USP 797 Implementation
“The Ugly, the Bad and the Good”

Martin J. Goldberg, RPh, MBA – Director of Pharmacy – Good Samaritan Medical Center

Objectives

- Review of key USP 797 sterile compounding standards
- Review of USP 797 implementation considerations/issue
- Describe our “real life” experiences with USP 797 compliance
- Discuss proposed Massachusetts regulations pertaining to USP 797 compliance
My Personal Objectives

- Cover the required objectives
- Tell our story of moving from non-compliance to compliance
- Tell you what they have not told you in ALL of our required CE’s to date
- What happens when the ... hits the fan
- The key to success: Document, Document, Document

My “other” titles

- Introduced as Registered Pharmacist with an MBA and Director of Pharmacy
- However, when you are involved with implementing and/or managing USP797 you are an:
  - Honorary Architect
  - Honorary Mechanical Engineer
  - Honorary Electrical Engineer
  - Honorary Environmental Service Manager
  - Honorary Microbiologist
  - Honorary IT specialist
  - And all around nice guy (except when you can’t be)
Review of key USP 797 Sterile Compounding Standards
Key USP 797 Standard

- Each organization MUST have Standard Operating Procedures. Those procedures, at a minimum, must cover these areas:
  1. Provide a general overview of USP 797 requirements for sterile compounding
  2. Define the compounding risk level for your facility
  3. Define the roles and responsibilities of personnel involved in sterile compounding.
  4. Provide standards for the various functions involved in the preparation of Compounded Sterile Products (CSP)
  5. Serve as the basis for developing personnel competency and training programs

Standard Operating Procedures – Key Sections

- Environmental Quality Control
- Cleaning and Garbing Process ****
- Finished Product Release/Beyond Use Dating
- Hazardous Medications (which brings in USP 800, which is out of scope for today)
- Quality Assurance/Corrective Action Plans
**Environmental Quality Control**

1. Environmental Sampling plan for viable and non-viable particle sample testing at least every 6 months by current USP 797 standards
2. Pressure Differential Monitoring
3. Temperature Monitoring
4. Humidity Monitoring
5. Corrective Action Plan (CAP) process to address excursions

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**Environmental Quality Control (Plan)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Frequency</th>
<th>Monitored By</th>
<th>Record Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonviable Particle Levels</td>
<td>Every 6 months or whenever major changes are made</td>
<td>Certified contractor</td>
<td>10 years or life of the device, whichever comes first</td>
</tr>
<tr>
<td>Viable Particle Levels</td>
<td>Every 6 months</td>
<td>Certified contractor</td>
<td>10 years</td>
</tr>
<tr>
<td>Pressure Differentials</td>
<td>Daily / Every 6 months</td>
<td>Compounding personnel / Certified contractor</td>
<td>CAPs – 10 years</td>
</tr>
<tr>
<td>Temperature</td>
<td>Daily / Every 6 months</td>
<td>Compounding Personnel</td>
<td>CAPs – 10 years</td>
</tr>
<tr>
<td>ACPH</td>
<td>Every 6 months</td>
<td>Certified contractor</td>
<td>10 years</td>
</tr>
<tr>
<td>Humidity</td>
<td>Daily</td>
<td>Compounding Personnel</td>
<td>CAPs – 10 years</td>
</tr>
</tbody>
</table>
Garbing and Cleaning

- The most important of ALL of your SOP’s
- If you cannot get the garbing and cleaning right you cannot get to compliance
- As we will see later – this was the number one issue in moving from Ugly to Bad to Good
- MUST involve ALL personnel who will step foot into the clean room, especially EVS and/or other cleaning personnel, and facilities when something goes wrong – and something ALWAYS goes wrong

Picture of our clean room
Garbing Instructions

Garbing Procedure for THIS IV Clean Room

- All personnel intending to enter the area must enter the buffer room first. When entering the buffer room, please perform the following check and garbing procedure:
  - Personal shall put on shoe covers one at a time
  - Personal shall then step over to the clean side of the area room to perform hand cleaning per below
  - Personal shall then put on hair and beard covers and ensure that all hair is neatly tucked away
  - Personal shall don appropriately fitted face mask (FFP respirators required for hazardous IV preparations and cleaning with a chemical disinfectant or a terpenoid) if entering the buffer area

For Compounding Personnel:

- Personnel that performs hand cleaning as follows:
  - Disposable, hair, and forearms (up to elbows) are cleansed under warm running water with soap for at least 30 seconds, starting at the fingers and working towards the elbows in a downward motion.
  - Long-throws are used to dry hands and forearms.
  - Personal shall then don non-shedding gloves - closed at the ends and fitted at the wrists.
  - Personal shall enter the buffer room(s) staff
  - Scrub their hands, using a waterless alcohol-based surgical hand rub, which is allowed to fully dry.
  - Wear protective gloves before corresponding to cleaning room parents, placing hands after wearing certified barrier-breaking glasses (sterile) used during hazardous IV preparations and cleaning.
  - Gloves shall be decontaminated using sterile IPA (isopropyl alcohol) during the cleaning process and whenever contamination has occurred or is suspected and shall be inspected for holes and/or other defects before use

- When exiting the clean rooms, personnel shall remove and dispose of all PPE

- Personal shall repeat the above steps whenever re-entering the clean rooms

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Garbing Instructions – No Street Clothes

**NOTICE**

**PROPER ATTIRE REQUIRED THIS AREA**

*Scrubs ONLY!* – Street clothes NOT allowed past the line of demarcation
Garbing Instructions – Prohibited from Clean Room

PROHIBITED FROM IV CLEAN ROOM

- No Make-up Allowed.
- No cosmetics and hairstyles.

- No Cell Phones allowed.
- No artificial nails or nail extenders and nail polish. (this, too!)}
Picture – Front Door of Clean Room

Cleaning Procedures

Cleaning procedures in clean rooms:
The compounding supervisor (IV Room Pharmacist) shall be responsible for ensuring that the clean rooms (both buffer rooms and anteroom) are appropriately cleaned per the following schedule:

<table>
<thead>
<tr>
<th>Area of Clean Room</th>
<th>Frequency</th>
<th>Responsible Party</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laminar Airflow Workbenches (LAWs)</td>
<td>At the beginning of each shift</td>
<td>Pharmacy Personnel per guidelines below</td>
</tr>
<tr>
<td></td>
<td>Before each batch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After spills</td>
<td></td>
</tr>
<tr>
<td></td>
<td>At the end of each shift</td>
<td></td>
</tr>
<tr>
<td>Counters and work surfaces (includes all carts and all pass-through)</td>
<td>Daily</td>
<td>Pharmacy Personnel per guidelines below</td>
</tr>
<tr>
<td>High touch Surfaces (phones, door knobs, light switches)</td>
<td>Daily</td>
<td>EVS Personnel</td>
</tr>
<tr>
<td>Floors (dry mop plus disinfectant)</td>
<td>Daily</td>
<td>EVS Personnel</td>
</tr>
</tbody>
</table>
Beginning of Compounding Day Checklist

End of Shift Checklist
Cleaning Schedule

The Pharmacy Director (or designee) shall be responsible for ensuring that the clean rooms are appropriately cleaned per the following schedule:

<table>
<thead>
<tr>
<th>Area of Clean Room</th>
<th>Minimum Frequency</th>
<th>Responsible Party</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walls &amp; Ceilings</td>
<td>Weekly</td>
<td>EVS Personnel</td>
</tr>
<tr>
<td>Storage Shelving</td>
<td>Monthly</td>
<td>Pharmacy</td>
</tr>
</tbody>
</table>

Cleaning Competencies

- EVS Daily Clean Competency
- EVS Weekly Clean Competency
- Pharmacy Monthly Clean Competency
### EVS Daily Clean Competency – Page 1

<table>
<thead>
<tr>
<th>Competency: Disinfection and Sterilization of Equipment and Materials</th>
<th>Date of Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluatee Name</td>
<td>Position</td>
</tr>
<tr>
<td>----------------</td>
<td>----------</td>
</tr>
<tr>
<td>Evaluated By</td>
<td>Position</td>
</tr>
<tr>
<td>Type</td>
<td>Notes</td>
</tr>
<tr>
<td>Notes</td>
<td>Notes</td>
</tr>
</tbody>
</table>

#### General Guidelines

- Thoroughly clean and disinfect all equipment and materials used in patient care areas, including examination rooms, surgical suites, and all patient接触 areas.
- Ensure all equipment and materials are properly labeled and tracked.
- Monitor and record all disinfection and sterilization procedures.

#### disinfection

- Properly disinfect all equipment and materials used in patient care areas.
- Ensure all equipment and materials are properly cleaned and disinfected.

#### sterilization

- Properly sterilize all equipment and materials used in patient care areas.
- Ensure all equipment and materials are properly cleaned and sterilized.

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### EVS Daily Clean Competency – Page 2

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Question #1

The key to successful USP 797 compliance is

A. Having a robust environmental sampling plan
B. Having a monitoring system for pressure differential, particle counts, temperature and humidity ranges
C. Hoping that the room maintains its pressure differential, particle counts, temperature and humidity ranges, and stays clean on its own because I am too busy to monitor all that stuff.
D. Having a robust garbing and cleaning procedure, including personnel competencies.
E. A, B and D ONLY

Review of USP 797 Implementation considerations/issues
You have to build a new room (or I need to maintain my existing room) – now what!

The four highlights:
- Light Fixture are smooth, mounted flush
- Relative Humidity maintained 25%-60%
- A line of demarcation to differentiate dirty/clean
- Dispenser for lint free wipes
### The six highlights:

- Ceiling in buffer room is painted gypsum board, finish is epoxy paint
- Pressure differential readings can be read daily
- Buffer room—a minimum of 0.02" wc positive to adjacent spaces
- Controlled compounding environments are constructed with physical walls, and maintain a minimum positive pressure of 0.02" wc
- Anteroom adjacent to negative pressure buffer rooms used for hazardous drug compounding maintains ISO 7 or better
- Controlled environments that are constructed to accommodate the storage of hazardous drugs are physically separated from an ISO 7 anteroom and maintain negative pressure of 0.01" wc to the adjacent space

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### Implement in Phases – Phase 1

**Phase 1 Site Logistics Option “A”** This is the most ideal logistics plan. This set provides your pharmacy with the best most efficient and local storage throughout Phase 1. This is the set that the most users choose.
Phase 1 – Picture – Non-Hazardous Buffer Room

Phase 1 – Picture – Hazardous Room
Phase 2 – Open New IV room, Close the old IV room, and build new multi-office space

Phase 2 Site Logistics Option "A" This is the most ideal logistics plan.

This will provide your employees with the best/most work atmosphere and least interference throughout phase 2.

This will be the most secure option.

Picture of Multi-Office Space
Question 2

- Which factors should be considered when implementing (or maintaining existing) clean room?

A. A line of demarcation from clean/dirty must be in place

B. Ceilings in the buffer room is painted gypsum board with epoxy paint

C. A requirement of the chapter is that pressure differentials need to be reviewed and recorded on a log daily

D. All of the above

Describe our “real life” experiences with USP 797 compliance
Where to begin?

- Let’s start right before we open our new IV clean room, then…
- Room Pressurization issues, then…
- Environmental Monitoring issue, then…
- Smoke Test issues, then…
- We would have journeyed from Ugly to Bad, to Good!

Brand New Room – Should be clean but…

**USP 797 - CORRECTIVE ACTION PLAN (CAP) FORM**

<table>
<thead>
<tr>
<th>ID</th>
<th>OPENED ON: 11-14-15</th>
<th>CLOSED ON: 12/1/15</th>
<th>CAP OWNER: Martin Goldberg, Director of Pharmacy</th>
</tr>
</thead>
</table>

**ISSUE / PROBLEM DESCRIPTION:** Result from Environmental Monitoring performed by Micro Clean

<table>
<thead>
<tr>
<th>Site/Location</th>
<th>Result</th>
<th>Concern Level</th>
<th>Alert Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>AV10 - TSA - Ante Room</td>
<td>4 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Alert Level</td>
<td>Due to presence of possible Coag Positive Staph</td>
</tr>
<tr>
<td>AV14 - TSA - Ante Room</td>
<td>2 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Alert Level</td>
<td>Due to presence of possible Coag Positive Staph</td>
</tr>
<tr>
<td>AV15 - TSA - Hazardous Room</td>
<td>2 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Alert Level</td>
<td>Due to presence of possible Coag Positive Staph</td>
</tr>
<tr>
<td>AV16 - TSA - Hazardous Room</td>
<td>2 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Alert Level</td>
<td>Due to presence of possible Coag Positive Staph</td>
</tr>
<tr>
<td>SV18 - TSA - Ante Room</td>
<td>74 cfu/plate</td>
<td>&gt; 5 cfu/plate</td>
<td>Action Level</td>
<td>Due to exceeded levels and presence of mold</td>
</tr>
</tbody>
</table>
The rest of CAP #001

**ROOT CAUSE ANALYSIS:** Result thought to be due to construction activities

**ACTION PLAN & TIMEFRAME**
- Alert and Action levels thought to be due to construction activity
- Prior to room opening performed a thorough terminal clean process (12/1/15)
- Plan is to enforce proper garbage and cleaning procedures once the room is open
- Retest the room at normal re-certification time in May, 2016
- Maintain our 12 hour Beyond Use Date (BUD) standards

**RESOLUTION:**
Retest scheduled for May 2016 as part of semi-annual recertification

**CAP RESOLUTION DATE (SIGN & DATE)**

*Martin J. Goldberg* 12-1-15

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Then came the Winter of 2016...

**GOOD SAMARITAN MEDICAL CENTER**

**USP 797 - CORRECTIVE ACTION PLAN (CAP) FORM**

<table>
<thead>
<tr>
<th>CAP #002</th>
<th>OPENED ON: 2-29-16</th>
<th>CLOSED ON: 5-26-16</th>
<th>CAP OWNER: Martin Goldberg, Director of Pharmacy</th>
</tr>
</thead>
</table>

**ISSUE / PROBLEM DESCRIPTION:** The IV room is NOT keeping the differential pressures required for USP 797 compliance
CAP #002 (con’t)

ROOT CAUSE ANALYSIS: Several

ACTION PLAN & TIMEFRAME
See attached action plan

The issues... and the many hats we wear!

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Close Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Object Activation Daemon (OAD) is to be set to a minimum position. The flow station should be a monitoring point and not a control point. The damper was set to 85% on Thursday, 2/25/16, to stabilize the room pressure. The balancing contractor shall confirm the minimum damper position.</td>
<td>Complete</td>
</tr>
<tr>
<td>2</td>
<td>The flow meter should be replaced and the damper operation is to be configured for economizer use only. It was confirmed that the damper is designed to be closed in the minimum position as we do not need a minimum relief set point. The economizer sequence is to remain off until the actuator is replaced.</td>
<td>Complete</td>
</tr>
<tr>
<td>3</td>
<td>The Variable Frequency Drive (VFD) controller is to be relocated to an external VFD box. This will allow for trouble shooting while the power is still on to obtain the VFD alarm codes.</td>
<td>Complete</td>
</tr>
<tr>
<td>4</td>
<td>Replace the supply fan disconnect door and repair the override button as required.</td>
<td>Complete</td>
</tr>
<tr>
<td>5</td>
<td>Replace the Differential Pressure (DP) sensor for room 124 and calibrate same.</td>
<td>Complete</td>
</tr>
<tr>
<td>6</td>
<td>The Balancer shall check and recalibrate all of the room DP sensors. We would also recommend that ODE be present while the suite is being certified to calibrate the sensors as required. ODE is to set up alarm points for the room pressures. Negative room 124: -0.099&quot; for 60 seconds or -0.06&quot; for 60 seconds. Positive rooms: -0.02&quot; for 60 seconds or -0.06&quot; for 60 seconds.</td>
<td>Complete</td>
</tr>
<tr>
<td>7</td>
<td>Schedule a shutdown of the exhaust fan on the roof to verify the alarm is functioning.</td>
<td>Complete</td>
</tr>
<tr>
<td>8</td>
<td>Cytotoxic room 124: Adjust the closer on the door as a first step. If this is found to be unacceptable, the exhaust fan can be slowed down to obtain a minimum -0.02&quot; differential pressure.</td>
<td>Complete</td>
</tr>
</tbody>
</table>
The issues... and the many hats we wear! – Slide 2

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Close Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>AMU freeze stat trip: The sketch has been issued to add the baffle. This will force the outside air stream to merge with the return air stream and eliminate the stratification of the mixed air. Upon a restart after a trip, we recommend the discharge air sensor be reset to 68°F for a period of 5 minutes to allow the control valve on the steam coil to open prior to start up. This will prevent the slug of cold air from tripping the freeze stat again.</td>
<td>Complete</td>
</tr>
<tr>
<td>10</td>
<td>Consult the manufacturer to verify the VFD settings allow for an auto restart. We understand one fan starts automatically but the other does not. This operation does not help to maintain proper room pressures. The fans are to be interlocked to maintain room pressures whenever possible. The contractor has stated the interlock is complete and we would recommend this be tested for final confirmation.</td>
<td>Complete</td>
</tr>
<tr>
<td>11</td>
<td>Confirm extended warranty with manufacturer.</td>
<td>Complete</td>
</tr>
<tr>
<td>12</td>
<td>MicroClean Certification after system is operational.</td>
<td>Complete</td>
</tr>
</tbody>
</table>

CAP #002 – Resolved (finally)!

RESOLUTION
Pressurization issues resolved by May 2016 room recertification and the room passed all recertification requirements

CAP RESOLUTION DATE (SIGN & DATE)
Martin J. Goldberg 5-26-16
The rest of the story is ALL about environmental monitoring

- CAP #003 – 5-26-2016 - The Ugly
- CAP #004 – 8-3-2016 – The Better
- CAP #005 – 9-1-2016 – The Bad
- CAP #006 – 11-17-2016 – The still not Good
- CAP #009 – 12-21-2016 – The Good

CAP #003 – The Ugly

<table>
<thead>
<tr>
<th>Site/Packet/Location</th>
<th>Result</th>
<th>Concern Level</th>
<th>Alert/Action Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>203 – Non-Hazardous Buffer Room</td>
<td>20.4 cpm</td>
<td>&gt; 20.0 cpm</td>
<td>Alert Level</td>
<td>Due to increased levels and presence of lead</td>
</tr>
<tr>
<td>459 – MA – Anti Room</td>
<td>2.6 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>4008 – MA – Anti Room</td>
<td>22.3 cpm</td>
<td>&gt; 20.0 cpm</td>
<td>Action Level</td>
<td>Due to increased levels</td>
</tr>
<tr>
<td>4011 – MA – Anti Room</td>
<td>6.3 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>4012 – MA – Anti Room</td>
<td>6.3 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>4013 – MA – Anti Room</td>
<td>3.4 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>4014 – MA – Anti Room</td>
<td>0.10 cpm</td>
<td>&gt; 0.01 cpm</td>
<td>Alert Level</td>
<td>Due to presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>4015 – MA – Hazardous Buffer Room</td>
<td>2.4 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to increased levels and presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>4017 – MA – Hazardous Buffer Room</td>
<td>22.3 cpm</td>
<td>&gt; 20.0 cpm</td>
<td>Action Level</td>
<td>Due to increased levels and presence of lead and presence of lead</td>
</tr>
<tr>
<td>509 - MA – Non-Hazardous Buffer Room</td>
<td>5.1 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Action Level</td>
<td>Due to increased levels and presence of lead</td>
</tr>
<tr>
<td>509S - MA – Non-Hazardous Buffer Room</td>
<td>5.1 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Action Level</td>
<td>Due to increased levels and presence of lead</td>
</tr>
<tr>
<td>5005 – MA – Anti Room</td>
<td>3.4 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to increased levels and presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>5007 – MA – Anti Room</td>
<td>3.4 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to increased levels and presence of possible Clog Positive Flush</td>
</tr>
<tr>
<td>5002 – MA – Anti Room – Can</td>
<td>7.1 cpm</td>
<td>&gt; 2.0 cpm</td>
<td>Alert Level</td>
<td>Due to increased levels and presence of possible Clog Positive Flush</td>
</tr>
</tbody>
</table>
Clean Room Design & Testing Plan

The plan

Corrective Action Plan:
Performed an immediate terminal clean of all rooms and surface with Coverage TB and with Spor-Kleen (including the Laminar Flow Hoods)
Engaged ENH to perform rigorous test of the air handling system and to restest for spores
Engaged the support of EVS and Infection control to evaluate and recommend appropriate cleaning solutions/processes
Moved scrubs from Pharmacy Storeroom to Housekeeping closet to decrease distance traveled to clean room
Instituted the requirement for "bunny suits" in the IV room.
Determined that "bunny suits" would be disposable after 1 use for all IV room personnel (including EVS)
Installed an Intercom system by the outside pass-through to minimize number of times the main door opens/closed
Determined that Oxiwet TB wipes and Avert for daily and weekly/monthly respectively would be the best choice
Performed terminal clean with above products on August 2, 2016
Scheduled recertification with Micro Clean for August 3, 2016
Maintained our 12 hour Beyond Use Date (BUD) standards
### CAP #004 – The Better

**Environmental Monitoring Record for USP 797 Clean Room**

**Site/Location:** Av9 - TSC - Jami Room

<table>
<thead>
<tr>
<th>Date</th>
<th>Result</th>
<th>Concern Level</th>
<th>Alert/Action Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/1/2016</td>
<td>22 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Action Level</td>
<td>Due to expected levels and presence of possible Gram positive path and the presence of possible Gram - growth</td>
</tr>
</tbody>
</table>

**AV30 - TSC - Jami Room**

<table>
<thead>
<tr>
<th>Date</th>
<th>Result</th>
<th>Concern Level</th>
<th>Alert/Action Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/1/2016</td>
<td>14 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Action Level</td>
<td>Due to expected levels and presence of possible Gram positive path and the presence of possible Gram - growth</td>
</tr>
</tbody>
</table>

**AV36 – TSC - Hazardous Buffer Room**

<table>
<thead>
<tr>
<th>Date</th>
<th>Result</th>
<th>Concern Level</th>
<th>Alert/Action Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/1/2016</td>
<td>4 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Alert Level</td>
<td>Due to the presence of possible Gram - growth</td>
</tr>
</tbody>
</table>

**Corrective Action Plan:**

- All areas from the 5-20-15 test passed except
- AV9, AV30, and AV36 still at risk
- Perform terminal clean by EVS
- Perform monthly clean by Pharmacy
- Maintained our 12-hour Hospital Use Date (HUSD) standards
- Schedule next test for 6/3/2016

### CAP #005 – The Bad (because it’s not good yet)!

**Environmental Monitoring Record for USP 797 Clean Room**

**Site/Location:** Av17

<table>
<thead>
<tr>
<th>Date</th>
<th>Result</th>
<th>Concern Level</th>
<th>Alert/Action Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/1/2016</td>
<td>23 cfu/m³</td>
<td>&gt; 10 cfu/m³</td>
<td>Action Level</td>
<td>Due to expected levels and presence of possible Gram positive path and the presence of possible Gram - growth</td>
</tr>
</tbody>
</table>

**Corrective Action Plan:**

- All areas from the 8-3-16 test passed
- AV17 was converted to buffer room had action level
- Review EVS and Pharmacy cleaning competencies
- Review EVS and Pharmacy personnel on revised competencies
- Maintained our 12-hour Hospital Use Date (HUSD) standards
- Schedule next test for 11/3/2016 (normal frequency)
### CAP #006 – The still not Good Yet

<table>
<thead>
<tr>
<th>Site/Media/Location</th>
<th>Result</th>
<th>12/21/2014</th>
<th>Concern Level</th>
<th>Alert Level</th>
<th>Notes/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SV21 - TSA - Ante Room - Sink</td>
<td>1 cfu/plate</td>
<td>&gt; 5 cfu/plate</td>
<td>Alert Level</td>
<td>Due to exceeded levels and presence of possible Cg positive growth</td>
<td></td>
</tr>
<tr>
<td>SV22 - TSA - Ante Room - Sink</td>
<td>2 cfu/plate</td>
<td>&gt; 5 cfu/plate</td>
<td>Alert Level</td>
<td>Due to exceeded levels and presence of possible Cg positive growth</td>
<td></td>
</tr>
<tr>
<td>AV10 - MEA - Ante Room</td>
<td>2 cfu/ml</td>
<td>&gt; 10 cfu/ml</td>
<td>Alert Level</td>
<td>Due to exceeded levels and presence of possible Cg positive growth</td>
<td></td>
</tr>
<tr>
<td>SV21 - MEA - Ante Room - Sink</td>
<td>2 cfu/ml</td>
<td>&gt; 5 cfu/ml</td>
<td>Action level</td>
<td>Due to presence of mold</td>
<td></td>
</tr>
</tbody>
</table>

Corrective Action Plan:
- All areas of the 9.1.16 test passed (AV17)
- Results from SV21, SV22, and AV10 at Alert Levels
- Results from SV21 - MEA - Ante Room Sink - below CSL, but had mold
- Results are much better and need to focus on sink area
- Adjusted the water pressure in the sink
- Adjusted cleaning procedure to increase dwell time at the sink

### CAP #009 – THE GOOD!!!

<table>
<thead>
<tr>
<th>Site/Media/Location</th>
<th>Result</th>
<th>12/21/2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>SV21 - TSA - Ante Room - Sink</td>
<td>Passed</td>
<td></td>
</tr>
<tr>
<td>SV22 - TSA - Ante Room - Sink</td>
<td>Passed</td>
<td></td>
</tr>
<tr>
<td>AV10 - MEA - Ante Room</td>
<td>Passed</td>
<td></td>
</tr>
<tr>
<td>SV21 - MEA - Ante Room - Sink</td>
<td>Passed</td>
<td></td>
</tr>
</tbody>
</table>

Corrective Action Plan:
- None required - USP 797 Compliant
- Monthly EM will take place in 2017
What happened to CAP #007 and #008?

- CAP #007 – Smoke Test Issue
- CAP #008 – HEPA Filter Assembly Unit Damaged

Environmental Monitoring Results 2017 – To Date

- January 2017 – All areas passed
- February 2017 – All areas passed
- March 2017 - All areas passed
- April 2017 – All areas passed
Question #3

- What are the two most common “real” life issues in maintaining a USP 797 Clean Room?

A. Time and Money  
B. Time and People  
C. Room Pressurization and Environmental Monitoring  
D. None of the above  
E. All of the above
MA Board of Pharmacy Regulations

What coming down the pike…

- 247-cmr-6:00 Licensure of Pharmacies
- Institutional Sterile Compounding: Facility Request Form
- Institutional Sterile Compounding: Information Request Form
- Institutional Sterile Compounding: Compliance Requirements (127 standards)
247-cmr-6:08 Licensure of Pharmacies - Institutional

6.08 Applications for Institutional Sterile Compounding Pharmacy Licenses

(1) In support of an application for a license to operate an institutional sterile compounding pharmacy, the applicant shall also submit:
   (a) all documentation identified in 247 CMR 6.04(2);
   (b) a copy of the institution’s pharmacy-related license(s) and registration(s);
   (c) certified blueprints of the compounding area(s) that depict the location and indicate the ISO classification for each primary and secondary engineering control;
   (d) detailed HVAC design plans and written description; and
   (e) attestation of intent to engage in compounding signed by the Manager of Record, pharmacist in charge of sterile compounding, as applicable, and applicant(s).

(2) The applicant shall achieve a satisfactory Board inspection of the proposed institutional sterile compounding pharmacy prior to the issuance of an initial institutional sterile compounding pharmacy license.

(3) Renewal of an institutional sterile compounding pharmacy license
   (a) Each institutional sterile compounding pharmacy license issued by the Board shall expire on December 31st of each year following the date of its issuance.
   (b) In connection with an application to renew an institutional sterile compounding pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to any pharmacy-related inspection by any state or federal agency, or any entity inspecting on behalf of any state or federal agency, that occurred within that licensing period.

Institutional Sterile Compounding: **Facility Request Form**
Institutional Sterile Compounding: Information Request Form 1 of 7

The Commonwealth of Massachusetts
Board of Registration in Pharmacy
239 Causeway Street, Suite 500, 5th Floor, Boston, MA 02114
Phone: (617) 727-0800 - Fax: (617) 973-0960

Institutional Sterile Compounding Information Request Form

Please complete one of these forms for each sterile compounding location identified on the “Institutional Sterile Compounding Facility Request Form”.

<table>
<thead>
<tr>
<th>Institution and Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Institution</td>
</tr>
<tr>
<td>Main address</td>
</tr>
<tr>
<td>Name of Pharmacy Director</td>
</tr>
<tr>
<td>Pharmacy License No.</td>
</tr>
<tr>
<td>Phone #</td>
</tr>
<tr>
<td>E-Mail</td>
</tr>
<tr>
<td>Department of Public Health License</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Location within Institution</th>
<th>Building/Room</th>
<th>Address</th>
<th>Telephone</th>
<th>Key/Code</th>
<th>Manager of Record (HCO)</th>
<th>License Number</th>
<th>Phone Number</th>
<th>E-Mail Address</th>
</tr>
</thead>
</table>

Institutional Sterile Compounding: Information Request Form Page 2 of 7

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Institutional Sterile Compounding Information Request Form

[Diagram or table related to Institutional Sterile Compounding Information Request Form]
Institutional Sterile Compounding: Information Request Form - Staffing

Institutional Sterile Compounding: Compliance Requirements Page 1 of 17
Institutional Sterile Compounding: **Compliance Requirements - Sample**

<table>
<thead>
<tr>
<th>No.</th>
<th>Required</th>
<th>Soc.</th>
<th>N.</th>
<th>A.</th>
<th>N/A</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>13</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
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<td></td>
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<td></td>
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<td>16</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
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<td>17</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>20</td>
<td>Compounded products should be made by a licensed pharmacist in an area that meets all federal, state, and institutional requirements for the manufacture of sterile compounds.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Best Advice**

- Ensure you have Standard Operating Procedures that meet the key elements
- Ensure your clean room meets all standards for differential pressures
- Ensure robust garbing and cleaning procedures
- Ensure you have routine environmental monitoring – highly recommend monthly
- Ensure you have both Pharmacy and EVS competencies for cleaning
- Ensure you have a Corrective Action Plan process
- Document, Document, Document and lastly ….
Keep Calm and Good Luck!!!

KEEP CALM AND GOOD LUCK!

Massachusetts Society of Health-System Pharmacists
2017 Annual Meeting