Q: Where can I find a copy of the presentation?

A: You may download a PDF of the presentation at http://bit.ly/AAH1904

Q: Where can I find a recording of the webinar?

A: All recent AAH webinars, including this one, are available to stream on the AAH Vimeo channel: <https://vimeo.com/channels/1248268>

Q: Can the two NIOSH 797 rooms share the anteroom?

A: A clarification of terms is in order before answering the question. Compounding under Chapter 797 is limited to non-hazardous sterile compounding. Sterile compounding using a hazardous (or highly potent drug-see NIOSH List of Hazardous Drugs) drugs is covered under USP Chapter 800. A typical configuration would locate an ante-room in between a positive pressure sterile compounding area for non-hazardous sterile preparations and a negative pressure sterile compounding area for handling sterile hazardous drug preparations. Air flow generally would be from the positive pressure buffer room into the ante-room then into the negative pressure compounding area which is vented outside the building

Q: If relative humidity top number is 65% what is the minimum relative humidity?

A: Directly from the new 797:

* The cleanroom suite should be maintained at a temperature of 20° or cooler and a relative humidity below 60%
* The temperature and humidity must be monitored in each room of the dean room suite each day that
compounding is performed, either manually or by a continuous recording device and the data must be
retrievable.
* Temperature and humidity in the dean room suite must be controlled through a heating, ventilation, and air conditioning (HVAC) system not free-standing humidifiers/dehumidifiers and air conditioners must not be used within the classified area or within the perimeter of the SCA.

Q: What limitations are on location of hood exhaust to outdoors?

A: They should be 6“off the wall in the Buffer room to allow for cleaning behind. They should not be located under a HEPA filter inlet

Q: For the slide with the typo, please specify where the typo is.

A: The number 797 was typed 707

Q: What ceiling systems are permitted?

A: Ceilings must be cleanable. If a grid system is used, ceiling tiles must be “cleanroom grade” and must be sealed around the edges to the grid system. The grid system must be able to support the additional weight of cleanroom grade tiles. Ports should be installed to allow challenging HEPA filters for leak testing without disrupting the ceiling tile seal. Gasketed ceiling grids are not acceptable, and tiles must be sealed in place.

Q: Can you please review the ISO classifications?
A: ISO Classification of Particulate Matter in Room Air (limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])\*

|  |  |
| --- | --- |
| **Class Name** | **Particle Count** |
| **ISO Class** | **U.S. FS 209E** | **ISO, m3** | **FS 209E, ft3** |
| 3 | Class 1 | 35.2 | 1 |
| 4 | Class 10 | 352 | 10 |
| 5 | Class 100 | 3,520 | 100 |
| 6 | Class 1,000 | 35,200 | 1,000 |
| 7 | Class 10,000 | 352,000 | 10,000 |
| 8 | Class 100,000 | 3,520,000 | 100,000 |
| \* Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5 µm per m3 or larger (ISO Class 5) is equivalent to 100 particles per ft3 (Class 100) (1 m3 = 35.2 ft3). |

Q: Have you seen corner guards installed in Anterooms? If so, is there any inherent trouble with the plastic resin type with end caps?

A: If installed they must be sealed around all gaps to eliminate any gaps where dust, dirt or other contaminants might accumulate. Otherwise must be cleanable and non-reactive to cleaning agents.

Q: Pass throughs should be HEPA filtered in USP <800> walls, yes?

A: NO, HEPA filtration is not required by USP <800> for pass-throughs. However, they must have seals on the doors, and the doors must be designed with an interlocking mechanism that prevents both doors being open simultaneously.

Q: In sterile compounding - For high risk preparations, such as weighing of powders, that needs to be performed within a powder containment hood: where should this activity be performed?

A: Hazardous drugs requiring manipulation (e.g. crushing, compounding or other manipulation other than handling a finished dosage form must be done in a negative pressure room using a containment primary engineering control (examples of a C-PEC include a BSC or powder containment hood). The C-PEC must be externally vented directly, or if not, it must have redundant HEPA filters installed. Double HEPA filters are required for safety in case one filter fails, which would allow HD residue to be blown into the HD work area. Regardless of configuration the HD drug compounding area must be externally vented with a minimum of 12 Air Changes Per Hour (ACPH). The venting can be through the C-PEC or the room can be vented to the outside.

Q: Must the hood be on emergency power?

A: C-PEC’s must run continuously because these devices contain HD residue trapped on its HEPA filters. Power loss could grossly contaminate the room where these devices are contained.

Q: Does a window located between an ante room and the unclassified area need interlocking doors according to 797? Or can it be single glazed?

A: windows should be sealed and unmovable, as and little of a lip as possible. Any ledge must be easily cleanable.

Q: Can you epoxy paint a solid core wood door in lieu of using metal doors?

A: Yes, but some boards of pharmacy will not allow that for sterile, I truly do not think it is a good idea

Q: Do ceilings need to be covered to the walls?

A: Ceiling grids must be sealed with a cleanroom grade caulk or sealant at all junctions but coving is not required for the ceiling.

Q: In an SCA, do sprinklers have to be recessed per 797?
A: From new 797” If installed, sprinkler systems should be recessed and covered, and the cover should be easily cleanable.” No reference to a SCA but I would do it

Q: Can you recirculate HEPA filtered air in an HD room and exhausted directly to the exterior through the

Hood?

A: <795> yes through a double HEPA C-PEC. In sterile, no, although a BSC A2 does so within itself

Q: In an SCA, can systems furniture be utilized?

A: Do not know what systems furniture is…however, stainless steel is the preferred material. Whatever surfaces are used they must be easily cleanable and impervious to chemicals used for decontamination and disinfection.

Q: The low return-looks to be horizontal from the floor-important? Can it be vertical on the wall?

A: From 797-“Air returns in the cleanroom suite must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate.”

Q: If sink can be located outside of the Anteroom, how could it also be located on the clean side of the LOD? I could see that setup being useful if space constraints come into play, but meeting both requirements seems counterintuitive?

A: This is an Either-Or situation. Ideally the sink would be located within the ante-room on the C lean side of the line of demarcation.

Q: What are the most common deficiencies facilities find when trying to meet the new USP <800> requirements?

A: Compliance with the Chapter is not required until December 1, 2019 but Exhaust and negative pressure).01 to 0.03 WG

Q: Have you seen integration of robotics in the compounding process and how do you think they will / can affect the space design of the compounding labs?

A: If the volume is high very positive idea

Q: I'm in California, under OSHPD and their A2 Guidelines. We are designing a USP800 Sterile HD Suite. We have a Type II, B2 Bio Safety Cabinet exhausting to exterior. Does the Pharmacy Board consider this Biosafety Cabinet as a Fume Hood? The answer may affect our duct routing, rating, and assembly?

A: Need to ask California Board of Pharmacy this question.

Q: What about requirements for testing ports in the HVAC diffusers?

A: there is not a requirement but a very good idea to introduce a leak detection challenge during non-viable testing

Q: Does waste water require any treatment?

A: That is subject to the volume and type of drugs and local engineering

Q: Can pass-through cabinets be located so they connect the buffer rooms and a non-ante room area, like a work room before entering an ante room?

A: yes

Q: Can HD receiving happens in HD storage room?

A: It should ne in a dedicated stop in receiving equal or negative to adjoining spaces.

Q: Can you clarify if a separate storage room is needed for sterile and non-sterile?

A: no but must be separated within the room

Q: Can you elaborate on the bUD thresholds and effects on distances?

A: Sorry I do not understand this question, Beyond Use Date???

A: BUD meaning beyond-use-date?

Q: Do you typically use pass-through interlocking cabinets with HEPA filtration?

A: not with HEPA’s typically

Q: Does the pass thru have to open into the buffer room?

A: if can as clearly it saves ungowning

Q: Are buffer rooms required for immediate use hazardous drug prep?

A: A segregated compounding area would be more appropriate for immediate use HD preparations.

Q: Use of SS ductwork, exhaust and supply?

A: a very effective installation but frequently galvanized is used

Q: Is a line of demarcation required within all buffer rooms?

A: no only HD

Q: What is your thought on having pressurized pass-throughs to provide a transfer of product from an ISO-8 prep room into the ISO-7 NIOSH Hazardous Compounding room?

A: That worries me as the rooms are already set for proper pressure differentials, I feel a double door not pressurized is enough

Q: Is this open for types?

A: Sorry do not understand the question

Q: Why use a double HEPA over single HEPA when the number of total air change remain the same?

A: Non-Sterile-the minimum does remain 12 The logic behind redundant HEPA filtration in a powder containment hood (C-PEC) is to provide a fail-safe device in case the 1st filter in line fails. With certification occurring only every 12 months, a long time could elapse before a HEPA filter failure would ACPH but if the PEC is vented its volume plus the thimble assembly very likely will exceed 12 acph

Q: Do the ante and buffer rooms need to be ADA compliant?

A: That is a local city question, but has been argued wheel chairs cannot be sterile.

Q: Is a low return needed in the Non-hazardous prep room?

A: no but a good idea

Q: Is an Ante Room required for immediate use hazardous drug prep

A: not in Non-sterile or SCA’s

Q: For the HD storage, you noted that the ACPH was a minimum exhaust requirement. For the ante room, USP 800 calls specifically for 30 ACPH supply air versus exhaust air. For which rooms is the ACPH supply air versus exhaust air?

A: The Minimum Air change is as follows:

* Non-Sterile <800> 12 ACPH – room will require exhaust
* Sterile Not HD<797> Anteroom as of December 1…20 ACPH - ISO 8
* Sterile HD<797> <800> Anteroom as of December 1…30 ACPH – ISO 7
* Sterile ISO 7 Buffer room period …30 ACPH– room will require exhaust – room will require exhaust if it is <800>

Q: Can you clarify what the typo was on slide 17?

A: Just the number 707=797

Q: If we access a HD and a non-HD buffer room from an anteroom, do we need to have an airlock between anteroom and HD buffer room?

A: No but it is very convenient

Q: Please provide recommendations for HD Compounding in seismic zones.

A: I am not qualified to do so

Q: How do the USP requirements relate to Bio Safety Lab Class Levels?

A: This is up to a local engineer to determine what level of safety is required.

Q: Can the pass-through devices be ducted to provide pressurization differential through that device?

A: Sure, not frequently done

Q: Some of your slides indicated Ante rooms and 797 positive rooms with +0.03" pressure. Is that a typo or a change that will be in June 1 documents?

A: it was a recommendation 0.02 is Minimum I prefer 0.03 to prevent falling under 0.02

Q: Pass-throughs in illustrations are shown between compounding and buffer or anterooms. May they be placed to transition directly to main pharmacy workrooms?

A: Yes, with possible state mandated restrictions

Q: Should you not use sliding doors rather than swing doors between the buffer rooms and the anti-room?

A: Sliding doors are typically very loose and subject to viable testing issues, they are allowed

Q: Is 65% RH a typo, or is that a change coming in June 1 documents?

A: It was from a local state reference as the new <797> was not out, it is indeed 60% NOT 65%

Q: Is a pass-thru required for non-sterile/no-hazardous compounding? Can non-sterile, non-hazardous compounding occur in main pharmacy space

A: No not required

Q: Is there a minimum dimension required from pass-through to sink / doors or other pass-throughs?

A: no

Q: Want recommendations for a non-modular storefront window system? Trying to reduce ledges.

A: Which is very important but, in this format, it is not proper to do so

Q: Is there a guideline for power shut down length and will shutdowns require hood recertification?

A: There are no guidelines other than that Containment Primary Engineering Controls must run continuously.

Q: Can a gasketed grid system be used in lieu of sealing the tiles in with joint sealant?

A: From new 797: If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame.

Q: Is maximum 65% or 60% relative humidity required in the rooms?

A: 60%

Q: Do you need to seal around outlet covers in buffer rooms?

A: Sterile yes please

Q: Is there a healthcare agency that has to review and approve the design documents?

A: Yes, Pharmacies and Hospitals differ as to whom

Q: Are pass throughs permitted from a Hazardous Drug Compounding Buffer Room (ISO 7) to the general pharmacy work area?

A: After the New England Compounding issue the answer became no they may not. There is no reference to this in the new <797> or <800>. My local Board is now allowing this use now but wants it HEPA filtered, I can only suggest checking with the local authorities.