Pharmacist is responsible for ensuring that compounded sterile preparations are properly prepared, labeled, stored, dispensed and delivered.

- USP
- ASHP
- NABP
- JCAHO

Centralized IV Admixture Service

- Economical
  - Batch preparation
  - Reduce personnel time
- Enhanced safety with standardized solutions.
- Double check process on all prepared solutions.
- Cleaner, more controlled environment.
USP-797

• New standards effective Jan 2004
• Standards will be enforced by Boards of Pharmacy.
• Sterile product preparations are categorized as high, medium or low risk preparations based on the potential for microbial, chemical and physical contamination.

Buffer Room

• Must be ISO Class 7 (Class 10,000)
• Prepared in a ISO Class 5 (Class 100) laminar airflow workbench
• Positive pressure room with HEPA filtered air.
• Access is restricted in Buffer area.

ISO Class 7

• Also referred to as a Class 10,000 environment.
• Air particle count does not exceed 10,000 particles 0.5 microns or larger per cubic foot of air.
Buffer Rooms

- Walls, floors, ceiling should be smooth, no cracks and crevices.
- Ceilings should be sealed.
- Floors coved.
- No sinks in Buffer area.
- Only non-shedding paper products in area.

Ante-Room or Ante-Area

- Gowning and hand-washing.
- No food or beverages.
- No carts moving back and forth from buffer zone to ante-area.
- Wipe down of products before introducing into the buffer area.
Laminar Flow Hoods

- Horizontal
- Vertical
- Barrier Isolators
- Certified every 6 mo.
- ISO Class 5 (Class 100) environment.
Gowning

- Remove make-up, jewelry.
- Scrub hands and arms to elbow.
- Non-shedding gown, knee length with a zip or snap front.
- Shoe covers, hair covers, face mask and gloves.

Risk Classification

<table>
<thead>
<tr>
<th>Risk Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Risk Compounding</td>
<td>Simple admixtures using closed system transfer methods.</td>
</tr>
<tr>
<td>Medium-Risk Compounding</td>
<td>Admixtures using multiple additives or batch preparations.</td>
</tr>
<tr>
<td>High-Risk Compounding</td>
<td>Non-sterile ingredients or open-system transfers.</td>
</tr>
</tbody>
</table>
Beyond-Use Dating

- Storage period before administration.
- When compounded sterile products are stored for prolonged periods of time there is potential for microbial growth and pyrogen formation.
  - Chemical stability
  - Microbial sterility

Beyond-Use Dating

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Room Temp</th>
<th>Refrigeration</th>
<th>Freezer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>48 hrs</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium</td>
<td>30 hrs</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hrs</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Personnel

- Documented education, training and competency.
  - Didactic training.
  - Competency tests.
  - Return demonstration/observation.
  - Media-fill testing of aseptic manipulative skills.
Media-fill test kit

Media-fill challenge testing
– Sterile bacterial culture medium transferred via a variety of aseptic manipulations
– Test should represent the most challenging products made for a particular risk level
– Products are monitored for microbial growth, indicated by visual turbidity, for 14 days
– Done annually and for new employees

Environmental Controls and Testing
• Routine cleaning schedule.
• Laminar flow hood certification every 6 months.
• Particle-count testing.
• Electric air samplers or agar settling plates.
Total Parenteral Nutrition

• Multiple ingredients (1-3 liters).
• Standard Operating Procedures.
• Automated Compounders
  – Improve accuracy and efficiency.
  – Accuracy verified by weight, volume.

Hazardous Drugs

• NIOSH (National Institute for Occupational Safety and Health) Guidelines.
• Vertical flow hood vented to the outside to protect operator.
• Pharmacy attaches tubing to reduce RN exposure.
• Negative pressure room.
• Separate storage/Receiving procedures.
Resources

- United States Pharmacopeia (USP) web site: www.usp.org
- American Society of Health-System Pharmacists (ASHP) web site: www.ashp.org