Sterile Compounding: Personnel Metrics

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## Important Inspector Evaluation Metrics

### Personnel Metrics

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<td>• Evaluate Policy/Procedure/Training</td>
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<td>• Observation of practice</td>
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<td>• Evaluate Policy/Procedure/Training</td>
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<td></td>
<td>• Observation of practice</td>
</tr>
<tr>
<td></td>
<td>• Initial Media Fill Unit (MFU) results</td>
</tr>
<tr>
<td></td>
<td>• Ongoing MFU results (with GFS)</td>
</tr>
<tr>
<td></td>
<td>• Surface sampling (SS) results (not required but this is excellent time to perform SS)</td>
</tr>
<tr>
<td></td>
<td>• Environmental Sampling Plan</td>
</tr>
</tbody>
</table>
What is garbing?

- Garbing is the act of donning required PPE before compounding begins or before a worker enters a particular controlled pharmacy compounding space (such as a buffer area or the clean side of an anteroom or segregated compounding area) to work inside of a Primary Engineering Control that provides an ISO Class 5 environment.
What is garbing?

• Garbing must occur before entering the buffer area (or Segregated Compounding Area-SCA) to compound or to perform cleaning, environmental sampling or any activity that occurs inside a cleanroom.

• Garbing must also occur before using isolators (CAIs) unless the isolator manufacturer provides written documentation (based on validated environmental testing) that any component/s of PPE are not required to maintain the ISO Class 5 area.
Polling Question

USP Chapter <797> requires the use of sterile gloves while compounding.

1. True
2. False
Polling question

After performing hand hygiene and donning gown but before donning sterile gloves, USP <797> requires the use of an alcohol based hand rub with persistent activity.

Is Purell acceptable for this use?

1. Yes
2. No
Garbing “Shalls”

- Remove before LOD
  - outer garments
  - jewelry
  - no piercings above neck
  - no artificial nails
- Garb dirtiest to cleanest
  - Don hair and beard cover, mask and shoe covers before performing hand hygiene
  - Hand hygiene includes nails and arms up to elbows
  - After drying hands must apply antimicrobial rub with persistent activity before donning gloves (Avagard D or Sterillium)

- Use Sterile gloves ONLY
- If exposed to < ISO Class 8 air, repeat hand hygiene and garb
Evidence that there is a mechanism where personnel with the following conditions (cause higher rates of shedding and particle generation, thus increasing the possibility for contamination of CSPs) do not perform compounding related activities:

- Severe skin rashes
- Severe Sunburn
- Weeping Sores
- Conjunctivitis (“pink eye”)
- Symptoms of active respiratory infection

Garbing required with CAIs unless documentation based on validated testing shows not needed to maintain sterility of CSPs.
Polling Question

Which of the following is the largest source of particulate contamination in controlled compounding environments?

1. Equipment
2. Facility structure
3. Corrugated cardboard
4. Personnel
Why is garbing important?

• Humans are “particle generators.” Even though we can’t “see” them, it is generally agreed that we shed about 9 pounds of dead skin cells from the stratum corneum (the outer layer of the skin) per year.\(^1\)

• Particles generated by humans, our clothes, and our activities can transport microorganisms to critical sites (e.g. vial septa, needles) during the compounding process.

# How many particles do we shed?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Particles ≥ 0.3 μ/minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting/Standing (motionless)</td>
<td>100,000</td>
</tr>
<tr>
<td>Movement head, arm, neck or leg</td>
<td>500,000</td>
</tr>
<tr>
<td>Sitting to standing</td>
<td>2,500,000</td>
</tr>
<tr>
<td>Slow walking (2 mph)</td>
<td>5,000,000</td>
</tr>
<tr>
<td>Moderate walking (3.5 mph)</td>
<td>7,500,000</td>
</tr>
<tr>
<td>Fast walking (5 mph)</td>
<td>10,000,000</td>
</tr>
</tbody>
</table>

Garbing Considerations

- Remove all outer garments (e.g., bandannas, coats, hats, jackets, fuzzy sweaters, scarves and vests)
- It’s best to wear the least amount of clothing that is socially acceptable under the required garb.
- Scrubs are recommended for employee comfort. They may generate less lint and particulate contamination than do street clothes (if used properly).
- Natural fingernails must be clean and neatly trimmed (1/4 inch or less recommended)
- According to the CDC, many studies have documented that areas under and around fingernails, harbor high concentrations of bacteria, including staphylococci, gram-negative rods (Pseudomonas), diptheroids, and yeasts.\(^1\)

What not to wear?

- No cosmetics or makeup of any kind
- No jewelry on hands, neck and head
- No artificial nails or gel nails...chapter says “natural” nails but does not explicitly say no nail polish
- No large expanses of exposed skin (e.g. wearing of shorts or skirts without hosiery)
- No open toed shoes and shoes worn without socks (such that ankles and legs are exposed)
Polling Question

What is the best gauge for the length of time required to perform hand hygiene?

1. Until hands and nails look clean
2. Sing “Happy Birthday” to self
3. 30 seconds timed by looking at a clock
4. Until all surfaces have been vigorously scrubbed
Best Practices Garbing Order

Generally speaking, garbing is performed "dirtiest to cleanest“ but the actual garbing order in each facility may differ slightly, depending upon their physical space (e.g., some may don head covers before shoe covers or shoe covers before head covers - both can be correct).

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Don head cover, facemask, facial hair cover and optional safety glasses.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 2</td>
<td>Don shoe covers (or dedicated shoes) one at a time while stepping over the line of demarcation as each shoe cover is donned.</td>
</tr>
<tr>
<td>Step 3</td>
<td>Perform hand hygiene for at least 30 seconds. Wash hands up to the elbow with soap and warm water. Remove debris under fingernails. Dry hands thoroughly with low-linting wipe.</td>
</tr>
<tr>
<td>Step 4</td>
<td>Don low-shedding gown.</td>
</tr>
<tr>
<td>Step 5</td>
<td>Perform hand cleansing with waterless alcohol-based hand rub with persistent activity. Allow hands to dry.</td>
</tr>
<tr>
<td>Step 6</td>
<td>Don sterile gloves (either before or after entering the buffer area)</td>
</tr>
</tbody>
</table>
When is re-garbing required?

- Regarbing must occur if garb is exposed to less than ISO Class 8 conditions, but garb should not be worn outside of the anteroom.

- If compounders leave the anteroom, they must completely re-garb, including the washing hands and antiseptic hand hygiene with application of alcohol-based hand scrub.

- Those working in a segregated compounding area (SCA), must regarb whenever they leave the SCA.

- If staff work inside a compounding aseptic isolator (CAI), then regarbing must occur if they leave the isolator and stop compounding (depending on the extent to which you garb).
Can garb be reused?

Garb that may be reused

- If not visibly soiled, the gown may be reused for current work shift only.
- It must be discarded if worn outside the ante-area or SCA.
- Task-specific eye shields and dedicated shoes may be reused, but they must be stored in the ante-area or SCA and routinely cleaned with germicidal disinfectant.

Garb that may not be reused

- Head and facial hair covers
- Facemasks
- Shoe Covers
- Gloves
- Gowns or sleeves used for blood labeling are for single use only
A word about garbing and isolators...
Polling Question

Gloved Fingertip Sampling is only required during the initial hand hygiene and garbing competency.

1. True
2. False
What is gloved fingertip sampling?

- Gloved Fingertip Sampling detects the presence of microorganisms on the fingertips of gloves from improper donning of sterile gloves, poor aseptic technique and improper disinfection of gloves.

<table>
<thead>
<tr>
<th>Initial GFS</th>
<th>Ongoing GFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the initial hand hygiene and garbing competency</td>
<td>On an ongoing basis during the preparation of personnel aseptic media-fill units</td>
</tr>
</tbody>
</table>
Initial GFS

• To pass, staff must successfully perform 3 consecutive gloved fingertip samples during their initial hand hygiene and garbing competency.

• The GFS is taken from both hands immediately after the staff member has donned sterile gloves (before they are disinfected with sIPA).

• Once incubated, these samples must contain a total of ZERO CFUs for both hands.

• If a pharmacy uses isolators, then the initial GFSs must be performed when the sterile gloves are donned inside the isolator.
Ongoing GFS

• Ongoing GFS is required in association with the annual or semiannual personnel aseptic media fill unit preparation
  – annually for low and medium risk compounding operations
  – semi-annually for high risk compounding operations
• Performed by presenting the staff member with 2 plates (one for each hand) immediately after they complete their MFUs.
• This must be performed inside of an isolator if that is where compounding occurs.

• Though the operator should be routinely disinfecting hands with sIPA and during MFU is no exception, the samples will be obtained immediately after the completion of the MFU procedure (e.g., the staff are not allowed to resanitize hands after completing the MFUs).
# GFS Recap

<table>
<thead>
<tr>
<th>Initially</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When:</strong> Prior to preparing CSPs for human use, compounding staff must successfully complete:</td>
<td><strong>When:</strong> At the time Personnel Aseptic Media Fill is performed</td>
</tr>
<tr>
<td>• the hand hygiene and garbing competency evaluation and</td>
<td>• Annually (low/medium risk)</td>
</tr>
<tr>
<td>• 3 consecutive GFS fingertip/thumb samples</td>
<td>• Semiannually (high risk)</td>
</tr>
<tr>
<td><strong>How:</strong> GFS samples taken immediately after donning sterile gloves to verify that compounding can garb without contaminating hands (in anteroom or in isolator if isolators are used)</td>
<td><strong>How:</strong> Obtain samples while employee is in ISO Class 5 environment during preparation of personnel media-fill units but not immediately after gloves have been disinfected with sIPA</td>
</tr>
<tr>
<td><strong>Passing results:</strong> 0 CFUs both hands</td>
<td><strong>Passing results:</strong> ≤ 3 CFUs (total both hands) if collected in ISO Class 5 air</td>
</tr>
</tbody>
</table>
Inspector Evaluation Metrics: Garbing

• Evaluate written SOPs for both alpha and beta gap:
  – Alpha gap: difference between requirements (regulatory and standard of practice) and what is reflected in policy
  – Beta gap: difference between what is reflected in policy and what occurs in actual work practice

• Review documentation of employee training
  – Theoretical principles and practical skills
  – Pass written tests

• Review documentation of hand hygiene and garbing competency verification (1 of 3 competencies required by USP <797>)
  – Does it reflect policy?
  – Is it performed initially before being allowed to compound?
  – Does it include successful GFS x 3 conducted during garbing?
  – What type of media is used? Is it capable of supporting growth?
## 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 check 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.*

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

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, 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>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature of Qualified Evaluator</th>
<th>Printed Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Inspector Evaluation Metrics: Garbing

- Name of person obtaining the plates
- Date samples obtained
- Manufacturer
- Lot # of media
- Expiration date of media

Sample Employee Gloved Fingertip Sampling and Media-Fill Results Log

<table>
<thead>
<tr>
<th>Initial Operator Qualification</th>
<th>Operator Re-qualification</th>
<th>Equipment Qualification</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name Compounding Employee: ________________________________</td>
<td>Sampling Date: ____________</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Gloved Fingertip Sampling

Samples pulled by: ________________________________

Manufacturer: _______ Lot Number: _______ Expiration Date: ____________

Action Level Designation* Depends on Location GFS Occurs:

- Immediately after donning sterile gloves/before applying IPA Action Level = 0 CFU
- During compounding in PEC Action Level = >3 CFU

Time in Incubator: _______ AM/PM

<table>
<thead>
<tr>
<th># CFU Plate 1 (left hand)</th>
<th># CFU Plate 2 (right hand)</th>
<th>Total CFUs = Both Plates</th>
<th>Action Level Both Plates* (see above)</th>
<th>Date/Time Removed &amp; Read</th>
<th>Signature Person Reading Plates</th>
</tr>
</thead>
</table>

*If CFUs exceed action level, notify manager. Minimum response must include review and documentation of hand hygiene, garbing, glove and surface disinfection and aseptic work practices.
Inspector Evaluation Metrics: Garbing

• Observe staff garbing

• When you are performing hand hygiene and garbing prior to entering the buffer area to observe, look for the following:
  – Is required garb located on correct side of line of demarcation?
  – Are various sizes available?
  – Is it accessible?

• Other clues to issues

<table>
<thead>
<tr>
<th>Mirror in ante-area?</th>
<th>Clock with second hand?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where do they get soap?</td>
<td>Water controls</td>
</tr>
<tr>
<td>Disposable nail picks</td>
<td>Avagard D or Sterillium Rub</td>
</tr>
<tr>
<td>Spray bottles sIPA</td>
<td>Low-linting towels</td>
</tr>
<tr>
<td>General organization</td>
<td>Hooks for Gowns</td>
</tr>
</tbody>
</table>
Aseptic Technique and Conduct of Personnel

• Touch contamination by compounding personnel is the most common cause CSP contamination.

• Most CSPs are administered intravenously or intraspinally where the body’s natural defense mechanisms have been circumvented.

• Principles and practices of aseptic technique and the risk to the patient resulting from non-compliance and lack of vigilance should be understood by all personnel.

• CSP integrity must be maintained and every precaution taken to assure sterility.

Personnel non-compliance and lack of vigilance relative to aseptic technique and other work practices (such as cleaning, hand hygiene and garbing) can and has overcome the protections afforded by even the best primary and secondary engineering controls.
Polling Question

Which of the following is correct for acceptable results during the *initial* gloved fingertip sampling?

1. Zero CFUs for one hand
2. 3 or less CFUs both hands
3. **Zero CFUs for both hands**
4. 3 CFUs each hand
Aseptic Technique “Shalls”

- Material handling
  - Material uncartoned and wiped with disinfectant prior to entering cleanroom or SCA
  - No food/drink in controlled environments
  - Supplies and drug components wiped with disinfectant prior to introduction to ISO Class 5
  - Syringes, needles and tubing remain in individual packages and opened in ISO 5 only
Aseptic Technique “Shalls”

• Personnel
  – Inspect components for particulates, defect or anything rendering it unacceptable
  – Prevent touch contamination
  – Discard if contamination suspected
  – Work 6 inches in from edge of LAFW
  – Disinfect critical sites with sIPA and allow to dry before entry
  – MDVs/SDVs date/time outside ISO Class 5
Aseptic Technique “Shalls” (continued)

• Compounding

  – Proper use of Direct Compounding Area (DCA)
  – No interruption HEPA filtered “first air” over critical sites
  – Sterile gloves disinfected with sIPA before entry/reentry to ISO Class 5 and whenever touching nonsterile item
  – Inspect sterile gloves regularly for wear and tear; replace if needed

The DCA is only the portion of the PEC where the Critical Site is exposed to unidirectional HEPA-filtered air during an aseptic manipulation.
Polling Question

The image below demonstrates proper use of first air?

1. Yes
2. No
Proper Use of First Air

Horizontal Flow

Vertical Flow
Blocked first air
Personnel Training and Competency Assessment

- Training must be completed & documented before any compounding is performed.
- Aseptic skill observation must be completed successfully and documented.
- Media-Fill Testing (MFT) must be performed and successfully completed (incubation totally complete)
  - Initially before being allowed to perform compounding
  - Annually (low/medium risk) or semi-annually (high risk) thereafter
- Evidence of mechanisms to reinstruct and re-evaluate employees who fail testing, skills observation, MFUs, GFS, or other evaluation.
Conduct of Compounding Personnel

- Entry into controlled areas shall be limited to the number of personnel in the ante-area/buffer area/cleanroom should be limited to only those required for essential operations (ask if they let visitors into their controlled environments).
- All entry passages to controlled areas must remain closed and never left propped open.
- Eating, drinking, gum chewing, tobacco chewing, spitting and smoking are prohibited in any controlled areas.
- Limit conversations in the buffer area to reduce airborne particles.
- Avoid coughing, sneezing and talking directly into the primary engineering control.
- # CSPs prepared in each work area consistent with the amount of work space in the critical area without impacting the HEPA filtered airflow.
Conduct of Personnel (continued)

- All containers (fluids, vials and ampules) must be examined prior to use. Products that exhibit turbidity, cloudiness or particulate matter will not be used.

- All critical sites such as vials tops, injection port covers, ampules, and rubber must be cleaned with 70% sterile IPA and allow to air dry prior to entry with a needle.

- Should any break in technique occur, the drug or additive must be discarded, and new drugs and compounding materials obtained and utilized.

- No food or drinks will be stored in any of the controlled area’s refrigerators or warehouse at any time.

- All trash will be removed from the controlled areas on an as needed basis and at the end of the day.
How often to disinfect gloves?

• Gloves should be disinfected routinely throughout the day and throughout a single compounding run; at least every 30 minutes.

• Additionally, gloves should be disinfected during compounding, whenever hands leave the ISO Class 5 work area and whenever gloves touch a non-sterile surface such as vial shields, chairs, countertops and carts.

• Always disinfect gloves just prior to performing any aseptic procedures.
Disinfecting gloves

- Gloves become contaminated when they come into contact with non-sterile surfaces (e.g. phones, keyboards, vial shields) and must be disinfected regularly.

- Disinfect gloves using sterile 70% Isopropyl Alcohol (sIPA). Spray gloved hands with sIPA to palm and rub together, including in between fingers, to ensure that the sIPA comes into contact with all surfaces of the gloves.

- Allow gloves to thoroughly dry prior to beginning or continuing the preparation of CSPs.
Polling Question

According to the current USP Chapter <797>, pharmacies that perform high risk level compounding are required to verify the aseptic technique of their personnel by performing media fill testing how often?

1. Once/year
2. Twice/year
3. Weekly
4. Monthly

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What is Personnel Media-Fill Testing (MFT)?

- Media fill tests are one of the most useful methods to evaluate aseptic compounding processes.
- Aseptic processing only achieves a sterility assurance level (SAL) of $10^{-3}$ versus $10^{-6}$ when CSPs are terminally sterilized.
- A well-designed media fill **mimic the most complex compounding processes and should be conducted under “worst-case” conditions.**
- Procedures outlined in USP <797> are only examples
- Kits are available but buying the actual TSB supplies is probably most desirable
  - Less expensive
  - Flexibility to design a procedure that mimics each pharmacy’s most complex compounding operation
How often is Media-Fill Testing Performed?

• Initially it is used to verify the technique of:
  – Current personnel (so if a pharmacy has not started performing MFT, all staff must go thru MFT)
  – Newly hired staff members

• Ongoing
  – Every 12 months (low and medium risk operations)
  – Every 6 months (high risk operations)
  – Can be performed more often such as in the event of the observation of unacceptable technique or outcome
How many MFUs are required?

• The chapter is silent on the number of MFUs that must be prepared by each compounding staff member.
• Commonly kits that are purchased prepare 1 – 3 MFUs
• Best practice might be something more like:
  – 10 MFUs daily x 3 days initially then
  – 10 units weekly (high risk)
  – 10 units monthly (low/medium risk)
• What is most important (and required) is that the MFT procedure:
  – Mimic each pharmacy’s most complex compounding procedure
  – Performed under worst case scenario (end of compounding day)
A word about aseptic process control...

- Three thousand (3,000) or more MFUs without media positives (media failure since a media positive demonstrates growth) is what is thought to really demonstrate aseptic process control and...

- A rate of contamination that is no more than 0.1% (1 positive per 1,000 units) at a confidence level of 95%
Media Fill Supplies
What is Process Verification?

- A critical quality metric that demonstrates the operating capability of a process
  - What evidence can be produced to “prove” that a TPN bag can be aseptically compounded on an ACD?
  - Process verification procedure
  - Mimic compounding procedure using TSB as the components instead of macro and micro additives
  - Perform it under “worst-case” scenarios and in a robust manner
Inspector Evaluation Metrics: Aseptic Technique

• Evaluate written SOPs/PnP for both alpha and beta gap
• Review documentation of employee training (didactic testing)
• Review documentation of Aseptic Technique competency verification which is one of the 3 competencies required by USP <797>
  – Is it performed initially and on an ongoing basis in association with MFTs?
  – Chapter <797> Appendix IV is a Sample Form to use for an Aseptic Skill Behavioral Checklist
### 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 checks 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.

- Completes the Hand Hygiene and Garbing Competency Assessment Form.
- Performs proper hand hygiene, garbing, 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 necks by wiping with sterile 70% IPA and allows sufficient time to dry.
- Affixes needles to syringes without contact contamination.
- Punctures vial stoppers and spike 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 compounder”) 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 check marks, 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>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature of Qualified Evaluator</td>
<td>Printed Name</td>
<td>Date</td>
</tr>
</tbody>
</table>
Inspector Evaluation Metrics: Aseptic Technique

- Observe staff performing staging, compounding, labeling, and packaging
- Other commonly observed issues with aseptic technique and conduct in controlled compounding environments

<table>
<thead>
<tr>
<th>Issue</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touching face</td>
<td>Frequent adjustments to gowns</td>
</tr>
<tr>
<td>Gaps between cuff and glove</td>
<td>Non sterile gloves used</td>
</tr>
<tr>
<td>Improper garbing</td>
<td>Infrequent glove disinfection</td>
</tr>
<tr>
<td>Failure to properly sanitize critical sites before entry</td>
<td>Leaving ISO 5 frequently to get additional components</td>
</tr>
<tr>
<td>Disorganized/crowded work surface/area clearance</td>
<td>First air disrupted over critical sites</td>
</tr>
<tr>
<td>Head/Torso inside ISO 5</td>
<td>Pens and paper inside ISO Class 5</td>
</tr>
<tr>
<td>Use of headphones/cell phones</td>
<td>Work activity not slow/deliberate</td>
</tr>
<tr>
<td>Failure to sanitize items before introduction to ISO 5</td>
<td>Daily cleaning of all equipment within the ISO 5</td>
</tr>
</tbody>
</table>
Inspector Evaluation Metrics: Media Fill Testing

- Written PnP details MFU procedure
- Type of procedure (represents most challenging and stressful conditions faced at pharmacy)
- GFS is performed immediately after MFUs are completed
- Documentation indicates MFUs incubated
  - at room temperature (20-25°C) and/or
  - 30-35°C for
  - minimum of 14 days

- Documentation indicates each employee has performed and successfully completes MFT (full 14 days shows no turbidity)
  - Before being allowed to compound CSPs
  - Ongoing: Semi-annually or Annually
### Yearly Staff Competency Testing

<table>
<thead>
<tr>
<th>Name</th>
<th>RPh</th>
<th>IV Tech</th>
<th>Student</th>
</tr>
</thead>
</table>

#### Growth Media Testing

<table>
<thead>
<tr>
<th>Bag</th>
<th>Hood</th>
<th>Growth Media Bag Lot #/Exp</th>
<th>Growth Media Vial Lot #/Exp</th>
<th>Comments</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>D</td>
<td>1120201 7-13</td>
<td>15411653-14</td>
<td>GROWTH</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: Incubate at 30-35°C for 14 days*

#### Syringe Testing

<table>
<thead>
<tr>
<th>Syringe</th>
<th>Hood</th>
<th>Growth Media Lot #/Exp</th>
<th>Comments</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>TSA 100-07971-10</td>
<td>GROWTH</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: Incubate at 30-35°C for minimum of 48 hrs*
### Gloved Fingertip Sampling

**Sampling Date:** 11-29-12  
**Date Samples pulled:** 11-29-12

**Manufacturer:**  
**Lot Number:** n/a  
**Expiration Date:** n/a

**Action Level Designation** Depends on Location GFS Occurs:  
- Immediately after donning sterile gloves/before applying IPA  
- Action Level = 0 CFU  
- During compounding in PEC  
- Action Level = >3 CFU

**Time in Incubator:** AM/PM  
May be read in 48 hours (date: time: AM/PM)  
but must be read in 72 hours (date: time: AM/PM)

<table>
<thead>
<tr>
<th># CFU Plate 1 (left hand)</th>
<th># CFU Plate 2 (right hand)</th>
<th>Total CFUs = Both Plates</th>
<th>Action Level Both Plates* (see above)</th>
<th>Date/Time Removed &amp; Read</th>
<th>Signature Person Reading Plates</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

*If CFUs exceed action level, notify manager. Minimum response must include review and documentation of hand hygiene, garbing, glove and surface disinfection and aseptic work practices.

### Aseptic Media-Fill Testing

#### Days of Inspection

<table>
<thead>
<tr>
<th>Bag #</th>
<th>Hood #</th>
<th>Results</th>
<th>Initials of Reader</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>Pass</td>
<td>SpL</td>
<td>12/11/12</td>
</tr>
<tr>
<td>2</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>12</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>12</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>12</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>12</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Incubate at Room Temperature:** Days 1 through 7
- **Incubate at 30-35 Celsius:** Days 8 through 14

If bag is clear, initial and date the top boxes and place a check mark in the boxes on day of inspection BUT if bag is cloudy, mark an X in the box & line out remaining days. Indicate “FAIL” in space provided and notify Pharmacy Supervisor.

**Lot # H2O Viola:** 3068  
**Exp. Date:** 12/12/12  
**Mfg:** Hospira

**Date:** 12/14/12

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Polling Question

According to Chapter <797>, how often is Surface Sampling required to be performed?

1. Twice/year with facility certification
2. Annually
3. Periodically
4. Not required
What about Surface Sampling?

- Surface sampling tests for viable contamination on surfaces.
- Evaluates:
  - effectiveness of the daily cleaning and disinfection and
  - degree to which compounding personnel properly disinfect the deck during compounding
Surface Sampling “Shalls”

- Perform in all ISO Classified spaces on a “periodic basis”
- Use plate (24-30 cm²) containing tryptic soy agar with polysorbate 80 and lecithin added to neutralize cleaning agents
- Perform using swab or plate method
- Incubate by inverting plates and incubate plates at 30-35°C for 48 to 72 hours
Surface Sampling “Shalls”

• Sample surface at the end of compounding (before the deck is cleaned)
• Clean area after sampling
• Frequency, location and Action Levels are detailed in the Environmental Sampling plan and written PnP
Surface Sampling “Shalls”

- LAFW = laminar flow
- LLF = left laminar flow
- RLF = right laminar flow
- BA = buffer area air
- AA = ante area air

**Sample Pharmacy**

**SAMPLE Environmental Viable Sampling Plan Diagram**

- Purpose of diagram is to illustrate a potential sampling plan and is not intended to suggest design or engineering considerations.

- LAFW = laminar flow
- LLF = left laminar flow
- RLF = right laminar flow
- BA = buffer area air
- AA = ante area air

**ISO Class**

<table>
<thead>
<tr>
<th>ISO Class</th>
<th>Volumetric Air Sampling Action Level CFU per 1000 liters of air/plate**</th>
<th>Surface Sampling Action Level CFU/plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5</td>
<td>&gt; 1 CFU</td>
<td>&gt; 3 CFU</td>
</tr>
<tr>
<td>ISO Class 7</td>
<td>&gt; 10 CFU</td>
<td>&gt; 5 CFU</td>
</tr>
<tr>
<td>ISO Class 8</td>
<td>&gt;100 CFU</td>
<td>&gt; 100 CFU</td>
</tr>
</tbody>
</table>

If < 1000 liters of air sampled per plate must convert to 1000 liter equivalent (e.g. If 400 liters sampled in ISO Class 7, Action Level = >4 CFU/plate)
Surface Sampling Frequency and Timing

- The chapter *does not provide any guidance* about when to perform surface sampling...other than “periodic basis”

- Factors which may influence frequency and timing include:
  - Compounding risk level (more frequently at high risk level)
  - Environmental sampling results history (more frequently at compounding facilities with no environmental sampling history)
  - Tenure of compounding staff
  - Other factors which may impact work practices
    - periods of short staffing
    - if custodial staff are assuming selected cleaning activities
    - changes in cleaning or material handling PnP
  - Consider random sampling to prevent Hawthorne Effect
Surface Sampling Frequency and Timing

• Since surface sampling is a personnel metric, it is recommended that results be associated in some way with specific personnel and specific PECs.
• Must occur at end of day to simulate worst case conditions
• Samples taken from cleanest to dirtiest

Surface Sampling Results are said to trigger the Action Level (fail) if the number of CFUs exceeds:

<table>
<thead>
<tr>
<th>Location</th>
<th>Action Level*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5</td>
<td>Greater than 3 CFU / plate</td>
</tr>
<tr>
<td>LAFW, BSC, CAI &amp; CACI</td>
<td></td>
</tr>
<tr>
<td>ISO Class 7</td>
<td>Greater than 5 CFU / plate</td>
</tr>
<tr>
<td>Buffer area/ISO 7 Ante-area</td>
<td></td>
</tr>
<tr>
<td>ISO Class 8</td>
<td>Greater than &gt; 100 cfu / plate</td>
</tr>
<tr>
<td>ISO Class 8 Ante-area</td>
<td></td>
</tr>
</tbody>
</table>
## Inspector Evaluation Metrics

<table>
<thead>
<tr>
<th>Classification</th>
<th>Volumetric Air Sample Required*</th>
<th>Gloved Finger Tip Sample</th>
<th>Surface Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5</td>
<td>&gt; 1</td>
<td>Initial</td>
<td>&gt; 3</td>
</tr>
<tr>
<td>ISO Class 7</td>
<td>&gt; 10</td>
<td>Zero</td>
<td>&gt; 5</td>
</tr>
<tr>
<td>ISO Class 8</td>
<td>&gt; 100</td>
<td>x 3</td>
<td>&gt; 100</td>
</tr>
</tbody>
</table>

* CFUs per cubic meter of air per plate (cubic meter = 1000 liters) so if < 1000 liters of air sampled per plate must convert to 1000 liter equivalent (e.g., If 400 liters sampled in ISO Class 7, Action Level = >4 CFU/plate).
## Inspector Evaluation Metrics

<table>
<thead>
<tr>
<th>Testing</th>
<th>Required Frequency in USP Chapter &lt;797&gt;</th>
<th>Suggested Best Practice Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Media Fill Testing (MFT)</strong></td>
<td>• Initially before compounding CSPs&lt;br&gt;• Every 6 months for high risk operations&lt;br&gt;• Every 12 months for low/medium risk operations</td>
<td>• Initially before compounding CSPs (10 units x 3 consecutive days)&lt;br&gt;• Weekly for high risk (at least 10 units)&lt;br&gt;• Monthly for low/medium risk (at least 10 units)</td>
</tr>
<tr>
<td><strong>Gloved Fingertip Sampling</strong></td>
<td>• Initially during garbing x 3&lt;br&gt;• During MFT every 6 months for high risk operations&lt;br&gt;• During MFT annually for low and medium risk operations</td>
<td>• Initially during garbing x 3&lt;br&gt;• During MFT weekly for high risk&lt;br&gt;• During MFTs monthly for low/medium risk</td>
</tr>
<tr>
<td><strong>Surface Sampling</strong></td>
<td>• “Periodic”&lt;br&gt;• Policy/procedure and forms must define when, where and how surface sampling occurs</td>
<td>• Weekly for high risk&lt;br&gt;• Monthly for low/medium risk</td>
</tr>
</tbody>
</table>
Polling Question

Which of the following are considered personnel metrics?

1. Viable Air Sampling
2. Surface Sampling
3. Gloved Fingertip Sampling
4. Particulate Counts
Summary of Personnel Metrics

• Compliance with hand hygiene and garbing as well as aseptic technique and appropriate conduct in controlled sterile compounding environments hugely influences a pharmacy’s ability to maintain a “state of control.”

• Gloved Fingertip Sampling and Surface Sampling are Environmental Sampling Metrics that measure the degree to which personnel work practices are contributing to the maintenance (or not) of a state of control.

• Work practices related to facility maintenance and Facility Environmental Sampling will be discussed after the break.