Enhanced Sterile Medication Compounding Evaluation

APIC Chicago

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The Joint Commission
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1 Joint Commission
   Updating EM EPs to
   Maintain Alignment with CMS
   Final Rule on Emergency
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   Review Project

Reducing Risk Associated with Sterile Medication Compounding

8 Risk of Harm to Self or Others

11 “Clarifications and Expectations” Column on Hiatus

12 Reducing Risk Associated with Sterile Medication Compounding
Accreditation chapters utilized

- Environment of Care
- Human Resources
- Infection Control
- Leadership
- Medication Management

No new standards were written for hospital accreditation program
Medication Compounding*

SAFER Matrix Distribution

<table>
<thead>
<tr>
<th>IT</th>
<th>2.80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>6.29%</td>
</tr>
<tr>
<td>MOD</td>
<td>13.29%</td>
</tr>
<tr>
<td>LOW</td>
<td>11.19%</td>
</tr>
</tbody>
</table>

30.77% 45.45% 20.98%

*not limited to Medication Management Chapter
• Proper aseptic technique
• Proper PPE
• Media Fill Competency
• Finger tip testing competency
• Didactic Competency
• Hazardous Medication Competency

• Oversight - Accountability
• Policy Implementation
• Knowledge

• Proper product storage
• Proper product labeling
• Appropriate BUD assignment
• Correct complexity level assessment

• Proper PEC placement
• Proper Testing and Certification
• Correct ISO level designations
• Reduction of highly pathogenic organisms
• Reduction of excessive CFU bacterial growth

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Risk Levels

- Low Risk
- Medium Risk
- High Risk (rare)

Note: some Low Risk items may become Medium Risk based on compounding practices
Survey process

- Competencies
- Evaluation of environment
- Review of test/certification reports of engineering controls
- Observation of compounding process
- Labeling and storage
People

Products

Environment

PRECISION

STERILITY

PROCESS
Competencies
Competencies

- Fingertip testing
  - Initial and ongoing
- Media fill test
  - Match most complex level of compounding
- Didactic test
  - Must establish a passing level
- Observation of handwashing and donning PPE
Competencies frequency

- Low-Risk and Medium-Risk Sterile
  - Annually for staff performing
    - defined as every 12 months +/- one month
- High-Risk Sterile Compounding
  - Every 6 months
Evaluation of the Compounding Environment
Compounding environment

Walls
- Surface should be smooth
- Resistant to cleaning activities
- Where flooring meets walls should be evaluated
  - Typical installation leaves a ledge that creates risk for dusk accumulation

Ceilings
- Either solid surface or if drop in tiles
  - Tiles must be sealed
  - Tiles must be caulked into the support framing
- Sprinkler heads

Floors
- Must be solid
Testing/Certification Reports Review
## Primary Engineering Control (PEC) Certification/Testing Requirements

<table>
<thead>
<tr>
<th>Test every 6 months (or if the PEC is relocated or moved)</th>
<th>Result Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Level</td>
<td>5 or better (less)</td>
</tr>
<tr>
<td>Air Microbial Sampling</td>
<td>≤ 1 cfu/cubic meter [1000 liters] of air per plate *</td>
</tr>
<tr>
<td>Surface Microbial Sampling</td>
<td>≤ 3 cfu/ contact plate *</td>
</tr>
<tr>
<td>Air velocity</td>
<td>Per Manufactures Requirements</td>
</tr>
<tr>
<td>HEPA filter leak test</td>
<td>No leak greater than 0.01%</td>
</tr>
</tbody>
</table>

*Evidence of remediation along with re-culturing is required when CFU count is exceeded or for any CFU of highly pathogenic organisms.*
## Secondary Engineering Control (SEC) Certification/Testing Requirements

<table>
<thead>
<tr>
<th>Test every 6 months</th>
<th>Ante Room Requirement</th>
<th>Buffer Room Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO level</td>
<td>8 or better</td>
<td>7 or better</td>
</tr>
<tr>
<td>HEPA filter leak test</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>Room air exchanges</td>
<td>30 ACPH</td>
<td>30 ACPH (no more than 15 can be supplied by hood)</td>
</tr>
<tr>
<td>Room pressurization</td>
<td>+</td>
<td>N.H. +0.02” w/c H - 0.01” w/c</td>
</tr>
<tr>
<td>Surface microbial sampling</td>
<td>≤ 100 cfu/ contact plate *</td>
<td>≤ 5 cfu/ contact plate *</td>
</tr>
<tr>
<td>Air microbial sampling</td>
<td>≤ 100 cfu/cubic meter *</td>
<td>≤ 10 cfu/cubic meter *</td>
</tr>
</tbody>
</table>

*Evidence of remediation along with re-culturing is required when CFU count is exceeded or for any CFU of highly pathogenic organisms.*
Compounding Direct Observation
Compounding Observation

- Item placement
- Protecting critical sites
- Single dose vial use and labeling
- Large volume bag use and labeling
- Correct Primary Engineering Control used
Critical Sites

- Areas that cannot be touched during the compounding process after being swabbed with sterile alcohol

- Ampule
- Vial Septum
- Vial Top
First Air

Air coming from the HEPA filter which is essentially particle-free. **First air should never be blocked during the compounding process.**
Labeling and Storage
## BUD Assignment for Final Products

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Room Temperature</th>
<th>Refrigerated</th>
<th>Frozen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(68-77°F) (20-25°C)</td>
<td>(36-46°F) (2-8°C)</td>
<td>(-13 to + 14°F) (-25 to -10°C)</td>
</tr>
<tr>
<td>Low</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium</td>
<td>30 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Special consideration should be taken when the BUD utilizes hours so that the product label reflects that level of detail.

Items should be stored appropriately once compounding and verification are completed in accordance with the BUD applied.
Labeling and storage

- Beyond use date (BUD) application
- BUD must match compounding complexity and storage
- Evaluating items returned to the pharmacy
- Addressing re-dispensed items
Single Dose Vials

- Single dose vials can be used up to 6 hours if they are maintained in an ISO 5 environment
- This also applies to large volume IV bags used for reconstitution
Large Volume Bags BUD

- 2 liter bags used in TPN compounding have shortened expiration dating (Typically 4 hours).

- Vials attached to the TPN compounding should be labeled with 6 hour BUD unless shorter by manufacturer.
Suggested Compliance Tactics

- Perform a GAP analysis of Engineering Control Testing and Certification
- Perform a GAP analysis of Compounding Operations
- Complete periodic evaluations of practices occurring in the compounding suite
- Develop a quality dashboard for Sterile Compounding
- Make Sterile Compounding an organizational priority
Frequently Asked Questions
Posted Frequently asked questions

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<tr>
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<td>Featured ▼ New ▼ Medication - Sterile Compounding - Secondary Engineering Control (SEC) Testing/Certification Requirements</td>
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<tr>
<td>Featured ▼ New ▼ Medication - Sterile Compounding - Segregated Compounding Area (SCA)</td>
</tr>
<tr>
<td>Featured ▼ New ▼ Medication - Sterile Compounding - Testing/Certification Remediation Requirements for Primary and Secondary Engineering</td>
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<tr>
<td>Featured ▼ New ▼ Medication - Sterile Compounding - Unit Dose Alcohol Swabs</td>
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<td>Featured ▼ New ▼ Medication - Sterile Compounding - Using Primary and Secondary Engineering Controls with Testing/Certification Failures</td>
</tr>
<tr>
<td>Medication Administration - Incorporating Patient Preference Into Medication Administration Practices</td>
</tr>
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Have Questions..... Need Answers?

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