of being compounded, but it runs for 144 hours. Is this OK?
- 16.4 Is the maximum BUD for nonsterile compounding described in USP <795>? I don't understand why this isn't included in USP <800>.

Chapter 17: Packaging

- 17.1 Is unit dosing of antineoplastics considered compounding, and does it have to be performed in a controlled environment?
- 17.2 Is it OK to use a packaging machine to unit dose HDs?
- 17.3 Which oral dosage forms of HDs don't require counting in negative rooms?
- 17.4 Even though <800> allows antineoplastics in final forms that require only counting or packaging, why wouldn't I use a powder hood or BSC to pre-package them?
- 17.5 What precautions are needed for crushing tablets or opening capsules of HDs?
- 17.6 Our obstetric department uses misoprostol in 25-mcg tablets. They are available only in 100-mcg tablets. How can we best comply with their needs?
- 17.7 Do patient-specific doses of antineoplastic oral solution HDs need to be drawn up in a negative pressure room? How about non-antineoplastic HD oral solutions?
- 17.8 Is it OK to use a packaging machine for HDs that aren't antineoplastic?
- 17.9 How are hospitals managing warfarin administration if it requires cutting/splitting of tablets?
- 17.10 Who crushes tablets for nasogastric tube administration—pharmacy or nursing?
- 17.11 What precautions should be taken when unit-dosing liquids are on the HD list?

List of Questions (continued)

- 17.12 If pharmacy unit doses a HD, does that mean it's a final dosage form?
- 17.13 After I have compounded or packaged nonsterile antineoplastic agents into the finished dosage form, how do I need to store them prior to dispensing or patient pick-up?
- 17.14 USP <800> says that when you make a non-HD in a chemo hood, you have to label it with PPE handling precautions. Where are the precautions listed? Are they in the Safety Data Sheet, Department of Transportation information, or somewhere else?

Chapter 18: Dispensing Hazardous Drugs

- 18.1 Do I need a separate counting tray for each different HD?
- 18.1 Dispensing Finished Dosage Forms to Patient Care Units**
- 18.1-1 What precautions need to be taken for chemo bags between the pharmacy, and where will they be administered?
- 18.1-2 Is it OK to store HDs in ADCs?
- 18.1-3 Is it OK to deliver HDs in pneumatic tubes?
- 18.2 Dispensing Finished Dosage Forms to Ambulatory Patients**
- 18.2-1 What precautions need to be taken for an oral chemo dispensed and waiting for patient pick-up?
- 18.2-2 Do I need to decontaminate a nonsterile HD preparation after I make it?
- 18.2-3 The NIOSH list states that single gloves should be worn with administration from unit-dose packages. How does this impact community pharmacies where pharmacists and technicians have the potential to touch these final dosage forms during dispensing?

Chapter 19: Transporting Hazardous Drugs

- 19.1 Why can't pneumatic tubes be used for transporting HDs?
- 19.2 Can HDs be transported in tubes, robots, patient carts, etc.?
- 19.3 Can volunteers transport finished chemo to our oncology center?

Chapter 20: Administering Hazardous Drugs

- 20.1 What PPE is required for administration of parenteral HDs?
- 20.2 Is PPE (other than gloves) required for the administration of oral HDs?
- 20.3 Is there a list of recommended PPE to wear based on the dosage form administered?
- 20.4 If nurses have to wear gloves for administration of HDs, do they need to change the gloves between patients?
- 20.5 Can a nurse crush a HD tablet at the bedside?
- 20.6 What does <800> mean by a *plastic pouch* to contain particles?
- 20.7 What PPE should a nurse wear when crushing HDs?
- 20.8 Our Emergency Department nurses might administer IM methotrexate at night when the pharmacy is closed. Do they need to take any precautions when they prepare the dose?
- 20.9 Why do nurses need to use a CSTD when administering chemo?
- 20.10 What precautions must be made for administering oral chemotherapy through a feeding tube? There are issues in mixing the doses administered to the patient, but there are no CSTDs for this process.
- 20.11 What happens when a stat oxytocin drip is needed?
- 20.12 What precautions must be in place for the nursing staff who administer HDs to patients in an outpatient infusion setting?
- 20.13 Does a non-antineoplastic drug like premixed oxytocin require a CSTD?
- 20.14 Where can I find nursing competencies?

List of Questions (continued)

Chapter 21: Decontamination and Cleaning

- 21.1 What is the difference between cleaning and decontamination?
- 21.2 How is cleaning a chemo hood different from what's done for the regular hood?
- 21.3 Do I need to wear PPE when cleaning?
- 21.4 Is it OK for Environmental Services to clean the floors while we are compounding?
- 21.5 What agents deactivate HDs?
- 21.6 What agents decontaminate HD areas?
- 21.7 What agents clean HD areas?
- 21.8 What agents disinfect HD areas?
- 21.9 Is alcohol sufficient to decontaminate and clean the HD areas?
- 21.10 Who should clean the BSC and CACI?
- 21.11 Who should clean the SECs?
- 21.12 Are there specific cleaning guidelines under USP <800>?
- 21.13 Is there a single process I can use to deactivate all HDs?
- 21.14 What concentration of bleach should I use?
- 21.15 How do I know I am using the correct dilutions of decontamination and cleaning solutions?
- 21.16 Do I need to clean the whole hood between mixing different chemo preps?
- 21.17 What should I use to decontaminate the chemo hood between chemo preps?
- 21.18 Why shouldn't I use a spray bottle of alcohol?
- 21.19 What should I use to disinfect the chemo hood between preparations?
- 21.20 How do I decontaminate the floor?
- 21.21 How often should I use sterile alcohol to clean the floor?
- 21.22 Are specific cleaning supplies required by USP <800>?
- 21.23 Are reusable mops acceptable to use?
- 21.24 What is the best way to monitor that cleaning has been done?
- 21.25 What do I do about a rusty hood?
- 21.26 How can I tell if we are removing the contaminants?

Chapter 22: Environmental Monitoring

- 22.1 What types of quality assurance and quality control activities are required or recommended in USP <800>?
- 22.2 USP <795> doesn't include a requirement for microbial monitoring for nonsterile compounding areas. Should this be considered?
- 22.3 Is surface sampling the only quality point that needs to be considered?
- 22.4 Are wipe samples required?
- 22.5 Are there different requirements if we are using an isolator instead of a BSC?
- 22.6 How often should wipe samples be collected?
- 22.7 Where should wipe samples be collected?
- 22.8 Are we likely to find contamination?
- 22.9 What drugs are commonly assayed?
- 22.10 How many surface samples are usually taken?
- 22.11 What action do we need to take if antineoplastic contamination is found? How can we get the level to zero?
- 22.12 What is the responsibility of the *designated person* regarding surface sampling results?
- 22.13 What are the acceptable limits for the results of HD surface contamination?
- 22.14 Once contamination is found on wipe samples and the issue is addressed, should we expect the next levels to show zero contamination?
- 22.15 Why is surface sampling only *recommended* and *not required*?

List of Questions (continued)

Chapter 23: Hazardous Waste

- 23.1 Does it seem like the section about disposal got the short end of the stick? It just says “all applicable federal, state, and local regulations.”¹ Disposition of hazardous components within the healthcare setting seems to me to be just as important as the other areas listed in the chapter.
- 23.2 Is proper disposal of HDs part of a compounding’s responsibilities under USP <800>?
- 23.3 Who can provide the information our health system needs to know about disposal of HDs and the federal and state requirements?
- 23.4 Does pharmacy need to control the handling of hazardous materials for the health system?

Chapter 24: Spills

- 24.1 What is a *spill*?
- 24.2 Are antineoplastic agents the only concern?
- 24.3 What is a *spill kit*?
- 24.4 What spill kit contents does USP <800> require?
- 24.5 Is there a standard spill kit that I can purchase?
- 24.6 Where do spill kits need to be located?
- 24.7 What should be in a spill kit?
- 24.8 How big a spill can a spill kit handle?
- 24.9 What resources can I use to develop a policy concerning spill cleanup?
- 24.10 Who should clean up a spill?
- 24.11 If a facility contracts Hazmat for all hazardous spills, do infusion staff still need to be trained in HD spill cleanup, and are spill kits required in cleanrooms?
- 24.12 What is the best way to test our policy and procedure?

Chapter 25: What Do I Do Now?

- 25.1 I’m overwhelmed with this information. Where do I start?
- 25.2 Where can I find a gap analysis?
- 25.3 What can I do to comply with <800> while waiting for capital improvements to my compounding facility to be completed?
- 25.4 Is there a template Action Plan I could use to start assessing the compliance at my organization?

Reference

- 1. United States Pharmacopeial Convention. General chapter <800> hazardous drugs—handling in healthcare settings. *USP 40–NF 35*; 2017.