COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

NOTICE OF A SPECIALLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY

October 18, 2018
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Beth Rabasco, Phone: 617-624-5291 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Contact
4:00	**I**	**CALL TO ORDER**	M. Godek
	II	**APPROVAL OF AGENDA**	
	III	**FLEX** • Pharmacy Substance Use Disorder Program(PSUD)- Appointment of Pharmacy Technician to the Rehabilitation Evaluation Committee	
	IV	**REGULATIONS** • 247 CMR 17.00 – Sterile Compounding	
8:00	**V**	**ADJOURNMENT**	

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
October 18, 2018

Board Members Present

Michael Godek, RPh. President
Andrew Stein, Pharm D, RPh. President Elect
Kim Tanzer, PharmD, RPh. Secretary
Susan Cornacchio, JD, RN
Patrick Gannon, RPh
Julie Lanza, CPhT
Timothy Fensky, RPh
Sebastian Hamilton, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh

Board Members Not Present

Dawn Perry, JD
Carly Jean-Francois, RN, NP
Leah Giambarresi, Pharm D, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Heather Engman, JD Board Council
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor

TOPIC I. Attendance by roll call:

CALL TO ORDER 4:00 PM
A quorum of the Board was present, established by roll call. President M. Godek chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; P. Gannon, yes;
T. Fensky, yes; S. Hamilton, yes; M. Godek, yes

S. Hernandez joins meeting at 4:05 PM
S. Cornacchio joins meeting at 4:10 PM

Topic II. **Approval of Agenda** **TIME 4:03 PM**

Agenda October 18, 2018

DISCUSSION:
Change to Agenda: None

ACTION:
Motion by P. Gannon, seconded by T. Fensky, and voted unanimously to approve the agenda with noted changes.

TOPIC III. **FLEX** **TIME: 4:10 PM**
1. PSUD REC PT Appointment
Presented by Ed Taglieri

Ed presented the application for consideration to the Board of Pharmacy for the open Pharmacy Technician seat on the Rehabilitation Evaluation Committee (REC) for PSUD. The position has been open since July when the previous person resigned due to scheduling conflicts with a new position.

The applicant presented is Janelle Ogle, CPhT, who has cleared the background checks of: licensing, CORI, FDA, DEA and OIG list as well as being reviewed and approved by the DPH Commissioner's office. REC has reviewed the applicant and welcomes her as a member as long as the Board approves appointment. The Board has had to opportunity to review Janelle's cover letter and resume and ask questions.

ACTION:
Motion by T. Fensky, seconded by S. Hamilton, and voted unanimously to approve the appointment of Janelle Ogle, CPhT to the pharmacy technician seat on REC for a 4-year term. A. Stein abstains.

Topic IV: **Regulation** **TIME: 4:13 PM**
247 CMR 17.00 Sterile Compounding
Presented by: William Frisch, Michelle Chan and Heather Engman

The board discussed and deliberated public comment to 247 CMR 17.00 Sterile Compounding. Please find attached a grid of: Original Proposed Regulation, Public Comment, Suggested Board Action and Board input given at this and previous meetings. This is the results of Board deliberation and input.

Board staff will consolidate and update proposed language for 247 CMR 17.00 Sterile Compounding from this process and bring back to the Board at its 11/1/18 meeting for review and approval. The next step will be for the Pharmacy Advisory Committee to review and give expert input on 11/29/18 for the Board to consider at its 12/11/18 Board meeting for final edits prior to voting on executive review and promulgation.

Topic V: **ADJOURMENT OF MEETING** **TIME: 7:20 PM**

ACTION: Motion by P. Gannon seconded by J. Lanza and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. PSUD Rehabilitation Evaluation Committee appointment request, Janelle Ogle, CPhT
2. Summary of Public regarding Proposed New Regulation 247 CMR 17.00 including Board Inpute

Respectfully Submitted,
Kim Tanzer, PharmD, RPh
Secretary

Summary of Public Comment regarding Proposed New Regulation 247 CMR 17.00

****Suggested Board Actions are non-binding and subject to change**

Cite	Regulation	Party	Comment	Suggested Board Action
				Discuss the DCR concept vs. SCA If allow SCA, need to develop some additional requirements. 8.2.18 (Board): Strike DCR and add SCA.
		Allegra DePietro	The regulation does not clarify how it applies to nuclear pharmacies, although it mentions radiopharmaceuticals. The Board should be aware of FDA guidance re radiopharmaceuticals. The Board should also be aware that USP is developing a separate chapter applicable to radiopharmaceuticals that will be published in December 2018. The cost and complications of this regulation may force hospitals to eliminate services and/or outsource procedures that may be better off being kept in-house. Provides specific example in written comment.	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required.
		Atrius Health	USP 797 and 800 are currently under revision; strongly urge the Board to wait until revisions to USP 797 and 800 are finalized before implementing proposed sterile compounding regulation in order to ensure consistency.	USP <800> is complete with a 12/1/19 implementation date and the draft of <797> released at the end of July. Board staff is reviewing draft <797> for potential

				impact.
		MHA/MSHP	The proposed regulation is not aligned with evidence based practices and nationally recognized industry standards for sterile compounding. The regulation exceeds the standards in USP 797 without evidence to show improvements to patient care. Many of the proposed changes will result in increased costs and operational disruption. Need a definitions section.	Definitions to be updated upon promulgation in 247 CMR 2.00.
		Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	As written, this regulation will be an unachievable standard that will ultimate result in lack of patient access to sterile compounded medications. The regulations pose significant logistical, operational, and financial burdens that will force most, if not all pharmacies to discontinue sterile compounding. Board should align regulation with USP 797.	
		Beth Israel Deaconess Medical Center	With USP 800 deferred until 12-1-19 and USP 797 under revision it would be prudent for the Board to wait until the federal regulations have come out before completing its regulations. Federal and state regs should complement each other.	USP <800> is complete with a 12/1/19 implementation date and the draft of <797> released at the end of July. Board staff is reviewing draft <797> for potential impact.
		BMC / Horbowicz	Many sections of the draft regulations deviate significantly from current and proposed USP 797 standards. If enacted as written, Massachusetts hospitals could need to undertake massive and costly renovation projects and employ additional personnel. In a time of severe cuts to hospital reimbursement, these types of renovations and additional human resources are not only cost prohibitive, but there is no basis in evidence that requirements exceeding USP 797 will bring improvement to patients. Of notable concern, some sections specifically prohibit industry standard cleanroom designs which are commonly employed in hospitals. Where renovation is not possible, hospital pharmacies will find them shelves prohibited from compounding medications in a sterile hood for patients, and may revert back to having medications prepared at the bedside by nursing staff or physician, taking a major step backwards in medication safety practice.	

		Partners (Nuclear Medicine)	Clarify whether and how 247 CMR 17.00 applies to nuclear pharmacies. How will nuclear medicine departments and nuclear medicine technologists - under physician oversight – be regulated by the Board? How will USP 825 be used in the Board's regulatory scheme? Based on the unique nature of radiopharmaceuticals, we recommend that the regulation of sterile radiopharmaceutical preparation remain within the existing 247 CMR 13.00	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required.
		Bruce Hill	Veterinarian who is concerned about impact of 247 CMR 17.00 on veterinarian's ability to obtain necessary compounded medications.	
		Dana Farber	Dana Farber is deeply concerned the proposed regulations exceed established standards of practice and are not evidence based. Additionally, the regulations will increase costs at Dana Farber by approximately $550,000.	
		Elizabeth Golovchenko; Kathleen Hoffman; Marie Chartier; Ray Cahill; Therese Durette	Veterinarians concerned that regulation will have a profound negative impact on her ability to care for patients. Because needs of veterinary patients can vary for any number of reasons, access to compounded sterile preparations if vital to effective patient care.	
		Heiber's Pharmacy	We live in a time where compounding pharmacy is at risk for being regulated out of business. I have been doing sterile compounding for over 17 years and there have been some regulations which… increased patient safety e.g. USP 71, USP 797. There are some people who, based on theoretical rather than on a scientific basis want to enact more regulations beyond USP 71 and USP 797. In some ways, the FDA and Big Pharma would like to put "square wheels" on compounding pharmacies… Apparently passing sterility test… and all the certifications necessary to make preparations in an ISO 5 environment does not satisfy some people.	
		Jason Brenner	Supports IACP's comments.	
		Michael Blaire	Compounding pharmacist who specializes in veterinary medications. Pharmacies must be able to compound non-patient specific	Current statute does not permit dispensing medications for office

			medications in the event of shortages. 503Bs cannot produce drugs as quickly in the event of a shortage because of cGMP. The lack of availability of drugs compounded at a pharmacy has led to increased compounding by physician's offices, dental offices, and veterinary clinics. Many animals require compounded oil-based or suspension based eye drops that cannot be terminally sterilized. Reptiles require emulsions; Rabbits, birds and zoo animals frequently require antibiotic impregnated beads or pellets. It should be the prescriber's experience and the pharmacist's judgment that determines what types of dosage forms are compounded, not regulations.	use.
		National Community Pharmacists Association ("NCPA")	Closer alignment of proposed new regulation 247 CMR 17.00 with current USP guidelines, especially USP 797, will provide that balance of providing adequate regulation to ensure safety and quality while avoiding the creation of undue burden on compounding pharmacists and medication access issues for patients. A number of sections in the proposed regulation will have a costly impact on the operation and construction of small compounding pharmacy businesses. Some of the requirements will require small compounding pharmacies to hire additional employees beyond third party vendors and could deter the formation of compounding facilities in this state. The regulation would require pharmacies to make significant capital investments in facilities in order to comply. NCPA believes the fiscal effect of proposed new regulation outweighs its benefit in its current form.	
		Petnet	Nuclear pharmacy has numerous factors that distinguish it from other sterile process pharmacy settings. USP 797 and 800 to not encompass constraints involved with radioactive materials. Radiopharmaceuticals have a short half-life and that limited the BUD for the majority of products to low risk with BUD of 12 hours or less. Nuclear pharmacies are constrained by controlled distribution systems – meds are not dispensed directly to patient.	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required.
		Rye Beach Pharmacy	I have read most of IACP's comments. I am baffled about where some of the requirements are coming from. USP <797> has been written and thus successfully guided a nation of pharmacists to compound safely. When the existing rules are followed, pharmacists have been able to provide safe and effective sterile prescription medications. Not all but many of your draft propositions change or add requirements to USP <797>. If you are trying to prevent another NECC tragedy, inspecting that	

			location and properly enforcing USP <797> would have done it. If you are trying to prevent pharmacists from continuing be able to provide sterile medications at an affordable price, thus limiting patient access, the draft accomplishes this. All these "extra" requirements do not accomplish anything without proper inspections. I am in favor of having more inspections but follow the guide that has successfully worked for years. Do not write another guide which only confuses the process, adds unnecessary costs and hurts patients' access. I hope you take the suggestions from IACP as guidance from other pharmacists across the nation that have studied, researched and performed USP <797> guidelines for years. Their level of expertise and experience is far reaching so please lean on that as you decide how to shape your draft proposition.	
		Samir Melki	Supports IACP's comments.	
		Seth DePasquale	Echos many of the concerns presented by IACP. The regulation should allow for more flexibility or changes in practice. Basically, arguing for performance standards rather than design standards. Opposed to use of CETA's application guides. Regulation is an overreach; drive by fear and without rational thought and scientifically backed evidence.	
		Southcoast Health	Southcoast largely signs on to MHA's comments, while adding some of its own comments as well.	
		Valerie Sullivan	247 CMR 17.00 will severely limit, if not completely eliminate, access to sterile compounded medications to those patients who benefit. To me, the benefits of compounded medications for patients must be preserved by the Commonwealth. Specifically, the sections regarding environmental monitoring, personnel monitoring, analytical testing, and facility construction are so burdensome and such a far departure from the nationally accepted standards found in USP <797> that pharmacies will not have the resources necessary to meet these unprecedented regulations. That is bad for patients.	

			There have been suggestions by knowledgeable experts in compounding that the Board of Pharmacy seek to align state regulations regarding sterile compounding with standards found in USP <797>. Aligning with USP <797> will provide adequate regulation with respect to safety and quality measures associated with sterile compounding while still permitting patient access to sterile compounded medications. Please do not implement regulations that are so restrictive that patients will be denied access to important sources of medication therapy.	
17.01	Authority and Purpose	Berkshire Health Systems	Clarify who this regulation applies to.	"247 CMR 17.00 applies to pharmacies that hold a sterile compounding pharmacy license, non-resident sterile compounding pharmacy license, or institutional sterile compounding pharmacy license."
17.02(1)	A pharmacy licensed by the Board shall comply with 21 U.S.C. § 353a, M.G.L. c. 94C, §§ 17 & 22, and M.G.L. c. 112, § 39F. A pharmacy may not dispense a compounded sterile preparation ("CSP") prior to receipt of a patient-specific prescription.	MHA/MSHP Blaire Pharmacy Consulting BMC / Horbowicz Cardinal Health GE Healthcare Jamie Resnick	Regulation does not specify requirements for medication orders seen in the institutional environments vs commercial areas that are based on a prescription. Most hospital systems rely on the ability to dispense compounded preparations to ADMs and clinic areas for use. Blaire: M.G.L. c.112 Sec. 58A1/2 allows a pharmacy to distribute compounded preparations for veterinary office stock, and for veterinarians to dispense up to a 5 day supply of compounded office stock medications to a patient. Add language: unless said CSP is distributed in compliance with M.G.L.c.112 Sec.58A 1/2. Cardinal: Diagnostic radiopharmaceuticals are often dispensed without a patient name available such as in the case when radiopharmaceuticals are provided to a nuclear medicine department for use overnight in the event of a patient presenting to the hospital's ED. GE: Make an exception for radiopharmaceuticals. Due to the special nature of radiopharmaceuticals, nuclear pharmacies should be able to dispense without prescription provided the pharmacy obtains the prescription information within 72 hours after dispensing. Resnick: Prohibition on office use medication will adversely affect	Clarify to: "…patient-specific prescription **or order**." ADM's should not "release" a drug without an order. Need to discuss "clinic use". 8.2.18 (Board): There are emergency cases. A provision for emergent radiopharmaceuticals without a patient name already exists. Current statute does not permit dispensing medications for office use. Suggested language: "A pharmacy shall only dispense a compounded sterile preparation ("CSP") pursuant to a patient-specific prescription or order."

			veterinary patients.	10/18/18 Board: use language above
17.02(4)	A pharmacy shall train its employees annually in lean concepts, in accordance with M.G.L. c. 112, § 39G. Lean concepts are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency.	IACP BioScrip	Strike this requirement, as it is too broad and is difficult to understand both the expectations for compliance and overall benefit to public health. Requirement of lean concepts training is beyond the scope and mandate for Board. The cost and value should be proven by study before such a requirement is imposed.	No change; this is a statutory requirement.
17.03(2)	A pharmacy may not pool or prepare stock solutions utilizing single dose vials to extend a beyond use date (BUD) beyond 6 hours after puncture within ISO Class 5	MHA/MSHP BMC / Horbowicz Dana Farber Mount Auburn Southcoast BioScrip	MHA: Use current USP <797> Standards for a Medium Risk Product in the absence of sterility testing: BUD = 30 hours RT or 9 days Refrigerated OR use draft version of the 2015 USP <797> for a Category 2 product in the absence of sterility testing, no preservative added, prepared from sterile starting components BUD = 6 days RT or 9 days refrigerated MHA / Mt. Auburn: Clarification requested: (1) As drafted this statement appears to imply that there is a specific practice of pooling SDV with the intent to extend a BUD. It is reasonable and well within <797> to draw up two 1G SDVs of vanco into one syringe (i.e. pooled) and inject into a bag. Is the intent of this requirement to eliminate this type of compounding? (2) Is the intent to make it crystal clear that pooling SDVs does not alter the 6 hour BUD requirement assigned to puncture SDV in an ISO5 space? In other words, pooling of SDV to make a single dose or multiple doses is a necessity of practice however, that pooled solution only has a 6 hour BUD? If left as written, pharmacies will have increased waste and FTE requirements to sustain operations for short dated pooling solutions. Patients will be subjected to multiple stops and changes in IV infusions, increasing the risk for central line blood stream infections. Some critical medications can only be prepared by pooling solutions of single dose vial, such as IVIG, Lasix drips, terbutaline infusions, glucagon infusions, etc. This section will introduce impractical and less safe barriers to delivering such life-saving medications to patients. Dana Farber: Consider allowing vial to be 12 hours BUD, if mixed in ISO 5 within and ISO 7 buffer room. These conditions listed are	Recommend to strike. USP standard is already clear enough. Note: revised USP <797> on stock solutions. The compounded stock solution must only be entered or punctured in an ISO Class 5 or cleaner air. It may be used for up to 6 hours after initial entry or puncture. The remainder must be discarded.

			equal to the risk level similar to 17.05 (DCR). BioScrip: The prohibition on pharmacies not pooling utilizing single dose containers in CSPs with a BUD beyond 6 hours is impractical for patients and providers compounding TPN. This narrow BUD window will make the provision of care currently provided nationwide without incident impossible.	
17.05	A licensee shall prepare a non-hazardous, non-radiopharmaceutical, low risk level CSP with a 12 hour BUD at room temperature or 24 hour BUD refrigerated in an ISO Class 7 buffer room or an ISO Class 8 dedicated compounding room ("DCR") equipped with a commercially manufactured Primary Engineering Control ("PEC") such as a laminar air flow workbench ("LAFW") or biological safety cabinet ("BSC") and shall comply with all other provisions of 247 CMR 17.00, unless otherwise provided.	Allegra DePietro MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Partners (Nuclear Medicine) Dana Farber Partners Healthcare	This provision is not consistent with USP 797 because it does not allow low risk, 12 hour BUD radiopharmaceuticals to be compounded in segregated compound area. Most radiopharmaceuticals have 12 hour BUD due to short half -lives of radioactive drugs. The proposed regulation runs contrary to current practice with radiopharmaceuticals. Partners: How does this provision apply to nuclear pharmacies? MHA: Recommend make this provision consistent with current USP 797 standard, proposed new USP 797 standard, or retain the 12 hour BUD restriction but remove "in an ISO Class 7 buffer room or an ISO Class 8 dedicated compounding room" and replace with "in a segregated compounding area, per USP 797 standards." MHA: The existing rule is suitable for satellite pharmacy areas that employ a hood for just in time compounding, such as emergency departments and operating rooms and allergy ambulatory clinics. The new proposed regulation would cause massive costly renovations and/or would force nurses and doctors to compound at bedside instead of in a hood. MHA: **(1)** Why would a PEC located in an ISO Class 7 buffer room be required to meet the Low Risk Level 12-hour Room Temperature or 24-hour Refrigerated BUD? **(2)** A PEC is defined as a device or zone that provides an ISO Class 5 environment for sterile compounding. Therefore, a CAI or CACI would fit the definition of a PEC. It is our interpretation that the 12-hour room temperature/24-hour refrigerated BUD language in 17.05 could also apply to a CAI or CACI located in a DCR. Is this correct or would a CAI/CACI located in a DCR have the BUD listed in 17.16, namely, 36 hours room temperature or 9 days refrigerated? **(3)** Massachusetts pharmacies are preparing to meet requirements for both the draft 247 CMR 17.00	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required. Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited. Suggested language: "A licensee **may** prepare a non-hazardous, non-radiopharmaceutical, **low risk level** CSP with a 12 hour maximum BUD at room temperature or 24 hour maximum BUD refrigerated **in a unclassified segregated compounding area (SCA)** equipped with a commercially manufactured **positive pressure** Primary Engineering Control ("PEC") such as a laminar air flow workbench ("LAFW") or ~~biological safety cabinet ("BSC")~~ compounding aseptic isolator (CAI) and shall comply with all other provisions of 247 CMR 17.00, unless otherwise provided"

			regulations and the draft revised USP Chapter <797>. In the draft revised <797>, the term RABS (Restricted Access Barrier System) refers to CAIs and CACIs. Under Section 4.2 (Facility Design and Environmental Controls) subtitle RABS of the draft revised <797> it states: "If used to prepare Category 2 CSPs, the area surrounding the RABS must meet ISO Class 7 or better air quality." It is our interpretation that a CAI/CACI could be placed in a DCR meeting an ISO Class 7 air quality. Our position is further based on 247 CMR 17.00 Section 17.15 (3) (Dedicated Compounding Room ("DCR")) which states that "A DCR shall: Be ISO Class 8 or better." Therefore, a CAI/CACI placed in an ISO Class 7 DCR would allow the pharmacy to meet the criteria for compounding Category 2 CSPs per the draft revised USP <797>. Why would this interpretation not be correct? Partners: There are hospitals in the Partners network that currently have segregated compounding areas within the pharmacy that are not ISO classified. These facilities are in the smaller community hospitals in which they compound all medications for their inpatient census. Many of the Partners hospital currently service operating room, emergency departments, and ambulatory infusion clinics that have primary engineering controls in an area that is not ISO classified. The regulation will not allow community pharmacies to provide patient specific compounded medications.	Note: BUD aligns with Category 1 in newly revised draft <797>
17.06(1)	A pharmacy may not engage in high risk level sterile compounding until and unless the pharmacy: (a) submits an attestation of intent to engage in high risk level sterile compounding signed by the manager of record, pharmacist in charge of sterile compounding, and licensee, as applicable; and (b) receives notification from the Board stating the pharmacy achieved a satisfactory Board inspection specifically pertaining to high risk level sterile compounding. All costs associated with inspections of non-resident sterile compounding	IACP	Need to add an effective date. Need clarification on who will be conducting non-resident pharmacy inspections.	Recommend to strike as requirements will be outlined in licensing regulation.

	pharmacies shall be paid by the non-resident pharmacy or applicant.			
17.06(2)	A pharmacy may not prepare high risk level CSPs in suspension, emulsion, pellet, metered dose inhaler, or depot form.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Blaire Pharmacy Consulting Kelly Barnes	The proposed regulation does not take into consideration drug shortages and lack of patient access. Recommend update language to reflect these dosage forms may not be dispensed without successful completion of process and sterilization validation and evidence of stability throughout the duration of BUD. Blaire: Numerous sterile suspensions, emulsions, pellets and depot formulations have been compounded for veterinary patients for over 2 decades. This rule anticipates these dosage forms being found "Too Difficult to Compound" by PCAC. Since PCAC's recommendations will not be finalized for some years, language should read: A pharmacy may not prepare high-risk level CSPs that have been deemed "too difficult to compound" by FDA. Barnes: Change to "A pharmacy may not prepare high risk level CSPs **identified as demonstrably difficult to compound by the FDA or the Board**."	Suggested language: "A pharmacy may not prepare high risk level CSPs identified as demonstrably difficult to compound by the FDA or the Board."
17.06(3)	A pharmacy may prepare high risk level CSPs with components the pharmacy sterilized by different sterilization methods so long as the final patient CSP is sterilized prior to dispensing.	Blaire Pharmacy Consulting	Many CSP require the combination of pre-sterilized ingredients (e.g.: PZI Insulin, Cyclosporine Ophthalmic Drops) because it is impossible to sterilize the final product. Section should be struck or language should be changed to: ...so long as sterility of the final patient CSP is confirmed.	Recommend to strike. See 17.06(7) edits.
17.06(4)	A pharmacy may not utilize lyophilization equipment to prepare lyophilized drug substances or ingredients used in CSPs.	Anazao Health	Recommend strike this provision or modify to allow lyophilization in a sterile environment in a buffer room. DMSA (dimercaptosuccinic acid) is only available from a compounding pharmacy. It is a nuclear medicine where technetium 99m is mixed in a lyophilized kit at the hospital. It is the only diagnostic agent for detecting polycystic kidney disease in children. The prohibition on lyophilization would adversely impact patient care.	No change recommended.
17.06(5)	A pharmacy may not compound a component of a CSP from API when a version of that component is commercially available.	MHA/MSHP IACP Johnson Compounding / Walczyk /	It is necessary to compound components of CSP in the case of a drug shortage. Recommend add "unless products are on the national drug shortage list." Strike this requirement. Regulation does not account for drug shortages, that final concentrations of compounded preparations may not be achievable using only commercially available products, or that	The proposed regulation already accounts for commercial availability. 8.2.18 (Board): Review FDA bulk compound guidance. May not be available but not on the FDA drug

		Fallon / Allibhani / Petrosillo MIPA NCPA Patrick Carpenter BioScrip	commercially available products may have excipients an other ingredients that are intolerable to the patient. NCPA: Remove requirement. Commercially available products may contain excipients that are intolerable to a patient and compounding from APIs may be necessary. Carpenter: Language is unclear. If the meaning is that commercially available drugs should be used as ingredients in a compound rather than API being used as ingredients in a compound, this will add considerably to the cost of compounds and I believe restrict patient access. Commercially available phentolamine from Bedford labs costs $200 for 10 mg. Phentolamine APA costs 1 cent for 10 mg. BioScrip: This could possibly expose patients to unneeded or dangerous exceptions or other additives, when a safer more patient appropriate source of the drug is available.	shortage list. Board staff update: Guidance on bulk drug substances does not include any reference to drug shortages. 10/18/18 Board: edit definition of commercially available; ie. not available through usual channels FDA Guidance: **Commercially Available Drug Product** For purposes of this guidance, a drug product is commercially available if it is a marketed drug product. We do not consider a drug product to be commercially available if • the drug product has been discontinued and is no longer marketed or • the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act. A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database Compounding definition: MGL 112 section 39d: "a price difference shall not be a significant difference

				to justify compounding"
17.06(7)	A pharmacy shall sterilize the final preparation of a high risk level CSP. A pharmacy shall ensure the sterility of the final preparation of a high risk level CSP in accordance with USP 71.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Blaire Pharmacy Consulting Pentec	This requirement is not practical. Change to: "A pharmacy shall sterilize the final preparation of a high risk level CSP. A pharmacy shall perform sterility testing on high risk level CSPs in accordance with USP 797. Sterility testing shall be performed in accordance with USP 71." Blaire: See comment to 17.06(3). Pentec: For 503A pharmacies making one dose for one patient pursuant to a prescription, it is impossible to quarantine a high risk compound with a 3 day BUD until results of USP <71> have been received. In addition, in order for a pharmacy to dispense one syringe, they will need to compound 5 so a minimum of 4 (10% or 4, whichever is greater)* can be tested to be compliant with USP 71.	Suggested language: Prior to dispensing, a pharmacy shall sterilize the final ~~**dispensed**~~ preparation of a high risk level CSP. ~~A pharmacy shall ensure the sterility of the final preparation of a high risk level CSP in accordance with USP 71.~~ Consider combining with 17.39(3) (see below) to have one standard. Requirements for sterility testing are covered elsewhere. 10/18/18 Board: accept suggestions; adjust language
17.06(8)	A pharmacy may not dispense a high risk level CSP without preservatives unless the CSP is dispensed in a single use container and labeled as "single use only."	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center NCPA	Strike this requirement or modify to permit multiple doses of preservative free CSP so long as the container is verified to prevent contamination. This provision does not allow for advancement in device technology. There are medications that are in very short supply and/or very expensive. They can be repurposed in sterile SD vials for 9 day BUD to save drug for later use in patients. NCPA: Remove requirement. Technologically advanced multiple use containers are currently available that prevent contamination of preservative free formulations of high risk level CSPs.	Preservative-free multiple use containers are not specifically addressed in the most recent <797> chapter. Most recent USP 797: "A compounded single-dose container is intended for one-time administration (e.g., injection, infusion, case) for a single patient." Consider adapting language to include containers that have been validated to prevent microbial growth. 8.2.18(Board): Reword to include technology.

				Suggested language: A pharmacy may not dispense a high risk level CSP without preservatives unless the CSP is dispensed in a single use container and labeled as "single use only", **unless said container has been validated to prevent contamination of the CSP**. 10/10/18 Board: accept language above
17.07(1)	A BUD must be calculated from the time of compounding and shall include the time a drug will reside inside an implantable infusion pump reservoir.	Anazao Health MHA/MSHP Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Mt. Auburn Hospital Pentec BioScrip	Anazao: Modify language to comply with current USP 797 standards and also meeting CETA application guide which is referenced in USP 797. MHA: It is not industry standard to include the time the drug is inside the reservoir in the calculation of a BUD. This regulation creates unnecessary extra steps, time, and effort that could impact patient care for products that do not need to be treated any differently than any other CSP. MHA: According to 17.41, the max BUD is 14 days (refrigerated) or 48 hours (room temp). Including the dwell time in this BUD would be nonsensical and result in patient needing to change pump more frequently, increasing risk of infection, etc. The BUD should include the infusion time but not the dwell time. Drug delivery would not be possible if BUD included pump infusion time. MAH: Adjust so that BUD may not extend beyond infusion time. Pentec: Adhere to the USP <797> definition of beyond use dating surrounding low, medium and high risk compounds. Amending the BUD definition as proposed in this regulation for implantable pumps will decrease the life of the pump septum and increase the patient's potential for infection with each additional access.	Most recent USP <797>:"The BUD is determined from the date/time that preparation of the CSP is initiated. The BUD is not intended to limit the time during which the CSP is administered (e.g., infused)." January 2014 General Session Board Minutes:"…[Pharmacy name] will not compound unapproved CSPs or unapproved combinations of CSPs unless and until it obtains scientific evidence demonstrating that the CSPs maintain their stability and sterility for the entire time they are present in the infusion pump." Unanimous vote. 8.2.18(Board): Demonstrate stability and sterility from a relevant and reliable source. Reword the language.

			Medtronic pump puncture life is 500 punctures (Medtronic Synchromed II Programmable Pumps, page 8 Table 2). With the average fill rate of every 57 days (based on our patient population) the septum puncture life is well within the life of the pump. Changing the BUD for high risk to include dwell time would mean a fill every 3 days, drastically reducing the life of the pump. Patients and insurance companies would bear the undue financial burden of medication being unnecessarily dispensed and refilled every 3 days. BioScrip: This requirement is onerous and impractical. The manufacturer of the device should provide guidance for this matter. Further, what is the direction from the Board if the patient's supply should run beyond the calculated BUD provided by the pharmacy?	Suggested language: "A pharmacy shall obtain documentation from reliable and relevant sources demonstrating that CSPs intended for implantable infusion pumps maintain their stability and sterility for the entire time they are present in the infusion pump." **10/18/18 Board: Discuss with Advisory Committee**
17.07(2)	In addition to standard prescription labeling requirements, a pharmacy shall include the date of compounding on the label for CSPs prepared for administration by an implantable pump.	Dana Farber Pentec	DF: Recommend aligning with USP 797 for BUD definition stating the date after which compounded prescription shall not be used. Consistency with BUD dating definition will cause less confusion and more consistent practice. Pentec: Remove this provision. Including a second date on the label will cause confusion. Additionally, software may not allow the formatting change.	Recommend to strike.
17.08	CSPs as Stock Solutions	NCPA	Align this section with USP 797.	**Board Discussion** **Revised <797>** **14.2 Use of Compounded Stock Solutions** A compounded stock solution is a sterile mixture of components that is used to prepare CSP(s). The compounded stock solution must be stored according to storage conditions for the BUD assigned. The compounded stock solution must only be entered or punctured in an ISO Class 5 or cleaner air. **It may be used for up to 6 hours after initial entry or puncture.** The remainder must be discarded.

17.08(1)	A pharmacy that prepares intermediate or stock solutions from commercially available sterile components, excluding the pooling of commercially available single dose vials, may not assign a BUD that is longer than a medium risk BUD in accordance with 247 CMR 17.41, to each intermediate or stock solution.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Strike this requirement. If preparing a low risk-level intermediate solution, low risk dating should be applicable and acceptable. USP <797> allows for extended dating for all risk levels, so long as a sterility and stability program has been established for that specific preparation. If sterility testing in accordance with USP <71> has occurred and there is evidence to support stability beyond USP <797>, what is the justification to limiting dating to medium risk?	Recommend to strike.
17.09	CSPs made with a patient's blood-derived or biological material	MHA/MSHP Cardinal Health Dana Farber	**Recommendation:** remove this section entirely or change this entire section to be specific to biohazard material only. This should not apply to sterile albumin and/or Intravenous Immune Globulin. The policies and procedures should be no different from any other CSP **Clarification requested:** 17.09 as written is specific to using blood derived or biologic material from a single patient ("a patient's").Statements in this section, if read alone may be confusing as they do not reiterate the single patient piece. IVIG is a marketed FDA approved product and the active ingredient is derived from human plasma (blood). This requirement should not apply in the case of IVIG and under the heading of 17.09 it would not. Recommend clarifying sub-points in this section to make it clear. Cardinal: A patient dose of radiolabeled autologous leukocytes is not a CSP. Patient's blood derived or biological material is assumed to contain pathogens. The end product is not sterilized but is returned to the patient from whom it was obtained. A radiopharmaceutical made with a patient's blood derived or biological material is handled aseptically in and ISO class 5 BSC, but the resultant end product is not sterile and not a CSP. Dana Farber needs further clarification: After step (a), do staff doff garb as described in 17.30 (13) a-c? Step d would be eliminated if the pharmacist will return to the buffer room. Is the intention to allow re-use of the garbing, as in 17:30(12), or to doff and dispose? Does the "hand hygiene" referred to in (b) refer to the hand hygiene described in 17.30 6(a)? Also recommend giving examples of Blood-derived or Biological material as guidance as to which products should be	Suggested language: "CSPs made with **a patient's own** blood-derived or other biological material" Change throughout the section.

			classified under this category. Is this meant to include all medications such at vaccines, Immune globulins, Insulin, growth factors same as blood factors?	
17.09(2)	The procedures for compounding CSPs using blood-derived or other biological material shall require compounding to be separate from routine material-handling procedures and must describe cleaning of PEC and other equipment used in CSP preparation in order to avoid cross-contamination.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Need definition for "blood derived" and "other biological material" so that substances such as insulin are not misinterpreted as being a biological material.	See above.
17.10	Allergen Extracts as CSPs	BioScrip	This section restricts compounders from their usual and customary practices. Consultation of the conditions and processes required for the compounding of these extracts should come from the manufacturers of these extracts. The House sub-committee has questioned the USP's meddling in this very issue, and has cautioned that USP 797 was beyond its mandate as well as the intent of Congress as outlined with the DQSA.	8.2.18(Board): Review the most recently revised <797> for allergenic extracts. Recommend striking 17.10 (2) and (3) and retaining (1): A pharmacy shall prepare allergen extracts in accordance with 247 CMR 17.00. 10/18/18 Board: as above agree with 247 CMR 17
17.12	Sterile Compounding Facility; General	Beth Israel Deaconess Medical Center	BI: Many clinics that do not have cleanrooms but treat patients with sterile product, this poses treatment concerns for patients.	Pertains to the SCA as below.
17.12	Sterile Compounding Facility; General	Kelly Barnes	Recommend adding requirement that sterile compounding pharmacy be maintained under clean and sanitary conditions. Recommend adding requirement that pharmacy shall maintain on the pharmacy premises a current copy or electronic version of references/resources to sterile compounding appropriate to the practice stetting approved by the manager of record.	Agree with comment. 8.2.18(Board): No addition.
17.12(1)	A licensee may not conduct sterile compounding in a segregated compounding area that is not ISO classified.	MHA/MSHP Boston Medical	Recommend following the standard proposed in new USP 797: Category 1 CSPs may be compounded in a PEC located in a segregated compounding area. Segregated compounding areas are necessary for ambulatory clinics and procedural areas. The alternative	Suggested language: "A pharmacy may utilize a segregated compounding area

		Center / Horbowicz / Vreeland Dana Farber	is immediate use compounding on the countertop, which is clearly inferior to compounding inside a PEC. It is critical to maintain the designation of segregated compounding areas for institutional pharmacies in order to maintain safe medication practices, such as those currently provided by the ED and OR satellites in our facility. The alternative could be to continue to perform compounding under immediate-use standards, but on a wiped down countertop, rather than inside of a hood. Clearly this is inferior to compounding the product inside a PEC. If left as written, hospitals are prohibited from using PECs anywhere outside of an ISO 8 or better room, even where we may desire to use a PEC in the setting of immediate use compounding. In many satellite operations outside of an Emergency room, a 1hr BUD is impractical and the 12 hour BUD permissible by USP 797 allows more than sufficient time for administration. This is safe and effective without the need for costly renovations to achieve an ISO 8 environment. If left as written, hospital pharmacies will not be able to continue providing service to many ambulatory infusion clinics and procedural areas such as ORs and Emergency Departments. Compounding outside of a PEC will still take place, but will be a set-back in medications safety practices for Massachusetts. Also see impact comments for 17.05 Possible conflict with 17.15(1)(e).	(SCA) if it holds an institutional sterile compounding pharmacy license, issued under M.G.L. c. 112, § 39I ~~and the CSPs are administered on site~~." 10/18/18 Board: accept as above
17.12(2)	Each ISO classified area built after January 1, 2017, shall allow for visual observation of the classified space from outside the classified space through windows or technology.	Kelly Barnes NCPA	Adjust date. NCPA: Extend deadlines to 18 months post-promulgation.	Suggested language: Newly constructed ISO classified areas shall allow for visual observation of the classified space from outside the classified space through windows or technology.
17.13(2)	An ISO Class 8 room shall maintain a minimum of 20 air changes per hour.	IACP	Strike this requirement. The origin of 20 air changes per hour is unclear. USP 797 does not have an air change requirement for ISO 8 environment.	No change recommended. Required by newly revised USP 797.
17.13(3)	The air changes shall come from the HEPA filtered air. HEPA filtered air shall be introduced at the ceiling. Any air exchanges supplied to buffer	MHA/MSHP IACP	Adjust language to allow for the addition of PEC air in the calculation in order to be consistent with USP 797 and CETA guidelines.	**For Board discussion.** If minimum ACPH depends on PEC and PEC fails, the ISO7 room

	room from the PEC must be in addition to the 30 air changes per hour ("ACPH").	Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital Patrick Carpenter		would be non-compliant with the standard. 8.2.18(Board): Review CETA guidelines. CETA allows 15ACPH from PEC. Recommend a grandfathering provision related to renovations or new builds. Suggested language: The air changes shall come from the HEPA filtered air. HEPA filtered air shall be introduced at the ceiling. **For newly constructed buffer rooms** any air exchanges supplied to buffer room from the PEC must be in addition to the 30 air changes per hour ("ACPH"). 10/18/18 Board: accept as above
17.13(4)	A pharmacy may not utilize any ISO classified area for both sterile and non-sterile compounding.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Brigham and Women's Faulkner Hospital Dana Farber Southcoast	This should be a best practice rather than a requirement. This provision would prohibit satellite pharmacies – especially pediatric satellites – from compounding non-sterile medications routinely needed for patients because they also compound CSPs in the same room. BMC: Recommendation: "A pharmacy should not routinely utilize ISO Class 5 areas for both sterile and non-sterile compounding without thoroughly cleaning between compounding sessions." Wording should reflect USP 800: "For occasional nonsterile HD compounding, a C-PEC used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding." Hospitals with minimal non-sterile HD compounding needs need to be able to use sterile compounding PEC or they will be forced to install costly, underutilized non-sterile hood.	For Board discussion. Preliminary review of revised draft <797> - does not appear to be addressed. 8.2.18(Board): Get some more information from stakeholders. Recommend to edit to specify non-HD environments and recommend addressing HD issues in 247 CMR 19.00. Suggested language: A pharmacy may not utilize any

		BioScrip	Southcoast: Agree with the recommendation made by MSHP/MHA regarding the use of a shared use of the negative pressure BSC for hazardous non-sterile compounding in addition to hazardous sterile compounding. As long as there is a thorough disinfection (cleaning procedure) in between compounding sessions (sterile and non-sterile) , pharmacy personnel will be able to safely compound hazardous non-sterile compounds , especially in those pharmacy locations where there is limited space and an additional BSC for hazardous non- sterile compounding is not feasible. BioScrip; This is inconsistent with current USP guidance. The use of sterile areas for some limited non-sterile compounding may occasionally be in the best interest of patients. Pharmacies are capable of thoroughly cleaning and disinfecting these areas.	**non-hazardous** ISO classified area for both sterile and non-sterile compounding. 10/18/18 Board: accept as above
17.13(7)	Beginning January 1, 2018, the doors to ante rooms and buffer rooms shall be constructed with an interlocking design to prevent the ante room door and buffer room door from opening at the same time.	Atrius Health MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center Cardinal Health GE Healthcare	The implementation date is not realistic. Interlocking doors are extremely costly. Consider alternative such as alarm system so that only one door can be open at a time. Consider pass through designed as an ISO class 5 HEPA filtered device with 1 minute air purge between ISO class 7 buffer room and unclassified space. This could decrease the amount of traffic/activity between ante and buffer rooms. Costly; timeline not practical. GE: Compliance with the rule as written poses a substantial safety risk to workers. Recommend adding "… or an audible and/or visual alarm to deter personnel from opening doors at the same time." Lynch: Clarify whether this is new construction only? Does this apply to all existing rooms (including non-modular)? Barnes: Adjust date. Add "If prohibited by fire code, a pharmacy shall implement a passive interlock system to prevent both doors from being opened at the same time. NCPA: An interlocking design is very costly and may not be possible to implement in all sterile compounding labs without extensive	Adjust implementation date. Clarify to: "…constructed with an active or passive interlocking design…" Suggested language: Beginning <date>, the doors to ante rooms and buffer rooms shall be constructed with an **active or passive interlocking** design to prevent **or minimize** the ante room door and buffer room door from opening at the same time. 10/18/18 Board: accept as above

		Jeffrey Lynch Kelly Barnes NCPA	reconstruction.	
17.13(9)(c)	A pass through shall not have an opening larger than 4 square feet.	GE Healthcare	Delete this provision. Nuclear pharmacy operations require use of lead lined containers to ensure safety; the movement of heavy containers warrants need for larger pass throughs.	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required. Also, this may be waived or possibly consider carve out for Nuclear Pharmacies.
17.13(9)(d)	Beginning January 1, 2018, a pass through shall: (b) have a double interlocking door design; (d) be located between: (1) ISO Class 7 buffer room and ISO Class 8 area or better; (2) ISO Class 8 area to unclassified space or better; or (3) ISO Class 7 ante room to unclassified space or better.	Atrius Health MHA/MSHP IACP Boston Medical Center / Horbowicz / Vreeland Cardinal Health Mount Auburn Hospital NCPA	Atrius agrees with MHA/MSHSP comment. Additionally, the implementation date is not realistic. MHA: Change "a pass through shall be located" to "a pass through may be located." Otherwise the regulation reads that pass throughs are required between all classified spaces, whether they are needed or not. Alternatively, consider removing requiring at 17.13(9)(d)(1). IACP needs clarification as stated in 17.13(7). Cardinal: Certain pass throughs are used for one way egress from buffer room to unclassified space due to short half-lives and possibility of high radiation exposure rates. Pass throughs should be addressed in USP 825. MAH: How does a double interlocking door compare to the interlocking design required in point 7 in this section? The goal is the same in that only one door should open, recommend removing "double" or clarifying how these are different. NCPA: Consider allowing more cost effective options that serve the same purpose as interlocking design.	Adjust implementation date. Board discussion: Consider striking section (d); or Require HEPA filtered units if located between ISO 7 and unclassified space 10/4/18 Board: strike (d) Patrick/Andy all

17.13(12)	A pharmacy shall determine the recovery time of each primary and secondary engineering controls for particle count, temperature, and humidity, following activities including personnel entering and exiting, gowning, staging, material transfer, compounding, labeling, cleaning, and testing.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Kelly Barnes Mount Auburn Hospital Pentec	Remove from regulation and make a best practice. Semi-annual recertification of the PEC is used to determine the maintenance of functionality of the PEC. The functional recovery time of a PEC is almost immediate, typically less than 1 minute. Recovery time of a SEC, can be noted within the room recertification under dynamic operating conditions. A standard 30 minutes as stated in these regulations along with a 1 hour standard for SEC coupled with cleaning and disinfection procedures handled on a local policy level provides substantial safety for continuation of compounding. The addition of a continuity of care plan as stated in these regulations provides an outline for managing situations directly related to planned or unplanned interruptions of airflow. Also, would need to clarify the standard for the evaluation of recovery time. Need clarification on how this requirement could be operationalized. Barnes: Change to "…following activities including personnel entering and exiting, gowning, staging, material transfer, compounding, labeling, cleaning, testing, **and HVAC interruption**." Pentec: Remove requirement. This standard is not set forth in USP 797 or cGMP. If routine environmental monitoring are performed and the results are monitoring and trended, another annual analysis would not be necessary and places undue financial burden on pharmacy.	Strike and add to Best Practices. 10/18/18 Board: add overarching statement regarding HVAC failure
17.13(14)	A pharmacy may not locate a refrigerator, dishwasher, incubator, or other appliance in an ISO classified area.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo	Change to "any appliances that use running water (i.e., dishwasher) or used to promote microbial growth (i.e., incubator). It is necessary to allow for pass throughs that are carousels (refrigerated and non-refrigerated) as well as robotics with cooling systems. Also need to account for autoclaves and depyrogenation ovens, which could be considered "appliances." Refrigerators in ISO classified ante area has not caused problem in past. This provision would create cost and storage problem.	Staff to reword with verbiage to clarify appliances that may contribute to elevated particulate levels and microbial growth. Suggested language: A pharmacy may not locate a refrigerator, dishwasher, incubator, or other appliance **that has**

		MIPA Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Cardinal Health Dana Farber Mount Auburn Hospital NCPA Partners Healthcare Pentec BioScrip	There are multiple appliances required for preparation and dispensing of radiopharmaceuticals, including computers, printers, dose calibrators, multi-channel analyzers, radio chromatogram scanners, and heating devices. Appliance is too broad of a word. Recommend revising to allow technology or devices to be used if low particulate and no moisture component. This would help pharmacies struggling to meeting space constraints. MAH: The USP 800 draft allows the storage of hazardous agents within a classified space. Clarification will be necessary in this statement regarding differentiation between non-hazardous and hazardous requirements. NCPA: Consider specifying types of appliances not allowed, such as "appliances connected to a water source instead of prohibiting all appliances in general. Pentec: Make exception for microwaves. BioScrip: The prohibition on the placement of refrigerators in an ISO classified area is inconsistent with current USP guidance and would force compounding operations to create additional areas for the storage of refrigerated HD drugs. The inclusion of these devices within ISO classified spaces will require additional cleaning by compounders and will be monitored by the increased environmental testing required by USP 797.	**potential to promote microbial growth** in an ISO classified area. 10/18/18 Board: accept as above
17.13(16)	All counter tops, work surfaces, and racks shall be constructed of stainless steel or other non-porous material.	Kelly Barnes	Add "non-shedding" to qualifications of material.	Agree to change. Suggested language: All counter tops, work surfaces, and racks shall be constructed of stainless steel or other non-porous, **non-shedding** material. 10/18/18 Board: accept as above
17.13(17)	A pharmacy may only utilize	Kelly Barnes	Change to: "A pharmacy may only **utilize carts in ISO classified**	Agree to change.

	stainless steel or non-porous molded plastic carts that are cleanable and resistant to degradation by cleaning agents in ISO classified areas.		**areas that are constructed of** stainless steel, **molded plastic, or other non-shedding, non-porous materials** that are cleanable and resistant to degradation by cleaning agents."	Suggested language: A pharmacy may only **utilize carts in ISO classified areas that are constructed of** stainless steel, **molded plastic, or other non-shedding, non-porous materials** that are cleanable and resistant to degradation by cleaning agents."
17.13(18)	An ISO classified area constructed or renovated after January 1, 2017 may not contain dust collecting overhangs or ledges.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Mount Auburn Hospital Pentec	Remove requirement. One hood provides more dust collecting area than a ¼ inch ledge around a window or door. Regular cleaning is sufficient. Adjust date. IACP suggests, "An ISO classified area constructed or renovated after DATE shall be constructed to minimize dust collecting unnecessary overhangs or ledges." Pentec: Modify to allow for ledges ½ inch, as there will always be a slight ledge on frame work of doors.	Adjust implementation date. Suggested language: Newly constructed or renovated ISO classified areas may not contain dust collecting overhangs **such a utility pipes** or ledges **such as windowsills**. USP <797> most recent draft: "Classified areas should minimize dust-collecting overhangs such as utility pipes and ledges such as windowsills. If overhangs or ledges are present, they must be easily cleanable." 10/18/18 Board: accept as above
17.13(19)	A pharmacy shall utilize cleanroom grade lights in all classified areas.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Need further explanation on cleanroom grade lighting.	Consider combining (19) and (20). Suggested language: "A pharmacy shall utilize lighting fixtures designed for clean rooms in all ISO classified areas and the exterior surface of ceiling lighting fixtures shall be smooth, mounted flush with the ceiling surface, and sealed."

17.13(22)	Ceiling panels, fixtures, and other penetrations through the ceiling (e.g., sprinkler heads) shall be smooth, mounted flush with ceiling tiles, and sealed around the perimeter.	Pentec	Pentec: Modify language to "…mounted as flush as possible…" Cleanroom grade sprinkler heads should be acceptable as not all sprinkler heads are fully flush with the ceiling depending on the model.	Clarify Suggested language: "Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter."
17.13(23)	Beginning January 1, 2018, sprinkler heads in all ISO classified areas shall be specifically designed for clean rooms and installed in such a manner to withstand weight-bearing loads on the ceiling.	Atrius Health IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Jeffrey Lynch/ NCPA/ Pentec	The implementation date is not realistic. Change to: "sprinkler heads in all ISO classified areas shall be specifically designed for clean rooms." What is the importance of having sprinkler heads be load bearing? Clarify whether this applies to new construction only? Does this apply to all existing rooms? NCPA: Installing sprinkler heads that will withstand weight bearing loads on the ceiling would be difficult and costly to implement and would outweigh any presumed additional benefit.	Adjust implementation date. Suggested language: "Beginning <date>, sprinkler heads in all ISO classified areas shall be recessed and covered, and must be easily cleanable ~~specifically designed for clean rooms. and installed in such a manner to withstand weight bearing loads on the ceiling~~."
17.13(25)	Floors shall be cleanable and composed of wide sheet vinyl that is heat sealed at seams or other solid, smooth surface. Floors shall be coved at the wall or appropriately sealed.	BioScrip	The Board has omitted all material by sheet vinyl construction of floors. Epoxy or other suitable flooring is accepted, and in current use in may compounders right now, without incident.	No change: Other solid smooth surfaces are permitted.
17.14(1)	A pharmacy shall locate an ISO Class 5 PEC for non-hazardous drug compounding within a positive pressure ISO Class 7 buffer room or ISO Class 8 DCR.	MHA/MSHP Boston MC / Horbowicz / Vreeland	It is necessary to be able to use a PEC in an unclassified segregated compounding area. See comments above at 17.05 and 17.12(1).	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.14(2)	A pharmacy may only use	MHA/MSHP	Remove requirement. Certification of the PEC with required	Comment appears to be from a

	compounding equipment in a PEC with vertical laminar airflow.	Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	equipment in place can be used to show airflow dynamics and minimize turbulent airflow. Cleaning is effective in managing equipment. Practically speaking, this is virtually impossible. Cost implications if PECs need to be replaced. Staff will not be able to operate in a vertical hood.	previous draft. It has been removed.
17.14(4)	Unless the pharmacy is utilizing a DCR with a CAI, BSC, or LAFW in accordance with 247 CMR 17.00, a pharmacy shall prepare CSPs in an ISO Class 5 environment within an ISO Class 7 buffer room that is adjacent to an ISO Class 7 or 8 ante room.	Cardinal Health	USP 797 allows radiopharmaceuticals to be compounded using appropriately shielded vials and syringes in a properly functioning PEC located in ISO Class 8 or cleaner environment.	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required. Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.14(5)	A pharmacy shall prepare CSPs in a commercially manufactured ISO Class 5 PEC. A pharmacy may not prepare CSPs in a vertically integrated ISO Class 5 workbench or ISO Class 5 open buffer room design.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland GE Healthcare Pentec BioScrip	Hospitals that currently have this design will be forced to undergo significant and costly renovations, causing major interruptions to patient care. Recommendation: remove section entirely, or adjust to include USP <797> 2015 definition of a LAFS (Laminar airflow system). BMC: If left as written, institutions with this design will be prohibited from operating, forcing them to undergo significant and costly renovations, which will cause major interruptions in patient care. Our brand new pharmacy clean room employs a LAFS open buffer room design and would be prohibited under this restriction. Our room was designed as a state of the art LAFS design because these rooms are easier to clean and maintain than traditional hoods. LAFS are often used in FDA approved facilities. With proper environmental monitoring, controls, and cleaning procedures, these designs are equally safe and effective as conventional commercially manufactured PECs.	Board discussion: This may be waived or could edit to: "A pharmacy may only prepare CSPs in a non–commercially manufactured ISO Class 5 workbench or ISO Class 5 open buffer room design as long as unidirectional airflow is proven and maintained." Changes may impact other sections of the regulation. Revised draft USP <797> [NOTE—Smoke studies have shown that it is difficult to achieve

			GE: Change to "A pharmacy shall prepare CSPs in a commercially manufactured **or Board approved** ISO Class 5 PEC." Due to the need for lead shielding, it is often necessary for nuclear pharmacy operations to construct specialized PECs that are commercially available. Pentec: Several device manufacturers make vertical flow ISO class 5 devices specifically for USP <797>. If properly designed and validated with smoke studies, a VLF should be a viable PEC if users are properly trained on positioning the CSP puncture locations within the "First Air". BioScrip: Inconsistent with current practice. The creation of integrated laminar flow workbenches within ISO 7 classed spaces is an accepted configuration for the creation of ISO 5 laminar flow work zones with ISO classed 7 secondary engineering areas. Would the Board consider the contractor, builder, or provider of the components of this type of construction to provide "commercially manufactured?" Once installed and tested according to accepted standard guidance for cleanrooms, would that not prove that these workbenches provide an equivalent environment for compounding? Was it considered that in many instances this type of construction is exactly the construction employed by commercial drug manufacturers to provide ISO 5 air for their fill lines?	this type of design and also achieve and maintain unidirectional airflow under dynamic operating conditions.] 10/4/18 Board: no change; may apply for waiver
17.14(6)	A pharmacy may not locate computer screens, keyboards, computer mouse, or printer within an ISO Class 5 area unless it is essential to compounding.	MHA/MSHP Cardinal Health Mount Auburn Hospital	Reword this section to better address the intent as Workflow Management systems that utilize computerized mechanisms (camera) for visual aid and gravimetric readings are critical to reducing errors. Is the goal here to prevent items that can generate particulates or possible be impossible to clean (key board)? There are screens that are cleanable and do not create dust. The practice of radiopharmacy requires the placement of computer screen, keyboard, computer mouse, and printer within the ISO Class 5 area.	Suggested language: "A pharmacy may not locate any equipment or supplies within an ISO Class 5 area unless it is essential to the compounding process."
17.15(1)(a)	A buffer room shall be at least 144 square feet.	Atrius Health MHA/MSHP IACP	Square footage is not a requirement of USP 797 or 800. The room should be built to the size needed to perform the necessary operations. Compliance would pose significant financial burden and would create large space to clean and test. Recommend existing pharmacies be grandfathered or this requirement eliminated.	Consider reducing size to 100 square feet and including grandfathering provision related to renovations or new builds.

		Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Boulevard Pharmacy Mount Auburn Hospital NCPA Partners Healthcare Southcoast	If requirement not eliminated consider formula for minimum square footage such as 64 square feet plus 8 square feet for every linear foot of hood, etc. The minimum square footage may not be possible at some institutions. Boulevard: Our recently renovated cleanroom facility would not be compliant with the suggested minimum size. Due to layout of building, there is no room to expand. Remove requirement.	Waiver process available. 10/4/18 Board: accept recommendation as above (100 sq feet and grandfathering) Tim/Julie all Suggested language: Newly constructed buffer rooms shall be at least 100 square feet. 10/18/18 Board: accept as above
17.15(1)(c)	Buffer room doors shall be hands free.	Cardinal Health Dana Farber Pentec	This requirement is unnecessary and not consistent with USP 797. Doors should not be motion activated. Pentec: We request that the Board provide further clarification if a touch plate can be utilized to open the door as long as personnel are not using their hands but instead another part of their body to open the	No change recommended.

			door (i.e. elbow). The use of a sensor only door (fully hands free) will restrict the ability to move within the buffer room and anteroom without continual interruptions from the door self-opening and unnecessarily increase the risk of contamination within the ISO 5 and ISO 7 areas.	
17.15(1)(e)	A buffer room shall be ISO class 7 unless the pharmacy is utilizing a DCR in accordance with 247 CMR 17.15(3).	Cardinal Health	USP 797 allows radiopharmaceuticals to be compounded using appropriately shielded vials and syringes in a properly functioning PEC located in ISO Class 8 or cleaner environment.	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required.
17.15(1)(g)	Unless prohibited by local building or fire code, a buffer room may not have more than one door.	Dana Farber GE Healthcare BioScrip	Dana Farber: A second door that leads to a second ISO7 anteroom should be allowed as an "EXIT-ONLY" option for large buffer rooms. This design allows waste removal activities to be restricted to the exit-only anteroom, and reduces the risk of cross-contamination in the anteroom which is used solely personnel entry, exit and PPE storage. GE: Need to account for emergency egress doors. BioScrip: This will limit innovation and could be burdensome to providers. Why is this necessary?	No change recommended. May be waived.
17.15(2)(c)	Unless prohibited by local building or fire code, an ante room may not have more than one door between the ante room and an unclassified space.	Pentec BioScrip	Remove requirement or grandfather in existing pharmacies. We feel that depending on the volume and/or size of supplies going in and out of an anteroom, simply utilizing a pass-through may not be sufficient. If there is only one entrance all supplies according to this proposed regulation would have to pass through all of the zones/demarcations lines that personnel do who are un-gowned with exposed skin. This will most certainly lead to an increased risk of potential buffer room contamination and action level excursions on a regular basis. We believe as long as there are policies and procedures in place to control the risk of contamination of the cleanroom, the use of multiple doors should be permitted. USP <797> does not restrict the access to an anteroom to one door only. This may not be feasible depending on the type of sterile compounding the facility does and/or the volume/size of supplies and equipment needed to enter the cleanroom space. Best practices in pharmaceutical manufacturing suggest unidirectional flow such that personnel entry is separate from material entry and raw materials are separate from finished products. Requiring no more than one door would conflict with best practices.	No change recommended. May be waived.

17.15(2)(d)	An ante room shall be at least 100 square feet.	Atrius Health IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital NCPA Partners Healthcare Southcoast	Square footage is not required by USP 797 or 800. Recommend existing pharmacies be grandfathered or this requirement eliminated. The size of the room should be dependent on the work occurring within and the available space to implement a buffer room or cleanroom suite operation of a given size. Remove requirement.	Consider reducing size to 72 square feet and including grandfathering provision related to renovations or new builds. Waiver process available. 10/4/18: Board Tim/Julie: accept as above Suggested language: Newly constructed ante rooms shall be at least 72 square feet. 10/18/18 Board: accept as above
17.15(2)(f)	An ante room shall have a stainless steel sink…	Allegra DePietro GE Healthcare	DePietro: Microbiology consultants recommend not placing sinks in ante rooms and using hand sanitizers instead; this is the standard in the biotech industry locally. GE: Sinks inside the ante room pose unacceptable risk to cleanroom environment.	No change recommended. All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required.

17.15(2)(h)	An ante room shall have lint free, disposable towels located in proximity to sink to minimize water dripping and splashing.	Beth Israel Deaconess Medical Center Mount Auburn Hospital	BI: Water should not be in anterooms where mold and fungi can potentially grow. If the scrub area is adjacent to anteroom but segregated by a door, does this standard apply? MAH: Request change "lint free" to "low lint," as the "lint free" products in the market actually still develop some lint.	Facility specific issues will be reviewed on a case by case basis. Suggested language: "An ante room shall have **low lint**, disposable towels located in proximity to sink to minimize water dripping and splashing."
17.15(2)(i)	An ante room may not contain automatic hand dryers.	Beth Israel Deaconess Medical Center	Clarify if the scrub area is adjacent to the anteroom but segregated by a door, will this standard apply.	Facility specific issues will be reviewed on a case by case basis.
17.15(2)(l)	A pharmacy may not place a "tacky" mat inside an ISO classified area. If using a tacky mat outside of the ante room door, the pharmacy shall replace the tacky mat at least once per day and when visibly soiled.	Beth Israel Deaconess Medical Center Cardinal Health Pentec	Clarify whether this applies to ante to buffer or scrub to ante. Cardinal: It is sufficient to replace tacky mat when it is visibly soiled. Pentec: Recommend – "A pharmacy may not place a contamination control mat inside an ISO classified area. If using a mat outside the ante room door, the pharmacy shall replace or clean the mat at least once daily and when visibly soiled." This regulation does not allow for other alternatives to a tacky mat to be utilized (i.e. Dycem® mat), and restricts pharmacies as additional new technologies are developed to replace the tacky mat with a superior product. We feel the wording should be modified to allow for other alternative devices used for this purpose.	This pertains to the placement of the tacky mat in unclassified space immediately preceding the classified space. Generally agree with Pentec's comment. Board staff will suggest language for rewording. Suggested language: A pharmacy may not place a **contamination control mat, such as a** "tacky" mat**,** inside an ISO classified area. If using a ~~tacky~~ **contamination control** mat outside of the ante room door, the pharmacy shall replace the tacky mat at least once per day and when visibly soiled. 10/18/18 Board: accept as above
17.15(2)	Ante Room	Kelly Barnes	Add a new provision prohibiting floor drains in ante rooms.	Agree to add.

				Suggested language: An ante room may not contain a floor drain.
17.15(3)	Dedicated Compounding Room	Partners (Nuclear Medicine)	How does this apply to nuclear pharmacy?	All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required. Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited. Suggested Language: **Segregated Compounding Area Requirements:** An unclassified Segregated Compounding Area (SCA) shall: Be a dedicated closed room restricted to sterile compounding activities. Be located away from unsealed windows, doors that connect to the outdoors, traffic flow, and any environmental control challenges such as restrooms, warehouses, or food preparation areas. Be constructed with nonporous, smooth, non-shedding, impermeable material that is free from cracks and crevices, is cleanable, and resistant to degradation by cleaning agents.

				Limit furniture, equipment, and supplies to those essential for sterile compounding and be low-shedding, easily cleaned, and disinfected. Have a stainless-steel sink that: a. is equipped with hands-free controls for water and soap dispensing; b. has proper depth and capacity for hand washing up to the elbows; c. minimizes splashing and dripping of water on adjacent walls and floor; d. does not have an aerator mechanism on the nozzle; and e. is located at least one meter away from the PEC Have lint-free, disposable towels located in proximity to sink. Not contain automatic hand dryers. Not contain a floor drain. ~~Adhere to all sections of 247 CMR 17.00, unless otherwise specified.~~ 10/18/18 Board: edit sink location
17.15(3)(a)	Dedicated Compounding Room: (a) A pharmacy may only prepare CSPs in a DCR if it holds an institutional sterile compounding pharmacy license… and the CSPs are	MHA/MSHP Cardinal Health	Need clarification on intent and process. Cardinal: We do not understand the prohibition against preparing radiopharmaceuticals in a DCR.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.

	administered on-site.			
17.15(3)(b)(2)	A pharmacy may not prepare the following types of CSPs in a DCR: 1. high risk level CSPs 2. hazardous CSPs; or 3. radiopharmaceuticals.	BioScrip	The prohibition on compounding HD drugs in DCR conflicts with USP 800 and will burden compounders. Pharmacies and doctor's offices will be unable to provide services to the public they are currently providing without incident.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.15(3)(d)	A DCR shall… contain a positive pressure PEC which may only be a CAI, BSC, or LAFW;	Dana Farber BioScrip	Recommend replacing DCR with SCA; see comment above. Also, BSCs are not positive pressure. BioScrip: Same comment as above.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.15(3)(f)	A buffer space in a DCR shall include 40% of the square footage in the DCR.	MHA/MSHP Boston MC / Horbowicz / Vreeland Southcoast BioScrip	There is currently no standard size of a buffer or ante room. The size should be dependent on the work. Recommend: remove square footage requirement or make substantial adjustments to a more practical minimum square foot like linear feet of hood space plus amount of reasonable space that a human body needs to work, etc. BioScrip: The percentage requirements on the configuration of compounding areas are burdensome and unnecessary.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.15(3)(g)	An ante space in a DCR shall…include at least 60% of the square footage in the DCR.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland BioScrip	There is currently no standard size of a buffer or ante room. The size should be dependent on the work. Recommend: remove square footage requirement or make substantial adjustments to a more practical minimum square foot like linear feet of hood space plus amount of reasonable space that a human body needs to work, etc. BioScrip: The percentage requirements on the configuration of compounding areas are burdensome and unnecessary.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.15(3)	Dedicated Compounding Rooms	Kelly Barnes	Add a new provision prohibiting floor drains in DCRs.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.16(3)	A pharmacy may not assign a BUD to any CSP prepared in a CAI located outside of an ISO Class 7 buffer room that exceeds 36 hours at room temperature or 9 days refrigerated. A pharmacy may not freeze a CSP prepared in a CAI dedicated compounding room.	MHA/MSHP Kelly Barnes	MHA: Need clarification as to how this fits with 17.41. BUDs for medium risk are 30 hours or 9 days. Where did 36 hours come from? Barnes: Change to "A pharmacy may not assign a BUD that exceeds 36 hours at room temperature or nine days refrigerated to any CSP prepared in a CAI located in a dedicated compounding room. A pharmacy may not freeze a CSP prepared in a CAI located in a dedicated compounding room."	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.

17.17(1)	A pharmacy may not locate a LAFW outside of an ISO Class 7 buffer room, unless: (a) the LAFW is located in a DCR; (b) the pharmacy holds an institutional sterile compounding pharmacy license issued under M.G.L. c 112, § 39I; and (c) the CSPs are prepared for on-site administration.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland	This section is redundant with section 17.14. LAFW should be permitted for use in a segregated compounding area. See comments above.	Board has voted to eliminate DCR and allow SCA. All DCR sections will be edited.
17.18	Sterile Compounding Facility; HVAC Systems	Cardinal Health Dana Farber Mount Auburn Hospital	Cardinal: We do not understand the prescriptive nature of this section. This differs from the current USP 797 chapter as well as proposed revisions to 797. DF: Change the wording in the section to reflect fact that hospital pharmacies must work with building facilities to monitor and maintain all HVAC systems. MAH: This entire section should be a "best practice."	See below.
17.18(1)	A pharmacy that does not have a dedicated air handling unit for ISO classified areas shall ensure the HVAC systems supplying HEPA-filtered air to ISO classified areas are designed to minimize contamination of recirculated air and maintain proper temperature and humidity.	Beth Israel Deaconess Medical Center Kelly Barnes Mount Auburn Hospital	BI: Is this practical and/or possible in some institutions? Can we get a waiver it if is not possible? Barnes: Delete "of recirculated air" in order to account for negative pressure environments where air is not recirculated. MAH: A dedicated AHU for existing intuitions is virtually impossible to install.	Strike and add to Best Practices 10/18/18 Board: accept as above
17.18(2)	A pharmacy shall maintain a detailed HVAC design plan that includes air flow diagrams.	MHA/MSHP Mount Auburn Hospital	Need to address facility management in hospital settings.	Clarify. Suggested language: "A pharmacy shall **readily retrievable** a detailed HVAC design plan that includes air flow diagrams" 10/18/18 Board: edit wording

17.18(3)	A pharmacy shall utilize a closed loop ducted system, a sealed plenum system, or other similar contamination control system approved by the Executive Director or his or her designee for HVAC systems supplying HEPA-filtered air to ISO-classified spaces.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Clarify role of Executive Director. As the major importance for both air supply and air conditioning is the supply entering at the ceiling, a properly developed maintenance and preventative action plan is as effective. The implementation of policies and procedures managed at the local level is most appropriate and extremely important.	Strike: "approved by the Executive Director or his or her designee" Consider a grandfathering provision related to renovations or new builds. Suggested language: **Newly constructed clean rooms (or similar language)** shall utilize a closed loop ducted system, a sealed plenum system, or other similar contamination control system ~~approved by the Executive Director or his or her designee~~ for HVAC systems supplying HEPA-filtered air to ISO-classified spaces..
17.18(6)	A pharmacy shall conduct engineering control performance verification in accordance with USP 797 in the event of a planned or unplanned interruption of HVAC operations.	MHA/MSHP GE Healthcare Jeffry Lynch Kelly Barnes Mount Auburn Hospital Pentec	MHA: Include consideration for downtime procedures to be implemented in place of a performance verification plan. Room recovery is a mathematical calculation that can be determined in place of a validation test. Development of polices and procedure regarding planned and/or unplanned interruptions in HVAC operations can provide the same benefit and safety as performance verification. A continuity of care plan as stated in these draft regulation can be utilized to manage these situations. GE Healthcare: Add "… where the system fails to resume normal operating pressure differentials and temperatures." Normal HVAC system service may result in planned short term interruption without any negative effective on the environment and should not be require performance verification if parameters return to normal. Lynch: Does this mean re-cert? Or HVAC vendor assessment? What is BOP definition of "interruption"? Barnes: Change to "A pharmacy shall **verify** engineering control performance in accordance with **the pharmacy's validated recovery time** in the event of a planned or unplanned interruption of HVAC	Strike and add to Best Practices.

			operations." This would draw distinction between having to perform full certification versus verifying the performance of PEC and SEC based on pharmacy's validated recovery time. Pentec: This is confusing. How does Board define "performance verification"?	
17.18(7)	A pharmacy shall operate and monitor the HVAC systems that supply conditioned air to the non-classified areas of the pharmacy 24 hours per day, seven days per week.	Atrius Health MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital / NCPA / Pentec	This requirement should be performed by the engineering or facilities department rather than the pharmacy department. The hospital engineering departments control the HVAC, not the pharmacies. Audible alarms provide the same benefit. IACP suggests removing requirement or adding "where prescription medications are handled and stored." NCPA: Remove requirement. Requiring this level of monitoring to all non-classified areas of a pharmacy would place a costly, undue burden upon the pharmacy. Pentec: We are unsure of the rationale behind this as retail pharmacies do not have continuous monitoring of their drug storage or non-drug storage spaces. Once daily monitoring should be sufficient for non-classified spaces. USP <797> does not speak to non-classified spaces and implementing continuous monitoring of HVAC systems in all pharmacies regardless of their practice type is unnecessary and is not supported by any current regulation, guideline, or governing body.	Agree to strike.
17.18(8)	A pharmacy shall operate and monitor the HVAC systems that supply HEPA filtered air to ISO classified areas 24 hours per day, seven days per week.	MHA/MSHP Boston Medical Center / Horbowicz /	Include exemption for hospital pharmacies. See comment above. Recommend: "The HVAC systems that supply HEPA filtered air to ISO classified areas shall be operated at full capacity 24 hours per day, seven days per week." Pharmacy departments do not operate HVAC systems in a hospital setting.	Clarify to: "A pharmacy shall **ensure that** the HVAC systems that supply HEPA filtered air to ISO classified areas **are operated and monitored** 24 hours…"

		Vreeland Pentec	Pentec: Need clarification, since other items in the proposed regulation already dictate that temperature, humidity, and pressures need continuous monitoring. Redundant to 17.20(3) and 17.21(4).	
17.18(9)	A pharmacy shall immediately assess the impact on the classified environment for any HVAC failure and implement a CAPA.	MHA/MSHP Mount Auburn Hospital Pentec	The development of a CAPA program is vitally important to the overall quality management program. As stated above regarding the dedicated AHU and HVAC systems for Pharmacies, the implementation of an appropriate CAPA and risk management program coupled with a solid remediation plan is as effective as the addition of a dedicated air handling unit. Pentec: Further clarification required regarding that constitutes an HVAC "failure."	Strike and add to Best Practices document.
17.18(10)	Each secondary engineering control shall have ducted air returns mounted low on the wall in order to create a general top down dilution of room air with HEPA filtered make up air.	Anazao Health MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Modify language to comply with current USP 797 standard and CETA application guide. While low wall air returns are preferred and should be installed with any new renovation or new build, the CETA guidelines should be sufficient for existing facilities. MHA: The overall ISO classification is determinate on particulate count regardless of return locations. Remove this provision from regulation; this should be a best practice. .	No change recommended. May be waived.
17.18(11)	Relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent ISO classified space or ambient air.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn	The overall ISO classification is determinate on particulate count regardless of return locations. Remove this provision from regulation; this should be a best practice.	Suggested language: **If utilized**, relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent ISO classified space or ambient air

		Hospital		
17.19(1)	A pharmacy shall utilize an Institute of Environmental Sciences and Technology ("IEST") rated type C or K HEPA filters tested to achieve a minimum of 99.97% efficiency rating using 0.3µm micron particle size.	Pentec	We feel this proposed regulation is confusing. A type C HEPA filter is 99.99% efficient at 0.3 µm using a thermally generated challenge and then scan tested to 0.010% for individual leaks. A type K HEPA filter is 99.995% efficient determined as the lower efficiency when tested for particle size ranges of 0.1-0.2 and 0.2-0.3 um. The designated leak for the filter is 0.008%.	~~Suggest adding "to achieve **at least** a minimum…" and word more generally.~~ Suggested language: A pharmacy shall utilize ~~an Institute of Environmental Sciences and Technology ("IEST") rated type C or K~~ HEPA filters tested to achieve a minimum efficiency rating as defined in the most current chapter of USP <797>.
17.19(2)	Each HEPA filter shall be leak tested using the most penetrating particle size according to the most current Controlled Environment Testing Association ("CETA") guidelines at the factory, then leak tested again in situ after installation as part of initial certification and recertification (every 6 months) and any time a HEPA filter is repaired or replaced.	MHA/MSHP	This appears to say that the room would need to be recertified after a HEPA filter is replaced even if the room passed certification with the defective filter. Is this the intention? What is the intent for the visual inspection? The HEPA filters in our PECs are protected behind metal filter guards and, therefore, cannot be visibly inspected without removing this guard which would significantly disrupt the environment and the daily workflow.	This standard applies to filter integrity tests, not certification. Suggested language: HEPA filters must be leak tested ~~at the factory and then leak tested again~~ after installation and as part of recertification and any time a HEPA filter is repaired.
17.19(3)	A pharmacy shall immediately remediate a failed HEPA filter by properly repairing or replacing the HEPA filter, recertifying the affected ISO classified area, and performing environmental monitoring in all classified areas according to the full environmental monitoring sampling map.	Dana Farber GE Healthcare	Dana Farber: If the filter in a PEC that is a BSC fails, the environmental monitoring should be limited to the PEC. If a facility ceiling filter fails, the environmental monitoring should be limited to the area likely to be affected by a single failed filter. An appropriate sampling plan for various scenarios should be developed in advance of a filter failure event – this should be based on a risk assessment developed after consultation with design engineer, certifier, microbiologist or industry hygienist. The Failed Filter Plan should be a section of the Business Continuity Plan. GE: The requirement for environmental monitoring following a failed HEPA filter should be limited to the classified area with the failed HEPA filter.	Change to: "environmental monitoring in affected classified areas" (in accordance with the Board Advisory regarding Failed HEPA filters). Suggested language: A pharmacy shall immediately remediate a failed HEPA filter by properly repairing or replacing the HEPA filter, recertifying the affected ISO classified area, and performing environmental monitoring in ~~all~~ **the affected**

				classified ~~according to the full environmental monitoring sampling map~~.
17.19(5)	A licensee shall visually inspect the external portion of PEC filters at least daily.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Blaire Pharmacy Consulting Dana Farber Mount Auburn Hospital	Need clarification on the extent of visual inspection. Clarify what the inspection entails. Pharmacy staff is not easily able to inspect PEC filters. HEPA filters are checked routinely during recertification. If you have proper alarms set on your PEC, it will alert you if not working properly.	Suggested language: "A **pharmacy** shall have a procedure requiring routine visual inspection of the external portion of PEC filters for signs of gross contamination and proper remediation."
17.20(2)	ISO Class 5 PEC shall include a pressure differential gauge and/or a low flow device displaying the positive pressure differential between the upstream and downstream air flow in accordance with manufacturer specifications. The pressure shall be logged daily prior to compounding. Should the PEC display a loss of pressure exceeding 10% of the last reading, compounding in the PEC shall be suspended until remediated.	IACP Cardinal Health	Strike last sentence or change to "should the PEC display a pressure differential below the minimum standards required by the manufacturer, compounding in the PEC shall be suspended until remediated." The significance of 10% drop is not clear. Cardinal: The lead shielded vertical LAFW hoods used in radiopharmacy are not equipped with installed magnahelic gauges. This requirement is unnecessary and would be disruptive to the entire industry without any proven gain in patient safety.	Strike and add to Best Practice document.
17.20(3)	A pharmacy shall measure the differential pressure between each ISO-classified area with a gauge and shall document the differential	MHA/MSHP Boston Medical	Current standards only require documentation of pressure differential daily. Remove this requirement from regulation. Additional burden without proven gain.	Suggested language: A pharmacy shall measure the

	pressure at each location 24 hours per day, seven days per week, by a continuous recording device.	Center / Horbowicz / Vreeland Cardinal Health GE Healthcare Mount Auburn Hospital Pentec	Change to "at least once daily or by a continuous recording device" in order to be consistent with USP 797. Pentec: We believe continuous monitoring should be defined as either a continuous recording system or a system that will make it clear if the proper pressures are not maintained over a given time period.	differential pressure between each ISO-classified area ~~with a gauge~~ and shall document the differential pressure at each location ~~24 hours per day, seven days per week~~, **at least once daily or** by a continuous recording device.
17.20(4)	Beginning January 1, 2017, a pharmacy shall mount all pressure differential gauges for secondary engineering controls in the non-classified area adjacent to the classified areas.	MHA/MSHP Kelly Barnes Mount Auburn Hospital NCPA	MHA: Adjust this to be a "Best Practice". Although it would be nice to have a state-of-the-art facility, interior monitors can be recorded by properly garbed compounding staff members and prevent negative effects on the environment. Properly alarmed devices will provide awareness to staff on issue with pressurization to stem investigation. Barnes/NCPA: Adjust date.	Strike and add to Best Practices document.
17.20(5)	A pharmacy shall review differential pressure logs and continuous monitoring device reports daily and shall document the review and response to any out of range pressure.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland	Remove "pharmacy." Consideration should be made for new technology and continuous monitoring devices and alerting for out of specification results. Technology eliminates the need to have someone manually document reviews daily. Unexpected or egregious out of range results should be documented and responded to, there are instances in which differential pressures may be out of range that do not require response. Every time a door opens between labs, pressure differentials drop. The way this requirement is currently written, pharmacies would be required to keep a log of every time the pressure drops due to a door opening. Strike this requirement or modify language to require that the pharmacy respond and document any UNEXPECTED out of range result	Clarify to: Suggested language: "A pharmacy shall respond to any **unexpected or prolonged** out of range differential pressure and document the response."
17.21(1)&(2)	All ISO Classified areas shall maintain a temperature of 68 degrees	Allegra DePietro	DePietro: A maximum temperature is very restrictive and will be too cold for certain individuals. The purpose is for operator comfort while	Most recent <797> version: "The

	or less. All ISO Classified areas shall maintain a relative humidity of 65% or less.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland Cardinal Health Dana Farber / Kelly Barnes / Pentec	wearing full garbing; some leeway should be given for individuals within the ambient drug storage temperature guidelines. MHA: Need to account for seasonable fluctuations in temperature and humidity. Current facility unable to maintain low humidity without increase temperature above 68 during the summer; may require new HVAC in order to comply. This requirement should be made consistent with USP 797. Cleaning often causes the humidity to rise above 65%. Very costly if not impossible to maintain. In this part of the country, it is difficult to maintain humidity under 65%, especially in an old facility. Dana Farber: Minimum humidity is not defined. Barnes: Adjust language to read "**constant** temperature" and "**constant** relative humidity." Pentec: Remove requirement. USP 797 indicates the temperature of 68 is for the overall comfort of personnel performing the compounding, and not due to a potential negative impact on products. Requirement is unnecessary.	cleanroom suite should be continuously maintained at a temperature of 20° or cooler and a relative humidity below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for compounding personnel attired in the required garb." **10/4/18 Board: have Advisory Committee provide guidance** Suggested language (for Advisory Committee): All ISO Classified areas shall **be continuously maintained** at a temperature of 68 degrees **Fahrenheit** or less. All ISO Classified areas shall **be continuously maintained** at a relative humidity of 65% or less.
17.21(3)	Each secondary engineering control shall have a probe or sensor to measure temperature and humidity.	Cardinal Health Dana Farber GE Healthcare Pentec	Not required by USP 797. Additional burden without proven gain. Dana Farber / GE: (3) and (4) should be combined. Pentec: Change to – "Secondary engineering controls shall be monitored for temperature and humidity through a sensor or probe." The proposed regulation mandates each SEC have a separate device for monitoring. For ISO 7 and 8 rooms that share the same HVAC system, one monitoring device should be sufficient.	Recommend to strike. Spirit of proposed standard was no portable monitoring equipment in classified areas.
17.21(4)	A license shall document the temperature and humidity of each	Cardinal Health	Not required by USP 797. Additional burden without proven gain.	Suggested language:

	secondary engineering control 24 hours per day, seven days per week, by a continuous record device.	GE Healthcare Pentec	The requirement to monitor temperature and humidity should be limited to areas where CSPs are prepared and "at least once daily or by a continuous recording device." Pentec: Change to – "A licensee shall document the temperature and humidity of SECs at least once per work shift." Monitoring of temperature and humidity during hours of operation should be sufficient to protect integrity of SEC.	A license shall document the temperature and humidity of each secondary engineering control ~~24 hours per day, seven days per week,~~ **at least daily** or by a continuous recording device.
17.22(1)	Primary and secondary engineering controls shall be certified at least: (a) once every 6 months; (b) whenever a PEC is relocated, added, or removed; (c) whenever the room is altered; and (d) immediately following any major repair or major servicing of the compounding facility or engineering controls.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Barnes	Remove requirement at (c) for "altered"; this language is too vague. Barnes: Change to: Primary and secondary engineering controls shall be certified ~~at least~~: (a) once every 6 months; (b) whenever a PEC is relocated **or altered**, added, or removed; (c) whenever the room is **relocated or** altered; and (d) immediately following any major repair or major servicing of the compounding facility or engineering controls. **(e) whenever a HEPA filter(s) is/are repaired or replaced.**	Consider aligning language with revised USP <797> Draft (e.g. remodeling or change in configuration or square footage) and add provision for HEPA filters. Revised USP <797> Draft: Classified areas must additionally be recertified if there are changes to the area such as redesign, construction, or replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality. Suggested language: Primary and secondary engineering controls shall be certified at least: (a) once every 6 months; (b) whenever a PEC is relocated, added, **replaced**, or removed; (c) whenever the room is ~~altered~~ **remodeled or upon a change in configuration or square footage**; and (d) immediately following

				any **construction or** major repair or major servicing of the compounding facility or engineering controls. 10/18/18 Board: accept as above
17.22(2)	The certification testing shall be completed in its entirety within a 72 hour time period. Certification testing includes: (a) airflow and velocity test; (b) airflow smoke pattern test; (c) room pressurization test; (d) air flow displacement test, as applicable; (e) HEPA filter leak test; (f) induction leak and back streaming test; (g) airborne non-viable particle counting, conducted under dynamic operating conditions; and (h) temperature and humidity test.	MHA/MSHP IACP NCPA Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel Deaconess Medical Center Dana Farber Kelly Barnes Mount Auburn Hospital	Remove the temperature and humidity test, as it is not necessary and is only optional under CETA guidelines. Remove the "airflow smoke pattern test." There is no evidence showing this requirement is necessary and it is an optional test under CETA guidelines. Beth Israel: Is requirement at (e) to conduct a leak test overkill? If using magnhelixes, do you really need the smoke test? Dana Farber: (h) temperature and humidity should be checked daily to ensure it is comfortable for staff wearing PPE. Kelly Barnes: adjust (c) to read "room pressurization test, including recalibration of all gauges;" NCPA: Remove requirement. There is currently no evidence that smoke studies improve quality, and this is an optional test within CETA requirements. This could place a costly, undue burden upon the pharmacy.	Suggested language: "Certification testing shall be conducted in accordance with the most recent version of USP <797>. The certification testing shall be completed in its entirety within a 72 hour time period." Specific required tests can be included as part of variable alternating inspection criteria. 10/18/18 Board: accept as above
17.22(3)	In the event a primary or secondary engineering control requires major repair or major servicing, a pharmacy shall stop compounding and may not resume compounding until: (a) the repair or service is complete; (b) the affected engineering control has been certified; and (c) environmental monitoring results in the affected engineering	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo	**Recommendation:** Instead of stopping compounding completely, put a 12 hour time frame (commonly used in practice today), to prevent pharmacies from having to shut down any action level. It has been proven that you are bound to and should get positive results by having ISO 7 negative pressure adjacent anteroom and a sink. **Clarification requested:** 1. It can take up to 7 days before the viable results of the environmental monitoring are available. Many hospitals would not be able to function for a full week without	This section refers to activities around major repair/service and requires a Renovation/Expansion application in accordance with Board advisory. For Board discussion: (c) From Major Repair Advisory: Major Repair / Major Service is defined as significant

	control within USP <797> action levels are obtained.	MIPA Boston Medical Center / Horbowicz / Vreeland Dana Farber GE Healthcare Jeffery Lynch NCPA Pentec	operating clean rooms. 2. If a facility followed the repair with an intensive cleaning and disinfecting of the area and an environmental testing, is it necessary to wait the 7 days before compounding can resume? The re-test could immediately confirm that the HEPA filters and PECs are working properly and the particle counts are within range for the room ISO classification(s). 3. In the event of an unscheduled down time, it could take many days before it is possible to arrange for a testing company to arrive on site. This delay could push out the ability to use the clean room to up to 2 weeks. In the event that one of the ISO 5 SEC needed to be repaired, would the entire room need to be shut down or can compounding continue in other ISO 5 SECs? BMC: Pharmacies should have a plan for unplanned PEC and SEC malfunction, which may or may not require a complete stop in compounding. We agree that if a PEC fails, compounding in that PEC should cease until repairs are made and recertification is complete. However, compounding in other PECs in the same room can continue with implementation of a 12 hour BUD (commonly used in practice today), to prevent institutional pharmacies from having to shut down. While retail businesses may be able to completely cease operations, hospitals must have flexibility to continue to provide medications for acutely ill patients. Dana Farber: Need further clarification. For example, advice that parallels 17.28. GE / Lynch: Need to clearly define major repair and major service. NCPA: Remove requirement. Environmental monitoring results could take up to 7 days to be obtained and halting all sterile compounding for this length of time could place an undue burden upon patients and the pharmacy. Pentec: The way the proposed regulation currently reads, all compounding would have to cease if one of multiple PECs needs repair. We are unsure if this was the intent of the Board or if the regulation needs further clarification for pharmacies. We believe the	modifications, repairs, or service to the compounding pharmacy that may not affect the floor plan but may result in changes to airflow dynamics and / or the generation of environmental contaminants. 10/4/18 Board: strike all of 17.22(3)

			PEC that requires repair should be removed from production for servicing while all other PECs and secondary engineering controls are still freely utilized for compounding.	
17.22(6)	A pharmacy shall verify the maximum number of compounding personnel simultaneously capable of working in a buffer room or buffer space without disrupting ISO classification at least once per year. The verification procedures shall include non-viable air, viable air, and surface sampling.	Atrius Heath MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Mount Auburn Hospital / Pentec	Atrius: It is unclear how pharmacies are to determine the maximum number of compounding personnel simultaneously capable of working in a buffer room. Need clarification. MHA: Remove this section. Regular certification process already delineated in 17.00. CETA does not provide guidelines for this. Certification occurs based on the people, activities and conditions of the room at the time of certification. In the past, when asked, CNBT certifiers have stated they cannot provide a maximum number of people to us because it depends on the materials and activities going on in the room. It will be very difficult for pharmacies to comply with this regulation, which required cooperation of the CNBT certifiers. Pentec: Yearly validation without a change to the square footage of the area is not necessary and places an additional financial burden on the pharmacy.	Strike and add to Best Practices.
17.23	Sterile Compounding Facility; Smoke Studies	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Dana Farber NCPA	Remove this section entirely. There is no evidence that this improves quality and secondary engineering control smoke tests are not required by FDA or CETA. No mention of SEC smoke tests in USP 797. There is no definition for a “failed smoke study,” which could result in subjective interpretation. If this section is not removed, at least strike (7), “a pharmacy shall initiate an investigation and develop and implement a CAPA in response to a failed smoke study.” Dana Farber: Smoke studies are unquestionable demonstrations of appropriate ventilation controls. NCPA: Remove requirement. There is currently no evidence that smoke studies improve quality, and this is an optional test within CETA requirements. This could place a costly, undue burden upon the pharmacy.	See below
17.23(1)	A pharmacy shall conduct a smoke study of primary and secondary	MHA/MSHP	Remove section entirely. No evidence smoke study improves quality. SEC smoke tests are not required by current USP 797 or proposed	Consider edits: (1) A pharmacy shall conduct a

	engineering controls: (a) upon initial certification; (b) annually at recertification for secondary engineering controls; (c) at least each certification for PECs; and (d) immediately following any major repair or service, movement of engineering control, or addition or permanent removal of equipment located within the PEC.	Boston Medical Center / Horbowicz / Vreeland Dana Farber Kelly Barnes Mount Auburn Hospital	new USP 797. Dana Farber: Smoke studies have an impact on compounding operations, so the repetition of the test should be limited to instances when smoke study data will add value to the state of control. For example, when new procedures are conducted or new equipment is added. Repeat tests should be scheduled for cause. Barnes: Adjust (c) and (d) as follows – (c) at least **at** each certification for PECs; and (d) immediately following any major repair or service, **relocation** of engineering control, or addition or permanent removal of equipment ~~located within the PEC~~; **(e) Any other repair or service that may impact airflow dynamics.**	smoke study ~~of primary and secondary engineering controls~~: (a) of all primary and secondary engineering controls upon initial certification; ~~(b) annually at recertification for secondary engineering controls;~~ (c) ~~at least~~ with each PEC certification or recertification ~~for PECs~~; and ~~(d) immediately following any major repair or service, movement of engineering control, or addition or permanent removal of equipment located within the primary engineering control~~. immediately following the remodeling or change in configuration or square footage of any secondary engineering control; and (e) upon the addition, permanent relocation, or permanent removal of any equipment located within the primary or secondary engineering control. Note: (e) would include a PEC as equipment. 10/4/18 Board: accept above recommendations Tim/Patrick all
17.23(2)	A pharmacy shall conduct a smoke study: (a) to verify unidirectional airflow, sweeping action over and away from the critical compounding area, and interface with compounding personnel for each PEC; (b) to verify a general top-down	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland	Remove section entirely. No evidence smoke study improves quality. SEC smoke tests are not required by current USP 797 or proposed new USP 797. Need clarification on (b) – it would have to be done in sections at larger facilities. Also, (2)(b) should not be required to be repeated annually; it should be required when troubleshooting failed certification or loss of state of control.	Strike and include information in a guidance document on smoke studies.

	dilution of room air with HEPA-filtered make-up air and sweeping action to the low wall mounted returns for each secondary engineering control; (c) around all openings, doorways, and pass-throughs to confirm positive pressure or negative pressure; and (d) around compounding equipment to confirm air flow.	Dana Farber Mount Auburn Hospital		
17.23(5)	A pharmacy shall video record a smoke study of each primary and secondary engineering control at least once per year.	Pentec	Limit requirement to primary engineering controls.	Include as best practice.
17.23(6)	A pharmacy shall document the results of each smoke study.	Pentec	Need clarification about the type of documentation Board will require.	Consider: Suggested language: "A pharmacy shall ensure that a description and result of each smoke study conducted are documented in the certification report."
17.23(7)	A pharmacy shall initiate an investigation and develop and implement a CAPA plan in response to a failed smoke study.	Edward Fallon	There is no definition for a "failed smoke study". This will cause great confusion and determination will be left in the hands of the inspectors and/ or the certifiers.	Strike and add to guidance document.
17.24	Environmental Monitoring	Beth Israel Deaconess Medical Center Dana Farber Kelly Barnes	Requirements regarding environmental monitoring are unnecessary, costly, and not realistic. Dana Farber: Insert the word "ensure" in some sections, since third party certified vendors may do the viable monitoring. Barnes: Relocate provisions (13) – (16) to a different section, as they do not pertaining to environmental monitoring.	Agree to make these edits. Agree to relocate sections.

		NCPA Partners Healthcare	NCPA: Align this section with USP 797. Partners: Adding daily environmental testing in addition to the product testing for these preparations will require more time, resources, and space that does not exist in the hospital setting. Increased environmental monitoring can result in increased contamination or false positive results. Many hospitals use an outside vendor to perform the environmental monitoring. In the current market, the supply of vendors would not meet the demand of hospitals and the new requirement of daily monitoring. In addition, there is no evidence-based literature that shows a correlation between daily environmental monitoring and infection rates.	
17.24(1)	A pharmacy shall develop an environmental monitoring sampling plan in conjunction with a qualified professional such as a microbiologist, industrial hygienist, or infection control professional.	Cardinal Health BioScrip	Cardinal: A pharmacist should be considered a qualified professional. BioScrip: Burdensome and unnecessary if the compounder follows authoritative scientific and regulatory guidance.	No change recommend. Language does not limit "qualified professionals".
17.24(2)	A pharmacy shall conduct viable air and surface sampling for bacterial and fungal organisms.	Cardinal Health	Radiopharmaceuticals are expressly called out in USP 797 as being low risk CSPs. The use of fungal specific media such as MEA is only required when performing high risk level compounding.	Comment is not applicable to this section. All nuclear pharmacy issues, including licensing, will primarily be addressed in 247 CMR 13.00 with linkages to other sections as required.
17.24(7)	A pharmacy shall conduct environmental monitoring of each primary and secondary engineering control: (a) as part of a routine environmental monitoring program and in accordance with 247 CMR 17.24(8); (b) as part of the commissioning and certification of new facilities and equipment; (c) immediately following any repairs or servicing of facilities and equipment;	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Cardinal	Please define "significant change in staffing or workload." IACP: The language at (g), (h), and (j) is extremely vague and subjective. Remove requirements and replace with "as required to determine the root cause of a contaminated CSP." In (h), remove "defect or". Defect is not defined; could be potency, container defect, incorrect ingredient, etc. Requirement at (j) is subjective and broad. Why would change in staffing or workload trigger environmental monitoring? Pentec: Section (d) should apply to primary engineering controls and the buffer area only. We do not feel it is needed to extend this testing	Agree to strike: (j) Consider these edits: (d) immediately following any planned or unplanned interruptions of HVAC operations ~~lasting longer than 4 hours~~; (g) in response to identified ~~problems with staff technique~~ trends such as repeated failed gloved fingertip tests or media fills;

	(d) immediately following any planned or unplanned interruptions of HVAC operations lasting longer than 4 hours; (e) immediately following addition, removal, or relocation of a PEC; (f) as part of the re-certification of facilities and equipment; (g) in response to identified problems with staff technique; (h) in response to an actual or suspected defect or contaminant of a CSP or potential patient infection; (i) in response to an above action level environmental monitoring result or adverse environmental monitoring trend; and (j) in response to a sudden or significant change in staffing or workload.	Health Pentec BioScrip	to the anteroom. In addition, we would like to understand the source of the 4 hour limit. USP and cGMP mention nothing related to this time limit, we would like to request the evidence to support this cutoff. For planned or unplanned interruptions lasting less than 4 hours the proposed regulation, as is, is suggesting no EM needs to be performed. Pentec: Section (g) – we do not believe secondary engineering controls need testing if a staff is identified as having concerns with aseptic technique. BioScrip: Section (j) – Since the regulation requires that the compounder defines "dynamic operating conditions" in party by noting the number of compounding operators present at the time of testing, this has already been established. Any changes to staffing levels or compounding load should be at the discretion of MOR.	(h) in response to ~~an actual or suspected defect or contaminant of~~ a contaminated CSP ~~or potential patient infection;~~ **10/4/18 Board:** **-Ask Advisory Committee to weigh in on (d) Strike** **-Strike (j)** **-Accept above changes to (h)** **-Staff to rework (g) Strike** Suggested language: A pharmacy shall conduct environmental monitoring of each primary and secondary engineering control: (a) as part of a routine environmental monitoring program and in accordance with 247 CMR 17.24(8); (b) as part of the commissioning and certification of new facilities and equipment; (c) immediately following any **construction**, repairs or servicing of facilities and equipment; (d) ~~immediately following any planned or unplanned interruptions of HVAC operations lasting longer than 4 hours;~~ **(include in Best Practice / Board Advisory)** **10/18/18 Board: refer to policy for interruptions greater than 4 hours; overarching requirement in another section; 17.13(12)**

				(e) immediately following **the** addition, removal, **replacement**, or relocation of a PEC; (f) as part of the re-certification of facilities and equipment; (g) ~~in response to identified problems with staff technique;~~ (h) in response to ~~an actual or suspected defect or contaminant of~~ a contaminated CSP ~~or potential patient infection~~; (i) ~~in response to an above action level environmental monitoring result or adverse environmental monitoring trend;~~ and **(Note: requirement for EM to be covered in Board Policy)** (j) ~~in response to a sudden or significant change in staffing or workload~~
17.24(8)	At minimum, a pharmacy shall conduct routine environmental monitoring of each primary and secondary engineering control at the following intervals: (a) low and medium risk level CSPs that are assignment standard room or refrigerated temperature BUDs… (c) high risk level CSPs… (d) high risk level CSPs with extended BUDs, and high risk level intermediate or stock solutions:	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Blaire Pharmacy Consulting Boston	MHA: Remove this requirement. This requirement does not appear to be evidence-based and is not required by 797. Non-viable and viable air sampling monthly poses as a significant financial burden especially for smaller operations. MHA: Due to 3-4 high risk compounded ophthalmic preparations that serve a critical patient need, the institution will be required to conduct extensive environmental monitoring. An additional FTE will be required to satisfy these conditions. Additionally, technicians with the skillset to conduct this level of monitoring are very difficult to find in the greater Boston area. The institution will be forced to invest in additional monitoring equipment and will incur significant monitoring costs. Costs to the patient will be increased to account for the increased overhead. IACP: The frequency of environmental monitoring under this regulation will be too much and will greatly interfere with hospital and pharmacy operations. The requirement is not evidenced based	EM may be performed by any qualified personnel. Consider removal of "day of" testing and other changes below: 1) **Viable and Non-Viable Air**: - **Quarterly** for low/medium risk - **Monthly** for high risk 2) **Viable Surface**: monthly **9/6/18 Board vote to approve 1 and 2 above: Tim/Patrick (all)** Suggested language: A pharmacy engaged in

		Medical Center / Horbowicz / Vreeland Boulevard Cardinal Health Dana Farber GE Healthcare Kelly Barnes NCPA Pentec Southcoast BioScrip	and is not required by USP 797. The frequency proposed would require some pharmacies to perform environmental monitoring on a daily basis. This provision will greatly interfere with pharmacy operations and result in operating costs that far exceed what any company could afford, potentially eliminating an organization's ability to perform sterile compounding. Recommendation: frequency of environmental monitoring should be in compliance with USP 797. Blaire: Proposed Environmental monitoring requirements far exceed USP requirements and pose economic and workflow constraints for sterile compounding facilities. These requirements are more aligned with cGMP regulations. Cost of equipment and testing media may become overly burdensome, so much so as to force sterile compounding pharmacies to close their doors. Boulevard: Daily environment testing seems very excessive. We would like to know what the scientific rationale behind these proposed requirements is. Currently our facility spends $15,000-$20,000 per year on environmental testing and certification of cleanrooms. If these regulations pass the way they are, it would cost the pharmacy between $85,000 and $100,000 for the same services. Being one of the two pharmacies that provides high-risk sterile prescriptions, we would be forced to discontinue our sterile operation. Cardinal: This frequency of environmental monitoring differs from USP 797 and is unnecessary for preparation of FDA approved, low risk level CSP radiopharmaceuticals with BUD less than 24 hours. Dana Farber: On (a), would recommend quarterly sampling for low and medium risk level CSPs that are assignment standard room or refrigerated temperature BUDs. GE: Environmental monitoring requirement for low and medium risk level CSPs that are assignment standard room or refrigerated temperature BUDs… should be once per quarter. Barnes: On the table for (8)(a), change "PEC used for compounding"	compounding low or medium risk level CSPs shall conduct routine viable and non-viable air environmental monitoring of each primary and secondary engineering control **at least quarterly**. A pharmacy engaged in compounding high risk level CSPs shall conduct routine viable and non-viable air environmental monitoring of each primary and secondary engineering control **at least monthly**. A pharmacy engaged in compounding low, medium, or high risk level CSPs shall conduct routine viable surface **(sampling)** environmental monitoring of each primary and secondary engineering control **at least monthly**.

			to "all PECs." NCPA: The frequency proposed could require sterile compounding pharmacies to perform daily environmental monitoring. This level of monitoring would result in greatly increased operating costs. There is no evidence of benefit for this testing frequency. Pentec: Performing non-viable air sampling prior to compounding would not be considered dynamic sampling, it would be static sampling. We believe dynamic sampling should be performed to assess the particulates personnel are producing during actual production. Pentec: We believe the requirement to perform environmental surface monitoring each day high risk compounds are performed is excessive, and we believe once monthly is appropriate for these compounding circumstances. USP does not separate how often sampling should be performed based on the risk level, although we do agree with the Board that increased sampling should occur for facilities performing high risk compounding. We feel monthly environmental monitoring is appropriate for pharmacies performing high risk compounding. For pharmacies only performing low and/or medium risk compounding we feel they should be required to adhere to USP <797> sampling standards of every 6 months or possibly increase the frequency to every 3 months if the Board so desires. Need definition of "extended BUDs." Southcoast: This regulation does not specify whether the monthly environmental testing is required to be performed by a third party vendor or as in house testing. If required to contract with a third party, hospital pharmacies will incur high costs. Also, we must consider that certification companies will not be able to meet the increased demand for testing services in the state if every hospital pharmacy requires a monthly environmental monitoring performed by third party. BioScrip: The frequency of testing should be aligned with USP 797. These additional intervals are burdensome.	
17.24(9)	Environmental monitoring samples	Blaire	How does the Board intend to inspect for and enforce this regulation?	Recommend to strike.

	shall be collected in the following order: ISO Class 5, then ISO Class 7, and then ISO Class 8.	Pharmacy Consulting		Process to be included in EM sampling plan (method of collection).
17.24(10)	Personnel that perform environmental monitoring shall be qualified and shall demonstrate competency and proficiency in all sampling techniques including media selection, media preparation, sample collection, incubation protocols, identification of positive results, proper handling of samples for contracted lab distribution, and proper disposal of sampling plates.	MHA/MSHP BioScrip	MHA: Include considerations for hospitals that routinely use microbiologists to incubate, identify positive results, and dispose of plates. The regulations need to reflect and take into consideration if facilities are already employing staff that provides these services so that we are not adding to the overall costs to operate pharmacy. BioScrip: The Board has not provided sufficient detail for the personnel that perform environmental monitoring; a thorough assessment of these requirements cannot be accessed. However, since this testing is a simple gross collection of samples, competent pharmacy personnel can be trained to function this way. Requiring a third party or some other specialized provider here would add cost and not value to this process.	Consider edit: Suggested language: Personnel that perform environmental monitoring shall be ~~qualified~~ **properly trained** and ~~shall~~ demonstrate competency and proficiency in all sampling techniques. ~~including media selection, media preparation, sample collection, incubation protocols, identification of positive results, proper handling of samples for contracted lab distribution, and proper disposal of sampling plates~~ This does not restrict to third party testers.
17.24(11)	Qualified personnel that perform environmental monitoring shall utilize proper equipment and shall demonstrate competency in the use of that equipment.	BioScrip	The equipment used for these collections is well within the competency of pharmacy personnel, especially if advised by the provider or manufacturer of this basic equipment.	Consider: Suggested language: "Personnel that perform environmental monitoring shall utilize ~~proper~~ **properly maintained and calibrated** equipment **and be trained** and demonstrate competency in the use of that equipment."
17.24(13)	If a pharmacy has a water purification system, the pharmacy shall also test source water and water at point of use for microorganisms quarterly or in accordance with manufacturer specifications.	IACP Pentec	Clarify language. The regulation does not indicate an acceptable test method nor acceptable microbial limits for tested water. Pentec: We feel the need to test the source water and the point of use water is unnecessary as the only water that actually may add additional microorganisms into an anteroom is the source water. We believe an initial semiannual test of the point of use water followed by an annual test would be sufficient and well above the standard as the	Barnes suggests moving (13) – (16) to section 17.13 Strike (13) – (16) and add to best practice document.

			need for a water filtration system is not required in a 503A pharmacy by USP <797>.	
17.24(16)	A pharmacy engaged in high risk level compounding shall have a water purification system for water supplied to the sink used for handwashing.	IACP Pentec	Strike provision. It is not clear what evidence was used to determine that the proposed requirements of (16) are adding any value to prevent microbial contamination, or why the requirements of (16) should only be applicable to the handwashing water used by personnel conducting high risk level sterile compounding versus other sterile compounding risk levels. Pentec: Pentec was unable to identify a water purification system currently on the market that that can be used with hot water, only systems that work with cold water or systems that filter and store the water which upon use is therefore room temperature. USP <797> states you need to wash your hands with warm running water and MA regulations require hot and cold running water in pharmacies for handwashing. We respectfully request the Board provide guidance on a system that will meet all the necessary requirements.	Strike (13) – (16) and add to best practice document.
17.24(17)	A pharmacy shall incubate environmental monitoring samples at the following temperatures:	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Pharmacies should incubate EM samples based on manufacturer instructions for sampling kits. Environmental monitoring of samples should be based on the instructions supplied by the manufacturing instructions and should align with current evidence based standards found in the current or proposed USP 797. It is unnecessary to provide this level of procedural detail in a statutory regulation.	Consider clarifying to: "…in accordance with USP and manufacturer guidelines." Suggested language: A pharmacy shall incubate environmental monitoring samples **in accordance with USP and manufacturer guidelines**.
17.24(19)	A pharmacy is responsible for ensuring that all Staphylococcus organisms are identified as coagulase positive or negative.	Beth Israel Deaconess Medical Center Pentec	BI: This provision is too costly. Recommend sending out samples for identification if the trends are in the upward direction, maximum every 4 months. Pentec: Requirement should be limited to organisms recovered from an ISO 5 PEC or ISO 7 buffer room and should not include anterooms unless sampling exceeds action limits. The intent of an anteroom is to sequentially apply sterile layers to prevent any organism from entering the ISO 7 area and in turn the ISO 5, therefore you will find more growth and from a variety of sources within the anteroom. Unless the action limits per USP <797> are exceeded we do not feel growth occurring within an anteroom should be seen as an immediate threat to the health of a patient.	Strike and include in policy.

17.24(20)	A pharmacy shall utilize a two plate method for collection of viable air and surface samples. One plate shall be a general growth medium and the other plate shall be a medium that specifically supports growth of fungus.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital Pentec	Allow for the incubation of one media at two temperatures or the utilization of two types of media. For example, an FDA approved kit to conduct surface sampling would not be allowed under this regulation. This level of detail is too specific for a regulation.	Recommend for high risk only; Otherwise, best practice. Suggested language: A pharmacy **engaged in high risk compounding** shall utilize a two plate method for collection of viable air and surface samples. One plate shall be a general growth medium and the other plate shall be a medium that specifically supports growth of fungus.
17.24(21)	A pharmacy that has qualified internal personnel collect environmental monitoring samples shall validate sampling procedures at least once every six months through a qualified third-party vendor.	IACP Beth Israel Deaconess Medical Center Ge Healthcare Pentec	Extremely subjective regarding what is sufficient evidence that a pharmacy has qualified a third-party vendor. It's also extremely unclear what is needed by that vendor to validate the pharmacy's sampling procedure. Clarify what is meant by "validate sampling procedures" and what a "qualified third-party vendor" is. This is too costly. GE: Delete this requirement. It is unclear how a third part vendor would "validate" sampling procedures. If an outside party sampling is the goal of the rule, it should be stated this way and an annual frequency should be sufficient to ensure qualified internal personnel are sampling properly. Pentec: We believe this should only be required if pharmacy personnel have not been qualified or trained in sampling procedures and are performing the pharmacy's environmental monitoring. We	Strike and add to best practices.

			feel if there is a qualified microbiologist/EM department on staff that either performs the sampling or trains pharmacy personnel to appropriately perform the sampling this should not be required.	
17.24(22)	A pharmacy shall obtain a "Growth Promotion Certificate" for environmental monitoring plates to validate that the media is able to support microbial growth.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Change to "growth promotion certificate or similar" documentation. Different manufacturers use different terms.	Agree to change. Suggested language: A pharmacy shall have documentation such as a "Growth Promotion Certificate" **or similar documentation** for environmental monitoring plates to validate that the media is able to support microbial growth.
17.24(23)	A pharmacy shall utilize plates intended for environmental monitoring and may not utilize plates intended for research-only	IACP	As written this proposed regulation would require pharmacies to somehow obtain plates labeled "For environmental monitoring". If there is a concern about specific differences in environmental monitoring plates versus research plates, those specifications should be described. Remove requirement.	Strike and add to best practices.
17.25(1)	A pharmacy shall collect air samples under dynamic conditions.	IACP	Clarify when this requirement is applicable, as it conflicts with non-viable air sampling requirements in 17.24(8) which specify "prior to compounding", which indicate static conditions.	No change. Changes are recommended for 17.24(8) (EM frequency)
17.25(5)	The minimum volume of a viable air sample at each sampling location is 1000 liters.	Dana Farber	USP 797 allows 400 to 1000 samples for ISO 7 and ISO 8.	No change recommended. New draft of 797 requires 1000ml
17.27	Environmental Monitoring; Action Levels	NCPA Partners Healthcare	Align this section with USP 797. Partners: Any time an abnormal result occurs, the best practice is to have a plan in place and to document all specifics of the event including the microbiology report and remediation plan. Clinical microbiology and environmental microbiology differ in that one identifies the treatment of an infection while the other is to remediate a quantifiable value. Many hospitals must use an outside microbiology lab because the clinical labs are not equipped to measure or report the results of environmental microbiology testing. The turn-around time for results from an outside vendor is typically much longer than performing testing on-site. A root-cause analysis is a lengthy process that involves exploring all avenues to determine the reason for the excursion. Often times in the hospital setting, there is a	Consider: Suggested language: "A pharmacy shall take immediate remedial actions ~~in the event~~ **upon notification of** environmental monitoring results exceed**ing** action levels."

			high level of bio-burden alongside many variables that might be a contributing factor to abnormal results. The depth of reporting and short turnaround time for submission to the Board is not easily attainable by a hospital. It is also not clear as to the turnaround time for communication from the Board back to the hospital pharmacy. If the Board will have comments, questions or directives regarding the abnormal results, the pharmacy would need a timely response to ensure no interruption to direct patient care.	
17.27(3)	Non-Viable Air Sample Action Levels	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Change requirements to match USP 797 standards. Use "greater than" rather than "greater than or equal to."	9/6/18 Board meeting: Defer to USP levels. Create policy to address remediation (delete 17.28, but keep reporting requirements) and highly pathogenic organisms. Suggested language change throughout per USP <797> revised: "nonviable airborne particle"
17.27(4)	Viable Air Sample Action Levels	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland Partners	Remove the "greater than or equal to" sign and replace with "greater than" sign. Placing the action level at 1 CFU is inconsistent with USP 797. Additionally, expectation of 0 CFU is not realistically attainable. This will result in unnecessary and burdensome reporting for and unnecessary additional work for the Board. Pentec: We believe this proposed regulation is not realistic for anterooms and that action levels related to highly pathogenic organisms should be limited to ISO Class 5 and ISO Class 7 buffer rooms as growth within an anteroom is expected as it's the intent of the room. Though there is variability in USP for action levels of air viable and surface sampling, consistency amongst action limits will reduce the risk of confusion and a potentially missed above action level sampling.	Recommend removing charts Suggested language: (3) Except for highly pathogenic microorganisms, environmental monitoring action levels for Non-Viable Air, Viable Air, and Viable Surface samples shall be in accordance with the most current chapter of USP <797>. (4) Add highly pathogenic organisms to policy. Keep general OOC language in reg. Define in section 2 as well as policy: "highly pathogenic microorganisms, including gram-

		Healthcare Pentec		negative rods, coagulase positive staphylococcus, molds, and yeasts, regardless of CFU count" 9.6.18 Board mtg: Patrick/Kim; all approved
17.27(5)	Surface Sample Action Levels	MHA/MSHP IACP / Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo / MIPA / Boston Medical Center / Horbowicz / Vreeland / Partners Healthcare / Pentec	Same comment as above, 17.27(4).	See above.
17.28	Environmental Monitoring; Remediation of Above Action Level Environmental Monitoring Results	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA NCPA	While outlining expected pharmacy activities in response to environmental results that have exceeded action levels, this proposed regulation is extremely unclear as to purpose, role, and benefit of the Board's involvement. The reporting requirements of 17.28(2) and (3) would seem to impose additional liability risk to the Board unless acted upon within a specified time frame. Indicate whether or not some or all of this section applies to non-viable and viable environmental sampling results. Indicate whether or not Board approval of a remediation plan is required prior to a pharmacy implementing such plan. If Board approval is required, indicate the time frame within which the Board must respond to pharmacy with their approval/denial. NCPA: Align this section with USP 797.	Reporting requirement is already in place is a requirement in existing and proposed reporting regulations. 24 hour requirement will provide Board with initial notification rather than waiting until the day after a pharmacy receives environmental monitoring report. Board approval of remediation plan not required. Include statement in Board policy along with documentation requirement. USP <797> does not provide

				specific guidance for remediation. 9.6.18: Delete and defer action to Board policy. Tim/Sebastian; all "A pharmacy shall respond to and remediate AAL in accordance with Board policy."
17.28(4)	A Pharmacy shall immediately assess above action level environmental monitoring results and may not prepare any CSPs until a remediation plan is developed and implemented in accordance with "Board Policy 2015-xx: Response to Above Action Level Environmental Monitoring Results."	Dana Farber	Recommend specifying "remediation plan for the affected area" based on a risk assessment. Depending on the location of the above action level environmental sample, other areas of the facility may be able to function appropriately, which would avoid unnecessary delay in providing compounded products.	Agree with recommendation: Suggested language: ~~A~~ Pharmacy shall immediately assess above action level environmental monitoring results and may not prepare any CSPs until a remediation plan for the affected area is developed and implemented, in accordance with "Board Policy.~~–xx: Response to Above Action Level Environmental Monitoring Results.~~ Include in policy.
17.28(6)	A pharmacy shall engage the assistance of qualified personnel, such as a microbiologist, infection control professional, or an industrial hygienist to develop a remediation plan.	BioScrip	This requirement discounts the MOR's experience and could be a burden that the pharmacy undertakes unnecessarily, especially if the contamination is a skin or soil based common contaminant, usually not known for being unusually pathogenic. These types of remediation will become common place as the frequency of testing ramps up, as outline in the proposed USP 797. The issue of redundancy in the design and operation of cleanroom meantime, only sites that have excess capacity, to be able to shut down operations under these types of demands. The shutdown, remediation, and retesting requirements will necessitate that the compounding establishment will need to suspend activity for 15-17 days while waiting for the proper microbiology under these rules. In the portions of the compounding spaces, while maintaining some operations until full operations can be restored. This type of situation will demand	Recommend to strike and keep in policy.

			larger investment in monetary resources, space, and will force some providers from the market, limiting access by patients and prescribers.	
17.28(9)	A pharmacy shall demonstrate successful remediation by performing repeat environmental monitoring of non-viable air and viable air and surface (bacterial and fungal) as part of remediation to above action level environmental monitoring results. The pharmacy may limit the repeat environmental monitoring to the affected ISO classified space based on the pharmacy's environmental monitoring sampling plan unless otherwise directed by the Board.	Pentec	We feel since this proposed regulation is so specific in nature it should not leave open the option for the Board to make alternative changes or recommendations. We believe providing a pharmacy with clear guidelines to manage above action limit results allows them to proceed with a plan of correction immediately providing autonomy over their daily operations.	Strike. Will add substantive requirement that response and remediation will be in accordance with Board policy.
17.28(10)	Conditions for Resuming Sterile Compounding following an above action level environmental monitoring result:	MHA/MSHP	Exclude prescriptions affecting patient care. There should be consideration for the impact of ceasing high risk compounding of certain drugs (like ophthalmic preparations), which will have a detrimental effect on patient care. The board should make differentiation between drugs such as ophthalmic topical preparations and other sterile dosage forms.	Rework this whole section. Conditions to resume compounding in accordance with policy.
17.28(10)(a)	A pharmacy may not resume compounding in an ISO Class 5 PEC following an above action level environmental monitoring result until remediation is completed and proven by microbiology reports of repeat environmental monitoring demonstrating results within acceptable levels.	Atrius Health MHA/MSHP Mount Auburn Hospital Southcoast	Atrius: Agree with comments provided by MHA/MSHSP. Atrius Health does not have a compounding partner that would be able to meet the needs of patients in the event the PEC was closed, which would result in undue hardship for patients. It would be preferable to allow sterile compounding pharmacies to reduce BUD on the CSP rather than to stop compounding altogether. MHA: This requirement would increase harm to patients in institutions with only one hood at the time these regs go into effect. The regulations should take into consideration options to add redundancy but those take time. Patient care must be maintained in any bridge scenario and if the hood cannot be used the compounding would be pushed to the point of care outside of the pharmacy operation as immediate use compounding. MAH: Recommend altering to allow use when no alternative is immediately available. This requirement would overall increase public risk and harm to patients in institutions with only one hood.	Move to policy. 10/5/15 Advisory Committee minutes: "A pharmacy may not resume compounding in an ISO-5 Primary Engineering Control (PEC) following an abnormal EM result until remediation is completed and proven by microbiology reports of repeat EM results within acceptable levels."

			Patient care must be maintained in any bridge scenario and if the hood cannot be used the compounding would be pushed to the point of care outside of the pharmacy operation as immediate use compounding. Compounding in a hood that had grown 3 CFUs on its surface and subsequently cleaned is obviously and immensely more sanitary than any bedside compounding area if forced to choose by these regulations. Any prudent pharmacist would protect the patient v their license, these regs should not place a pharmacist in that position. Southcoast: Will the BOP be able to address specific situations when a buffer area/pharmacy only accounts with a single Laminar Flow Hood /ISO 5 PEC for compounding? If a positive environmental test demonstrates growth in an ISO 5 location, pharmacy will be required to stop compounding activities altogether (and may not resume compounding) until remediation is completed. Some remediation procedures may include: performing thorough cleaning/disinfection of affected PEC's, review cleaning and garbing procedures with personnel, and resampling affected areas by a qualified certifier. Usually, certification companies may take from 1 to 2 weeks to schedule a visit to pharmacies for environmental testing and microbiology results may become available after 2 -3 weeks (including preliminary testing and final culture identification). In the meantime, the pharmacy may not resume compounding activities. In this instance, we are compromising patients care by not being able to compound CSP's and other options such as outsourcing products may take some considerable time to reach pharmacies. Another option is to compound CSP's following the immediate use clause by USP 797, which limits compounding to low risk level and under emergent situations , compromising patient's safety and quality of care. A recommendation for this clause would be to perform deep cleaning procedures (3-step cleaning) for each shift for the affected PEC's and during the retesting /remediation period, allow compounding of CSP's as long as the BUD assigned is 24 hrs room temperature or 3 days refrigerated (similar to BUD's for high-risk level compounding). Following this approach, will allow pharmacies that are in the remediation period serve patients by not disrupting their compounding operations.	
17.28(10)(b)	Upon receipt of an above action level environmental monitoring result in	MHA/MSHP	**Recommendation for part (A)**: Remove 6 month criteria. If testing is done monthly then any 3 consecutive action level findings will be	Rework this whole section. Move to a policy.

	ISO 7 buffer room, a pharmacy may resume compounding for low and medium risk level CSPs if: A. The environmental monitoring data does not indicate 3 or more consecutive sampling reports with above action level results within the last 6 months; and B. The pharmacy has immediately assessed the above action level environmental monitoring results, developed and implemented a remediation plan, and scheduled repeat monitoring.	Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland Kelly Barnes Mount Auburn Hospital Pentec BioScrip	within the last 6 months. Recommend considering that 3 consecutive action levels at different sites with different organisms is not the same as three consecutive fungal hits in the same air location sample **Recommendation for Part (B)**: Instead of stopping compounding completely, put a 12 hour time frame (commonly used in practice today), to prevent pharmacies from having to shut down any action level. It has been proven that you are bound to and should get positive results by having ISO 7 negative pressure adjacent anteroom and a sink. Remove 6 month in section A. A pharmacy must consider the nature of the action levels, what type of same, what they have done for previous mitigation, and then must act accordingly. Hospitals must continue to service patients in the safest way possible and there are very few action levels that dictate a complete shutdown of operations for an extended period of time. Since the pharmacy must submit its plan to the Board, the Executive Director's office needs to be staffed adequately to respond immediately if they feel a report should constitute shutdown, this includes a plan for weekends. A hospital pharmacy with a 24/7 operation and critically ill patients cannot wait even 24 hours for a response. If the Board cannot provide a level of immediate response, then rules need to be made such that pharmacy can exercise decision making appropriate to the action level in line with USP 797 recommendations. In addition, these sections should be re-evaluated for clarity. Sub-sections A and B in both (b) and (c) are repeated with conflicting information in sections (b) 4. and (c) 4. Section 4 conflicts with the high risk recommendations in both 10.(b)2 A, and 10 (c)2A. should be removed in both sections. Barnes: Add new provision – "A pharmacy may not engage in high risk level compounding upon receipt of an above action level environmental monitoring result in ISO 7 buffer room if the environmental monitoring data indicates 2 or more consecutive sampling reports with above action level results." This would correct technical omission. Also recommend the Board consider relying on more factors than consecutive results as basis for deterring when compounding should cease. Consider, "if the environmental	The regulation doesn't require shutting down; just pausing to evaluate and remediate.

			monitoring data indicates 2 or more sampling reports with above action level results <u>within the prior 6 months</u>," rather than consecutive reports with above action level results. MAH: Recommend removing 6 month criteria. If testing is done monthly then any 3 consecutive action level findings will be within the last 6 months. Recommend considering that 3 consecutive action levels at different sites with different organisms is not the same as 3 consecutive fungal hits in the same air location sample. Pentec: Eliminate requirement. We do not believe there should be variability in the timeframe a pharmacy can resume compounding it should be consistent no matter the risk level they compound. An exceeded action limit inherently places patients at risk and therefore all pharmacies should follow the same guidelines to ensure patient safety. In addition, selecting an arbitrary number such as 3 consecutive sampling reports in 6 months cannot be applied unless there is scientific evidence to show there is a direct correlation between the number of consecutive above action limit sampling reports and patient safety. BioSrip: The requirement that environmental monitoring data of 3 or more consecutive sampling reports with above action level (with in last 6 months) does not speak to the possibility that unrelated microbes or unrelated areas could be involved, making the fact that simply having "microbial hits" within the compounding space can be explained and since they're unrelated may not indicate a widespread problem.	
17.28(b)(2)(A)	The environmental monitoring data does not indicate 2 or more consecutive sampling reports with above action level results.	Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Add "within the last 6 months."	Rework this whole section. Move to a policy.
17.28(10)(b)(3)	A pharmacy resuming compounding of CSPs during remediation of ISO 7	IACP	**Change to:** A pharmacy resuming compounding of CSPs during remediation of ISO 7 buffer room above action level results shall	Rework this whole section. Move to a policy.

	buffer room above action level results shall limit the BUDs for CSPs to 24 hours room temperature, 3 days refrigerated or a timeframe agreed upon by the Executive Director or his or her designee until the repeat environmental monitoring reports demonstrate results within acceptable levels.	Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Pentec	limit the BUDs for CSPs prepared in that buffer room to shorter than or equal to USP 797 BUDs. Pentec: Eliminate requirement. Current USP <797> guidelines for BUDs of high risk compounds is 24 hours room temp and 3 days refrigerated. We believe modifying the BUD for a low or medium risk compound, which by their definition are less likely to cause patient harm; to the standard BUD of a high risk compound with no change in BUD dating of high risk compounds does not correlate with a reduction in the potential for patient harm. Additionally, per the proposed regulation 17.28(4) a pharmacy may not resume compounding until remediation has occurred and therefore we believe modifying BUDs of low and medium risk compounds is unnecessary.	
17.28(10)(b)(5)	A pharmacy may not freeze any CSP upon receipt of an above action level environmental monitoring result in ISO 7 buffer room until repeat monitoring reports demonstrate results within acceptable levels unless otherwise approved by the Executive Director or his or her designee	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Strike this provision. USP 797 allows for the preparation of CSPs that are stored in frozen storage conditions. There are compounded medications that require frozen storage for stability assurance. This requirement will limit patient access to these medications and will result in a gap in patient therapy.	Rework this whole section. Move to a policy.
17.28(10)(c)	Upon receipt of an above action level environmental monitoring result in ISO 7 ante room or ISO 8 classified area(s), a pharmacy may resume compounding of low and medium risk level CSPs if: A. The environmental monitoring data does not indicate 3 or more consecutive sampling reports with above action level results within the last 6 months; and B. The pharmacy has immediately assessed above action level environmental monitoring results, developed and implemented a remediation plan, and scheduled	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Mount Auburn Hospital	**Recommendation for Part (A)**: removing 6 month criteria. If testing is done monthly then any 3 consecutive action level findings will be within the last 6 months. **Recommendation for Part (B)::** considering that 3 consecutive action levels at different sites with different organisms is not the same as three consecutive fungal hits in the same air location sample. IACP: See comments for 17.28(10)(b). Pentec: See comment above.	Rework this whole section. Move to a policy.

	repeat monitoring.	Pentec		
17.28(11)(a)	A pharmacy's response to above action level environmental monitoring results shall include the following: (a) examination by an accredited laboratory;	MHA/MSHP Mount Auburn Hospital Pentec BioSrip	Remove (a). Utilizing a microbiologist, industrial hygienist or infection control professional on staff in most institutions will be more than adequate. Regulations should reflect that other staff that an institutional facility may have (as compared to a commercial pharmacy). Pentec: Needs clarification if this provision is referring to the entire excursion process or simply that an accredited lab will need to review/identify organisms. Also, need clarification on "accredited laboratory." BioScrip: Examination by an "accredited laboratory" is not well defined and the Board is not a qualified agency to properly make this determination. Some later determination by the Board could limit the available providers and therefore limit access by patients.	Rework this whole section. Move to a policy.
17.28(11)(d)	A pharmacy's response to above action level environmental monitoring results shall include the following: (d) comprehensive root cause analysis;	BioScrip	"comprehensive root cause analysis" is not well defined, and is ultimately a cGMP term, if used in the cGMP context, the requirement for a definitive cause maybe an impossible end result for the average pharmacy. Ultimately, drilling down to determine a definitive root cause may be unnecessary since responding to the two or three possible causes can be addressed simultaneously. Not requiring a protracted suspension of operations waiting for an excessive amount of testing. Remediation of the two or three possible causes, will allow for proper resolution of the issue, while bringing compounding establishment back on line in the most expedient way possible.	Rework this whole section. Move to a policy.
17.29(7)	A licensee shall allow sterile 70% isopropyl alcohol to remain in contact with surfaces to be disinfected for 30 seconds before compounding activates are started.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Clarify that sterile IPA is to be used inside the ISO Class 5 PEC and/or immediately prior to transferring materials into the ISO 5 PEC. Non-Sterile IPA is permitted on surface outside of the ISO 5 PEC in the ISO 7 buffer room (such as stainless steel tables were staging occurs). This regulation is confusing and gives the impression that only sterile 70% IPA is permitted for used in sterile compounding (including outside of the ISO 5 PEC). Non-sterile IPA is traditionally acceptable when disinfecting items outside of the PEC (surfaces, staging materials, etc.)	From new 797 revision: "The manufacturer's directions or published data for the minimum contact time must be followed for the cleaning, disinfecting, and sporicidal agents used." Suggested language: A licensee shall follow manufacturer's directions or published data for the minimum contact time for cleaning,

				disinfecting, and sporicidal agents used in classified environments.
17.29(11)	A pharmacy shall sanitize a sink drain with a disinfectant at least once per week.	Boston Medical Center / Horbowicz / Vreeland	Remove this section. There is no precedent in USP 797 or elsewhere for attempting to sanitize a sink drain. It is a dangerous practice to pour disinfectant chemicals into a sink in the volume that would be sufficient to sanitize a drain. Splashing can occur that has potential to harm compounding personnel, from both topical contact and inhalation of volatized disinfectant. Surface cleaning of the sink with disinfectant should be a part of the daily surface cleaning SOP.	Strike and defer to microbiologist recommendation per facility.
17.29(13)	A pharmacy may not engage in compounding during daily or monthly cleaning activities.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Clarify "in the specific area being cleaned." For example, cleaning in one buffer room and compounding in a separate buffer room or separate area of the pharmacy. Consideration should be given to STAT patient medication orders.	Strike and include in guidance document.
17.29(14)	A pharmacy shall verify its cleaning agents are appropriate. A pharmacy shall maintain a certificate of analysis for each cleaning product, if available.	GE Healthcare BioScrip	Current language is unclear. Suggest: "A pharmacy shall use cleaning agents as deemed appropriate by the facility's quality program."	Strike and add to a guidance document.
17.30	Sterile Compounding Process; Hand	GE Healthcare	Add: "Personnel shall perform hand hygiene and don personal	No change recommended.

	Hygiene and Garbing		protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following is to be followed unless the pharmacy documents a method equivalent to or superior to the method described here:" Suggest adding this language to allow for methods of hand hygiene and garbing with sinks external to the ante room where the licensee can sufficiently prove to the Board the processes developed at the facility are equal to or superior to the method described.	Facilities with alternative designs may apply for a waiver.
17.30(2)	Compounding personnel shall wear clean, laundered scrubs only worn within the facility. Scrubs shall be laundered following each use. A pharmacy shall have a changing area for sterile compounding personnel to change that minimizes travel through non-classified areas.	GE Healthcare Pentec BioScrip	GE: Change to: "Compounding personnel shall wear clean, laundered clothing. Clothing shall be laundered following each work shift." The use of the term "each use" is too vague. Requirements regarding change room and scrubs are unnecessary and overly restrictive. Pentec: It is not necessary to state the changing area should "minimize travel…" since the travel distance will be different for each pharmacy based on facility design. As long as the scrubs are disposable or only worn within the facility, the intent of the regulation is clear. BioScrip: This should be a best practice. The policing of the requirement that scrubs shall be laundered after each use will be difficult to enforce. Will these trigger the necessity of business to provide centralized provision of scrub clothing and laundry services? Adding cost to the provision of care.	Board discussion on changing areas. Suggested edits: Compounding personnel shall wear clean, laundered scrubs only worn within the facility. ~~Scrubs shall be laundered following each use.~~ A pharmacy shall have a changing area for sterile compounding personnel to change that minimizes travel through non-classified areas.
17.30(3)	Compounding personnel shall use dedicated shoes or shoe covers while in classified areas.	Beth Israel Deaconess Medical Center Kelly Barnes Mount Auburn Hospital	BI: Storage issue. What is the issue with double booties? This is required in USP 800. MAH: Recommend removing. The utilization of booties provides a covering on shoes which can serve the same purpose and may allow for added protection. If regulation remains, would recommend clarifying the term dedicated to include that they must be stored in the ante room. Dedicated shoes stored in the employee's locker should not be allowed.	No change recommended. Double shoe covers or dedicated shoes and shoe covers. Facilities P&P can dictate storage.
17.30(4)	Prior to entering an ante room, compounding personnel shall don scrubs and dedicated shoes.	MHA/MSHP Boston	Add "or shoe covers" to align with 17.30(3).	Clarify to: "…either dedicated shoes **or shoe covers**."

		Medical Center / Horbowicz / Vreeland Kelly Barnes	Barnes: Add – "either dedicated shoes or shoe covers shall be donned immediately prior to entering the ante room."	Suggested language: Prior to entering an ante room, compounding personnel shall don scrubs and dedicated shoes **or shoe covers**.
17.30(6)(c)	Once on the clean side of the line of demarcation, but prior to entering the buffer room, compounding personnel shall perform the following tasks in the following order: (c) don: 1. a non-shedding disposable coverall for low and medium risk level compounding; or 2. a non-shedding sterile disposable coverall for high risk level compounding.	IACP Boston Medical Center / Horbowicz / Vreeland GE Healthcare Kelly Barnes	Remove "disposable" requirement from (2). If non-sterile coverall is used, it is appropriate to require that coverall to be disposable, however if a sterile coverall is used, it seems unnecessary to require that sterile coverall to be disposed after use; many sterile coveralls are reusable in that they are laundered, sealed, and re-sterilized by an outside company prior to being sent back to the pharmacy. Also need adjustment to 17.30(12). GE: The requirement for coveralls for low and medium risk compounding is excessive. Recommend: "a non-shedding disposable coverall **or full length lab coat with complete closure to the neckline** for low and medium risk level compounding" Barnes: Change to – 1. a non-shedding **clean** coverall for low and medium risk level compounding; or 2. a non-shedding sterile ~~**disposable**~~ coverall for high risk...	Agree to remove the word "disposable" and add "clean" to (1) Also remove "disposable" from 17.30(2) Nuclear pharmacy issues be handled separately. Suggested language: Once on the clean side of the line of demarcation, but prior to entering the buffer room, compounding personnel shall perform the following tasks in the following order: (c) don: 1. a non-shedding **clean** ~~disposable~~ coverall for low and medium risk level compounding; or 2. a non-shedding sterile ~~disposable~~ coverall for high risk level compounding.
17.30(10)	A compounding individual shall perform antiseptic hand cleansing using a waterless alcohol based surgical hand scrub and shall don new sterile gloves prior to reentering the buffer room if he/she exited the buffer room but did not cross the line of demarcation.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon /	Is It necessary to don a new pair of gloves if the compounding employee stays on the clean side of the line of demarcation in the ante room providing they follow the proper protocol for disinfecting and sanitizing their gloved hands upon re-entry into the buffer room? Recommendation: Allow the use of a separate cart pass through or product pass through room without the removal of gloves and re-donning. There is an increased risk for contamination with material	Strike.

		Allibhani / Petrosillo MIPA Kelly Barnes Mount Auburn Hospital NCPA BioScrip	transfer into cleanroom without gloves on. Sterile compounding personnel are permitted to move between the buffer room and the "clean" side of the anteroom without donning new sterile gloves when participating in cleaning activities, environmental monitoring activities, staging compounding materials in the buffer room, etc. The way this regulation is written, it can be interpreted that this would not be permitted. Change "A compounding individual" to "Prior to performing aseptic compounding, an individual…" Barnes: Change to – "…done new sterile glove prior to **re-engaging in sterile compounding** if he/she exited the buffer room…" NCPA: Consider modifying to specify individuals performing aseptic or sterile compounding. BioScrip: The need to dispose of gloves if a compounder exits the buffer room but does not cross the line of demarcation may cause two situations, both increasing the cost of service: (1) if personnel exits the buffer room to consult with staff to clarify a clinical question and then discards gloves repeatedly, the value of this process is in question; (2) if personnel cannot exit the buffer to retrieve essential supplies, no matter the quantity, this speaks to the necessity of the installation of pass thru cabinets.	
17.30(12)	The non-shedding disposable coverall may be removed and retained in the compounding area if not visibly soiled to be re-donned by the same personnel during that shift only. All other garb must be discarded and replaced with new garb before entering the compounding area.	Kelly Barnes	Remove "disposable."	Agree. See above. Suggested language: The non-shedding ~~disposable~~ coverall may be removed and retained in the compounding area if not visibly soiled to be re-donned by the same personnel during that shift only. All other garb must be discarded and replaced with new garb before entering the compounding area.
17.31(3)	A pharmacy may not use paper in an ISO 5 Classified area	Beth Israel Deaconess Medical	BI: What is this? Omnicell: Restate to say "a pharmacy must minimize the use of	Strike and edit 17.14(6) as above.

		Center Omnicell	paper…" This change is required in order to provide for labeling of compounding sterile products immediately after processing in order to prevent mislabeling or labeling mix-ups which are a much greater safety risk than the presence of paper in ISO 5.	
17.31(6)	Syringes, needles, and tubing are only removed from outer wrapper packaging in the ISO Class 5 area.	GE Healthcare	Change "syringes" to "needleless syringes." The introduction of the outer wrapping of hundreds of syringes with attached needles into the ISO Class 5 PECs during compounding activities at a nuclear pharmacy would pose a greater risk of contamination to the product than the controlled removal of outer wrappings of those closed systems in the ISO Class 8 or better air quality.	No change recommended.
17.32(2)	A pharmacy may not expose non-hazardous drug environments to hazardous drugs or components in any ISO classified area.	Boston Medical Center / Horbowicz / Vreeland Dana Farber	BMC: Remove this section. Hazardous buffer rooms are often built to share an ante room with a non-hazardous buffer room. This is section is in direct conflict with USP 800 which promotes the shared anteroom arrangement as the ideal clean room design. It will be impossible to meet this regulation if an institution has a USP 800 compliant cleanroom set-up within the main pharmacy space. If left as written, this would mean that hospitals would need to build entirely separate facilities for hazardous compounding. For our hospital and most others, this would not be feasible due limited physical plant space and cost constraints. Dana Farber: Recommend editing the statement to say, "on occasion may expose…" with appropriate labelling and proper PPE precautions taken. Certain Pharmacies who predominantly do Hazardous medications – it is not efficient to have a separate Hazardous and non-Hazardous area, if proper precautions and labelling take place, exposure can be contained just the same as with separate areas.	Strike and address in 247 CMR 19.00
17.32(5)	A pharmacy shall maintain a written continuity of care play that describes how patient needs will be met in the event the pharmacy is unexpectedly unable to compound or dispense CSPs.	Atrius Health	Atrius does not partner with another facility and would be unable to meet this requirement; Atrius would have to send its patients elsewhere.	No change recommended. Continuity of care plan to specify "backup" pharmacy
17.33(5)	Compounding personnel, including supervising pharmacists, shall pass didactic coursework, practical skill assessment through competency evaluation, media fill testing, and gloved fingertip/thumb sampling before being allowed to compound	MHA/MSHP Southcoast	Clarify whether per-diem workers, part-time employees, employees going on LOA be required to be requalified following the same guidelines of a new trainee (3 fingertip/3 media fill tests) , or treated as a re-evaluation competency (1 fingertip/1 media fill test). Southcoast: Please clarify term "supervising pharmacists." Does this include pharmacy managers and pharmacy directors? Also, there are	Suggested language: "All ~~compounding~~ personnel **who physically compound or directly supervise compounding** ~~including supervising pharmacists,~~ shall pass didactic coursework…"

	sterile preparations.		pharmacists who do not perform compounding procedures but assist in order entry, verifying and checking IV preparations in the pharmacy. Will all pharmacists be required to pass all competency testing? Leadership does not perform compounding procedures (in the course of 3 months), will they need to be retested to be qualified to supervise IV personnel?	This standard does not deal with requalification. See below.
17.33(6)	Compounding personnel shall be requalified in all core competencies if a pause in compounding exceeds three months.	Jeffrey Lynch BioScrip	Lynch: Places and extreme burden on pharmacy, time needed to repeat training, difficult to maintain per diem personnel. Six months would be more realistic. BioScrip: How will "pause" be defined? How will this requirement be enforced? What is the value of this requirement? If an on call or management professional is pressed into service, the provision could prevent patients from receiving emergency or other urgent services or could delay service will alternate staff is located.	New 797 draft: "After a pause in compounding: Personnel who have not compounded CSPs in more than 6 months must be requalified in all core competencies before they may resume compounding duties." Suggested language: Compounding personnel shall be requalified in all core competencies if a pause in compounding exceeds ~~three~~ **six** months. 10/18/18 Board: define requalification
17.33(7)	A pharmacy shall ensure all compounding personnel, including supervising pharmacists, are evaluated on hand hygiene and garbing, cleaning and disinfecting, and aseptic technique initially and at least:	Jeffrey Lynch	Since media fills are performed quarterly, does this mean they are not assessed in writing each time? Are they observed during media fill? Or can personnel perform the media fill independently?	Suggested language: A pharmacy shall ensure all personnel **who physically compound or directly supervise compounding,** are evaluated through visual observation on hand hygiene and garbing, cleaning and disinfecting, and aseptic technique initially and at least every 6 months.
17.33(11)	A pharmacy shall send each failed gloved fingertip/thumb sample and media fill sample for microbial identification to the genus level. All staphylococcus organisms must be	BioScrip	This is costly and excessive. Compounders will be removed from service until a "clean sample" can be obtained. The long term value of this testing against its costs is questionable.	Strike and include as best practice with language below: "A pharmacy shall investigate and document findings and corrective

	identified as coagulase positive or negative.			actions for each failed gloved fingertip/thumb sample and media fill sample."
17.33(12)	In the event a compounding individual fails a gloved fingertip/thumb sample or media fill sample, the pharmacy shall evaluate the CSPs prepared by that individual to detect potential contamination of the CSP.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo Berkshire Heath Systems MIPA Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital	Remove this provision. Gloved fingertip/thumb samples are retrospective data and the requirement to review compounding records and patient infection data provides only supplemental data within an institution. Administration procedures in non-classified spaces are a more likely source of line infections or bacteremia than the CSP itself. There is merit in obtaining CSP related contamination data in the event of a bacteremia or line infection in which the CSP is a theorized vector. Elaborate on the process that should be followed to "evaluate the CSPs prepared by the individual who failed the competency." It can take days to weeks to receive results of media fills and gloved fingertip samples.	Suggested language: "A pharmacy shall initiate an investigation and document actions in response to repeated failed gloved fingertip tests or media fills by a compounding individual including the potential impact on CSPs." 10/18/18 Board: edit "investigation; initiate/review?
17.33(14)	Personnel monitoring gloved fingertip/thumb sampling shall include the use of positive and negative controls.	Jeffrey Lynch Pentec BioScrip	Lynch: One positive and one negative control per manufacturer lot? Or per gloved fingertip/thumb sample? Pentec: We are unclear how a positive control would be utilized to verify media sampling. We do not feel there is a practical way to obtain a positive control, and additionally, the standard of practice is to utilize a negative control in laboratories. BioScrip: This will require pharmacies to bring known microbes into compounding operations, thus increasing the chance for a facility created contamination. The routine requirement for negative controls assures the media employed is appropriate and the consultation of the certificate of analysis for each batch of media will assure that the media supports the proper spectrum of growth without the added costs, complexity, or dangers of requiring positive media controls.	Strike.

17.33(15)	Personnel monitoring media fills shall include the use of negative controls. Personnel monitoring media fills shall also include the use of positive controls if…	Jeffrey Lynch	Commercially available media fill kids do not contain extra bags or vials of growth media to use as negative control. How would this be accomplished?	Strike (14), (15) and (16) and edit (13) to: Suggested language: A pharmacy shall verify and maintain Growth Promotion Certificates or similar documentation that each lot of media for personnel monitoring is able to support microbial growth.
17.34	Sterile Compounding Personnel Training; Gloved Fingertip/Thumb Sampling	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital NCPA Partners Healthcare	This section should be adjusted to allow for the use of fingertip sampling kits when used in accordance with manufacturer instructions. NCPA: Align this section with USP 797. Partners: It is imperative for all practitioners that perform and oversee sterile compounding have the skill set and knowledge base to avoid errors and contamination. While we are in support of more frequent fingertip and media fill challenge testing than is currently required, we are not equipped for daily and batch specific challenge testing. This will require time, resources and space that does not exist in the hospital setting. However, it would be very feasible for hospitals to comply with the new draft of <USP> 797 with quarterly media-fill and fingertip testing.	Rework this section (see below): Strike (9): plate size to allow for various "kits" ~~"After initial qualification, testing shall be every 3 months for extended BUDs, anticipatory compounding, or high risk compounding. Otherwise, testing shall occur every 6 months."~~ GFS after completing daily compounding will be added to best practices.
17.34(3)	All compounding personnel shall successfully complete at least 3 gloved fingertip/thumb sampling procedures before initially being allowed to prepare CSPs and annually thereafter. The action level for this gloved fingertip/thumb sample is 1 CFU for both gloves.	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Jeffrey Lynch	The requirements for gloved fingertip/thumb sampling in (3) and (6)(a) appear to conflict. (3) states annually and (6)(a) states quarterly. Lynch: So, after initial qualification, repeat x3 sets annually or x1 set annually?	Need to resolve conflict. As above from 17.24(8): Consider 1) **Gloved Thumb/ Fingertip (hand hygiene and garbing)**: Initially x3, then for any media fill or glove failure x3 2) **Gloved Thumb/ Fingertip (aseptic technique):** after each media fill

				10/4/18 Board: reword (1) in above Tim/Andy all Suggested language: All compounding personnel shall successfully complete at least 3 gloved fingertip/thumb sampling procedures before initially being allowed to prepare CSPs and ~~annually thereafter~~ and **must be repeated for any gloved fingertip/thumb sampling failure or media fill failure**. The action level for this gloved fingertip/thumb sample is 1 CFU for both gloves.
17.34(5)	All gloved fingertip/thumb sampling performed after the initial qualification shall be performed at the conclusion of compounding.	Jeffery Lynch	Does this mean quarterly media fill will include a GFS after, but not prior? And then once annually, perform GFS prior to media fill as well as after? How many sets?	After media fill. Suggested language: After initial qualification, all gloved fingertip/thumb sampling performed shall be performed ~~at the conclusion of compounding~~ **after each media fill.**
17.34(6)	Frequency of gloved fingertip/thumb sampling (a) Compounding personnel shall perform gloved fingertip/thumb sampling at least quarterly. (b) In addition to quarterly gloved fingertip/thumb sampling, an individual who prepares low or medium risk level CSPs with extended BUDs shall perform gloved fingertip/thumb sampling each day he/she prepares such CSPs. (c) An individual who prepares high risk level CSPs shall perform	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Beth Israel	MHA: This should be changed to align with new draft of USP 797; quarterly fingertip testing with no more than 3 CFUs for both hands. IACP: Align regulation with USP 797 requirements. Proposed regulation far exceeds existing standards and would require pharmacies to hire additional staff to perform and monitor tests. BI: Overkill; huge cost. NCPA: Testing at this frequency could require sterile compounding pharmacies to hire additional pharmacy personnel to perform and monitor gloved fingertip test media, resulting in greatly increased costs to the pharmacy. There is no evidence of benefit for this testing frequency.	See above. GFS after completing daily compounding will be added to best practices. 10/4/18: rework as above Suggested language: After initial qualification, compounding personnel who prepare low or medium risk level

	gloved fingertip/thumb sampling at least once per month and each day he/she prepares such a CSP. (d) Compounding personnel who prepare high risk level CSPs: 1. with extended BUDs; 2. in anticipation of a patient specific prescription or order; or 3. that include high risk intermediate or stock solutions shall perform gloved fingertip/thumb sampling at least once per week and each day he/she prepares such CSP.	Deaconess Medical Center Boston Medical Center / Horbowicz / Vreeland NCPA Pentec	Pentec: Remove. This provision is redundant to 17.35(1). Section (c) is excessive for 503A pharmacies.	CSPs shall perform gloved fingertip/thumb sampling **at least semi-annually after each media fill**. After initial qualification, compounding personnel who prepare high risk level CSPs shall perform gloved fingertip/thumb sampling **at least quarterly after each media fill.**
17.34(7)	A pharmacy that prepares high risk level CSPs or low and medium risk level CSPs with extended BUDs shall utilize both a general growth media and a fungal specific growth media for all gloved fingertip/thumb sampling.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA NCPA	TSA is a general growth media that is capable of growing both bacterial and fungal CFUs when incubated at appropriate temperatures. Requiring the use of two different media will result in unnecessary testing fees and an increase to the overall cost of healthcare. Strike this requirement or revise to include incubating a general growth media (TSA) at two temperature ranges; 30- for 24-48 hours, then 20- for 5-7 days to promote growth of both bacterial and fungal organisms NCPA: Consider modifying to require incubation of general growth media at appropriate temperatures to promote bacterial and fungal growth instead of requiring two different growth media.	Agree Otherwise, best practice (especially high risk).
17.35	Sterile Compounding Personnel Training: Media Fill Challenge Testing	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland NCPA	Align media fill testing with new draft of USP 797, which is quarterly testing. Suggest combining this with quarterly fingertip testing as description contradicts what is stated in 17.34. NCPA: Align this section with USP 797.	Align with GFS frequency As above from 17.24(8): Consider **Media Fills**: Initially x1, then: - **Semiannually** for low/medium risk - **Quarterly** for high risk 10/4/18 Board: as above Suggested language: Compounding personnel who prepare low or medium risk level CSPs shall complete a media fill

				before initially being allowed to prepare CSPs. Following initial qualification, compounding personnel who prepare low or medium risk level CSPS shall complete a media fill **at least semi-annually**. Compounding personnel who prepare high risk level CSPs shall complete a media fill before initially being allowed to prepare CSPs. Following initial qualification, compounding personnel who prepare high risk level CSPS shall complete a media fill **at least quarterly**.
17.35(1)	Compounding personnel who prepare low and medium and high risk level CSPs shall complete three media fills before initially being allowed to prepare CSPs. Following initial qualification, compounding personnel shall complete one media fill at least quarterly. Compounding personnel shall perform gloved fingertip/thumb sampling immediately following the last media fill test procedure.	Beth Israel Deaconess Medical Center Jeffrey Lynch	BI: Overkill; huge cost. Lynch: As above. When are sterile GFS repeated, if ever?	See above.
17.35(6)	A pharmacy shall incubate media fill units utilizing general microbial growth promotion media at 30- (86-95) for a minimum of 7 days, followed by an incubation at 20- (68-77 ºF) for 7 days.	Atrius Health MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn	Agree with comments from MHA/MSHP. Atrius' compounding pharmacy has only once incubator, and if it was required to use different temperatures, it would impose significant challenge. Adjust to allow for the use of validated media fill kits. This information is too specific for regulation and does not allow flexibility for advancements in sampling kits.	Consider clarifying to: Suggested language: "A pharmacy shall incubate media fill units utilizing general microbial growth promotion media **in accordance with USP and manufacturer guidelines**." Revised Draft of USP <797>:

		Hospital		Once the compounding simulation is completed and the final containers are filled with the test media, incubate them in an incubator for 7 days at 20°–25° followed by 7 days at 30°–35° to detect a broad spectrum of microorganisms. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days.
17.36(5)	A pharmacy shall ensure incubators are calibrated and certified to NSIT standards at least annually or more frequently in accordance with manufacturer specifications.	Kelly Barnes	Change "incubators" to "microbiological incubators." Spell out NIST as "National Institute of Standards and Technology."	Agree with recommendations Suggested language: A pharmacy shall ensure **microbiological** incubators are calibrated and certified to **National Institute of Standards and Technology (NIST)** standards at least annually or more frequently in accordance with manufacturer specifications.
17.36(7)	A pharmacy shall record temperatures of incubators daily.	IACP GE Healthcare	IACP: As written the proposed regulation would require daily temperature recording, including weekends or holidays, of incubators even if there are no samples being stored/incubated on that day. Add: "on business days when in use." GE: Change to: "A pharmacy shall record temperatures of incubator each day of use."	Agree with recommendation Suggested language: A pharmacy shall record temperatures of incubators **at least each business day when incubating samples** ~~daily~~.
17.37	Sterile Compounding Robotics	Omnicell	Recommend adding: "The use of IV compounding robots that prepare CSPs with strict automated process control in an aseptically closed environment is encouraged as they can improve the quality of compounded sterile products vs manual processing." Please see Omnicell's full comment for further details.	No change recommended.
17.37(13)	A pharmacy shall adhere to	MHA/MSHP	This is done electronically, so remove "pharmacy shall" and change	No change recommended.

	manufacturer recommendations pertaining to the maximum time ingredients or components may be stored in the sterile compounding robot. Documentation shall occur each instance an ingredient or component is added or replaced.		to "documentation must occur at each instance…"	
17.38(3)	A pharmacy that performs high risk level sterile compounding shall confirm that APIs meet the requirements of the FDCA, 503a.	IACP	Add the word "human" prior to the word "high." Section 503a is applicable to human patients only. As written, the proposed regulation would unnecessarily impose 503a requirements onto animal patients.	No change recommended.
17.39	Sterilization and Depyrogenation	NCPA	Align this section with USP 797.	See 17.39(2) below
17.39(1)	A pharmacy may not utilize ethylene oxide gas or irradiation to sterilize components, equipment, ingredients, or CSPs.	IACP	Remove this requirement. There is no known basis for this prohibition, other than to potentially support the proposed prohibition on the dosage forms found in 17.06(2). Components purchased by pharmacies pre-sterilized, such as sterile filters, sterile tubing, sterile syringes, etc. are normally sterilized via one of these sterilization methods. This proposed regulation would prevent a pharmacy from utilizing those components. In addition, a pharmacy that utilizes these sterilization methods according to a validated sterilization process, including stability testing of the finished preparation, should be permitted to continue to do so.	No change recommended. USP revised chapter references irradiation for terminal sterilization. This standard applies to pharmacies conducting the sterilization not pharmacies procuring manufactured components that have been sterilized by one of these methods. Pharmacies seeking to utilize one these methods may apply for a waiver. 10/18/18 Board: no change to standard
17.39(2)	A pharmacy may not utilize steam sterilization or dry heat sterilization if the CSP can be sterilized using filtration.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Strike this requirement. This proposed regulation appears to be in direct conflict with USP <797>, is in direct conflict with all principals of contamination control related to sterile medications, and if promulgated, will actually increase risk to the public. Steam sterilization and dry heat sterilization are typically performed to terminally sterilize the CSP in its final container. The fact that these sterilizations methods do not require manipulation of the CSP after sterilization make them significantly less risky than filtration sterilization, which requires the manipulation of the	Strike.

		Blaire Pharmacy Consulting	CSP after it has been sterilized. Blaire: USP prefers terminal sterilization to filtration. Why would Board issue regulations that require a less than ideal procedure for such a critical process?	
17.39(3)	A pharmacy shall sterilize the final preparation of a high risk level CSP, even if intermediate or stock solutions were previously sterilized.	Blaire Pharmacy Consulting	Blaire: See comment to 17.06(3). Many CSP require the combination of pre-sterilized ingredients (e.g.: PZI Insulin, Cyclosporine Ophthalmic Drops) because it is impossible to sterilize the final product. Section should be struck or language should be changed to: ...so long as sterility of the final patient CSP is confirmed.	Suggested language: A pharmacy shall sterilize the final preparation of a high risk level CSP, even if intermediate or stock solutions were previously sterilized, **unless any component cannot be sterilized and provided that the sterility of the final patient CSP is confirmed in accordance with USP <71>**.
17.39(4)	A pharmacy shall depyrogenate all glassware and containers, able to withstand dry heat, utilized for sterile compounding with dry heat.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Dana Farber	Add: "unless utilizing sealed, unopened, commercially depyrogenated glassware and containers…" Dana Farber: Recommend "a pharmacy shall ensure that all glassware and containers utilized for sterile compounding and able to withstand dry heat are depyrogenated with dry heat."	Agree with recommendations. Suggested language "A pharmacy shall ensure that all glassware and containers utilized for sterile compounding that are able to withstand dry heat are depyrogenated with dry heat unless utilizing sealed, unopened, commercially depyrogenated glassware and containers."
17.39(5)(c)	A pharmacy shall utilize sterile filters that are intended for human-use applications in sterilizing CSPs and suitable for the intended use.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Change "intended for human use" to "pharmaceutical grade." Most filters are labeled "Pharmaceutical Grade" not "intended for human-use" and most pharmaceutical manufacturers are hesitant to state that the filters are suitable for human use. Changing this verbiage to "pharmaceutical grade" will eliminate the use of "for research only filters", if that is the intent of the regulation.	Agree with recommendation USP Revised <797> draft refers to as "sterilizing-grade" filters Suggested language: A pharmacy shall utilize sterile filters that are **pharmaceutical or sterilizing grade** filters ~~that are intended for human use~~

		NCPA		~~applications in~~ for sterilizing CSPs and suitable for the intended use.
17.39(6)(a)	A pharmacy may not utilize dry heat sterilization if the materials can be sterilized using steam.	Dana Farber	Please provide a citation or explanation for this comment. Dry heat sterilizers, may provide more consistent results than steam autoclaves, and may be more cost-effective in some locations. Dry heat sterilization procedures are validated using thermocouples and biological indicators.	Recommend to strike. Edit 17.39(3) to add "in accordance with USP <797>" Revised Draft USP <797> When selecting the sterilization method for CSPs prepared from one or more nonsterile starting components, personnel must take into consideration the nature of the component(s), their physical and chemical properties, and the intended container–closure system. The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (e.g., affecting its strength, purity, and quality) or the packaging integrity. See also the ⟨1229⟩ family of chapters.
17.39(6)(b)	A pharmacy shall pass CSPs through a filter with a nominal pore size not larger than 1.2 um immediately prior to filling containers that will undergo terminal dry heat sterilization or steam sterilization.	IACP	Edit to specify CSPs that are solutions. Ophthalmic ointments or gels that will be terminally sterilized via dry heat or autoclave cannot pass through a filter.	Strike or edit as below: Suggested language: A pharmacy shall pass CSPs through a filter with a nominal pore size not larger than 1.2 um immediately prior to filling containers that will undergo terminal ~~dry heat sterilization or steam~~ sterilization, **unless said CSPs cannot be filtered.** Note: Revised draft of USP <797> only mentions for steam sterilization.

				10/18/18 Board: use suggested language
17.39(6)(c)	Prior to steam sterilization, a pharmacy shall tightly wrap plastic and glass in low particle shedding paper or sealed in envelopes that prevent post sterilization microbial penetration.	IACP	Clarify to indicate this is only applicable to components. There is no value to wrapping glass vials full of finished CSPs in envelops to prevent post sterilization contamination.	Recommend striking as there is a requirement for policies and procedures in 17.50
17.40	Sterility and Endotoxin Testing	NCPA	Align this section with USP 797.	
17.40(1)	A pharmacy shall conduct sterility testing on the following types of CSPs: (1) A pharmacy shall conduct sterility testing on the following types of CSPs: a) CSPs with extended BUDs, regardless of risk level; (b) high risk CSPs prepared in anticipation of a patient specific prescription or order; (c) high risk intermediate or stock solution (d) high risk level CSPs exposed longer than 12 hours at refrigerated temperature 2-8 ºC (36-46 ºF) before being sterilized; and (e) high risk level CSPs exposed longer than 6 hours at room temperature 8 ºC (46 ºF) before being sterilized.	Kelly Barnes Pentec	Barnes: Add new provision at (1)(f): High risk level CSPs that are prepared in groups of 25 identical individual single dose packages (e.g., ampules, bags, syringes, vials) for administration to multiple patients. Pentec: 17.06(7) as stated above indicates that "A pharmacy shall sterilize the final preparation of a high risk level CSP. A pharmacy shall ensure the sterility of the final preparation of a high risk level CSP in accordance with USP 71." Nothing is stated in a-e that high risk levels CSP made pursuant to a patient specific prescription requires sterility testing so we seek clarification from the Board if 17.40(1) does not apply to high risk level CSPs made pursuant to patient specific prescription.	Agree with recommendation. Suggested edits: (1) A pharmacy shall conduct sterility testing on the following types of CSPs: a) CSPs with ~~extended~~ BUDs beyond the USP <797> standard, regardless of risk level; (b) **high risk** level CSPs that are prepared in groups of 25 identical individual single dose packages (e.g., ampules, bags, syringes, vials) for administration to multiple patients ~~high risk CSPs prepared in anticipation of a patient specific prescription or order;~~ (c) high risk intermediate or stock solution (d) high risk level CSPs exposed longer than 12 hours at refrigerated temperature 2-8 ºC (36-46 ºF) before being sterilized; and (e) high risk level CSPs exposed longer than 6 hours at room temperature 8 ºC (46 ºF) before being sterilized. 17.40 (1) a-e does not apply to patient specific prescriptions

				dispensed within USP standard BUDs. Extended BUD to be defined = greater than standard BUD up to maximum BUD. **10/4/18 Board: will revisit (b) on Oct 18** **10/18/18 Board: accept suggested changes as above**
17.40(1)(B)	A pharmacy shall conduct sterility testing on high risk CSPs prepared in anticipation of a patient specific prescription or order…	Boulevard Pharmacy	In some cases we compound multiple units (5 or less) in anticipation for prescriptions. If sterility testing is required, not only would this reduce the time of use of the preparation, it would make cost prohibitive for patients.	Recommend to strike. See above.
17.40(4)	A pharmacy shall conduct sterility testing and test the proper number of articles in accordance with USP 71.	Blaire Pharmacy Consulting	Due to the short BUDs on some preparations and the fact that USP<71> Sterility Testing requires a minimum of 14 days, language should be changed to include: or a validated Rapid Microbial Method (RMM) test (e.g.: RapidScan RDI, Celsus).	Waivers may be requested for alternative testing methods. Note: Revised USP <797> specifies changes in articles for testing when batch is 1-39 units. Suggested language: A pharmacy shall conduct sterility testing and test the proper number of articles in accordance with USP ~~71~~.
17.40(6)	A pharmacy shall conduct bacterial endotoxin assay testing according to USP 85 on the following types of CSPs.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	USP <797> does not require USP <85> endotoxin testing on compounded preparations not intended for parenteral or intrathecal routes of administration, such as ophthalmic preparations. Change to: "A pharmacy shall conduct bacterial endotoxin assay testing according to USP 85 on the following types of CSPs intended for parenteral or intrathecal routes of administration":	Suggested language: **Except for inhalation and topical ophthalmic preparations,** a pharmacy shall conduct bacterial endotoxin assay testing according to USP 85 on the following types of CSPs. This section **must** mirror the sterility section.

17.41	Storage and Beyond Use Dating	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA NCPA	Align entire section with USP 797. Maximum BUDs are determined by USP expert counsel. The state of Massachusetts should align Chapter 17 requirements with the requirements of USP <797>. This is more consistent with what the rest of the country is doing. There is no scientific basis for these proposed BUD standards, and these artificial limitations will greatly reduce patient access to CSPs.	Revised draft USP <797 has new parameters for BUD, max is 90 days.
17.41(1)	Unless otherwise prescribed in 247 CMR 17.00, a pharmacy may not exceed the following BUDs:	MHA/MSHP Blaire Pharmacy Consulting Boston Medical Center / Horbowicz / Vreeland	The proposed regulation would result in an increased amount of medication waste and would not be able to store controlled substance per DEA requirements in automated dispensing machine. Recommendation: this provision should be made consistent with new draft of USP 797. Since there are numerous non-aqueous CSPs, language should be added stating: A pharmacy may not assign a BUD to a solid or non-aqueous (non-water containing) liquid preparation prepared in compliance with 247 CMR 17.40 that exceeds the earliest expiration date of any ingredient or 180 days, whichever is earlier. This is consistent with both USP and proposed 247 CMR 18.07(1)	~~Revised draft USP <797 has new parameters for BUD, max is 90 days.~~ ~~Keep existing default BUD chart or consider new language based on revised chapter.~~ Suggested language: ~~Unless otherwise prescribed in 247 CMR 17.00, a pharmacy may not exceed the following standard BUDs:~~ ~~Or~~ In the absence of a negative sterility test, a pharmacy may not exceed the shortest BUDs ~~(i.e. standard Category 2 BUDs)~~ listed in the most current version of USP <797> for aseptically prepared CSPs based on the nature of the starting components and specified storage conditions. 10/18/18/ Board: accept language

				as above
17.41(2)	A pharmacy that prepares CSPs in a DCR shall apply BUDs in accordance with 247 CMR 17.15.	Blaire Pharmacy Consulting	There is no mention of BUDs in 247 CMR 17.15.	17.16 and 17.17 pertains to BUD for DCR. Strike as DCR being eliminated.
17.41(4)	A pharmacy may not exceed BUDs unless it has scientific evidence that the CSP remains potent, stable, and sterile under specified storage conditions for the duration of the BUD. Such evidence may be from relevant and reliable sources or direct testing.	Blaire Pharmacy Consulting	Sections 17.41(5) and (6) should be removed, as they are superfluous and contradictory to section (4). Likewise, they anticipate proposed language in USP <797> that may or may not be adopted until December 1, 2019.	Revised Draft USP <797> maximum BUD is 90 days The section applies to BUDs that are greater than the default up to the proposed cap. Suggested language: A pharmacy may not exceed **standard** BUDs unless it has scientific evidence that the CSP remains potent, stable, and sterile under specified storage conditions for the duration of the BUD. Such evidence may be from relevant and reliable sources or direct testing.
17.41(5)	A pharmacy may not assign a BUD to a low or medium risk level CSP that is greater than 90 days from the date of compounding.	Blaire Pharmacy Consulting Pentec	Blaire: Sections (5) and (6) should be removed, as they are superfluous and contradictory to section (4). Likewise, they anticipate proposed language in USP <797> that may or may not be adopted until December 1, 2019. Pentec: Eliminate. We believe if a pharmacy has performed direct testing that indicates a medication retains its sterility and potency under the guides of USP <797>, the pharmacy should be allowed to dispense medications with increased BUD expirations without having a restriction imposed. We feel unless scientific evidence shows a patient is less susceptible to harm prior to the 45 day BUD and susceptible to increased harm after the 45 day BUD despite sterility and potency testing, this regulation imposes unnecessary restrictions on a pharmacy.	Board discussion Revised Draft USP <797> maximum BUD is 90 days 10/18/18 Board: use Table 12 in current draft, but must use the stricter of this or the current USP; absolute max of 90 days; delete the non-terminally sterilized row in Table 12
17.41(6)	A pharmacy may not assign a BUD to a high risk level CSP that is greater than 45 dates from eth date of compounding.	Blaire Pharmacy Consulting.	Sections (5) and (6) should be removed, as they are superfluous and contradictory to section (4). Likewise, they anticipate proposed language in USP <797> that may or may not be adopted until December 1, 2019.	Board discussion Revised Draft USP <797> maximum BUD is 90 days

				10/18/18 Board: see above
17.41(9)	A pharmacy shall utilize freezer units that freeze CSPs to a frozen state.	BioSrip	The term "freezer" is not defined. Further, the Board could limit the type and number of freezer companies. These sorts of limitations could raise the pricing of these items and therefore limit provision of service as the cost of service rises.	No change recommended.
17.43(2)	A pharmacy shall verify each master formulation record to ensure CSPs compounded pursuant to that master formulation record are stable and sterile and have the correct potency. A pharmacy shall conduct the verification: (a) upon the creation of the master formulation record; (b) at least annually for high risk CSPs; (c) upon any change in product, process, equipment, or supplies; (d) at least quarterly for high risk CSPs with extended BUDs or intermediate or stock solutions.	MHA/MSHP IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital NCPA Pentec	MHA and MAH recommend: Do not require master formulation record to be verified (by potency and sterility testing) in the case of low/medium anticipatory compounding when BUDs will not be extended. IACP: Revise to read: "A pharmacy shall create each master formulation record to ensure preparations compounded pursuant to that master formulation record would result in CSP with the correct potency, sterility, and stability for the BUD period assigned to that CSP." Within the proposed regulation, it is unclear what would constitute "verification" of the master formulation record, particularly what would be acceptable verification of stability. Assuming potency and stability have been established initially through some scientifically acceptable means, and sterility testing is occurring on each batch, there appears to be no benefit to public safety to conduct quarterly or annual potency, stability, or sterility testing on that formulation. Johnson: Verifying EVERY MFR that meets one or more of the criteria listed in 17.43(2)(a)-(c) would require testing beyond a pharmacy's means. No extemporaneous compounds will be prepared (in hospital or outpatient setting) because verifying the formulation upon first use would mean the preparation would exceed its BUD date before stability, potency, and sterility could be confirmed. Often patients don't have the time or the health to wait for 14 days for sterility, stability, and potency test results to come back before needing there medication. Requiring that EVERY MFR be verified will limit the formulations that pharmacies can prepare. Costs are too high and expenses are too great to perform this type of testing on each and every medication. Johnson's suggestion: A pharmacy shall validate each	Suggested language: A pharmacy shall validate that the following types of CSPs compounded pursuant to a master formulation record are sterile, stable, and have the correct potency for the assigned BUD: (a) High risk level intermediate or stock solutions (b) CSPs with extended BUD (i.e. greater than USP <797> standard BUDs) (c) CSPs prepared in batches that will be stored in the freezer A pharmacy shall conduct this validation initially, ~~at least annually,~~ and any time there is any change to the master formulation record. **10/18/18 Board: concept ok, adjust language**

			master formulation record to ensure CSPs compounded pursuant to that master formulation record are sterile and have the correct potency if the formulation is: (a) used a stock or intermediary solution; (b) assigned as BUD greater than USP <797> BUD standards; and/ or (c) prepared in anticipation of a patient specific prescription. Verification shall occur: (a) upon first use of the master formulation record; and (b) at least once annually. NCPA: Requiring the verification of every MFR would limit the formulations that sterile compounding pharmacies could prepare and would incur greatly increased costs. Pentec: Clarify what is "correct potency." Subsection (b) is excessive and places unnecessary financial burden on pharmacy. Testing should only be required if something in the process and/or supplies and equipment has changed since the previous testing.	
17.43(3)	A pharmacy shall utilize a qualified professional to conduct the stability, sterility, and potency tests.	BioScrip	This is not well defined. If the Board defines the term "qualified professional" this could limit the number of providers allowable, thus raising costs and potentially limiting access.	No change recommended.
17.43(4)	A master formulation record shall include:	Kelly Barnes	Add new provision at (4)(o) to align with 247 CMR 18.00 Labeling information, including: (i) generic name and quantity or concentration of each active ingredient; (ii) BUD; (iii) storage conditions; and (iv) prescription, lot, or control number, whichever is applicable.	Agree with recommendation; add all except lot number. Lot number to be added to compounding record.
17.43(4)(l)	Endotoxin limit, as applicable.	IACP Johnson Compounding / Walczyk / Fallon / Allibhani / Petrosillo MIPA	Remove this requirement. Endotoxin limits are in part, based on the average patient's weight and the volume of preparation to be administered. Endotoxin limit calculations are typically performed by the professionals performing the endotoxin tests and are provided to the pharmacy with the test results. It does not make sense to include this information on the MFR as it may change based on patient weight and max volume to be administered. This would also require that some pharmacies retroactively modify	Agree to strike

			their MFR's post compounding.	
17.44(1)	A compounding record shall include: (k) lot number, if applicable; (l) prescription or order number; (m) assigned BUD; (n) duplicate container label if prepared in a batch;	Kelly Barnes	Change to: (k) lot number, **prescription, or order number, as** applicable; (l) ~~**prescription or order number;**~~ (m) assigned BUD; (n) duplicate container label **or label elements as described in the Master Formulation Record** ~~**if prepared in a batch**~~;	Agree with recommendation. Label elements are not required in new draft of 797.
17.45(2)	After compounding is completed, a pharmacist shall visually examine each CSP for the presence of particulate matter with a lighted white and black background or high intensity LED light, unless the CSP is light sensitive.	Anazao Health GE Healthcare BioScrip	Anazao: Change requirement from "pharmacist shall…" to "properly trained person shall…" Every CSP should be examined, but the criteria for who performs the visual inspection should be training. GE: Change "… unless the CSP is light sensitive **or radioactive**." Visual examination of radiopharmaceuticals is extremely dangerous. BioScrip: The requirement to use a box rather than when a pharmacist is their professional judgment needs to supplement their initial visual inspection is onerous and unnecessary.	Suggested language: After compounding is completed, a pharmacist shall visually examine each CSP for the presence of particulate matter **or other defects** ~~with a lighted white and black background or high intensity LED light, unless the CSP is light sensitive.~~
17.46(1)	In addition to standard prescription labeling requirements, a pharmacy shall include the following information on the label or container of each CSP: (a) BUD; (b) batch or lot number of anticipatorily prepared CSPs; (c) storage and handling information; and (d) the statement, "this is a sterile compounded drug preparation."	MHA/MSHP Boston Medical Center / Horbowicz / Vreeland Mount Auburn Hospital Pentec	Remove "This is a" in place of "Sterile Compounded Drug Preparation." As real estate on a prescription label is limited, truncating this statement in place of more important label notes for end users is more important. Remove this requirement. ISMP recommendations for labeling advise that labels should be as clear as possible. Adding more required words will detract from the important information that is already there. Pentec: Regarding (d), we do not feel the wording as is should be placed on a label. Recommend the statement, "sterile compounded drug preparation" or "sterile compounded medication"	Suggested language: (d) a statement indicating that the product is a sterile compounded drug preparation
17.48(2)	In addition to the counseling described in M.G.L. c. 94C, § 21A, counseling on a CSP shall include the proper use, possible side effects, storage, handling, and disposal of the medication, as applicable.	Kelly Barnes	Clarify that counseling requirement contained within proposed 247 CMR 9.16(10) applies to all new prescriptions for CSPs and to align with proposed 247 CMR 18.00. Clarify counseling requirements to not apply to inpatient setting.	Counseling exception for inpatients is at 17.48(5).

17.50	Sterile Compounding Policies and Procedures	Kelly Barnes	Add two new categories: (19) cleaning and disinfecting; and (20) potency/stability testing, as applicable.	Agree with recommendation
17.50(7)	A pharmacy shall maintain a written policy and procedure pertaining to the following: (7) change control, including planning, implementation, and validation of new or changed facilities, equipment, or processes;	BioScrip	This language is extremely broad and the value of this section is questionable.	Agree to strike and make best practice