USP <797> : IP + Pharmacist as partners in Medication Safety

Presented by:
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Director, Clinical Epidemiology
Wolters Kluwer Health
Sentri7 Clinical Solutions
"Although I am a current member of the USP Compounding Expert Committee, I am speaking today as an Infection Preventionist and not as a member of the Committee or as a USP representative.

I am currently the Director of Clinical Epidemiology for Wolters Kluwer Health, serving as a consultant for Sentri7™ surveillance software solutions.

I wish to thank fellow USP committee member, Eric Kastango, for assistance with this presentation.
Learning Objectives

- Describe the reasons why adherence to USP <797> is important
- Highlight the current <797> standards for cleaning, disinfection, personnel cleansing and garbing, environmental microbial sampling
- Describe how the IP and Pharmacist can work together for medication safety sake
Pictures are worth a thousand words….when is the last time you visited your hospital pharmacy for EOC/IC rounds?

Identify the most important error that could introduce contamination to a sterile compounded preparation…(there may be more than one right answer)
Handwashing Sink in Sterile Compounding Area
A. Soap dispenser needs repair
B. Splash guard needs replacing
C. Sterile supplies are stored next to sink
D. Sterile and non-sterile supplies are mixed together
E. General clutter in the room
SCR = Sterile Compounding Room

A. SCR is too cluttered
B. Personnel not wearing masks
C. No handwashing sink available
D. Fan is present to cool staff working
A. Multi-bottle handling poses safety risk
B. Room is cluttered
C. Face mask worn improperly
D. Arms are exposed
A. No gloves worn inside hood
B. Hair is not covered
C. Gown is loose
D. Not wearing mask
The first nurse epidemiologist once said…

“The very first requirement in [healthcare] is that it should do the sick no harm.”

Florence Nightingale (1820-1910)
Raising awareness begins….

1990, Nebraska

- Patients died of bacterial infection from non-sterile cardioplegia solution compounded in a hospital

1993, Maryland

- ASHP publishes its first Technical Assistance Bulletin for Sterile Preparations.
More adverse events occur....

November 1998, California

- *Enterobacter cloacae* Bloodstream Infections Associated with Contaminated Prefilled Saline Syringes -- California, November 1998. MMWR Weekly November 13, 1998 / 47(44);959-960

- Scenario
  - 11 children developed sepsis; 10 had *Enterobacter cloacae* positive blood cultures
  - All children successfully treated with antibiotics and recovered

- Root Cause
  - Poor employee hand hygiene and garbing practices
  - Lack of leadership accountability/oversight
National Attention takes hold….

2000, Maryland

• USP Convention elects chairs of the new STERILE and NON-STERILE compounding committees on the Council of Experts for 2000-2005
Déjà vu…

March 2001, Missouri


- Scenario
  - Received IV ranitidine compounded with ACD while in the hospital.
  - Multidose source vial hung for 48 hours on ACD

- Action/Results
  - 4 patients developed an infection, 1 case of bacterial meningitis and transferred to another hospital

- Root Cause
  - Poor employee hand hygiene and garbing practices
  - Failure to comply with compounding practices
Outbreaks continue to occur....

September 2002, South Carolina

- *Exophiala* Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy --- United States, July--November 2002. MMWR December 13, 2002 / 51(49); 1109-1112

- Scenario
  - Five cases of *Exophiala* infection associated with injectable medication had occurred, one patient dies
  - Cases occurred up to 152 days following injection of contaminated CSP.

- Root Cause
  - Untrained compounding personnel
  - Failure to achieve sterility
    - Improper use of autoclave
December 2004, Maryland

- **Hepatitis C Virus Infections From a Contaminated Radiopharmaceutical Used in Myocardial Perfusion Studies.** JAMA, 26 Oct 06, Vol 296, 2005-11.

- Scenario
  - Sixteen (16) patients from three (3) clinics develop HCV infection after administration of Tc 99m radioisotope used in cardiac stress tests.
  - Contamination implicated to be a cross-contamination between a blood-labeling procedure and the preparation of the radioisotope.
  - Sixteen patients contract Hepatitis C
    - Several patients adversely affected (death and disease).

- Root Cause
  - Breaks in aseptic technique were identified at the pharmacy. Nuclear pharmacies that handle biological products should follow appropriate aseptic technique to prevent contamination of sterile radiopharmaceuticals.
Outbreaks continue to occur….

March 2011, Alabama

• Scenario
  – At least nineteen case of infection, 9 deaths from *Serratia* infection associated with parenteral nutrition (PN).
  – Pharmacy used nonsterile components to prepare the PN-amino acids.
  – The environmental contamination (sink, mixing tank, stirrer) that was found (genotype/phenotype) was the same found in the infected patients.

• Root Cause (probable)
  – Untrained compounding personnel
  – Failure to achieve sterility
    • Improper use of filter

Hospital pharmacies are among those pharmacies making compounding errors…

March 2011, Tennessee

• Scenario
  – Four patients received contaminated intravitreal injection of repackaged Avastin
  – One patient at the Tennessee Valley Healthcare System (VA system) has been permanently blinded and has permanent brain damage
  – The Avastin doses were prepared in the pharmacy of the V.A. hospital in Nashville.

Better reporting or a growing problem?

Trends in Patient Incidents Involving Compounding Errors

- 30% in 2009
- 33% in 2010
- 34% in 2011

N=413

34% of all hospitals recognize that they have had a patient incident(s) involving a compounding error over the past five years.

United States Pharmacopeial Convention (USP) Governance...

- Chapter <797> is the standard for quality in sterile compounding, according to an Act of U.S. Congress.
- Chapters numbered less than 1000 are part of the Federal Food, Drug, Cosmetic Act, and enforceable by the FDA. Chapters >1000 are informational only.
- <797> applies to pre-administration manipulations of compounded sterile preparations including compounding, transportation, and storage.
- Applies to all compounding personnel and facilities without distinction to practice setting or profession.
USP <797> became effective January 2004

• The intent of the chapter is “to prevent patient harm, including death, from 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability in the intended strength of correct ingredients, 4) unintended chemical and physical contaminants, 5) ingredients of inappropriate quality in compounded sterile preparations (CSPs).”

• Effective January 1, 2004
  – Revised December 2007
  – Official June 1, 2008
  – Next revision in process
## USP <797> Elements

There are three broad areas that contribute to meeting the objectives of USP <797>:

<table>
<thead>
<tr>
<th>Contamination Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Address particulate sources – people, products, process</td>
</tr>
<tr>
<td>• Create a “clean” environment where aseptic compounding will take place</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training and Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Compounding personnel are skilled, educated and trained</td>
</tr>
<tr>
<td>• Operator testing for proficiency</td>
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<tr>
<td>• Written policies, procedures</td>
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<tr>
<td>• Document training</td>
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</table>

<table>
<thead>
<tr>
<th>CSP Checks and Tests</th>
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<tbody>
<tr>
<td>• Reduce occurrence of contamination</td>
</tr>
<tr>
<td>• Verify the process produced correct CSPs</td>
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<tr>
<td>• Use the same process each time</td>
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<tr>
<td>• If contamination or error happens, detect it and take action</td>
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</tbody>
</table>
Underlying USP <797> Philosophy:
A risk based approach to CSPs

High Risk
Use non-sterile components
(ex: epidurals, alum)

Medium Risk
Uses multiple sterile components.
(ex: batch compounding, TPNs)

Low Risk
Simple, or single, sterile component mixing
(ex: one vial into one delivery container)

No Risk
(premixed or RTU single doses)

Who governs compounding & dispensing activities?

- **Regulatory**
  - FDA
  - State BOP
  - TJC (JCAHO), PCAB, USP

- **Institutional**
  - Pharmacist in Charge
  - RPh, PharmDs
  - Pharmacy Technicians (PT), Other Pharmacy Staff

- **Actual Activities**
  - License individual pharmacy facilities to practice pharmacy activities
  - Accredit overall facilities, serve as rulemaking bodies, or issue overall standards of good practice.
  - Most responsible person within pharmacy (required by law)
  - Supervise pharmacy techs and check dispensed and prepared medications
  - Actually perform compounding and dispensing activities

Note: BOP = Board of Pharmacy (State licensing organization for pharmacy)
State Board of Pharmacy Position USP <797>

http://www.clinicaliq.com/797-state-survey
The table below illustrates the regulatory status levels of States/DC in 2011. Each row and column is color-coded to indicate whether a state or DC has a 'No Reference', 'Indirect', or 'Direct' status.

<table>
<thead>
<tr>
<th>No Reference</th>
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<td>Oklahoma</td>
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<td>Utah</td>
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<td>Virginia</td>
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</table>

*As of January 2012, Wyoming has adopted regulations that move it into the “Direct” category.*
Level of Compliance

Overall Compliance by State Regulatory Status
N=1148

None
149 surveys
4 states
71.8%

Indirect
594 surveys
28 states & DC
73.3%

Direct
405 surveys
18 states
75.6%

Source: CriticalPoint’s 2011 USP <797> Compliance Study
Infection Control Requirements

USP Chapter <797>
Cleaning and Disinfection of Environment

- Chapter requirements based on USP Infection Control Advisory Committee* recommendations
- Goal: Reduce bioburden in compounding areas
- Use of a disinfectant chemical agent is required
- Cleaning should proceed from buffer area (cleanroom) to ante area
- Use dedicated cleaning equipment and recommended cleaning/disinfectant agents for floors, other environmental surfaces
- Floors, counters, work surfaces – at least daily
- Walls, ceilings, shelving – at least monthly

* ICAC Members: Keith St. John, Chair; Dr. Bill Rutala (SHEA), Dr. Arjun Srinivasan (CDC), Dr. Alice Weissfeld (ASM), Dr. Kathy Gura (ASHP), Judene Bartley (APIC)
<table>
<thead>
<tr>
<th>Germicide</th>
<th>Use Dilution</th>
<th>Level of Disinfection</th>
<th>Inactivation (^2)</th>
<th>Important Characteristics</th>
<th>Approx cost</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bacteria</td>
<td>Lipophilic Viruses</td>
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<td>Hydrophilic Viruses</td>
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<td>M. tuberculosis</td>
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<td>Mycotic agents</td>
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<td>Bacterial Spores</td>
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<td>Shelf life &gt;1 week</td>
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<td>Corrosive or deleterious effects</td>
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<td>Residue</td>
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<td>Inactivated by organic matter</td>
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<td>Skin irritant</td>
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<td></td>
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<td>Eye irritant</td>
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<td></td>
<td></td>
<td>Respiratory irritant</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Toxic</td>
<td></td>
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<tr>
<td>Isopropyl alcohol</td>
<td>60-95%</td>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>±</td>
</tr>
<tr>
<td>Accelerated Hydrogen peroxide</td>
<td>0.5%</td>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Quaternary Ammonium</td>
<td>0.4-1.6% aq</td>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>±</td>
</tr>
<tr>
<td>Phenolics</td>
<td>0.4-1.6% aq</td>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>±</td>
</tr>
<tr>
<td>Chlorine</td>
<td>100-5000 ppm</td>
<td>Low/HLD(^2)</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td>Iodophors</td>
<td>30-50 ppm</td>
<td>Low</td>
<td>+</td>
<td>+</td>
<td>±</td>
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<tr>
<td>Glutaraldehyde</td>
<td>&gt;2% HLD</td>
<td>HLD</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

\(^1\) Modified from World Health Organization, Laboratory Biosafety Manual 1983; and Rutala WA. 1995. Antisepsis, disinfection and sterilization in the hospital and related institutions. In Balows A, Manual of Clinical Microbiology, ASM, Washington DC. 227-245. Abbreviations and symbols: ow, low-level disinfectant used on noncritical surfaces or noncritical devices/equipment; HLD, high level disinfectant; +, yes; -, no; ±, variable results.

\(^2\) Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of >1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm against C. difficile spores [Perez J, 2005 AJIC]) to several hours.
USP <797> Frequency Requirements

Daily Cleaning/Disinfection:

- *ISO Class 5* surfaces
- *ISO Class 5* equipment
- Work surfaces near the *ISO Class 5* area such as carts
- Floors
  - Cleanroom
  - Anteroom
  - Must occur when compounding is NOT taking place
- Shipping containers
USP <797> Frequency Requirements

Weekly in cleanroom:
• Storage shelving
  – Empty bins of all supplies
  – Clean bins

Monthly in anteroom:
• Storage shelving
  – Empty bins of all supplies
  – Clean bins
USP 797 and Particulates
Why such an emphasis?

**Dust Particles**
- Microbes “ride” dust and particulates

**Breach of Aseptic Technique**
- Particles with microbes infiltrate CSP

**Contamination**
- Microbes grow within CSP

**Implication 1:** Control particulate, you reduce downstream contamination risk substantially

**Implication 2:** Since you never get “0” particulate, proper aseptic technique minimizes further contamination risk

Images courtesy ClinicalIQ, LLC.
Compounding Personnel

A human person in a cleanroom is considered a broad spectrum particle generator enclosed by inefficient mechanical filters which may also be sources of particles.

The human body harbors an average of 150-200 different classes of bacteria.

Hands have an average of 100,000 organisms / sq mm.

The body sheds 5 grams of skin fragments each day along with shedding 1 layer of skin every 5 days (size range 10 to 300 micron – 1000th of a mm).

1954, Charles Schultz
Copyright, United Feature Syndicate, Inc.
Concept of “Particle Limits”

1. **Rapid elimination** of particles from DCA
2. **Movement** from clean to “dirtier” areas
3. **Dilution** into air with a higher and higher particle limit (one particle among many)

<table>
<thead>
<tr>
<th></th>
<th>ISO “Class” Particles/m³</th>
<th>US “Class” Particles/ft³</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stockroom</strong></td>
<td>Uncontrolled</td>
<td></td>
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<tr>
<td></td>
<td>(no particle limits)</td>
<td></td>
</tr>
<tr>
<td><strong>Ante Area</strong></td>
<td>ISO Class 8</td>
<td>Class 100,000</td>
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<tr>
<td></td>
<td>3,520,000</td>
<td>100,000</td>
</tr>
<tr>
<td><strong>Buffer Area</strong></td>
<td>ISO Class 7</td>
<td>Class 10,000</td>
</tr>
<tr>
<td></td>
<td>352,000</td>
<td>10,000</td>
</tr>
<tr>
<td><strong>PEC (Hood, Isolator)</strong></td>
<td>ISO Class 5</td>
<td>Class 100</td>
</tr>
<tr>
<td></td>
<td>3,520</td>
<td>100</td>
</tr>
</tbody>
</table>

This is why we disinfect products entering clean area --- lower particulate burden as you move from stockroom to buffer area.
Surround the DCA with layers of protection…
Primary Engineering Controls

- Laminar Air Flow Workbench ("Hood")
- Biological Safety Cabinet ("Hood")
- Compounding Aseptic Isolator ("Glovebox")

ISO Class 5 Primary Engineering Control (PEC)

Direct Compounding Area (DCA)

Slide courtesy of BD corp.
## Sources of Microbial Contamination in Aseptic Processing

<table>
<thead>
<tr>
<th>Source</th>
<th>1986</th>
<th>2001</th>
</tr>
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<tbody>
<tr>
<td>Personnel</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Human error</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Aseptic assembly</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Non-routine activity</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Mechanical failure</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Airborne contaminants</td>
<td>7</td>
<td>6</td>
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<tr>
<td>Improper sanitization</td>
<td>6</td>
<td>7</td>
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<tr>
<td>Surface contaminants</td>
<td>7</td>
<td>7</td>
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<tr>
<td>0.2 μm filter failure</td>
<td>8</td>
<td>8</td>
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<tr>
<td>HEPA failure</td>
<td>9</td>
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</tr>
</tbody>
</table>

Compounding Personnel - PPE

- Hair net
- Beard cover and face mask
- Gown
  - Nonsterile
- Gloves
  - Sterile
- Shoe covers
Hand hygiene is paramount to safety when preparing medications!
Definitions

• Hand hygiene
  – Applies to handwashing, antiseptic handwash, alcohol-based handrub, surgical hand hygiene/antisepsis

• Handwashing
  – Refers to washing hands with plain soap and water

• Antiseptic handwash
  – Refers to washing hands with water and soap or other detergents containing an antiseptic chemical agent

• Alcohol-based handrub
  – Refers to rubbing hands with an alcohol-containing preparation

• Surgical hand hygiene/antisepsis
  – Refers to handwash or use of an alcohol-based hand rub, often having persistent antimicrobial activity.

*Guideline for Hand Hygiene in Health-care Settings, MMWR 2002; vol. 51, no. RR-16.*
Ability of Hand Hygiene Agents to Reduce Bacteria on Hands


![Graph showing bacterial reduction over time after disinfection with different hand hygiene agents.](image-url)
Hand Hygiene & Garbing – a multi-step process....

- After donning dedicated shoes or shoe covers, head/facial hair covering, and face mask, clean under finger nails with a nail cleaner under running water.
- Initial hand wash is for at least 30 seconds with either plain soap or antimicrobial soap and water, up to the elbows while in the ante-area. Scrub brushes are not recommended. Dry hands and forearms with lint-free disposable towels (preferred) or electronic hand dryer.
- Don a clean or sterile non-shedding gown closed at the wrists and enclosed at the neck.
- Prior to donning sterile gloves in the clean (buffer) area, apply an FDA approved alcohol-based surgical hand scrub with persistent antimicrobial activity for the recommended amount of time (per manufacturer) and allow to dry. (Some examples include: Avagard®, Sterillium Rub®, Triseptin®.)
Environmental Sampling Dilemma:

– One of the most contentious section of USP Chapter <797>

– Since the 1980’s, the US Centers for Disease Control (CDC) has not advocated routine microbial environmental culturing (sampling) of inanimate surfaces in the absence of an outbreak situation

– The US Food and Drug Administration requires sterile processing operations in manufacturing facilities to perform daily monitoring of viable air, surface and personnel glove fingertip samples
Environmental Sampling

Routine Viable Microbial Environmental Sampling (ES)

None → USP 797 → Daily

US Centers for Disease Control

US Food and Drug Administration
Environmental Sampling

- Environmental Sampling section has been separated into a facility-related performance metric and a personnel-related performance metric

- Facility-related Environmental Sampling
  - Viable air sampling via volumetric method (impaction) to occur at least every 6 months, in conjunction with hood certification

- Personnel-related Environmental Sampling
  - Personnel fingertip sampling during initial training, with media fills and as a competency assessment tool
  - Surface sampling for viable microorganisms in conjunction with cleaning and disinfection quality assurance measurements
Volumetric Air Sampling Equipment

Merck MAS100

Biotest RCS

BioScience SAS180

Biotest RCS Isolator
Principle of “First Air”

- Good aseptic technique in sterile compounding requires the understanding and proper use of “First-Air”.
  - “First-Air” is the air exiting the HEPA filter in a unidirectional air-stream and is virtually free of particulate contaminants.
  - All critical manipulations must be carried out in the unobstructed “first air” zone in the direct path of the HEPA filter discharge.
  - Proper product and process placement with respect to the supply and discharge will provide a contamination free compounding area.

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Zone of first-air
Simulated with smoke to show airflow
Quality Assurance Program

• A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs:
  – accuracy and precision of measuring and weighing;
  – the requirement for sterility; methods of sterilization and purification;
  – ranges for strength of ingredients; pH; labeling accuracy and completeness; BUD
  – assignment of responsibility for each step of process
  – packaging and storage requirements.
Quality Assurance Program

• Equipment-related activities
  – Written procedures identify equipment calibration, semi-annual maintenance, monitoring for proper functioning of engineering controls

• Inspection of Solution and Review of Compounding Procedures
  – Preparation records are inspected for accuracy
The Use of Checklists to Monitor Performance...

- Numerous studies have demonstrated that the use of process “checklists” for repetitive procedures/tasks is a valuable tool to ensure a high level of performance and reduction of human error.
Clinicians use standardization and evidence-based checklists to drive improvements in patient outcomes

  – 103 ICUs in Michigan reported data for the study. The mean infection rate fell from 7.7 per 1000 central line catheter (CLC) days at baseline to 1.4 per 1000 CLC days at 16-18 months. This evidence-based intervention resulted in a large and sustained reduction (up to 66%) in rates of catheter-related bloodstream infection that was maintained throughout the 18-month study period.

  – Monitoring consistent and vigilant work practices was a key intervention by using a checklist:
    • Participants performed adequate hand hygiene before the procedure
    • Full sterile barrier protection -- a sterile drape over patient rather than just keeping the insertion site sterile
    • All staff participating in the procedure wear sterile gloves, sterile gowns, hair nets and masks
    • patient’s skin disinfected with chlorhexidine/IPA antiseptic solution (Chloraprep®)
    • Use of sterile dressings
USP <797> Checklists – a partnership between the IP & Pharmacist

• In the latest 2008 revision, the appendices of the chapter include examples of checklists designed to monitor processes in the sterile compounding environment

• The following examples are included in <797> appendices, but recognize the IP can partner with their pharmacist and develop their own checklists and provide timely feedback to staff on compliance.
Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

| Printed name and position/title of person assessed: |
| Name of facility or location: |

**Hand Hygiene and Garbing Practices**: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

- **Presents in a clean appropriate attire and manner.**
- **Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into clean areas.**
- **Brings no food or drinks into or stored in the clean areas or buffer areas.**
- **Is aware of the lim of demarcation separating clean and dirty sides and observes required activities.**
- **Does shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.**
- **Does beard cover if necessary.**
- **Does hand cover ensuring that all hair is covered.**
- **Does face mask to cover bridge of nose down to include chin.**
- **Performs hand hygiene procedure by washing hands and forearms and washing using soap and warm water for at least 30 seconds.**
- **Dries hands and forearms using lint-free towel or hand dryer.**
- **Selects the appropriate sized gown examining for any holes, tears, or other defects.**
- **Does gown and ensures full closure.**
- **Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly, before donning sterile gloves.**
- **Does appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.**
- **Examines gloves ensuring that there are no defects, holes, or tears.**
- **While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to working in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.**
- **Removes PPE on the clean side of the ante-area.**
- **Removes gloves and performs hand hygiene.**
- **Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.**
- **Removes and discards masks, head cover, and beard cover (if used).**
- **Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is entered).**

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check mark, N/A, or N/O) and shown and informed of specific corrections.*

<table>
<thead>
<tr>
<th>Signature of Person Assessed</th>
<th>Printed Name</th>
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<th>Signature of Qualified Evaluator</th>
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Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel

Printed name and position/title of person assessed: ________________________________
Name of facility or location: ____________________________

Aseptic Technique, Safety, and Quality Assurance Practices: The qualified evaluator will mark (✓) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or NO if the activity was not observed.

- Completes the Hand Hygiene and Gowning Competency Assessment Form.
- Performs proper hand hygiene, garing, and gloving procedures according to SOPs.
- Disinfects ISO Class 5 device surfaces with an appropriate agent.
- Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.
- Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.
- Does not interrupt, impede, or divert flow of first air to critical sites.
- Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.
- Performs manipulations only in the appropriate DCA of the ISO Class 5 device.
- Does not expose critical sites to contact contamination or worse than ISO Class 5 air.
- Disinfects stoppers, injection ports, and ampul seals by wiping with sterile 70% IPA and allows sufficient time to dry.
- Attaches needles to syringes without contact contamination.
- Punctures vial stoppers and spikes infusion ports without contact contamination.
- Labels preparation(s) correctly.
- Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.
- Cleans, sets up, and calibrates automated compounding device (e.g., "TPN compounding") according to manufacturer’s instructions.
- Disposes of sharps and waste according to institutional policy or recognized guidelines.

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check mark, N/A, or NO) and shown and informed of specific corrections.

Signature of Person Assessed
Printed Name
Date

Signature of Qualified Evaluator
Printed Name
Date

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Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures

Print name and position/title of person assessed:

Name of facility or location:

Cleaning and Disinfection Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity. Prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Daily Tasks:

Prepare correct concentration of disinfectant solution according to manufacturer’s instructions.

Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).

Documents disinfectant solution preparation.

Follows proper cleaning procedures when performing any cleaning activities.

At the beginning of each shift, cleans all ISO Class 5 areas prior to compounding in the following order: walls, IV bar, automated compounding, and work surface.

Uses a lint-free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.

Removes all compounded components and cleans all ISO Class 5 areas as stated above at the end of each shift.

Cleans all counters and easily cleanable work surfaces.

Uses a mop labeled “floors” starting at the wall opposite the room entry door. Mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.

In the work area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.

Monthly Tasks:

 Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned.

Clean buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.

Once ISO Class 5 areas are clean, cleans compounding room ceiling, followed by walls and ceiling with the floor. Uses appropriate labeled microfiber or microfiber cleaning system.

Cleans all buffer area walls and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipes as needed.

Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipes, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses new wipes for each cart. Allows to dry. Wipes carts with sterile 70% IPA, wetted lint-free wipe to remove any disinfectant residue. Uses new wipes as needed.

Cleans buffer area chairs, the interior and exterior of train bins, and storage bins using disinfectant solution soaked lint free wipe.

Documents all cleaning activities as to who performed such activities with date and time noted.

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check mark, N/A, or N/O) and shown and informed of specific corrections.

Signature of Person Assessed  Printed Name  Date

Signature of Qualified Evaluator  Printed Name  Date

(Official June 1, 2008)