

Informal Commentary on Final Version of USP <797>

Part 1

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Introduction

The final version of USP 797 was available for free download early June 1, as promised, via the following link:

<http://go.usp.org/l/323321/2019-05-31/2dfgw>

This article is intended to provide a quick review of approximately the first half of this final version, hereafter referred to as the "FR." But first a few comments:

1. For convenience I refer to the current version, still valid until December 1 of this year, as the "CV," and the 1st and 2nd revisions as, respectively, "1R" and "2R."
2. What follows is not a complete review; I have focused on issues likely to be most important to sterile compounding: many smaller changes have not been mentioned, and in my haste may have missed even some relatively important matters.
3. If a section or subsection found in the table of contents is not commented upon, it generally means that I did not see significant changes or issues therein.
4. While the FR represents a vast improvement over the CV regarding organization and readability, there are still several sentences or paragraphs that are difficult (if not impossible) to interpret or are inconsistent.
5. Content seen as especially significant is **bolded**.
6. Very shortly a Sterile Compounding Consensus Statement, the product of the Sterile Compounding Consensus Group, will be posted on the **Compounding Today** website. This statement will be the consensus opinion of a diverse group of experts: readers are encouraged to download and read it for in depth analysis and commentary.
7. All interpretations and opinions expressed below, however, are my own.
8. I encourage readers to contact me regarding perceived errors or omissions at LRDillon123@gmail.com

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Commentary – Part 1

1. INTRODUCTION AND SCOPE

1.1 Scope

The final version retains the concept "designated person(s)" as responsible for most requirements of the chapter. This phrase appears many other times in the FR, as it does in both USP 795 and 800 - although in the latter it is always in the singular.

1.2 Administration

It is no longer stipulated in the final version that "immediate-use" CSPs may only be used in emergency situations - if several other criteria are met, namely:

Aseptic processes are used that are supported by written SOPs.

The preparation is based on sound stability and compatibility information.

Not more than three sterile products are used.

Any remaining contents in single-dose containers must be immediately discarded, and not used for another preparation.

Administration must begin within four hours of the beginning of the preparation; the current version and second draft only allowed one hour. If administration has not begun within four hours, however, the preparation must be discarded.

Unless administered by the same person who prepared it, the product must bear a label that includes (1) the names and amounts of all active ingredients (2) name or initials of the preparer (3) the four hour time period during which administration must occur.

1.4 Preparation Per Approved Labeling

Slightly elaborates on current version regarding "proprietary bag and vial systems" by stipulating that "docking" and "activating" these systems for immediate use is not considered compounding and may be performed in unclassified air.

"Docking" for future activation, however, is considered compounding and thus is subject to 797 - except for BUDs, which can be up to those set by the manufacturer's labeling.

The current version simply allows the following of manufacturer instructions.

1.5 CSP Categories

The FR has replaced the CV's "low, medium and high" risk categories with a division of all CSPs into one of two categories based upon their beyond-use dating (BUDs).

Category 1 CSPs bear BUDs of ≤ 12 hours at room temperature or ≤ 24 hours when refrigerated; Category 2 CSPs enjoy BUDs of > 12 hours at room temperature or > 24 hours when refrigerated, both if prepared as per the chapter's requirements.

2. PERSONNEL TRAINING AND EVALUATION

2.1 Demonstrating Proficiency in Core Competencies

Few changes from the second draft.

A contradiction found in the second revision remains in that Section 2.1 states that "Competency must be demonstrated every 12 months" while Sections 2.2 and 2.3 proceed to state that garbing and hand hygiene, and aseptic technique "and related processes" must be visually observed "initially and every 6 months."

As this will predictably cause significant confusion, it should be clarified.

This does however represent a retreat from the first revision, which required these activities quarterly.

See Attachment A for a summary of these changes.

Facilities with only one sterile compounder are required to obtain documented training and competency for this person, presumably through coordination with other qualified workers on site or remotely.

2.2 Demonstrating Competency in Garbing and Hand Hygiene

While Box 2.1 provides a helpful description of the steps involved in fingertip testing, Sections 2.2 and 2.3 taken together present confusing guidance as to exactly what is to be done where. Below is a preliminary consensus concerning exactly what should occur:

New compounder:

Initial

1. Observed and documented hand hygiene and garbing
2. Go into buffer or SCA
3. Don gloves outside of PEC
4. Do gloved fingertip testing without spraying with SIPA*
5. Exit the compounding area
6. Repeat two times
7. Incubate plates

Once trained but before compounding independently:

1. Now you reenter, do hand hygiene and garbing, go into buffer or SCA
2. Don gloves outside of PEC
3. Perform media fill
4. Do gloved fingertip testing without spraying gloves with SIPA in PEC
5. Exit the compounding area
6. Incubate plates

Every 6 months for all compounders:

1. Observed and documented hand hygiene and garbing
2. Go into buffer or SCA
3. Don gloves outside of PEC
4. Do gloved fingertip testing without spraying with SIPA
5. Exit the compounding area

2.2 Demonstrating Competency in Garbing and Hand Hygiene

As with prior drafts, the use of two incubation temperature ranges is required and stipulated: 30-35oC x 48 hrs then 20-25oC x 5 days

Although a new compounder might be "cleared" regarding fingertip testing within 7 days, simultaneous media fill testing will require a total of 14 days as noted below.

Although not mentioned in any version of this chapter, the daily monitoring of media for growth might detect the detection of unacceptable growth, allowing the compounder to restart the process sooner than 7 days.

The action level number of cfus for initial gloved fingertip testing after garbing has been reduced from no more than one to zero.

2.3 Competency Testing in Aseptic Manipulation

As with the second draft, media fill testing is required every six months for all categories of sterile compounding in conjunction with observed and documented sterile technique.

While the second draft allowed either for a control media fill or certificate of analysis (COA) to ensure the ability of it to support microbial growth, the final version requires a COA.

As with prior drafts, the use of two incubation temperature ranges is required and stipulated: 20-25oC x 7 days then 30-35oC x 7 days

As with the existing version and all subsequent versions, a new compounder cannot be "cleared" before 14 days.

Although not mentioned in any version of this chapter, the daily monitoring of media for growth might detect the detection of unacceptable growth, allowing the compounder to restart the process sooner than 14 days.

3. PERSONAL HYGIENE AND GARBING

3.1 Personnel Preparation

Similar to 2R. A clause prohibiting "electronic devices that are not necessary for compounding or other required tasks into the compounding area" is seen as allowing smart phones used by some compounders to communicate with the pharmacy and in some cases to take photographs.

A new clause generically allows the designated person(s) to "permit accommodations" that do not compromise the CSP or compounding environment. This vague statement is possibly designed for the sake of disabled workers.

3.2 Hand Hygiene

Blow dryers, once seen as a favored means of drying hand, continue to be prohibited.

A new Box 3-2 concerning hand sanitizing procedures is a useful addition.

3.3 Garbing Requirements

Unlike in the CV, the FR leaves the order of garbing to the facility, albeit "in an order that reduces the risk of contamination."

Just as compliance with the CV's reasonable detailed garbing order has become common, this requirement is removed. Many experts predict problems based on faulty interpretation of the phrase "in an order that reduces the risk of contamination."

Cotton garments, if low-lint, are now again allowed.

As was the case with the 2R, reusable gowns are again allowed. (The compounder should carefully note, however, that reusable gowns would be interpreted as those provided by qualified vendors - not garments washed and dried by the pharmacy.)

Importantly, gowns may now be reused if left in the buffer / SCA for "the same shift."

Again, as was the case in the second draft, the requirement for sterile sleeve covers is not present - in fact, sleeve covers are not even mentioned.

4. FACILITIES AND ENGINEERING CONTROLS

4.2 Facility Design and Environmental Controls

While 1R required compounding facilities to maintain a temperature of 20 C or lower and a relative humidity of 60% or lower, the 2R and FR make this a "should."

It should be noted that low temperatures are required for the sake of worker comfort and potential microbial growth: temperatures should be set so as to prevent perspiration on the part of heavily garbed workers.

Potential microbial growth based on small temperature differentials - especially in environments containing few if any microbes - is a minor issue.

To this end it is important to note the change from 2R's "The cleanroom suite should be continuously maintained" to FR's "The cleanroom suite should be maintained" is an important change.

Compounders at their discretion may allow for reasonably higher temperatures and humidities at times when the compounding facilities are not in use.

There are few other changes from the prior draft.

Soft-walled sterile compounding facilities or doors remain prohibited.

It is generally assumed that new language in the second draft and final version concerning a "continuous monitoring device" allows the avoidance of visual inspection and recording of temperature, humidity and pressure values, as long as out-of-range alarm systems are in place and are periodically validated, and data can be retrieved if needed.

A line of demarcation within the ante room, or two separate ante rooms, is now required, as in the second draft.

The chapter states that "Required garb must be donned prior to entering the clean side/room of the ante-room" (that is, crossing the line of demarcation).

This statement is unfortunately ambiguous in that it allows for two significantly different interpretations: (1) All garb must be donned before crossing the line of demarcation, meaning the "dirty" side must include a sink for hand hygiene (2) "Required" means what the facility SOPs require: as is the common practice now with facilities already using a line of demarcation, the worker dons shoe covers while stepping over this line, then proceeds with additional garbing and hand hygiene on the "clean" side.

Welcome clarification regarding "airlocks and interacting doors" ("pass-throughs") has been added to the final version.

The chapter specifically mentions such devices between an ante room and unclassified air area, but does not specifically mention one connecting a buffer room and an unclassified area.

It does not on the other hand forbid such devices.

What is required is that both doors must not be open at the same time, and doors should be interlocking.

Note that this language requires double-doored devices, a stipulation that will obsolete many pass-through "windows."

This double-door requirement for pass-throughs linking non-hazardous ante and buffer rooms is irrational, since, as with the door connecting these rooms, air of at least equal quality is flowing out through the device.

The concept of a segregated compounding area (SCA) remains, with almost no change in language from the second draft.

Contrary to a recent assumption, the chapter does not state that an SCA must be a separate enclosed room - although this should certainly be seen as a best practice recommendation.

Hands-free doors within sterile suites fortunately remain preferred but not required.

Such doors should not use "seals and sweeps," presumably due to their difficulty in cleaning and impediment of air flowing from room to room.

"Tacky mats" must not be used within any ISO-classified area, meaning that the common practice of placing such mats inside ante rooms is not acceptable.

While tacky mats are often seen as a best practice recommendation, they should however be placed in the ambient air environment prior to entering the ante room.

The new term "integrated vertical laminar flow zone" (LVLVZ), first introduced in the second draft, remains. It defines an arrangement whereby ISO Class 5 air flows down over a work bench from ceiling mounted HEPA filters.

While the chapter cautions that such setups are challenging to create, and smoke studies must be used to confirm air flow, it is valuable that such arrangements, which have actually been in use for decades, are specifically mentioned.

While the text states that a physical vertical barrier, e.g. a sheet of Plexiglas, must be used to direct Class 5 air within a Class 7 buffer room, many such arrangements employ Class 6 or even Class 5 air: does this "barrier" requirement apply to them as well, or is this therefore an "N/A" situation?

Common sense would dictate that if it can be shown through smoke studies and nonviable particle studies that any arrangement capable of creating an ISO Class 5 air environment in the compounding area under actual compounding situations should be acceptable.

The new term "laminar airflow system" (LAFS) is created to include both LVLFFZs and, far more commonly, laminar airflow workbenches (LAFWs) and biological safety cabinets (BSCs).

As with the second draft, LAFSs may be placed within SCAs for the preparation of Category 1 CSPs, but must be placed within a cleanroom suite if used to prepare Category 2 CSPs.

The requirement that even high tech "pharmaceutical isolators" must be placed in an ISO Class 8 room if used to prepare Category 2 CSPs, remains. This is seen by many as unfortunate in that (a) properly engineered devices are in effect miniature clean room suites presumably capable of better compounding conditions since a human being never enters the facility except via "gauntlets" (2) placing such devices in an SCA provides a cost-effective means of offering sterile compounding in many low-volume situations.

Unlike the case with temperature and humidity monitoring, minimally daily review and documentation of pressure differentials between ante and buffer rooms are still required - and this despite numerous submitted comments concerning this matter.

This is ill advised based on the widespread availability of monitoring systems like those described above for temperature and humidity.

A needed clarification first seen in the second revision remains in the final version that stipulates that at least 0.02 inch positive pressure differentials must exist between the buffer and ante room and ante room and unclassified area.

Language continues into the final version stipulating that the manipulation of nonsterile ingredients used in compounding Category 2 CSPs must occur in some form of containment ventilated enclosure (CVE), BSC or compounding aseptic containment Isolator (CACI) within a Class 8 or better room.

Remarkably, the buffer room is mentioned as a possible location for such activities even though a strong best practice recommendation would be to not perform such manipulations in this room.

4.3 Creating Areas to Achieve Easily Cleanable Conditions

Despite numerous comments submitted on this issue, and the existence of thousands of sterile compounding suites not employing "coved" flooring but nonetheless meeting all environmental

requirements, the FR continues to call this a "must." If fully enforced this provision would require major renovations for many facilities to no demonstrable end.

Features such as ledges or overhangs, forbidden in the first draft, have dropped to preferably avoided in the second and final versions.

The requirement that SCAs must be uncluttered and "dedicated to compounding," although commendable, will in the opinion of many be challenging to many hospital and clinic settings.

4.4 Water Sources

Daily cleaning and disinfection of sinks associated with sterile compounding is only required on days compounding occurs.

These sinks may be placed on either the "clean" or "dirty" side of an ante room or, remarkably near but outside the sterile compounding suite.

Most expert opinion discourages the placement of these sinks outside of ante rooms.

In the case of SCAs sinks must be placed at least 1 meter away from the PEC and not actually in the "perimeter" of the SCA.

4.5 Placement and Movement of Materials

Language remains in the final version stipulating that carts, including wheels (and by implication handheld bins, etc.) must be cleaned and disinfected if moved from the "dirty" to "clean" side of the ante room.

As this is very difficult and time-consuming, a best practice recommendation is to station a cart on each side of the line of demarcation; the same concept can be applied to "clean" and "dirty" bins.

A stipulation remains that if "equipment" is moved within a PEC that new smoke studies are required. This requirement should have included some conditional language, e.g. "significant change in position."

5. CERTIFICATION AND RECERTIFICATION

Note that "smoke pattern tests" must be formed for all PECs every six months, and these tests must be under "dynamic operating conditions" - while simulated compounding is being performed.

5.1 Total Airborne Particle Sampling

Similarly, nonviable air sampling must be conducted under such "dynamic operating conditions."

Language appropriately implies that more than one nonviable air sampling occurs within each PEC - a commonly observed issue.

6. MICROBIAL AIR AND SURFACE MONITORING

6.2 Monitoring Air Quality for Viable Airborne Particles

Fortunately, the retreat from the monthly viable air sampling required in the first draft to every six months seen in the second draft remains in the final version.

Alert levels for all ISO air classes are unchanged (see Attachment A).

As with prior drafts, the use of two incubation temperature ranges is required and stipulated: 30-35 C x 48 hrs then 20-25 C x 5 days

Two days may be saved by concurrently incubating one sample at 30-35 C x 48 hrs and another sample at 20-25 C x 5 days.

If a "fungal" media is used, they must be incubated at 20-25 C x 5 days.

The FR continues to require the identification of microbes only if action levels are exceeded.

While this means growth of 2 or more cfus for samples involving ISO Class 5 air (PECs or some rooms) still requires such identification, the action levels of >10 for ISO Class 7 and >100 for ISO Class 8 environments will significantly reduce the number of times such identification is needed in most sterile suites.

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6.3 Monitoring Surfaces for Viable Particles

Monthly surface sampling, originally appearing in the first draft, remains in the final version. At least this process may be performed relatively inexpensively by facility workers.

The monitoring of incubator temperatures may, as with facility temperature and humidity, be done via "continuous monitoring devices."

It is correctly stipulated that surface sampling should be done at the end of compounding activities but prior to cleaning.

A best practice recommendation is to perform this sampling just prior to monthly cleaning and disinfection activities.

It is also properly stipulated that sampling must include all PECs and equipment therein, work surfaces and "frequently touched surfaces," e.g. door handles.

The sampling of "crevices, corners, and spaces between surfaces" is also appropriately encouraged (but not required).

As with prior drafts, the use of two incubation temperature ranges is required and stipulated: 30-35 C x 48 hrs then 20-25 C x 5 days

Two days may be saved by concurrently incubating one sample at 30-35 C x 48 hrs and another sample at 20-25 C x 5 days.

If a "fungal" media is used, they must be incubated at 20-25 C x 5 days.

Alert levels for all ISO air classes are unchanged for ISO Class 5 and 7 but halved to 50 cfus for ISO Class 8 (see Attachment A).

7. CLEANING, DISINFECTING. AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING AREAS

7.1 Cleaning, Disinfecting, and Sporicidal Agents

This section remains poorly written and providing irrational advice.

Cleaning agents, disinfectants and sporicidal agents are appropriately enough distinguished in Table 7.

The text then state that "Surfaces must be cleaned prior to disinfection unless and EPA-registered "one-step" disinfectant cleaner is used," states that a sporicidal agent must be used, and goes on to correctly state that "Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties."

The logical outcome of this line of reasoning is that use of a one-step sporicidal agent would be all that a facility would require.

However, the text then states that "After cleaning and disinfecting or the application of a one-step disinfectant cleaner, or the application of a sporicidal agent in a PEC, apply sterile 70% IPA to remove any residue."

Yet many one-step agents do not leave residues, IPA is not an ideal solvent for residues that would exist, and the stipulated use of sterile IPA after the use of a sterile one-step sporicidal agent is an irrational waste of time and money.

Since the aforementioned sentence does not include the word "must," facilities may want to regard this as an optional step.

Of interest is the inclusion of the clause "if compounding is not performed daily, cleaning and disinfecting must be completed before initiating compounding." This is a valuable dispensation that will allow facilities to avoid the waste of time and resources.

7.2 Cleaning Supplies

It seems ill-advised for the text to state that "Wipers, pads, and mop heads should be disposable:" surely the reuse of most such products is not prudent.

Boxes 7-1 and 7-2 imply that all treatment of the interiors of PECs must involve three separate agents when at the beginning of this section it espouses the use of one-step agents.

Since it is again unclear whether these boxes represent required actions or only examples, facilities may want to assume the latter.

Current 797							New 797				
Risk Level	Cycle	Regimen	Cfu alert levels			Cycle	Regimen	Cfu alert levels			Incubation
			Within PEC	Buffer Room	Ante Room			Within PEC	Buffer Room	Ante Room	
			ISO 5	≤ ISO 7	≤ ISO 8			ISO 5	≤ ISO 7	≤ ISO 8	

Core Competencies - Personnel Qualifications	"Didactic" Training	Low, Medium	Yearly	Once per cycle	>3	N/A	N/A	Yearly	Initially, then once per cycle.	N/A				
		High	Every 6 months		>3	N/A	N/A							
	Hand Hygiene / Garbing Observation	Low, Medium	Yearly	3 initially, then once per cycle	N/A	N/A	N/A	Every 6 months	3 initially, then once per cycle	N/A				
		High	Every 6 months		N/A	N/A	N/A							
	Media Fills	Low, Medium	Yearly		0	N/A	N/A			0	N/A	N/A	20-25°C x 7 days then 30-35°C x 7 days	
		High	Every 6 months		N/A	N/A	N/A							
	Aseptic Technique Observation	Low, Medium	Yearly		N/A	N/A	N/A			N/A				
		High	Every 6 months		N/A	N/A	N/A							
	Gloved Fingertip Sampling	Low, Medium	Yearly		>3	N/A	N/A			>0 initial; >3 after	N/A	N/A	30-35°C x 48 hrs then 20-25°C x 5 days	
		High	Every 6 months		>3	N/A	N/A							
Cleaning and Disinfection Observation	Low, Medium	Yearly	N/A		N/A	N/A	When process changes			3 initially, then when process changes	N/A			
	High	Every 6 months	N/A		N/A	N/A								

Environmental Monitoring	PEC and SEC Certification	All	Every 6 months	Once per cycle	N/A	N/A	N/A	Every 6 months	N/A				
	Nonviable Air Sampling	All	Every 6 months		N/A	N/A	N/A	Every 6 months					
	Viable Air Sampling ¹	All	Every 6 months		>1	>10	>100	Monthly	>1	>10	>100	30-35°C x 48 hrs then 20-25°C x 5 days; 20-25°C x 5 days if fungal media ²	
	Surface Sampling ¹	All	Every 6 months		>3	>5	>100	Monthly	>3	>5	>50	30-35°C x 48 hrs then 20-25°C x 5 days; 20-25°C x 5 days if fungal media ²	

1 - if any growth, current version requires identification of microbe; final version does not unless action levels are exceeded

2 - Two days may be saved by concurrently incubating one sample at 30-35°C x 48 hrs and another sample at 20-25°C x 5 days.