Addressing the Standards: Meeting USP <797> Requirements in Small and Rural Hospitals

Patricia C. Kienle, R.Ph., M.P.A., FASHP
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions
WELCOME AND ANNOUNCEMENTS
Disclosure

All planners, presenters, and reviewers of this session report no financial relationships relevant to this activity.
Learning Objectives

• Discuss strategies to comply with pharmacy practice and occupational safety standards and guidelines.
• Review literature for strategies to overcome common barriers in small and rural hospitals.
• Develop an action plan and a proposal for adherence to standards.
Is your pharmacy compliant with ...

A. USP <797> and <800>
B. USP <797> and we are working on <800>
C. We don’t handle hazardous drugs, so only need to be compliant with <797>
D. We are not compliant with either
USP Standards

• USP sets standards
• Regulatory issues
  – Federal
  – State
• Accreditation
• Best practices

Photo courtesy of USP
Regulatory Compliance

• CMS Hospital and Critical Access Hospital Conditions of Participation
Regulatory Compliance

- Most states have specific compounding regulations
- Many regulations are more strict than the USP chapters
- Remain current with your state regulations and interpretations
Accreditation Organizations

• Hospital accreditors
  – The Joint Commission (TJC)
  – DNV Healthcare
  – Accreditation Association for Hospitals/Health Systems – Healthcare Facilities Accreditation Program (AAHHS/HFAP)
  – Center for Improvement in Healthcare Quality (CIHQ)

• Ambulatory accreditors

• Compounding certification
Lots of Moving Parts

- Standards
- Regulations
- Proposed revision of <797>
- <800> official date of July 1, 2018 extended to December 1, 2019
Compliance with <797> and <800>

• Facilities
• Policies and Procedures
  – Including Acknowledgement of Risk of Handling Hazardous Drugs
• Work practices
  – Garb and Personal Protective Equipment (PPE)
  – Use of Closed System Drug-Transfer Devices (CSTDs)
  – Cleaning
Where are most of your nonhazardous CSPs mixed?

A. Cleanroom (separate anteroom and buffer room)
B. Cleanroom (combined anteroom/buffer room)
C. Segregated Compounding Area
D. On the patient care units by nursing
Where are most of your chemos mixed?

A. Cleanroom (separate anteroom and buffer room)
B. Containment Segregated Compounding Area
C. CACI in a negative room that has 12 air changes per hour
D. Some other configuration
Facilities for Nonhazardous

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Allowed in Current &lt;797&gt;</th>
<th>Likely in Future &lt;797&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleanroom suite (anteroom + buffer room)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Combined ante/buffer room</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Segregated Compounding Area</td>
<td>Yes</td>
<td>Yes, but BUD will be limited to 12 hours for any type of PEC</td>
</tr>
</tbody>
</table>
### Minimum Room Requirements in <800>

<table>
<thead>
<tr>
<th>Contains hazard</th>
<th>Removes hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room with fixed walls that is separate from non-hazardous storage and compounding</td>
<td>Vented outside the building</td>
</tr>
<tr>
<td>Negative pressure of 0.01 to 0.03” to adjacent space</td>
<td>At least 12 air changes per hour</td>
</tr>
</tbody>
</table>
# Facilities for Hazardous Configuration

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Allowed in &lt;797&gt;</th>
<th>Allowed in &lt;800&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleanroom suite (ISO positive anteroom opening into ISO 7 negative buffer room)</td>
<td>Yes, with negative pressure of at least 0.01” negative to adjacent space</td>
<td>Yes, with pressure range of 0.01 to 0.03” negative to adjacent space</td>
</tr>
<tr>
<td>Low Use Exemption</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Containment Segregated Compounding Area</td>
<td>Not addressed in &lt;797&gt;</td>
<td>Yes, if externally vented and pressure range of 0.01 to 0.03” negative to adjacent space, but limited to 12 hour BUD</td>
</tr>
<tr>
<td>CACI in negative room with 12 air changes per hour</td>
<td>Yes, optimally vented</td>
<td></td>
</tr>
<tr>
<td>BSC outside of cleanroom</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Segregated Compounding Areas

• What’s different from a cleanroom
  – No need for ISO classified air in room
  – No need for HEPA-filtered ceiling air

• Does it have to be a separate room?
  – Recommended for nonhazardous (<797>)
  – Required for hazardous (<800>)

• What’s the tradeoff?
  – Maximum of 12 hour BUD
  – Maybe 24 hours refrigerated in future <797>
SCAs and C-SCAs

- It’s not just the facility
- Requirements for
  - Garb and PPE
  - Cleaning
  - Certification
- All elements must be compliant for you to use a 12 hour BUD
HD Engineering Controls

• Primary
  – BSC or CACI

• Secondary
  – Cleanroom or Containment Segregated Compounding Area

• Supplemental
  – Closed System Drug-Transfer Devices (CSTDs)

Photo courtesy of BD
CSTDs

- Recommended for compounding
- Required for administration when the dosage form allows
requires completion of an Assessment of Risk. What is the status at your hospital?

A. It’s completed
B. We are working on it
C. It hasn’t been started yet
D. We don’t need to do one since we don’t do chemo
NIOSH List of Hazardous Drugs

- Use of the list is required
  - Table 1 – Antineoplastic
  - Table 2 – Non-antineoplastic
  - Table 3 – Reproductive-only hazards

- Use of the Table 5 PPE information is not required, but provides a comprehensive list for policy development

www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf
Options

Handle all drugs and dosage forms with all containment and work practices listed in <800>

Perform an Assessment of Risk to determine alternative containment strategies and work practices
### Not All Drugs Have to Be Handled the Same Way

<table>
<thead>
<tr>
<th>All &lt;800&gt; Precautions Apply</th>
<th>Can Be Included in Assessment of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>API of any HD on the list</td>
<td>Antineoplastics that only need to be counted or packaged</td>
</tr>
<tr>
<td>Antineoplastics that need to be manipulated</td>
<td>Table 2 drugs</td>
</tr>
<tr>
<td>Items that don’t fit the Assessment of Risk</td>
<td>Table 3 drugs</td>
</tr>
</tbody>
</table>
Alternative Strategies

• If you entity-exempt some drugs in your Assessment of Risk, you must
  – Identify the drug to the dosage form level
  – List and implement alternative strategies

• Alternative strategies might include
  – Purchase unit-dose or unit-of-use packaging
  – Use of chemotherapy gloves that meet ASTM D6978
  – Identify by visual cue (yellow lidded bin, shelf stickers)
  – Restrictions based on the reason the drug is listed
Key Takeaways

- USP <797> has been official since 2004. The current version is from 2008. It is being revised.
- USP <800> will be official on December 1, 2019
- Evaluate your facilities to ensure compliance
- Complete an Assessment of Risk
Resources

• USP standards
• ASHP Sterile Compounding Resource Center
• Pharmacy Purchasing and Products
• Pharmacy Practice News
Resources for <800>

www.ashp.org

www.hazmedsafety.com