Agenda Item 7.0

Report of the Nursing Practice Committee

BRN Nursing Practice Committee| January 26, 2023

Nursing Practice Committee
January 26, 2023

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Agenda Item 7.2

Review and vote on whether to approve previous meeting minutes

BRN Nursing Practice Committee | January 26, 2023

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF REGISTERED NURSING
NURSING PRACTICE
COMMITTEE MEETING MINUTES

DRAFT

Date: October 26, 2022

9:34 am **Start Time:** 9:34

Location: **NOTE**: Pursuant to the provisions of Government Code section 11133 a physical meeting location was not provided.

The Nursing Practice Committee of the Board of Registered Nursing held a public meeting via a teleconference platform.

Wednesday, October 26, 2022 – 9:34 am – 12:45 pm Committee Meeting

9:34 am **7.0** **Call to Order/Roll Call/Establishment of a Quorum**
Elizabeth Woods, Chairperson, called the meeting to order at 9:34 am. All members present, except Elizabeth Woods. Quorum established at 9:35 am.

ELC Committee Members:
Jovita Dominguez, BSN, RN
Dr. Mary Fagan, Ph.D., R.N., NEA-BC
Vicki Granowitz
Dolores Trujillo, RN

Absent Member: Elizabeth Woods, RN, FNP, MSN – Chairperson

BRN Staff Representatives:
Loretta Melby, RN, BSN, MSN, Executive Officer (EO)
Reza Pejuhesh, DCA Legal Attorney

9:35 am **7.1** **Public Comment for Items Not on the Agenda; Items for Future Agendas**

Public Comment for Agenda Item 7.1: **Mary Adorno, California Association for Health Services at Home (CASAH):** Explained that there is a conflict with California Department of Public Health (CDPH) and Nurse Practitioners working under protocols until transition to practice regulations are complete to implement AB 890. She asked the BRN to reach out to the legal team to confirm this.

7.2 **Review and Vote on Whether to Approve Previous Meeting Minutes**

7.2.1 March 24, 2022

Committee Discussion: No committee comments or questions.

Motion: **Dolores Trujillo:** Motioned to accept the Nursing Practice Committee meeting minutes from March 24, 2022 and allow BRN Staff to make non-substantive changes to correct name misspellings and/or typos that may be discovered in the document.

Second: **Mary Fagan**

Public Comment for Agenda Item 7.2.1: No public comments.

Vote:

Vote	EW	DT	MF	VG	JD
	AB	Y	Y	A	Y
	Key: Yes: Y | No: N | Abstain: A | Absent for Vote: AB				

Motion Passed

9:43 am **7.3**

Information only: Update on the Board's sunset bill, Assembly Bill 2684 (Reg. Sess. 2021-2022), as it relates to nursing practice.
Presented by: Loretta Melby

Committee Discussion: Dolores Trujillo opened the agenda item and introduced Loretta Melby to provide updates on the Board's sunset bill.

Loretta Melby: Provided updates on sunset bill that impacts the Nursing Practice Committee. Including NP update, codifying NEWAC

There were no committee questions or comments.

Public Comment for Agenda Item 7.3: **Christi Delemos:** Appreciates that the Board is combining applications for licensure. Requested clarification on the combination of licensure.

Loretta Melby: Provided clarification that there will still be two separate licenses/certifications; however, there will be only one application. The next step may be combining the furnishing certifications; however, the law would have to be updated first.

9:53 am **7.4**

Advisory committee updates – Informational only

- **Nurse Practitioner Advisory Committee (NPAC)**
- **Nurse-Midwifery Advisory Committee (NMAC)**
- **Nurse Education and Workforce Advisory Committee (NEWAC)**
- **Advanced Practice Registered Nursing Advisory Committee (APRNAC)**

Presented by: Loretta Melby

Committee Discussion: Dolores Trujillo opened the agenda item and introduced Loretta Melby to provide updates on the NPAC.

Loretta Melby: Stated that there is an NPAC meeting on November 1, 2022, and there are not may updates since the last Nursing Practice Committee meeting as NPAC has not met since the last meeting. Also stated that BRN is currently in the 45-day public comment period for the AB 890 regulations. Provided an update on the NEWAC meeting held on July 28, 2022 where the committee discussed the CCR 1410 regulations update and set meeting dates for the upcoming year. Further explained that NMAC held a meeting on August 9, 2022, where the committee discussed updates to CCR 1463. The last update was on the APRNAC which held a meeting on September 22, 2022.

Public Comment for Agenda Item 7.4: **Dr. Sarah Giron, PhD, CRNA:** Thanked Loretta Melby for clarification about the RN pre-requisites for CRNA applicants. She asked how long the regulatory change would take.

Loretta Melby: Explained that a regulatory package typically takes a year or two.

7.5 **Discussion and possible action:** Regarding development of regulations for Clinical Nurse Specialists (CNS) and Certified Registered Nurse Anesthetists (CRNA).
Presented by: Loretta Melby

Committee Discussion: Dolores Trujillo opened the agenda item and introduced Loretta Melby to provide context on the need to develop regulations for CNS and CRNA.

Loretta Melby: Provided history that there has been no additional guidance since 1998 for CRNAs and 1997 for CNSs. Explained that this becomes problematic for academia and issuance of licenses.

There was no committee questions or comments.

Public Comment for Agenda Item 7.5: **Chris Gill, National Board of Certification and Recertification of CRNAs (NBCRNA):** Thanked the committee and offered his support and the support of his counterpart, Brett Morgan, Senior Director of Practice at American Association of Nurse Anesthetists. Explained that they offer their services to assist with CRNA practice or regulation issues.

Roxanne Gould, CACNS: CACNS has drafted regulations and would like to partner with the BRN on these regulations.

Melanie Rowe, Practice Director for CACRNA: Looks forward to working with the BRN to reflect the current practice.

Michelle Fedre Riingen, Dean and Point Loma: Stated that she is happy to hear that BRN is looking at regulations and asked the Board to look at current applicants and requests that current applicants not be placed on hold.

Jeannie Meyer, President of CACNS: Stated that CACNS already drafted regulations and is ready to work with the Board and is happy to work with academic institutions.

Motion: **Dolores Trujillo:** Motioned to approve the development of regulations for CNSs and CRNAs and direct staff to take all steps necessary to begin the rulemaking process.

Second: **Vicki Granowitz**

Vote:

Vote	EW	DT	MF	VG	JD
	AB	Y	Y	Y	Y
	Key: Yes: Y | No: N | Abstain: A | Absent for Vote: AB				

Motion Passed

10:25 am **7.6** **Discussion and possible action:** Regarding updates to Business and Professions Code section 2830.6 to amend the name of the national certifying body for CRNAs.
Presented by: Loretta Melby

Committee Discussion: Dolores Trujillo opened the agenda item and turned it over to Loretta Melby who provided context on the need to update section 2830.6 of the Business and Professions Code to amend the name of the national certifying body for CRNAs.

There was no committee questions or comments.

Public Comment for Agenda Item 7.6: **Melanie Rowe, CRNA and Practice Director for CACRNA:** Agree with the recommendation and appreciates the changes.

Motion: **Vicki Granowitz:** Motioned to approve updating Business and Professions code section 2830.6 to amend the name of the national certifying body for CRNAs. Delegate authority to the Executive Officer to work with legislative staff to amend statute, including making any technical or non-substantive changes required.

Second: **Dolores Trujillo**

Vote:

Vote	EW	DT	MF	VG	JD
	AB	Y	Y	Y	Y
	Key: Yes: Y | No: N | Abstain: A | Absent for Vote: AB				

Motion Passed

10:31 am **7.7** **Discussion and possible action:** Regarding the annual review of the role and continuation of the APRNAC.

Committee Discussion: **Loretta Melby:** Provided a summary of the role of the APRNAC and explained that the BRN has been very honest about the future of this committee and there are stakeholders in support of continuing this committee and other stakeholders in support to create the new advisory committees for CNS and CRNAs.

Dolores Trujillo: Asked if there is opportunity for the current CNS and CRNAs to move into the new committees.

Loretta Melby: Stated that would be optimal as they have experience and have the history and could mentor new members.

Vicki Granowitz: Asked how the public process will be involved with the new committee.

Loretta Melby: Explained that they would follow the same path as the NPAC and NMAC and provided a summary of the public input process of those committees. Further explained the regulations process and how the public is involved.

Vicki Granowitz: Explained that she comes form the land use process and commended the BRNs process as it is extensive and will provide ample opportunity for public input. Also stated that she was going to ask about the comments raised

After public comment

Dolores Trujillo: Asked if there is overlap between the APRNAC and the other committees.

Loretta Melby: Explained that yes, there is overlap with the current NPAC and NMAC and that is why the Board voted to XXXX. On the APRN census model, the BRN would be above and beyond that recommendation. Further explained that if the Board has flexibility to reestablish the APRNAC in a year if deemed necessary. Explained that

the Nursing Practice Committee should be the avenue where all APRNs come together.

Dolores Trujillo: Stated that it would seem that if the current members move over to the new committee, additional training will have to occur for APRNAC.

Loretta Melby: Explained that if APRNAC stay, she would request that the CNS and CRNA members go to the new advisory committees, and we would they recruit for those vacancies for the APRNAC.

Mary Fagan: Asked if there is there a possibility that all four groups could do a joint meeting or would that be a violation of the Bagley Keene Open Meetings Act. She stated that she can see a conflict with different members sitting on the APRNAC.

Loretta Melby: Explained that NMAC and NPAC have a meeting scheduled to deal with disciplinary guidelines because it is a joint issue in common. It is possible to have an annual meeting with all four committees.

Mary Fagan: Asked if that can be incorporated into the motion.

Loretta Melby: Stated that it can be incorporated into the motion.

Mary Fagan: Stated that she is interested in hearing from the public members.

Reza Pejuhesh: Wanted to touch on the scope of the APRNAC and remind the committee that when the NPAC/NMAC was created and at that time APRNAC was focused on all groups but then NP and CNMs were carved out. Stated that he would assume that if the new groups were formed, they would also be carved out so then the scope of the APRNAC would be only issues that impact all groups. The big question is how much affects all APRN groups that would justify an entire committee.

Public Comment for Agenda Item 7.7:

Cheryl Goldfarb-Greenwood: Submitted a joint letter in 2021 from all four APRNs advocating for the APRNAC and continues to advocate for this committee. Stated that she hopes that the new committees can be created and still maintain the APRNAC

Elizabeth Bamgbose, CRNA – President of CANA Agrees with previous commenter to keep APRNAC as well as creation of the new committees which will ensure the profession moves forward in unity.

Christi Delemos: Agrees with the last commentor and would like to see APRNAC continue with the addition of the other committees.

Elissa Brown, CNS member of APRNAC: Supports the continuation of this committee. Further states that the national model states that BONs should have an APRNAC that represents all APRN specialties.

Jeannie Meyer: Explained that this committee is a benefit, and she has seen the collaboration and support that comes out of it. She would like to see this committee to continue

Motion: **Dolores Trujillo:** Motioned to sunset the APRNAC and develop two new advisory committees for CNSs and CRNAs.

Second: **Mary Fagan**

Vote:

Vote	EW	DT	MF	VG	JD
	AB	Y	Y	Y	Y
	Key: Yes: Y | No: N | Abstain: A | Absent for Vote: AB				

Motion Passed

The committee took and planned break from 11:30 am – 12:15 pm. Meeting restarted at 12:19 and a quorum was established (Dolores Trujillo, Jovita Dominguez, Vicki Granowitz) Mary Fagan and Elizabeth Woods Absent. Mary Fagan rejoined meeting at 12:29 pm

12:20 pm **7.8** **Information only:** Update from the Department of Consumer Affairs, Office of Professional Examination Services (OPES), regarding occupational analysis mandated under Business and Professions Code section 2837.105.

Committee Discussion: Dolores Trujillo opened the agenda item and turned it over to Loretta Melby who read the statute pertaining to the OPES review. Loretta then introduced Heidi Lincer and Tracy Montez.

Tracy Montez: Explained that she will have an extensive presentation in November. OPES will be releasing the November report to the public today.

Heidi Lincer: Stated that she's happy to finish the work on the project and had a good working relationship with the BRN who was cooperative in all aspects. Reiterated that there is an extensive presentation during the November 1, 2022, NPAC meeting and at the November 14-15, 2022, Board meeting. Provided a brief summary that OPES felt that the competency exams that exist are sufficient and that a supplemental

exam is not needed and that the exams undergo periodic review. Also stated that the report will have recommendations to the BRN on the transition to practice.

Loretta Melby: Explained that this will go to NPAC on November 1, 2022, where we will get the NPAC recommendations that will be presented to the Board on November 14-15, 2022.

Public Comment for Agenda Item 7.8:

Shari Clark: NP who practices in orthopedics or aesthetics. Asked if her surgeons/MDs that she has worked with in the past be able to sign off on my hours for transition to practice for the 104 route in 2023.

Cynthia Jovanov, President CANP: Applauded the OPES team for completing the report well before the deadline. Supports that a supplemental report is not necessary; however, she stated that she is concerned with the recommendation of mentoring in the transition to practice. Further stated that she looks forward to the more in-depth presentation at the NPAC meeting

Merry, member of CANP and SEIU: Thanked the BRN and OPES. Wanted to confirm the physicians were contacted for input regarding transition to practice.

Leslie Blomquist, President CANP Tulare Chapter: Thanked the OPES that a supplemental report is not necessary. Would like more clarity on who was solicited for the transition to practice recommendation.

Nancy Trego, NP: Agrees with the prior commentors and would like to know with the OPES made a recommendation on the transition to practice.

Kathy Hughes, SEIU: Appreciates the work and the OPES recommendation that a supplemental exam is not needed. However, she does have concerns with the mentoring recommendation.

Mitchell Erickson: Reiterates the appreciation for the work of the OPES and agrees with the previous comments about the scope of the OPES.

Eileen Kelleher: Stated that she hopes that NPs have input into the OPES report

Christi Delemos: Stated that she has concerns with the acute care as it is no longer available. Asked if she is folding in the current acute care NPs into the current model.

12:45 pm **7.9** **Adjournment**

Dolores Truilijo, adjourned the meeting at 12:45 pm.

Submitted by:

Loretta Melby, RN, BSN, MSN
Executive Officer
Nursing Practice Committee
California Board of Registered Nursing

Accepted by:

Elizabeth Woods, RN, FNP, MSN
Chairperson
Nursing Practice Committee
California Board of Registered Nursing

Agenda Item 7.3

Information only: Update on the United States Pharmacopeia (USP) chapters 795 and 797 regarding compounding standards

BRN Nursing Practice Committee | January 26, 2023

BOARD OF REGISTERED NURSING
Nursing Practice Committee Meeting
Agenda Item Summary

AGENDA ITEM: 7.3
DATE: January 26, 2023

ACTION REQUESTED: **Information only:** Update to the United States Pharmacopeia (USP) chapters 795 and 797 regarding compounding standards

REQUESTED BY: Elizabeth (Betty) Woods, RN, FNP, MSN
Nursing Practice Committee Chair

BACKGROUND:

Loretta Melby, Executive Officer, will provide an overview of the updates to the USP chapters 795 and 797 regarding compounding standards.

On November 1, 2022, USP published updates to the USP General Chapters on compounding nonsterile and sterile preparations. The revisions to the chapters reflect advancements in science and practice to help ensure quality compounded preparations, promote public health, and protect patients and healthcare workers. The standards also incorporate extensive stakeholder feedback from more than 1,400 public comments received during the public comment period from September 2021 to March 2022. Additionally, the USP Compounding Expert Committee voted to extend the date on which these chapters become official to November 1, 2023, to allow for increased flexibility and engagement for adoption.

RESOURCES:

Information on USP Chapter 795: https://www.usp.org/compounding/general-chapter-795

Information on USP Chapter 797: https://www.usp.org/compounding/general-chapter-797

NEXT STEPS:

FISCAL IMPACT, IF ANY: None

PERSON(S) TO CONTACT: McCaulie Feusahrens
Chief of the Licensing Division
California Board of Registered Nursing
Mccaulie.feusahrens@dca.ca.gov

<795> FAQs

November 1, 2022

General

1. Where can I find FAQs and other information on USP Compounding Standards?

For FAQs on USP Compounding Standards, please see below:

- General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations*
- General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations*
- General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*
- General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*
- Compounded Preparation Monographs (CPMs)

2. Where can I find information about how to interpret and apply General Chapters?

The *General Notices and Requirements* describe the basic assumptions, definitions, and default conditions for the interpretation and application of *USP–NF* content. For example, Section *2.30. Legal Recognition* describes the legal recognition of USP and NF. Section *3.10.30 Applicability of Standards to the Practice of Compounding* describes when USP compounding practice standards are or are not applicable.

3. Can USP provide some clarity as to when a preparation needs to be prepared as sterile (CSP) as opposed to as nonsterile (CNSP)?

<795> and <797> both describe compounded preparations that are required to be sterile or can be prepared as nonsterile. In general, preparations designed to be delivered to any body space that does not normally freely "communicate" or have contact with the environment outside of the body, such as the bladder cavity or peritoneal cavity, are typically required to be sterile. Additionally, ophthalmic products and compounded aqueous inhalation solutions and suspensions are required to be sterile. Otic preparations are not required to be sterile unless being administered to a patient with a perforated eardrum. Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile, nor are nasal sprays.

Introduction and Scope

4. What is the definition of nonsterile compounding?

For purposes of General Chapter <795>, nonsterile compounding is defined as combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

5. To whom do the standards in General Chapter <795> apply?

The chapter applies to all persons who prepare compounded nonsterile preparations (CNSPs) and all places where CNSPs are prepared for human and animal patients. This includes but is not limited to pharmacists, technicians, nurses, physicians, dentists, naturopaths, and chiropractors, in all places including but not limited to pharmacies, hospitals and other healthcare institutions, patient treatment sites, and physicians' practice sites. Personnel engaged in the compounding of CNSPs must additionally comply with laws and regulations of the applicable regulatory jurisdiction. Compounding of nonsterile hazardous drugs (HDs) must additionally comply with General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*.

6. How do I know what are requirements versus recommendations in the chapter?

Generally, requirements in a General Chapter are conveyed by use of the term "must". Recommendations are conveyed by use of the terms "should" and "may".

7. What does "official date" mean?

The USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. USP has no role in enforcement.

All text in the United States Pharmacopeia (USP) or National Formulary (NF) that has reached its official date is "official text." Although all text of the *USP–NF* that has reached its official date is "official text," not all official text states requirements with which compendial users must comply. Some official text is intended to assist or guide compendial users or to serve informational purposes.

8. When do the revisions to General Chapter <795> become official?

The revision of <795> published on November 1, 2022, will become "official" on November 1, 2023. The "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. However, ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. Regulatory bodies such as state boards of pharmacy may have a different official date. USP has no role in enforcement.

9. Does the chapter apply for breaking or cutting a tablet into smaller portions?

No, breaking or cutting a tablet into smaller portions is not required to meet the standards in this chapter.

10. Does the chapter apply for reconstitution of conventionally manufactured nonsterile products (e.g., compounding kits)?

Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling is not required to meet the standards in this chapter. Reconstitution that is not performed according to manufacturer approved labeling is considered nonsterile compounding and is subject to the requirements in the chapter. Compounding kits are within the scope of the chapter unless they are FDA-approved and reconstitution is performed in accordance with the directions contained in the manufacturer approved labeling.

11. Am I required to use purified water for reconstitution of a conventionally manufactured product?

Reconstitution of a conventionally manufactured nonsterile product in accordance with the directions contained in the manufacturer approved labeling is out of the scope of the chapter. As such, the chapter does not specify the quality of water to be used for reconstitution. Compounders can reach out to other resources, such as the regulatory bodies in their jurisdiction or the manufacturer of the products, for additional information.

12. Is administration out of the scope of the chapter?

The intent of the chapter is to establish minimum standards for practitioners when preparing compounded nonsterile preparations in order to minimize harm, including death, to human and animal patients. The scope of the chapter is intended to be limited to compounding and the standards are designed to help ensure a CNSP maintains its integrity up until the time when administration begins. Administration is out of scope of the chapter, and for purposes of <795>, is defined as the preparation of a single dose for a single patient when administration will begin within 4 hours

13. Does the chapter address compounded radiopharmaceutical dosage forms?

No. Compounding of radiopharmaceuticals is not required to meet the standards of this chapter as they are subject to the requirements in General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*.

14. Are the temperatures in the chapter expressed in degrees Fahrenheit or Celsius?

Unless otherwise specified, all temperatures in the *USP–NF* are expressed in degrees centigrade (Celsius) (see also *General Notices 8.180 Temperatures*).

15. Are products manufactured by 503B facilities or conventionally manufactured products considered active pharmaceutical ingredients (APIs)?

No. The term "API" refers to any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).

16. Why were the categories of compounding (simple, moderate, and complex) in the previous chapter eliminated in the new revision?

These categories of compounding were originally adapted from <1075> *Good Compounding Practices* in 2011. They often led to confusion among users on how to apply the criteria and the chapter did not provide standards on how to use these categories in applying the compounding standards.

17. Who can be the designated person(s)?

The designated person is one or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded nonsterile preparations (CNSPs). Facilities must determine whether they have one or more designated person, select the designated person, and determine how to allocate responsibility if there is more than one designated person.

18. Does the chapter apply for repackaging of a conventionally manufactured product?

No, repackaging of conventionally manufactured drug products is not required to meet the standards in this chapter (see <1178> *Good Repackaging Practices* for recommendations).

19. Please clarify the phrase, "variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength)".

There may be variability from the labeled strength of a CNSP. The acceptable range is listed in the applicable monograph for official articles. The acceptable range is ±10% of the labeled strength for nonofficial articles (i.e., 90-110%).

20. This section defines altering a drug or bulk drug substance as nonsterile compounding. It is unclear whether flavoring a manufactured liquid would fall under this category or whether the preparation of premeasured kits, such as FIRST Magic Mouthwash and FIRST Omeprazole, would be required to meet the standards of this chapter.

Flavoring a manufactured product is compounding and must be conducted under compounding standards in accordance with the exemptions for compounding in the Federal Food, Drug, and Cosmetic Act, otherwise the drug product would be deemed adulterated under the Act. Compounding standards apply to the assembly of premeasured kits.

21. When repackaging capsules into unit dose containers using a robotic system, is the BUD limited to 180 days?

Repackaging nonsterile conventionally manufactured drug products is outside the scope of <795> so the BUD limits in *Table 4* do not apply. See <1178> *Good Repackaging Practices* for recommendations.

Personal Hygiene and Garbing

22. What garb is required for nonsterile compounding?

Gloves must be worn for all compounding activities. Other garb (e.g., shoe covers, head or hair covers, facial hair covers, face masks, and gowns) should be worn as required by the facility's standard operating procedures (SOPs). Garb is recommended for the protection of personnel and to minimize the risk of CNSP contamination. The garb must be appropriate for the type of compounding performed. The garbing requirements and frequency of changing the garb must be determined by the facility and documented in the facility's SOPs.

23. Are gloves required to be wiped or changed before beginning to compound a CNSP with different components?

The chapter recommends wiping or replacing gloves before beginning to compound a CNSP with different components to minimize the risk of cross-contaminating other CNSPs and contaminating other objects. General Chapter <795> does not describe the use of specific wipes or agents to use for wiping gloves. Facilities must determine whether gloves should be changed or replaced and the appropriate wipe/agent to use if they are wiped.

24. Can gowns be reused for multiple days if not soiled?

If gowns are worn, they may be re-used if not soiled. If gowns are visibly soiled or have tears or punctures, they must be changed immediately. Facilities must determine the frequency for changing gowns.

Buildings and Facilities

25. Is a compounding space required to be in an enclosed room (i.e., with walls and doors)?

No. While a room may be used as the compounding space, the chapter does not require a separate room. The chapter requires a space that is specifically designated for nonsterile compounding. A visible perimeter should establish the boundaries of the nonsterile compounding area.

26. What is considered an appropriate temperature range to store CNSPs or components?

The storage area must be maintained at a temperature that is appropriate for the CNSPs and components. The storage conditions for the CNSP would be dependent on the assigned beyond-use date (BUD) and CNSP-specific properties (see <795>, *10.2 Parameters to Consider in Establishing a BUD*). The storage conditions for components may be provided by the manufacturer or vendor on the labeling and/or specified in the USP monograph for that component (see also <659>).

27. Since reconstitution and repackaging are not considered compounding and are out of scope of the chapter, can they still be performed in the designated compounding space?

Yes, other activities may be performed in the compounding space when compounding is not occurring. The chapter requires that a compounding space be designated for nonsterile compounding, however, the space is not required to be dedicated for sole use in compounding. Other activities may occur in the compounding space, but they must not be occurring in the space at the same time as compounding.

Cleaning and Sanitizing

28. Can non-compounding personnel clean and sanitize the compounding space?

Facilities must determine the appropriate personnel for cleaning and sanitizing the compounding space. The chapter does not specify who may perform the cleaning and sanitization procedures. However, the chapter does specify that knowledge and competency must be demonstrated initially and at least every 12 months for those that are cleaning and sanitizing.

29. Is daily cleaning only required when nonsterile compounding has occurred?

Cleaning and sanitizing of the surfaces in the nonsterile compounding area(s) must occur on a regular basis at the minimum frequencies specified in *Table 1* or, if compounding is not performed daily, it must be performed before initiating compounding.

30. What is the difference between cleaning and sanitizing?

Cleaning is the process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. Sanitizing is the process of reducing, on inanimate surfaces, the number of all forms of microbial life including fungi, viruses, and bacteria.

31. Why does sterile compounding per <797> require cleaning daily, whereas for nonsterile compounding, cleaning is required at the beginning and end of a shift?

Cleaning and sanitizing of the surfaces in the nonsterile compounding area(s) must occur on a regular basis at the minimum frequencies specified in *Table 1* or, if compounding is not performed daily, it must be performed before initiating compounding.

Cleaning is required at the beginning and end of each shift in <795> due to the particle-generating nature of nonsterile compounding. Sterile compounding is less particle-generating than nonsterile, and compounders sanitize after preparing each batch of CSPs. There is greater risk of cross-contamination from particle-generation for nonsterile compounding.

32. If the dedicated compounding area is in the middle of a room (i.e., dedicated cart, island), does this mean we have to clean walls and storage shelving?

The designated person can define in an SOP what specifically constitutes the 'compounding area' that is specifically designated for nonsterile compounding. Defining the compounding area will determine what surfaces require cleaning and sanitizing per *Table 1*.

Equipment and Components

33. Are containment ventilated enclosures (CVEs) required for nonsterile compounding?

No. The chapter requires facilities to assess particle-generating activities (e.g., weighing, measuring, or other manipulation of components) to determine whether a closed-system processing device is needed. The chapter does not require a closed-system processing device but does require facilities to perform a process evaluation to determine whether a device is needed. A closed-system processing device reduces the potential exposure to personnel and contamination to the facility from airborne particles that weighing, measuring, or otherwise manipulating components could generate. A CVE is one example of a closed-system processing device; other examples include BSCs and single-use containment glove bags.

34. Why are APIs required to be obtained from an FDA-registered facility and components other than APIs only recommended to be obtained from an FDA-registered facility?

The Federal Food, Drug, and Cosmetic Act requires compounded preparations to be prepared from bulk drug substances that are obtained from FDA-registered facilities. The Expert Committee recognizes that there may be some components other than APIs that cannot be obtained from an FDA-registered facility, thus, it is a recommendation that these components be obtained from an FDA-registered facility but is not a requirement.

35. What does it mean when Purified Water is printed in italics?

It means the *Purified Water* is an official article and must meet the applicable monograph (e.g., Purified Water, USP).

36. When is the use of distilled water acceptable?

Purified Water, distilled water, or reverse osmosis water should be used for rinsing equipment and utensils. Note that *Purified Water* or better quality, e.g., *Sterile Water for Irrigation*, must be used for compounding CNSPs when formulations indicate the inclusion of water.

37. If *Sterile Water for Irrigation* is used as a component in a CNSP, what is the BUD of the *Sterile Water for Irrigation* once opened?

Purified Water or better quality, e.g., *Sterile Water for Irrigation*, must be used for compounding CNSPs when formulations indicate the inclusion of water. Since sterility is not required, *Sterile Water for Irrigation* may be used until its labeled expiration date if it is stored in its original container per the manufacturer's recommendations.

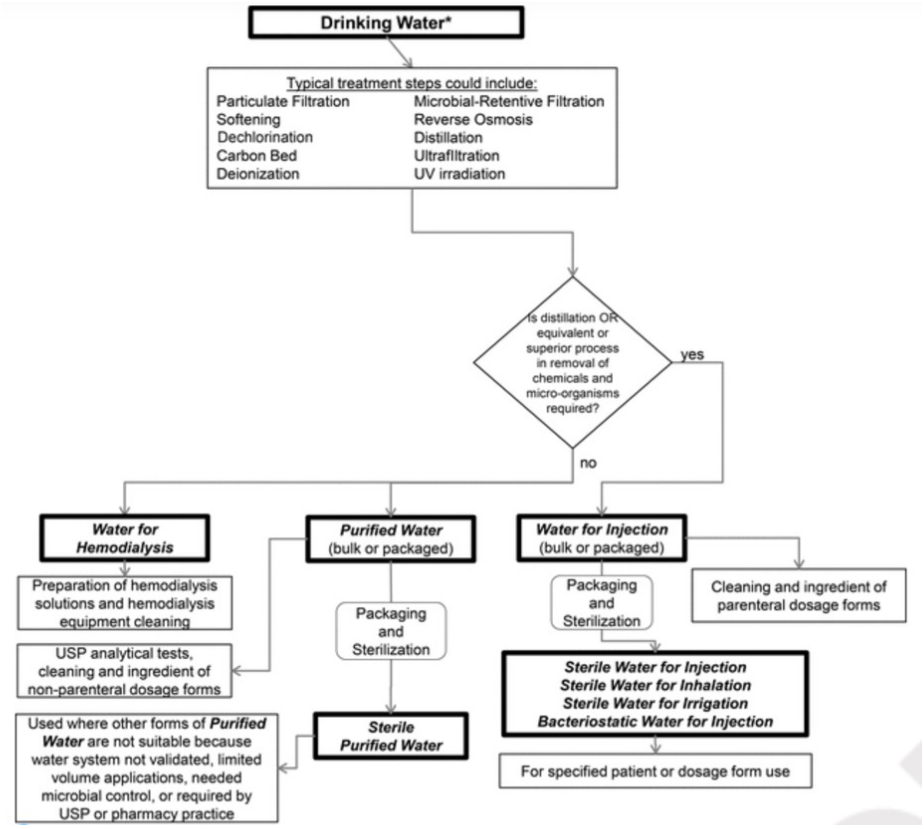
38. Our Board of Pharmacy inspector is questioning our use of *Sterile Water for Irrigation* in place of *Purified Water* in CNSPs. Does USP reference this in other general chapters?

Purified Water or better quality, e.g., *Sterile Water for Irrigation,* must be used for compounding nonsterile drug preparations when preparations indicate the inclusion of water. Per <1231> *Water for Pharmaceutical Purposes, 3.2.4, Sterile Water for Irrigation* may be used in other applications that do not have particulate matter specifications, including where *Purified Water* is indicated but where access to a validated water system is not practical.

39. FDA prescribing information for a specific brand of *Sterile Water for Irrigation* says, "Sterile Water for Irrigation is not potable water and is not intended for oral administration." If *Sterile Water for Irrigation* is labeled as non-potable, may it be used as a component in a CNSP intended for oral administration?

Sterile Water for Irrigation, USP is prepared from *Water for Injection* that is sterilized and suitably packaged. It contains no antimicrobial agent or other added substance. *Water for Injection* is water purified by distillation or a purification process that is equivalent or superior to distillation in the removal of chemicals and microorganisms. It is prepared from water complying with the U.S. Environmental Protection Agency National Primary Drinking Water Regulations or with the drinking water regulations of the European Union or of Japan or with the World Health Organization's Guidelines for Drinking Water Quality. Per <1231> *Water for Pharmaceutical Purposes, Sterile Water for Irrigation*, USP 'may be used in other applications that do not have particulate matter specifications, where bulk *Water for Injection* or *Purified Water* is indicated but where access to a validated water system is not practical, or where somewhat larger quantities are needed than are provided as *Sterile Water for Injection*.' However, if *Sterile Water for Irrigation* is labeled as non-potable, it must not be used in oral preparations.

Per <1231>



40. Is there any guidance on reverse osmosis (RO) systems, such as testing and maintenance requirements?

Water from RO systems that is used as a component in CNSPs must meet the monograph requirements for *Purified Water* including <643> *Total Organic Carbon* and <645> *Water Conductivity*. RO systems must be maintained per manufacturer's recommendations.

41. Regarding the statement, "Once removed from the original container, any component not used in compounding (e.g., excess after weighing) should be discarded and not returned to the original container to minimize the risk of contaminating the original container", given the risk of contamination that this could present, why isn't the "should" a "must"?

There may be instances (e.g., drug shortages, controlled drugs) when discarding excess component is not possible. Personnel who perform weighing procedures must be trained and demonstrate knowledge and competency on handling components to minimize the risk of contamination, and avoid using excessive materials.

42. What organizations certify BSCs or CVEs?

The Compounding Expert Committee removed all references to specific professional organizations and facilities must determine the appropriate certification guide to use for certifying their equipment. Some examples of organizations that provide certification guidance include the Controlled Environment Testing Association (CETA), NSF International, and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE).

43. Are these terms interchangeable: API, drug substance, drug product, active ingredient?

For the purposes of *USP* Chapters <795> and <797>, a bulk drug substance and an active pharmaceutical ingredient are the same. They are defined in the glossary of *USP* <795> and <797> as: Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body.

A conventionally manufactured drug product is not an API but is typically manufactured from an API(s). There is no statutory or USP definition for active ingredient, but the term is used generically in USP when referring to the active ingredient in either a conventionally manufactured drug product or API (e.g., when labeling a CSP or a CNSP).

For the purposes of the USP Compounding Chapters, a drug product is the same as a conventionally manufactured product and defined as: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions. Drug products and conventionally manufactured products are not CSPs or CNSPs.

Master Formulation and Compounding Records

44. Does a new master formulation record (MFR) need to be made for different batch sizes of final CNSP (e.g., same ointment of 120 grams and 60 grams)?

Yes, an MFR must be created for each unique preparation of a CNSP.

45. How specific must the description of the container closure be in the MFR?

A thorough description of the container closure would be considered best practice, which ideally would also include the material of composition that is in contact with the compounded preparation. The size of the container closure may vary depending on quantity of prescription dispensed. For example, "White opaque HDPE airless pump." There should be enough detail so the selection of that container closure could be made by someone else.

Labeling

46. Are all CNSPs required to be labeled, regardless of whether they are dispensed?

Yes. CNSPs must be labeled with the information specified in 9. *Labeling* regardless of whether or not they are dispensed. Labeling provides the information of the package contents.

Establishing Beyond-Use Dates

47. What is water activity (a_w)?

Put simply, water activity is the measure of free water that is available to participate in chemical reactions such as hydrolysis or may provide an environment that can support microbiological growth. See <922> and <1112> for more detailed information.

48. Are compounders expected to measure the a_w of CNSPs to determine the BUD?

No, the chapter does not require compounders to measure a_w for CNSPs. a_w is intended to be used as a guide for assigning BUDs. General Chapter <795> provides examples of dosage forms that have an $a_w < 0.6$ and those that have an $a_w \geq 0.6$. Additionally, General Chapter <1112> *Application of Water Activity Determination to Nonsterile Pharmaceutical Products* provides a list of products and corresponding a_w in *Table 2*.

49. Why is the BUD for nonaqueous oral liquid dosage forms with an $a_w < 0.6$ (e.g., oral suspensions or solutions) limited to 90 days?

Although many nonaqueous preparations, including anhydrous oil preparations, may be stable for a long period of time, this is not consistently demonstrated for all nonaqueous formulations. For example, a stability-indicating assay of doxycycline compounded in oil exhibited degradation before 90 days. Additionally, there are other ingredients that may oxidize or otherwise react with the fatty acids in the oil. The chapter provides a conservative approach due to examples where preparations in oil are not stable for 180 days. Further, the chapter allows the BUD of CNSPs to be extended up to 180 days if there is a stability study using a stability-indicating assay (see <795>, *10.5 Extending BUDs for CNSPs*).

50. If a stability study shows that a CNSP is stable for longer than 180 days, can that BUD be assigned?

No. General Chapter <795> specifies that the BUD for CNSPs may be extended up to a maximum of 180 days if there is a stability study (published or unpublished) using a stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used. If the CNSP is aqueous, the chapter additionally requires testing for antimicrobial effectiveness for extending BUDs beyond those contained in *Table 4* (see *10.5 Extending BUDs for CNSPs*).

However, if there is a *USP–NF* compounded preparation monograph for the CNSP, and the preparation is labeled to indicate that it meets the monograph specifications, the BUD must not exceed the BUD specified in the monograph. As stated in *General Notices 3.10*, monograph requirements supersede the requirements of General Chapters.

51. If I extend the BUD beyond those described in *Table 4. BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph* or *CNSP-Specific Stability Information*, why does the CNSP have to be tested for antimicrobial effectiveness?

The chapter allows an extension of BUD if there is stability data supported by a stability-indicating study. Although the CNSP may be stable, the CNSP may be susceptible to microbial proliferation especially from prolonged and repeated use. Antimicrobial effectiveness testing is recommended and only needs to be performed once for a particular CNSP. If a range of concentration is used in the same CNSP formulation and stored under the same conditions, the antimicrobial effectiveness test can be conducted for the highest and lowest concentrations. The results can be extrapolated for the concentrations within the range studied (e.g., bracketed study design).

52. Is there a difference between testing stability with a strength (potency) over time or a stability-indicating method?

Yes, a strength (potency) over time test determines the amount of active ingredient in a preparation, however, it may not be able to separate the active ingredient from its degradation products and impurities for quantitation depending on the analytical methods used for the test. A stability-indicating method will be able to quantitate the active ingredient and its degradation products or related impurities in the preparation by separating the active ingredient from its degradation products and impurities, and to show a change in the concentration of the active ingredient with increasing storage time. A stability-indicating method is used to determine stability of a drug and used to establish the beyond-use date. (See article, "Strength and Stability Testing for Compounded Preparations.")

53. What is the difference between a BUD and an expiration date?

Beyond-use dates (BUDs) and expiration dates are not the same. Expiration dates are assigned by manufacturers based on analytical and performance testing of the sterility, chemical and physical stability, and packaging integrity of the conventionally manufactured product, API, or added substance. Expiration dates are specific to a particular formulation in its container and at stated exposure conditions of illumination and temperature. Section *14.1 Terminology* in *USP* <797> and Section *10.1 Terminology* in *USP* <795> define an expiration date as: The time during which a product can be expected to meet the requirements of the *USP–NF* monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions. Beyond-use dates are assigned by compounders and apply to CSPs and CNSPs. The *Terminology* sections in *USP* <797> and <795> define a BUD as: Either the date, or hour and date, after which a compounded preparation must not be used. The BUD is determined from the date and time that preparation of the compounded preparation is initiated.

54. What is the BUD of a stock solution with no API?

Section *10.4* states, For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.

Examples of acceptable instances may include use of a pH-altering solution that has a 24 h BUD or preparing a methylcellulose or similar suspension (14 day BUD) for use during the same shift in CNSPs that are preserved (35 day BUD).

55. How may a BUD beyond *USP* <795> limits be assigned to a stock solution with no API?

Information may be found in the Stability Study Reference Document posted here. In general, the following tests must be considered:

- Appearance (e.g., appearance, color, clarity, and particulates)
- Antimicrobial effectiveness testing (*USP* <51>) for aqueous preparations
- pH
- Microbiological tests for water-containing formulations ($a_w \geq 0.6$)
- <61> *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*
- <62> *Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms*

56. How do I choose an appropriate preservative for my CNSP?

Preservative selection is dependent on the level of potential microbiological growth over the intended period of the BUD (amount of preservative in preparation must be sufficient to protect the preparation through the end of the BUD), the pH of the preparation being preserved (the preservative must have effectiveness at the pH of the preparation), specific microbiological organisms with which the preparation could be exposed (preservative system must be effective against the microbiological organism(s) that have a potential to propagate in the preparation), and chemical compatibility with the API and other excipients.

57. Given the water activity examples in *Table 3*, and the fact that these do not cover all formulation possibilities, how does a pharmacist determine total water activity of multi-ingredient compounds, and how should a pharmacist determine when water activity testing is needed?

Pharmacists can always reference <922> and <1112> for more information regarding a_w and its determination. The chapter does not require a compounded preparation to be tested for water activity, but a_w is the determining factor in categorizing a preparation as aqueous or nonaqueous. The table was meant to provide actual examples of formulations tested for water activity to assist the pharmacist in determining if a preparation would likely be squarely in the aqueous or nonaqueous category. It is also important to note that waters of hydration do not affect water activity. When in doubt, the best course of action to know water activity would be to test it. This is a one-time test for the specific preparation.

58. How is the BUD of a CNSP affected by pH-modifiers or other stock solutions that are used as components?

For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.

59. Must the stability studies used to extend BUDs to 180 days be published?

No. Any stability study that meets the requirements of a stability-indicating assay method can be used, whether published or unpublished, to extend beyond-use dates up to 180 days for a CNSP. To learn the requirements for a stability-indicating assay method, visit the Stability Study Reference Document posted here.

60. When must <51> testing be performed?

<51> testing should be performed to verify a formulation for a multiple-dose preparation is capable of meeting the antimicrobial effectiveness testing requirements. Changes in package size, container closure system, or preparation components may necessitate repeating the <51> testing. Testing is not necessary for every batch.

61. Must antimicrobial effectiveness testing results be provided by an FDA-registered facility?

The designated person(s) may rely on antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature as long as the CNSP formulation (including any preservative) and container closure materials of composition are the same as those tested (unless a bracketing study is performed). Outside of the United States, facilities must comply with the laws and regulations of the applicable regulatory jurisdiction.

62. Can unpublished antimicrobial effectiveness testing results be used?

Yes. Compounders are not required to perform their own *USP* <51> *Antimicrobial Effectiveness Testing* on each compound prepared. They may perform or contract the study themselves, or they may use published or unpublished peer-reviewed literature results or *USP* <51> results performed in an FDA-registered facility provided that the CNSP or CSP preparation (including any preservative) and container closure system are exactly the same as those that produced the preparation that produced the test results. Antimicrobial effectiveness testing may also be performed in what is known as a bracketing study by testing a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.

<797> FAQs

November 1, 2022

General

1. Where can I find FAQs and other information on USP Compounding Standards?

For FAQs on USP Compounding Standards, please see below:

- General Chapter <795> *Pharmaceutical Compounding—Nonsterile Preparations*
- General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations*
- General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*
- General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*
- Compounded Preparation Monographs (CPMs)

2. Where can I find information about how to interpret and apply General Chapters?

The *General Notices and Requirements* describe the basic assumptions, definitions, and default conditions for the interpretation and application of *USP–NF* content. For example, Section *2.30. Legal Recognition* describes the legal recognition of USP and NF. Section *3.10.30 Applicability of Standards to the Practice of Compounding* describes when USP compounding practice standards are or are not applicable.

Introduction and Scope

3. What is the definition of sterile compounding?

For purposes of General Chapter <797>, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. However, administration and preparation per the manufacturer's approved labeling are out of the scope of the chapter as described in *1.2 Administration* and *1.4 Preparation Per Approved Labeling*, respectively.

4. To whom do the standards in General Chapter <797> apply?

This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites. Any person entering a sterile compounding area, whether preparing a CSP or not, must meet the requirements in *3. Personal Hygiene and Garbing*.

Please note, compounding of sterile hazardous drugs (HDs) must additionally comply with General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*.

5. What is considered a compounding facility? Are there requirements that have to be met in order to be considered a compounding facility?

The requirements of the chapter apply to all places where CSPs are prepared for human and animal patients. Additionally, there may be local or federal requirements that must be met.

6. How do I know what are requirements versus recommendations in the chapter?

Generally, requirements in a General Chapter are conveyed by use of the term "must". Recommendations are conveyed by use of the terms "should" and "may".

7. What does "official date" mean?

The USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. USP has no role in enforcement. All text in the United States Pharmacopeia (USP) or National Formulary (NF) that has reached its official date is "official text." Although all text of the *USP–NF* that has reached its official date is "official text," not all official text states requirements with which compendial users must comply. Some official text is intended to assist or guide compendial users or to serve informational purposes.

8. When do the revisions to General Chapter <797> become official?

The revision of <797> published on November 1, 2022, will become "official" on November 1, 2023. The "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. However, ensuring compliance with the requirements of these standards is the responsibility of the applicable regulatory jurisdiction. Regulatory bodies such as state boards of pharmacy may have a different official date. USP has no role in enforcement.

9. Are the temperatures in the chapter expressed in degrees Fahrenheit or Celsius?

Unless otherwise specified, all temperatures in the *USP–NF* are expressed in degrees centigrade (Celsius) (see also *General Notices 8.180 Temperatures*).

10. Who can be the designated person(s)?

The designated person is one or more individuals assigned by the facility to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded sterile preparations (CSPs). Facilities must determine whether they have one or more designated person(s), select the designated person(s), and determine how to allocate responsibility if there is more than one designated person. The designated person(s) can delegate activities to an assigned trainer provided that is described in the organization's policies.

11. Why were the categories of low-risk, medium-risk, and high-risk CSPs renamed?

In the 2015 proposed revision of *USP* <797>, it was first introduced to change the compounded sterile preparation (CSP) categories from a three-termed format of low-risk, medium-risk, and high-risk to a two-termed format of Category 1 and Category 2. This change was to avoid inaccurately conferring a level of risk to a particular CSP without consideration for all factors that influence the quality of that CSP. Renaming the CSP categories as Category 1 and Category 2, distinguished primarily by the conditions under which they are made and the time within which they are used, is intended to be a neutral designation. The 2021 proposed revision of *USP* <797> added Category 3 which allows compounders who are willing to add additional quality assurance requirements, the ability to assign BUDs longer than Category 2 BUDs.

12. What are Category 3 CSPs?

Category 3 describes CSPs made in a compounding facility that meets additional quality assurance requirements. Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in *Table 14*, if compounded in accordance with all applicable requirements for Category 3 CSPs in <797>. Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequencies for environmental monitoring, and determining stability.

13. Does docking and activation of a proprietary bag and vial system for immediate administration in accordance with the manufacturer's labeling instructions have to occur under ISO 5 conditions?

No. Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for *immediate* administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment.

14. When does the chapter apply for docking a proprietary bag and vial system?

Docking of the proprietary bag and vial systems for f*uture activation* and administration is considered compounding and must be performed in an ISO Class 5 environment in accordance with <797>, with the exception of *14. Establishing Beyond-Use Dates*. BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling.

15. Am I required to keep proprietary bags and vials which have been docked for future activation in a classified cleanroom?

The chapter does not address storage of the docked proprietary bag and vial system, nor does the chapter require it to be stored in a cleanroom suite. The chapter states that docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in accordance with this chapter, with the exception of *14. Establishing Beyond-Use Dates*. Users should refer to the manufacturer's labeling for storage recommendations.

16. Does the chapter apply for repackaging of a conventionally manufactured sterile product?

Yes, repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements in this chapter.

17. Is administration out of the scope of the chapter?

Yes. The intent of the chapter is to establish minimum standards for practitioners when compounding sterile products in order to minimize harm, including death, to human and animal patients. The scope of the chapter is intended to ensure a CSP maintains its integrity up until the time when administration begins. Standard precautions such as the Centers for Disease Control and Prevention's (CDC's) safe injection practices apply to administration (see *1.2 Administration*).

18. Does a conventionally manufactured sterile product prepared for administration to a single patient in accordance with manufacturer's approved labeling outside of ISO Class 5 conditions have to be administered within 4 hours of reconstitution or mixing if it meets all the conditions in *1.4 Preparation Per Approved Labeling*?

No. When all of the conditions in *1.4 Preparation Per Approved Labeling* are met, the storage information in the manufacturer's approved labeling may be followed.

19. What is the appropriate BUD to assign when preparing a conventionally manufactured sterile product for administration?

Preparation of a single dose of a conventionally manufactured sterile product in accordance with the approved labeling that includes information about the diluent to be used, the resultant strength, storage time, and container closure system is not considered compounding and these preparations are not subject to the BUD limits in the chapter. The BUD provided in the approved labeling may be assigned to these preparations when the labeling contains the required information mentioned above. (See *1.4 Preparation per Approved Labeling*).

20. Is withdrawing a dose from a container of a conventionally manufactured sterile product or spiking an IV bag, without any further manipulation, for immediate administration to a patient considered compounding?

No, withdrawing a dose from a container or spiking an IV bag of a conventionally manufactured sterile product without any further manipulation is considered administration rather than compounding and is out of the scope of <797>. If the dose is further mixed with another product, it would be considered compounding and subject to the requirements of <797>.

21. Is spiking IV fluids (taking IV spikes and putting them into a bag; putting a set into an IV bag) considered compounding?

No, a facility's policies and procedures regarding spiking IV fluids is outside the scope of the chapter.

22. When compounding immediate-use CSPs, may more than three individual containers of a sterile product be used?

The immediate-use CSPs provision states that the preparation must not involve more than 3 different sterile products. Two or more of the same sterile components (product) may be used as long as there are not more than three different sterile components (products). For example, two vials of the same component (drug product) are reconstituted using two vials of *Sterile Water for Injection* (component products) and added to a single component product intravenous diluent bag such as NS or D5W. As another example, when the CSP requires combining 4 vials of the same component (drug product) into a single component product intravenous bag of diluent, only 2 different sterile components (products) are used to prepare the CSP. Both examples may be considered immediate- use as long as the criteria listed in *1.3 Immediate-Use CSPs* are met.

23. Are COVID-19 vaccines limited by the 4-hour immediate-use BUD or can the BUD from the manufacturer be used?

As long as the approved labeling or supplemental materials provided by the product's manufacturer includes information for the diluent, the resultant strength, the container closure system, and storage time, then this would be considered *1.4 Preparation Per Approved Labeling* and is not considered compounding.

24. Can a single-dose container be used to prepare doses for more than one patient when compounding an immediate-use CSP?

No. One of the conditions of the immediate-use CSP provision specifies that any unused starting components from a single-dose container must be discarded after preparation for the individual patient is complete. Single-dose containers must not be used for more than 1 patient when used for preparing immediate-use CSPs.

25. Why does the immediate-use CSP provision allow for administration to begin within 4 hours following the start of the preparation?

The immediate-use CSP provision was revised to allow up to 4 hours for beginning administration to balance the need for ensuring CSP quality with timely access to medication in a variety of healthcare settings. The allowance of up to 4 hours was based on the 4-to-6-hour lag phase of microbial growth, during which potential bacterial cells are adjusting to their environment and change very little, and they do not immediately start reproducing.[1] In the event bacterial cells were inadvertently introduced into a CSP during compounding, replication is unlikely and therefore there is a window of time in which a CSP can be held prior to administration.

[1] References:

- Daquigan N et al. Early recovery of *Salmonella* from food using a 6-hour non-selective pre-enrichment and reformulation of tetrathionate broth. *Front Microbiol*. 2016;7:2103.
- Jarvis, Basil. *Statistical Aspects of the Microbiological Examination of Foods, Third Edition*. Academic Press, 2016.
- Ryan, Kenneth et al. *Sherris Medical Microbiology, Sixth Edition*. McGraw-Hill Education, 2014.
- Wang J et al. A novel approach to predict the growth of *Staphylococcus aureus* on rice cake. *Front Microbiol*. 2017;8:1140.

26. Is it considered compounding if the steps used to prepare a single dose of a conventionally manufactured product are different from the directions contained in the manufacturer's approved labeling?

Yes. Any compounding (e.g., mixing, reconstituting) that is not performed according to the manufacturer's approved labeling is considered sterile compounding and is subject to the requirements in the chapter.

27. What information is needed to meet the requirements of Section *1.4 Preparation Per Approved Labeling?*

The approved labeling or supplemental materials provided by the product's manufacturer, including information for the diluent, the resultant strength, the container closure system, and storage time.

28. Does the chapter address compounded radiopharmaceutical dosage forms?

No. Compounding of radiopharmaceuticals is not required to meet the standards of this chapter as they are subject to the requirements in General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*.

29. Do pharmaceutical manufacturers have to comply with <797>?

No. Manufacturers must comply with FDA's current good manufacturing practices (CGMP) and/or laws and regulations of the applicable regulatory jurisdiction.

30. What is the difference between compounding and what is described in *1.4 Preparation Per Approved Labeling*?

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer if the product is prepared as a single dose for an individual patient and the approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time.

31. Where may Category 1 CSPs be prepared?

Category 1 CSPs must be prepared in a primary engineering control (PEC) that may be placed in an unclassified segregated compounding area (SCA) or a cleanroom suite.

32. What qualifications must a designated person have?

This must be determined by the facility's SOPs. Some states and accreditation organizations have more specific guidance.

33. Is the use of technology other than what is listed in the chapter allowed?

The introduction and scope section outlines the use of technologies, techniques, materials, and procedures not specifically covered by the chapter, as it would be impossible for this chapter to address all of the current technology on the market and potential for new technology coming to market in upcoming years after release of the finalized chapter. It is important that the technology that is being used as indicated in the manufacturers approval documentation or if it is being used for a different intended purpose that it is validated for that purpose. This ensures that any use of technology does not bypass any safety requirements within the chapter itself and meets or exceeds those requirements. *USP* chapters <1223> and <1225> can assist compounders in this validation process.

34. What is USP's position on drug vial optimization (DVO)?

USP <797> does not address drug vial optimization (DVO). The organization would need to determine if the process used is noninferior to the requirements of the chapter.

35. Will there be any future USP guidance on the use of technology in compounding?

The Compounding Expert Committee will consider the development of future resources or a standard related to the use of technology in compounding. The introduction and scope section of <797> outlines the use of technologies, techniques, materials, and procedures not specifically covered by the chapter, as it would be impossible for this chapter to address all of the current technology on the market and potential for new technology coming to market in upcoming years after release of the finalized chapter. It is important that the technology that is being used as indicated in the manufacturers approval documentation or if it is being used for a different intended purpose that it is validated for that purpose. This ensures that any use of technology does not bypass any safety requirements within the chapter itself and meets or exceeds those requirements. *USP* chapters <1223> and <1225> can assist compounders in this validation process.

36. If a device (e.g., a repeater pump) has undergone validation by the FDA, is the compounder required to verify the volumetric accuracy each day of use?

Yes. Before using automated compounding devices or other similar equipment, compounding personnel must conduct an accuracy assessment before the first use and again each day the equipment is used to compound CSPs.

37. Are albumin, IVIG, etc., included as part of "blood-derived and other biological materials" in Section *1.1.2*?

No. These commercial products have been processed by the manufacturer to be sterile. Blood or biological materials derived directly from a patient are not sterile.

38. Do facilities have to change their standard operating procedures (SOPs) and practices for immediate-use from 1 h to 4 h?

No, facilities may choose to maintain the 1-hour limit for administration of immediate-use CSPs, however increasing the time to 4 hours would be considered acceptable.

39. Can immediate-use CSPs be made in a batch for more than one patient?

Compounders can prepare multiple doses of immediate-use CSPs intended for use in one or more patients in a single batch as long as the conditions in Section *1.3* are met.

40. What does "directly administered" mean in *1.3 Immediate-Use CSPs*?

"Directly administered" refers to the dose being prepared and then immediately administered by the person who prepared it, or administration is witnessed by the person who prepared it. In a situation where a CSP may be prepared for direct and immediate administration there is risk involved if a CSP is unlabeled and the person who compounded it is not administering or present for the administration.

41. What are the training and competency assessment requirements for personnel who only prepare immediate-use CSPs?

Training and competency assessment requirements are determined by the specific tasks performed and the facility's SOPs, and must include aseptic processes to minimize the potential for contact with nonsterile surface surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.

42. How often does the training and competency of personnel who perform immediate-use products need to be performed?

Section *1.3 Immediate-Use CSPs* requires that personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. No specific frequency is identified for training and competency of personnel who perform compounding of immediate-use CSPs.

43. Is the use of dispensing pins allowed per <797>?

The chapter does not address the use of specific disposable supply items other than to say supplies in direct contact with the CSP must be sterile and depyrogenated. It is the responsibility of the facility to determine the appropriateness of specific items, including dispensing pins.

Personnel Training and Evaluation

44. Section *2.1 Demonstrating Knowledge and Competency of Core Skills* states that personnel must complete training and be able to demonstrate knowledge of principles initially and at least every 12 months. Does this mean that each person needs written or electronic testing on each of the listed topics in addition to competency testing?

The written training program must describe the required training and the process for evaluating the performance of personnel, but personnel must both demonstrate knowledge of principles and competency of skill for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions.

45. Must cleaning staff or personnel who restock the cleanroom undergo the same training as compounders?

Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must be initially trained and demonstrate competency in maintaining the quality of the environment in which they are performing their assigned task. At a minimum, these personnel must meet the requirements for personal hygiene and garbing that are described in *3. Personal Hygiene and Garbing*. Facility SOPs must outline what initial and ongoing training is required.

46. Must vendors and certifiers be trained before entering the cleanroom?

Section *1.1.3* specifies that any person entering a sterile compounding area, whether preparing a CSP or not, must meet the requirements in *3. Personal Hygiene and Garbing*. Facility SOPs must outline specific requirements.

47. Do supervising pharmacists that do not compound have to undergo training and evaluation?

Yes. The following must be included:

1. **Core skills:** <797> requires that personnel who do not compound, but supervise compounding personnel, have to be trained and demonstrate competency initially and at least every 12 months as outlined in Section *2.1 Demonstrating Knowledge and Competency of Core Skills*.
2. **Garbing Competency:** Initially and at least every 12 months.
3. **Aseptic Manipulation Competency:** Personnel who have direct oversight of compounding must complete an aseptic manipulation competency evaluation at least every 12 months. The evaluation should correspond to the type of activities of the personnel they oversee but does not require the same quantities.

48. Compounding independently is mentioned multiple times. Does that mean someone can compound for patients before passing testing as long as they are observed? Is this left entirely to SOPs?

Before beginning any compounding (independently or with supervision), personnel must successfully complete the initial garbing competency. Additionally, all personnel entering a compounding area must abide by *3. Personal Hygiene and Garbing*. The process of developing competency requires practice. Each compounding facility must develop a written training program that outlines what is permitted.

49. How many gloved fingertip and thumb sampling tests and media-fill tests must be done initially and subsequently?

In the revised chapter gloved fingertip and thumb samplings are taken during both the aseptic manipulation competency (i.e., immediately after media-fills) and the garbing competency evaluation (i.e., after garbing and gloving). The complete garbing competency evaluation, including gloved fingertip and thumb sampling, must be successfully completed no fewer than 3 separate times initially, and only 1 time on subsequent evaluations. All aseptic manipulation competency evaluations, including media-fill and gloved fingertip and thumb sampling after media-fill, must be successfully completed 1 time for the initial and 1 time for all subsequent evaluations.

50. What is the purpose of the increased frequency of the garbing competency?

Personal hygiene and garbing are essential to maintain microbial control of the environment. Most microorganisms detected in cleanrooms are transferred from individuals. Preparation of compounded sterile preparations by personnel who lack proper training and competency may result in increased contamination risk and potentially poor outcomes for patients. Preventing contamination by ensuring personnel are trained and competent is more impactful than detecting contamination through sampling methods.

51. Is documentation of gloved fingertip and thumb sampling and media-fill testing only required when results exceed action levels?

No. All results of the evaluations must be documented and maintained to provide a record and long-term assessment of personnel competency. Documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including the manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results.

52. If compounding personnel fail media-fill testing or gloved fingertip and thumb sampling, are they required to stop compounding until corrective action and reevaluation have been completed?

General Chapter <797> chapter does not require compounding personnel to cease compounding, however, the facility must evaluate the cause of failure and determine appropriate corrective actions. The results of the evaluation and corrective action must be documented, and the documentation must be maintained to provide a record and long-term assessment of personnel competency. General Chapter <797> describes gloved fingertip and thumb sampling and media-fill testing in Sections *2.2 Demonstrating Competency in Garbing* and *Hand Hygiene* and *2.3 Competency Testing in Aseptic Manipulation*, and required documentation in *20. Documentation*.

53. Why are incubation conditions different for media-fill testing, gloved fingertip and thumb sampling, and environmental air and surface sampling?

Environmental air and surface samples and gloved fingertip and thumb samples are incubated at a high temperature 30°–35° for no less than 48 h and then a low temperature 20°–25° for no less than 5 additional days. Incubation at a lower temperature first may compromise recovery of Gram-positive cocci which are often associated with humans. The incubation conditions are consistent with General Chapter <1116> *Microbiological Control and Monitoring of Aseptic Processing Environments*. Media-fill test samples are incubated for a longer period, 7 days each at two temperatures, 20°–25° and 30°–35° to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the facility's SOPs.

54. Why must a higher incubation temperature be used first for gloved fingertip and thumb sampling, and environmental air and surface sampling?

Incubating gloved fingertip and thumb samples, and environmental air and surface samples at a higher incubation temperature first helps recover bacteria first. Incubation at a lower temperature first may compromise recovery of Gram-positive cocci which are often associated with humans.

55. If the controlled room temperature is 20-25°, can the samples be incubated without an incubator?

No. Samples must be incubated in an incubator

56. Do the three initial gloved fingertip tests need to be done on the same day?

Not necessarily. The organization can determine the interval for the three initial gloved fingertip tests. In any case, these need to be three separate instances of hand hygiene, garbing, and the gloved fingertip test. Garbing once and completing three sets of gloved fingertip tests does not meet the requirement for the initial testing. The 3 successful completions must be in succession—failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row.

57. Are personnel who only prepare immediate-use CSPs required to perform media-fill testing?

No, but the facility's SOPs must determine how their competency will be evaluated. When specific conditions in <797> are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs. Personnel must be trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. The competency should include appropriate preparation (e.g., hand washing, cleaning the area that will be used) and technique that is evaluated and approved by a qualified individual.

58. Can gloved fingertip testing be done more frequently than what is in the chapter?

The chapter provides minimum compounding standards. Compounders can implement more frequent sampling if they deem it appropriate for their facility.

59. Media used for media-fill test doesn't filter easily and personnel may need to use additional filters for the media-fill test than used for the actual batch. Is this acceptable?

Yes. Additional filters may be used as necessary for the media-fill test. Using a pre-filter may help maximize the volume of the sterilizing filter. A filter integrity test (e.g., bubble point test) must be performed on all sterilizing filters used during media-fill testing.

60. Does the ongoing garbing competency include gloved fingertip and thumb sampling (GFT) after the visual observation of garbing?

Yes. Performing GFT after the visual observation of garbing ensures personnel can don sterile gloves without contaminating them.

61. Describe how to appropriately handle and store samples for media-fill testing, including the right temperature.

All samples must be incubated for 7 days each at two temperatures, 20°–25° and 30°–35°, to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the facility's SOPs. If sending samples to the laboratory for incubation, samples must be sent as soon as possible (e.g., within 24 h) for the most accurate results. Samples must be protected from damage as well as temperature and humidity extremes during transit. Refer to <1117> *Microbiological Best Laboratory Practices* for additional information.

62. How many personnel are allowed in the buffer room or SCA during media-fill testing?

Media-fill testing must simulate the most difficult and challenging aseptic compounding procedures encountered by the person, and it must capture all elements that could potentially affect the sterility of the CSP. The chapter does not specify the exact number of personnel in the buffer room or SCA, but it must simulate the conditions encountered by the compounder.

Personal Hygiene and Garbing

63. What is the order and location of garbing?

General Chapter <797> does not specify the order and location of garbing. The order and location of donning and doffing each article of required garb would depend on the type of garb used (e.g., sterile gowns) and the placement of the sink (e.g., if the sink is located inside or outside of the anteroom). The garbing order, location, and donning/doffing each article of required garb must be determined by the facility and documented in the facility's SOP. For example, if a sink is located outside of the anteroom, a facility's garbing policies and procedures may indicate that certain garb would be donned outside of the anteroom to more easily transition into hand hygiene procedures. Garb must be donned and doffed in an order that reduces the risk of contamination. Please note, sterile gloves must be donned in a classified room or SCA. Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands).

64. Can donning and doffing activities by different personnel occur in the same room at the same time?

The chapter recommends (but does not require) that donning and doffing not occur in the anteroom or the segregated compounding area (SCA) at the same time. Personnel must be aware of activity in the room to ensure that the integrity of garb is not compromised. For example, if one person is performing hand hygiene while another is donning a gown, personnel must consider the risk of contaminating the gown (e.g., from potential splashing).

65. What are examples of methods to cover jewelry that cannot be removed?

Examples of jewelry that cannot be removed are dermal piercings (also known as a microdermal piercing), which is a piercing that is held in place with a dermal anchor that is installed underneath the skin. Facilities must determine the appropriate method for covering dermal piercings to minimize the risk of contaminating the CSP and the environment. For example, depending on the location of the piercing, an adhesive bandage or head cover may be used to cover the jewelry.

66. Are wedding rings permitted to be worn under sterile gloves?

The chapter requires removing all hand jewelry that could interfere with the effectiveness of garbing or otherwise increase the risk of contamination of the CSP. Wedding rings may potentially compromise the integrity of the glove (e.g., tearing) and prevent adequate hand hygiene.

67. Are eyelash extensions allowed in the cleanroom?

No. Cosmetics are not permitted.

68. What accommodations can the designated person allow with regards to garbing in the cleanroom?

The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.

69. Must the accommodation to personnel preparation be documented each time or just once?

The accommodation must be documented per the facility's SOPs and *20. Documentation*.

70. Are 3 pairs of gloves required for using a compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)?

No, if using a CAI or CACI, the chapter recommends disposable gloves to be worn inside gloves attached to the restricted-access barrier system (RABS) sleeves. However, the chapter requires sterile gloves to be worn over the gloves attached to the RABS sleeves. The use of disposable gloves inside of gloves attached to the RABS sleeve is intended to maintain the cleanliness of the gloves attached to the RABS sleeve which may collect sweat or other touch contaminants. Sterile gloves outside of the gauntlet gloves help minimize the risk of contamination to the environment and the CSP.

71. If I am compounding Category 1 CSPs in an SCA, do I have to wear the same garb as when compounding Category 2 CSPs in a cleanroom suite?

Yes. Minimum garbing requirements are not stratified based on facility design. The chapter lists the minimum garbing requirements to protect the CSP and the environment. Sterile gloves are required for preparing CSPs inside an ISO Class 5 PEC.

72. Can gowns be re-used?

Yes. If compounding Category 1 and Category 2 CSPs, gowns used for nonhazardous compounding may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination. Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Additionally, gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing).

73. Regarding Section *3.1*, gum-chewing and mints are considered food. Why can't compounders have anything in their mouths or put anything in their mouths while in the cleanroom suite?

It is too easy to want to blow bubbles or move gum and candy around in the mouth that could spew additional wet into the mask and contaminate it. The candy or gum can also fall out of the mouth, out of the mask and onto a hood counter or floor and contaminate the area.

74. Why is the use of brushes not allowed for hand hygiene?

The practice of using a brush to scrub hands in hand-antisepsis can damage skin of personnel and result in an increase of bacteria shed from the hands. The CDC recommended discontinuing the use of the brushes and the brush side of scrub/sponge brushes in 2002. See the CDC Guideline for Hand Hygiene in Health-Care Settings, Morbidity and Mortality Weekly Report, October 25, 2002, 51(RR16); 1-44.

75. Where should I garb when preparing Category 1 CSPs in an SCA?

Sections *3.2* and *3.3* outline the requirements for hand hygiene and garbing for Category 1. The order of hand washing and garbing depends on the placement of the sink, is determined by the facility, and is documented in the facility's SOPs.

An example garbing procedure in a facility that has a sink in the SCA is as follows:

1. The compounder enters the SCA and dons head, face, and shoe covers in an order determined by the facility and documented in the facility's SOPs.
2. The compounder washes their hands then dons a gown.
3. The compounder applies alcohol-based hand rub to all surfaces of hands and fingers and allows hands to dry thoroughly then dons sterile gloves.

76. When sterile garb is required, does the equipment, such as goggles or PAPRs, need to be sterile as well?

No. Sterile garb is limited to powder-free gloves when compounding Category 1, 2, and 3 CSPs, and low-lint garb when compounding Category 3 CSPs. Facilities must have an SOP describing the disinfection procedures for reusable equipment.

77. For which categories must the facility's SOPs describe disinfection procedures for reusing goggles, respirators, and other reusable equipment?

For Category 1, 2, and 3 CSPs, the facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

78. When must laundering be performed with a validated cycle?

For facilities that compound Category 3 CSPs, laundered sterile garb must not be reused without being laundered and resterilized with a validated cycle. The facility's SOPs must describe this process.

79. When should I apply sterile 70% IPA to gloves?

Application of sterile 70% IPA to gloves must occur immediately before compounding (e.g., before entering the ISO Class 5 PEC) and regularly throughout the compounding process.

80. Do conditions such as dandruff, eczema, or psoriasis exclude someone from compounding CSPs?

These are all conditions that could cause someone to be at higher risk for contaminating a CSP or the environment so they must be reported to the designated person(s). The designated person(s) is responsible for evaluating the situation and making a decision on whether the affected person must be excluded from working in compounding areas until the condition is resolved.

Facilities and Engineering Controls

81. Why must the HEPA filter be located in the ceiling of the buffer and anterooms?

Placement of HEPA filters in the ceiling eliminates the potential for post-filtration contamination of the air stream. Air distribution systems with duct-mounted HEPA filters are susceptible to introduction of unfiltered air into the airstream after the air is filtered. HEPA filter placement in the ventilation duct is difficult to leak test and susceptible to contamination, especially in the event of water leakage or other breaches. Ceiling mounted filters help facilitate testing and servicing.

82. Why are CAIs and CACIs required to be placed in an ISO Class 7 buffer room with an ISO Class 8 anteroom for preparing Category 2 CSPs?

The PEC must be located in a controlled environment for preparing Category 2 CSPs to minimize the risk of contamination. Movement of materials in and out of the RABS (e.g., CAI or CACI) in unclassified air carries a higher risk of contamination. Placement of the RABS in a classified area mitigates the risk of inadvertent contamination of CSPs with the longer BUDs that are permitted for Category 2 CSPs.

83. Does the integrated vertical laminar flow zone (IVLFZ) require 100% HEPA filter coverage in the ceiling? Can returns be under the worktable?

In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns. Strategic location of air returns in addition to full coverage of HEPA filters above the work surface is required. Specific location of the air returns is not specified. Both static and dynamic smoke studies verifying a continuous flow of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (e.g., with video). [Note—Dynamic airflow smoke pattern tests have shown that it is difficult to achieve this type of design and also achieve and maintain unidirectional airflow under dynamic operating conditions.]

84. Can a containment ventilated enclosure (CVE) be used for presterilization procedures (e.g., weighing, mixing nonsterile components)?

Presterilization procedures must be performed in a single-use containment glove bag, CVI, BSC, or CACI to minimize the risk of airborne contamination.

85. When pass-through chambers are used, do the doors have to be interlocking?

The chapter recommends that pass-through doors be interlocking. However, if a pass-through is used, both doors must never be opened at the same time.

86. How often are visual smoke studies performed (e.g., in rooms where air returns are not located low on the wall)?

Air returns in the cleanroom suite must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. This smoke study along with environmental monitoring must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, change of HEPA filter units). A visual smoke study uses a visible source of smoke, which is neutrally buoyant, to verify an absence of stagnant airflow where particulates can accumulate in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow.

87. What is the difference between a pharmaceutical isolator and a RABS (i.e., a CAI or CACI)?

Unlike RABS, pharmaceutical isolators are different in that they contain 4 major elements: controlled workspace, transfer device, access device, and a decontamination system. A pharmaceutical isolator is equipped with a generator that distributes a sporicidal disinfectant throughout the chamber. If the isolator is used to prepare Category 2 CSPs, it must be placed in an ISO Class 8 or better positive-pressure room. In contrast, if a CAI or CACI is used to prepare Category 2 CSPs, the CAI or CACI must be placed in a cleanroom suite with an ISO Class 7 or better positive-pressure buffer room with an ISO Class 8 or better positive-pressure anteroom.

88. Can Magnehelic gauges be used for monitoring pressure differentials?

Yes, Magnehelic gauges may be used to monitor pressure. The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring. Users should note that Magnehelic gauges do not warn or alert personnel to events where there is a loss of pressure whereas there are other pressure monitoring systems may have audible or visible alarms.

89. Why are sinks allowed to be placed outside of the anteroom? Does the sink placement in <797> contradict the sink placement requirements in <800>?

In facilities with cleanroom suites, the sink used for hand hygiene may be placed either inside or outside of the anteroom. If the sink is located outside of the anteroom, it must be located in a clean space to minimize the risk of bringing in contaminants into the anteroom. Sinks are permitted outside of the anteroom to offer more flexibility to the cleanroom design and help minimize the risk of contamination from water sources to the classified areas. In facilities preparing hazardous drugs (HDs) in a cleanroom suite, General Chapter <800> requires the sink to be placed in the anteroom at least 1 meter away from the entrance of the HD buffer room to avoid contamination migration into the negative-pressure HD buffer room. There are no conflicts for the sink placement in <797> and <800>. Facilities compounding sterile HDs must meet the requirements in both <797> and <800>.

90. Is an SCA required to be in an enclosed room (i.e., walls and doors)?

No. An SCA is defined as a designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of only Category 1 CSPs.

91. Why do I need a line of demarcation in the anteroom?

The line of demarcation serves to create visible separation between the clean and dirty sides of the anteroom. Distinguishing the "dirty" side of the anteroom from the "clean" side ensures all personnel abide by the garbing and material transfer procedures defined by the sterile compounding organization's SOPs. The line of demarcation signifies the locations where specific contamination control principles are implemented to aid in decreasing the number of particles introduced into the buffer room. The facility may choose where the line of demarcation is located. Please note, the anteroom is entered through the dirty side, and the clean side is the area closest to the buffer room (see Section *4.2 Facility Design and Environmental Controls*). Facilities may also utilize a design with two physically separate anterooms, one clean and one dirty.

92. Can presterilization procedures (e.g., weighing) be performed in an unclassified environment?

Yes. Presterilization procedures can be performed in unclassified environments for Category 1 CSPs. For Category 2 and Category 3 CSPs, presterilization procedures must be completed in an ISO Class 8 or better environment (e.g., anteroom or buffer room) wherein the compounder uses a containment device (e.g., single-use containment glove bags, containment ventilated enclosure (CVE), BSC, or CACI) to minimize the risk of airborne contamination.

93. In an SCA, can the sink be in the same area or room?

The sink needs to be accessible to the compounding area. It can be inside the area defined as the SCA but cannot be closer than 1 meter to the PEC. That distance is intended to ensure that splashes do not reach the PEC.

94. How can the garbing location be in a classified area with a sink outside the anteroom?

The order of garbing must be determined by the facility and documented in the facility's SOPs. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb. Hands must also be sanitized with alcohol-based hand rub before donning sterile gloves.

An example garbing procedure in a facility that has a sink outside the anteroom is as follows:

1. The compounder washes their hands in the sink located outside of the anteroom.
2. The compounder enters the anteroom and applies alcohol-based hand rub to all surfaces of hands and fingers and allows hands to dry thoroughly.
3. The compounder dons garb in an order determined by the facility and documented in the facility's SOPs.
4. Before donning sterile gloves, hands are re-sanitized with alcohol-based hand rub and allowed to dry thoroughly.

95. What types of biological safety cabinets (BSCs) are appropriate for compounding?

A BSC is a ventilated cabinet that is typically used for compounding hazardous sterile and nonsterile preparations but may be used to compound nonhazardous sterile and nonsterile preparations as well. BSCs are divided into three general classes (Class I, Class II, and Class III). Class II and Class III BSCs provide an ISO Class 5 environment so are suitable for sterile compounding. Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1). Class I BSCs are suitable for nonsterile compounding only. A BSC used for hazardous drugs must exhaust to the outdoors.

Nonsterile Non-HD	Nonsterile HD	Sterile Non-HD	Sterile HD
Class I, II, or III	Class I, II, III Must exhaust to outdoors	Class II, III	Class II, III Must exhaust to outdoors

96. What are the requirements for temperature and humidity for an SCA?

There are no specific requirements for temperature or humidity in an SCA, but it is reasonable to use the requirements for a cleanroom suite as guidance. However, if drugs or supplies are stored in the SCA, there may be other USP, FDA, or manufacturer/supplier requirements. See *USP* <659> for additional information on storage requirements for drugs.

97. May personnel reach across the perimeter of the SCA to access supplies without actually stepping over the perimeter?

The chapter requires that when personnel exit the compounding area, garb, except for gowns, cannot be reused. At minimum, this would require changing the affected garb (e.g., gloves).

98. May an anteroom be shared between a Category 2 and Category 3 buffer room?

Yes.

99. May an anteroom be shared between an HD and non-HD buffer room?

Yes.

Certification and Recertification

100. Is certification of the compounding area required to be performed using the current Controlled Environment Testing Association (CETA) *Certification Guide for Sterile Compounding Facilities*?

Before a compounding area is used to compound either Category 1, Category 2, or Category 3 CSPs, it must be independently certified using the requirements in this chapter and when applicable, manufacturer specifications. Facilities must determine the appropriate certification guide to use for certifying their compounding area.

101. What is ASHRAE?

The American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) is a professional organization that provides certification (including healthcare facility design) and professional development for engineers in this field.

102. What is CETA?

The Controlled Environment Testing Association is a professional organization for controlled environment certification personnel that provides certification (including Registered Certification Professional – Sterile Compounding Facilities), education, and resources for certification personnel.

103. A facility may have several cleanrooms under the same corporate structure (e.g., within a healthcare system) but state law requirements may require separate licenses for each compounding area. Are personnel that float between the different cleanrooms required to complete training and competency at each location if they are working in the same type of primary and secondary engineering controls?

This is in the purview of the state board of pharmacy and outside the scope of <797>. The chapter requires that each compounding facility develop a written training program that describes the required training, the frequency of training, and the process for evaluating performance. This program must equip personnel with the appropriate knowledge and train them in the required skills necessary to perform their assigned tasks. The facility's SOPs should specify the training required for such tasks, and training and evaluation of personnel must be documented.

104. Regarding 'dynamic operating conditions', what does "the largest number of personnel and highest complexity" mean as it relates to certification of ISO-classified areas?

This refers to testing in a particular ISO-classified area (e.g., ISO Class 5 PEC, ISO Class 7 buffer room). The highest number of personnel that would be expected to work in a PEC and/or SEC should be present and performing the highest complexity of compounding expected including use of compounding equipment and performance of particle-generating activities (e.g., pre-sterilization activities such as weighing and mixing powders). Testing under dynamic operating conditions is required for particle testing of ISO-classified areas, air changes per hour (ACPH) of ISO-classified rooms, and some types of smoke studies.

Microbiological Air and Surface Monitoring

105. Why has the frequency of surface sampling changed?

Surface sampling was previously required "periodically", which was interpreted differently by users (e.g., monthly, quarterly, or biannually). The change requiring minimum frequencies based on the category of CSP the facility compounds is intended to provide an additional measure of control and monitoring in between viable air monitoring and certification requirements. Regular surface sampling provides additional data for trending and allows for monitoring of contamination risks.

106. How many microbiological air and surface samples are required based on the size of classified areas?

Microbiological air and surface testing must be conducted in all classified areas to confirm that the required environment quality is maintained. The microbiological air and surface sampling must be facility-specific and must be described in the facility's SOPs. The chapter does not specify a minimum number of air or surface samples based on the size of the room, however, the International Organization for Standards (ISO) 14644-1:2015(E) Table A.1 – 'Sampling locations related to cleanroom area' states the area of a cleanroom (m^2) and the minimum number of sampling locations to be tested (N_L) that are necessary for certification. Facilities must determine the appropriate number of locations and select the locations of sampling based on their relationship to the activities performed in the area.

107. Do microorganisms need to be identified to the genus level regardless of action level?

No. An attempt must be made to identify any microorganisms recovered to the genus level if the levels measured during sampling exceed the action levels in the chapter.

108. What is the rationale for only requiring an attempt to identify any microorganisms recovered to the genus level if the levels measured during sampling exceed the action levels in the chapter?

In some instances, microorganisms cannot be identified to the genus level because the microorganism is no longer viable, or if a mold, it may not be producing the reproductive structures necessary for identification. In these instances, the genus may not be identified, but the chapter does require than an attempt be made to identify the microorganism to the genus level.

109. Is changing HEPA filters considered "servicing facilities or equipment" for the purposes of requiring microbiological air and surface monitoring?

Yes, changing HEPA filters in the ceiling would require microbiological air and surface sampling because there is potential for unclassified air to enter the cleanroom. Changing HEPA filters in the ISO Class 5 PEC would also require microbiological air and surface sampling to ensure the PEC is operating as expected. Changing prefilters for the ISO-classified rooms and PECs usually would not require additional sampling because the downstream HEPA filter remains intact.

110. If two media samples are collected at a single location, how are the colony-forming units (CFU) counted?

If a facility were to choose to utilize two different media devices for sampling, they would sample each location according to their sampling map using both devices (e.g., TSA and MEA). If each device at one location demonstrates growth, the CFU are counted separately. For example, if a TSA plate grows 5 CFU and the MEA plate at the same location grows 3 CFU, the CFU would be recorded separately as 5 CFU and 3 CFU for the respective plates. The count would NOT be recorded as 8 CFU.

111. Is a self-enclosed robotic device different than a "closed RABS" as used in <1211?>? When should surface sampling occur in a self-enclosed robotic device?

This verbiage "self-enclosed robotic device" was specifically used in <797> as there are robotic enclosures on the market that do not meet the definition of a closed-RABS, whereas some would meet this definition. For self-enclosed robotic devices that meet the definition of closed-RABS, it would be detrimental to the air quality inside the device to surface sample at the completion of each batch. Therefore, the requirement for these specific devices is to be conducted at least once daily at the end of compounding operations. This is generally when the device is opened for cleaning and disinfecting.

112. May settle plates be used in place of an impaction air sampler for viable air sampling?

No. An impaction air sampler must be used to collect 1 cubic meter or 1000 L of air from each classified area.

113. When should samples be submitted by certifiers to the laboratory after collection?

If the certifier is sending samples to the laboratory for incubation and identification, samples must be sent as soon as possible (e.g., within 24 h) for the most accurate results. Samples must be protected from damage as well as temperature and humidity extremes during transit. Refer to <1117> *Microbiological Best Laboratory Practices* for additional information.

114. Describe the process and action levels associated with testing of pass-through chambers.

For entities compounding Category 1 and Category 2 CSPs, each pass-through chamber must have surface sampling performed monthly (see <1116> *Microbiological Control and Monitoring of Aseptic Processing Environments*). For entities compounding Category 3 CSPs, each pass-through chamber must have surface sampling completed prior to assigning a BUD longer than the limits established in *Table 13*, and at least weekly (see <1116>) on a regularly scheduled basis regardless of the frequency of compounding of Category 3 CSPs.

Neither General Chapter <797> nor <1116> states which ISO classification to correlate with. The facility's SOPs should describe how growth bacteria will be defined. For example, if a pass-through chamber goes between an ISO 7 and an ISO 8 area, the surface sampling growth criteria could be based on either the ISO 7 or ISO 8 limits.

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

115. What is the difference between cleaning and disinfecting?

Cleaning is the process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. Disinfecting is the process of destroying fungi, viruses, and bacteria on inanimate surfaces and objects.

Sporicidal disinfectants are also indicated in the chapter. A sporicidal disinfectant destroys bacterial and fungal spores and is expected to kill all vegetative microorganisms.

116. What is a one-step disinfectant cleaner?

A one-step disinfectant cleaner is a product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

It is important to note that sterile isopropyl alcohol (IPA) is not a one-step disinfectant cleaner. Sterile IPA is a sanitizing agent which, when used on inanimate surfaces and objects, reduces the number of all forms of microbial life including fungi, viruses, and bacteria.

117. Where can I find examples or sources of EPA-registered one-step disinfectant cleaners?

USP cannot endorse particular products. Users may research one-step disinfectant cleaners or contact cleaning/disinfecting agent manufacturers to get more information on available products.

118. Does *Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces* and *Applying Sporicidal Disinfectants in Classified Areas and in the SCA* apply to all surfaces in the SCA?

The minimum frequencies in *Table 10* apply to all surfaces within the perimeter of the SCA except the ceiling. Ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is known or suspected.

119. Does the equipment inside a PEC need to be cleaned?

Yes, the chapter requires equipment inside of the PEC to be cleaned, disinfected, and a sporicidal disinfectant applied (see *Table 10*).

120. Are cleaning supplies required to be sterile?

Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC. The chapter states that all cleaning supplies (e.g., wipers, sponges, and mop heads) with the exception of tool handles and holders must be low lint.

Further, the chapter recommends that wipers, sponges, and mop heads be disposable.

121. Are cleaning agents required to be sterile?

Cleaning, disinfecting, and sporicidal disinfectants used within the PEC must be sterile. In classified areas outside of the PEC, sterile cleaning and disinfecting agents should be used.

122. Where can I find information about the minimum contact time for the cleaning, disinfecting, and sporicidal disinfectants used?

Refer to the manufacturer's directions or published data for the minimum contact time for the agent used. The minimum contact time may differ depending on the agent used and on the intended purpose. For example, an agent may have a 1-minute contact time to be bactericidal and a 3-minute contact time to be sporicidal.

123. Does the chapter require a separate cleaning and disinfecting step in addition to applying a sporicidal disinfectant?

The chapter requires cleaning and disinfecting of the compounding areas. These steps can be combined if an EPA-registered one-step disinfectant is used. One-step disinfectants have been formulated to be effective in the presence of light to moderate soiling without a separate cleaning step. Sporicidal disinfectants must be used at least monthly. Some EPA-registered disinfectant cleaners may also have sporicidal properties. If the sporicidal disinfectant is an EPA-registered (or equivalent) one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.

124. Is a biological safety cabinet the only PEC that has a removable work surface tray?

No. CAIs, CACIs, and some laminar airflow workbenches (LAFWs) have removable work trays.

125. Do cleaners and disinfectants have to be EPA-registered?

In the U.S., yes. Disinfectants are registered with the EPA in the USA, and depending on the international location, registered with entities with an equivalent jurisdiction in that nation

126. Can containers of sterile supplies (such as bottles of sterile alcohol and containers of sterile saturated wipers) be used for more than one compounding session?

Yes, as long as they remain in the intended area once opened. This needs to be defined by the organization's policies, based on information provided by the manufacturer/supplier. Sterile solutions and supplies are used to avoid introducing spores or other contamination into the cleanroom. For example, a packet of saturated sterile alcohol wipers opened in the ISO 5 PEC can remain in the PEC until depleted, unless the packet is contaminated. A bottle of sterile alcohol can remain open and used in the ISO 7 cleanroom until depleted, unless contaminated.

127. Once opened, how long may a cleaning and disinfecting agent or package of sterile wipers be used?

Once opened, sterile cleaning and disinfecting agents and supplies (e.g., closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs.

128. Are personnel that only clean and disinfect ISO 7 and ISO 8 areas, but not ISO 5 areas, required to wear sterile gloves?

Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed including sterile gloves.

129. If an IV bag has tubing attached in one hood and compounding is done in a second hood, does the IV bag need to be wiped with sterile 70% IPA before bringing into the second hood?

Yes. Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.

130. Do personnel have to wipe gloves with sterile 70% IPA every time their hands enter the ISO Class 5 PEC even if not touching contaminated surfaces (e.g., throwing out trash without touching trash can or grabbing a supply that was disinfected for them prior to touching)?

Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process. The facility SOPs should describe this process. For example, gloves might be wiped with sterile 70% alcohol before beginning to stage items into the hood then re-wiped before beginning compounding, after handling trash, when retrieving items outside the hood, etc. Handling trash or retrieving a supply item outside the hood could contaminate gloves so they should be re-wiped with sterile 70% alcohol after performing these tasks.

Equipment, Supplies, and Components

131. Why are active pharmaceutical ingredients (APIs) required to be obtained from an FDA-registered facility and components other than APIs only recommended to be obtained from an FDA-registered facility?

The Federal Food, Drug, and Cosmetic Act requires compounded preparations to be prepared from bulk drug substances that are obtained from FDA-registered facilities. The Expert Committee recognizes that there may be some components other than APIs that cannot be obtained from an FDA-registered facility, thus, it is a recommendation that these components be obtained from an FDA-registered facility.

132. How often do I need to calibrate my temperature monitoring equipment or verify its accuracy?

Section *9.3.4 Component handling and storage* states that all monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer. For example, if the manufacturer specifies to calibrate every 2 years, then that would be the correct interval. If a manufacturer does not specify the calibration interval, then it must occur at least every 12 months.

133. Does API refer to conventionally manufactured drug products?

The term "API" refers to any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).

134. If a CSP is stored outside of the pharmacy, do we need to monitor and document temperature readings for nursing unit floor refrigerators or remote-access Pyxis refrigerators?

Once a CSP is dispensed, you should handle this as you would any other medication (manufactured or compounded). Temperature storage conditions in healthcare facilities such as hospitals have requirements from other regulators and accreditors concerning maintaining and documenting temperatures of medication storage areas. Generally, this requires at least daily monitoring and documentation.

135. "All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." Does this statement apply to humidity sensors, pressure monitors, and thermostats?

Yes. Those are examples of monitoring equipment

136. Do we need a certificate of quality for each lot of sterile empty bags we use? <797> states "Each lot of commercially available sterile, depyrogenated containers and container closure systems must be accompanied by a COA or other documentation showing conformance with established specifications (i.e., sterility and depyrogenation requirements)."

Sterile empty bags obtained from suppliers are described as such in the product labeling. The lot number is traceable back to the manufacturer/supplier if any concerns would be identified.

Sterilization and Depyrogenation

137. What is the difference between aseptic processing and terminal sterilization?

USP General Chapter <1229> *Sterilization of Compendial Articles* summarizes the common requirements for sterilization process: design, development, validation, and process control. *USP* <1229.4> *Sterilizing Filtration of Liquids* states, "Sterilization processes are divided broadly into two categories: destruction of microorganisms, and their physical removal from the material to be sterilized. Terminal sterilization (e.g., autoclaving) is an example of the former, and sterilizing filtration is an example of the latter."

Aseptic processing includes either 1) compounding with only sterile starting ingredient(s), or 2) compounding with nonsterile ingredient(s) followed by sterilization by filtration. Filtration sterilization is not terminal sterilization because it is not a lethal process of microbial destruction.

Terminal sterilization includes compounding with sterile and/or nonsterile starting ingredient(s) and subsequent sterilization with a lethal process intended to achieve a probability of a nonsterile unit (PNSU) of 10^{-6} (e.g., steam, dry heat, irradiation).

138. Can stoppered and crimped empty vials be sterilized using steam heat?

Sealed containers must be able to generate steam internally to be sterilized by steam heat. Stoppered and crimped empty vials must contain a small amount of sterile water to generate steam (see also <1229> *Sterilization of Compendial Articles*).

139. Why is a prefiltration step with a filter of a pore size of 1.2 µm required before sterilization procedures?

A prefiltration step with a filter of a pore size of 1.2 µm removes particulate matter in the solution before sterilization. This is only required if CSPs are known to contain excessive particulate matter, which may also be an indication that the formulation may be problematic and therefore the formulation and the process should be assessed and modified if necessary.

140. What is the PNSU for CSPs sterilized by filtration?

A PNSU value cannot be applied to CSPs that are sterilized by filtration because sterilization by filtration is not terminal sterilization.

141. Is a biological indicator required for each sterilization cycle using steam or dry heat?

Yes, the effectiveness of the steam and dry heat sterilization method must be verified and documented with each run or load using an appropriate biological indicator.

142. Why does the chapter continue to exclude terminal filtration container systems from its definition of terminal sterilization?

Filtration-based methods of sterilization are not considered to be a method of terminal sterilization because they are not a lethal process of microbial destruction.

Each method of sterilization must take into consideration the container closure system that holds the compounded preparation. Since there are many container closure systems and methods of terminal sterilization, it becomes a complex matrix that is specific to the container closure system and the method of sterilization. The permutations are too numerous to include in the chapter.

143. What is depyrogenation?

Pyrogens are organic compounds that are soluble in water and not removed by filtration or steam sterilization. They are endotoxins; lipo-polysaccharides produced by Gram-negative bacteria. Depyrogenation is the destruction or elimination of endotoxins (i.e., pyrogens). There are several methods that can be used to accomplish depyrogenation.

Master Formulation and Compounding Records

144. Do I need a master formulation record (MFR) for repackaged conventionally manufactured components?

Repackaging conventionally manufactured components is within the scope of the chapter. General Chapter <797> requires a master formulation record for CSPs created for more than 1 patient and for CSPs prepared from nonsterile ingredients. If the CSP is created for more than 1 patient, such as repackaging several units, a master formulation record is required.

145. Are master formulation records required for patient-specific CSPs?

A master formulation record must be created for CSPs prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s). If the CSP is only for a single patient and does not contain nonsterile ingredients, a master formulation record is not required.

146. When is a compounding record needed for immediate-use CSPs?

If the immediate-use CSPs are prepared in a batch and are intended for use in more than one patient, then a compounding record as described in Section *11.2 Creating Compounding Records* is required.

147. Does a change in any of the information listed in MFR requirement *Box 9* when compounding the same drug require an entirely new MFR, or can an MFR be created to contain the differences?

Any change to the process, ingredients, or packaging specified in an MFR are to be noted on a compounding record. The MFR is not changed.

If a preparation is made repeatedly that has differences in process, ingredients, or packaging, consideration should be given to creating a new MFR for that version of the preparation. Otherwise, all changes are to be noted on a compounding record.

148. Where does the documentation of compounding occur (in process, in the buffer room, outside of classified areas)?

The master formulation record would be established prior to compounding a CSP, usually outside of the cleanroom suite. The compounding record should be initiated before the components of the CSP are assembled. When documented on paper, this is usually performed outside of the cleanroom suite. Depending on your work practices, final sign-off on the CR would be done in the most appropriate area. While labels need to be available for placement on the completed CSP in the buffer room, exposure of paper records should be minimized in the buffer room. Those organizations with workflow technology that supports completion of the CR in the buffer room will likely have a different process than those with only manual records.

Release Inspections and Testing

149. What is required to be documented for the visual inspection of the CSP and the container closure system?

All CSPs must be visually inspected to determine whether the physical appearance of the CSP is as expected. The master formulation record must list specific requirements for a particular CSP. Examples of visible quality characteristics might include discoloration, visible particulates, or cloudiness. Examples of visual inspection of the container closure system might include checking for leakage, cracks in the container, or improper seals.

150. Why should CSPs administered epidurally have the same endotoxin limit as that of intrathecally administered CSPs?

CSPs delivered by implanted pumps may be administered over a long period of time and may be compounded from nonsterile components. Bacterial endotoxin testing helps ensure that CSPs do not contain excessive bacterial endotoxins. Although <797> refers to General Chapter <85> *Bacterial Endotoxins Test* for calculating endotoxin limits for the appropriate route of administration, <85> does not address products administered epidurally or administered directly into the central nervous system. Compounders should be aware that endotoxin testing is also important for CSPs administered epidurally due to the close proximity of the epidural and intrathecal spaces.

151. Do all Category 2 CSPs need to undergo bacterial endotoxins testing?

No. General Chapter <797> Section *12.3 Bacterial Endotoxins Testing* requires Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing per *Table 13* to undergo bacterial endotoxins testing. For example, ophthalmic compounded preparations are not required to undergo bacterial endotoxins testing because they are not Category 2 injectable CSPs. Category 2 injectable CSPs made from one or more nonsterile component(s) and assigned a BUD that does not require sterility testing are recommended to be tested for bacterial endotoxins.

152. How is the endotoxin limit of CSPs for non-human species determined?

Endotoxin limits for non-human species are calculated as described in *USP* <85> based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species unless a different limit is scientifically supported. The formula to calculate endotoxin limit is: K/M where K = the threshold pyrogenic limit for the dosage form (expressed as EU or endotoxin units), and where M = the largest dose/patient or per species average weight in kg per hour. K has been defined by route of administration as follows: injections = 5 EU/kg, radiopharmaceutical injections = 175 EU/dose, intrathecal injections = 0.2 EU/kg, and radiopharmaceutical intrathecal injections = 14 EU/dose. To calculate the endotoxin limit for compounded morphine sulfate 50 mg/ml injection in a 5 kg cat, the following calculations are performed. The maximum dose of morphine sulfate in cats is 0.25 mg/kg. K = 5 EU/kg/hr (as defined for injections) M = 0.25 mg x 5 kg x 1hr = 1.25 mg/kg/hr K/M = 5 EU/kg/hr / 1.25 mg/kg/hr = 4 EU/mg.

The average representative weights for non-human species can be found here: https://www.fda.gov/media/102469/download.

153. Why is there a maximum batch size of 250 units for CSPs requiring sterility testing?

Sterile compounding within 503A facilities is largely a manual process. The chapter sets a minimum standard for quality assurance that encompasses a wide variety of practice sites. These quality assurance parameters are not intended for outsourcing facilities or pharmaceutical manufacturers, as they were created to accommodate the equipment and processes normally performed by 503A facilities. The risk of contaminating a CSP is likely to increase as the batch size increases, especially for a manual process. For example, equipment limitations (such as the size of a PEC) may only permit a portion of a large batch to be packaged in one continuous process. If 25 units are packaged in one continuous process, a batch of 250 units would require repeating this process 10 times. A batch of 1000 units would require repeating this process 40 times. Smaller batches reduce the potential for operator error due to fatigue. To help ensure sterility assurance, batch size is limited to 250 final dosage units for CSPs that require sterility testing. Sterility testing does not guarantee that an entire batch is sterile, only the units tested. The possibility of detecting a contaminated preparation is about 10% for batch sizes between 10 and 100 but drops to about 4% for a batch size of 250 and only 2% for a batch size of 500.

154. Why is there not a batch size limit in <71> *Sterility Tests*?

USP General Chapter <71> *Sterility Tests* falls under the Microbiology Expert Committee and was created for facilities that follow current good manufacturing practices (CGMP). Following CGMP requires a level of quality assurance significantly higher than what is required by 503A facilities who follow <797>. Modifications have been made in <797> to require a fewer number of test samples with batch sizes 1 to 39 units and to limit batch size to 250 final dosage units. Other aspects of <71>, including method suitability, number of units to be tested (for batch sizes 40 to 250), and quantity per unit tested, are required.

155. Do I have to wait for the results of the sterility tests before releasing the CSP?

Sterility testing is not required for Category 1 CSPs. Category 2 and Category 3 CSPs that require sterility testing may be administered or dispensed prior to receiving the results of release testing (including sterility testing).

In order to do this, the facility must have procedures in place to:

- Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes)
- Recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy
- Investigate if other lots are affected and recall if necessary

An SOP for recall of out-of-specification dispensed CSPs must contain:

- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall
- Procedures to determine the distribution of any affected CSP, including the date and quantity of distribution
- Procedures to identify patients who have received the CSP
- Procedures for disposal and documentation of the recalled CSP
- Procedures to investigate and document the reason for failure

156. <797> states, "When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure that the CSP does not exhibit any defects such as precipitation, cloudiness, or leakage, which could develop during storage." Would this prohibit stocking CSPs on the floors in automated dispensing cabinets (i.e., Pyxis) to no more than a 24-hour supply?

No, releasing a CSP to the floor is similar to dispensing to a patient so a second check is not required by a pharmacist. Nurses should be educated to check all types of sterile preparations – manufactured, from a registered outsourcer, prepared by pharmacy, or those that they activate or mix – prior to administration to a patient.

157. Why is bacterial endotoxin testing required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing and Category 3 injectable CSPs compounded from one or more nonsterile component(s)?

The purpose of the bacterial endotoxins test is to ensure the source material does not contain excessive endotoxins and ensure any mitigation steps that were performed are adequate. Bacterial endotoxins entering patients' bloodstreams in sufficient concentrations can cause harmful effects such as fever and septic shock and can be fatal in the most severe cases.

Establishing Beyond-Use Dates

158. What is the difference between the beyond-use date (BUD) and "hang time" (e.g., administration time, infusion time)?

The BUD is the date, or the hour and date, after which the CSP must not be used. BUDs apply to CSPs and are not intended to limit the time during which a CSP is administered (e.g., infused). "Hang time" is often used to refer to the amount of time during which a CSP or conventionally manufactured product (e.g., pre-mix, large volume parenteral solution) may be infused before which either the tubing or the medication must be changed. General Chapter <797> does not address administration time (e.g., hang time).

159. Can a CSP be administered beyond the assigned BUD?

Administration cannot begin past the assigned BUD; however, it is not intended to limit administration that began before the BUD lapsed (see 14.1 *Terminology*). For example:

- An intravenous preparation begins 1 hour before the BUD lapses; however, it is scheduled to continue infusing for a total of 2 hours. The BUD is not intended to limit the dose from being completed.
- An ophthalmic preparation is scheduled to be given once daily for 14 days; however, the BUD will lapse in 10 days. The medication can continue to be administered up until the assigned BUD in 10 days, beyond which the preparation must not be used and must be discarded.

160. After the CSP has begun to infuse, does it need to be taken down and discarded after the BUD is met?

No. Administration must begin before the BUD. The administration process is outside the scope of <797>. Standard precautions such as the Centers for Disease Control and Prevention (CDC) safe injection practices apply to administration. See <800> for additional recommendations for the administration of hazardous drugs.

161. How does the storage condition affect the BUD of a CSP? What is the relationship between storage temperature and BUDs?

Generally, longer BUDs are permitted for CSPs stored in colder conditions than for CSPs stored at controlled room temperature as colder temperatures have been shown to slow the growth of most microorganisms.

Temperature affects chemical reaction rates; thus, storage at higher temperatures will accelerate degradation and reduce a BUD. The accepted rule of thumb is reaction rates increase two-fold for every 10 degree increase in temperature. This means that 1 year storage at 30 °C is equivalent to approximately 6 months at 40 °C and approximately 3 months at 50 °C. Correlating this concept to a refrigerated product (stored at 5 °C) estimates the BUD to be one-fourth at room temperature (25 °C). The exact mechanism of degradation and rate of reaction will determine the actual difference, which can only be determined through a stability evaluation over time.

162. Are BUDs cumulative?

No, BUDs must not be additive. The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage condition.

For example, a CSP that is assigned a BUD based on storage at room temperature cannot subsequently be refrigerated or frozen in order to extend the original BUD assigned. Likewise, the BUD of a frozen CSP must not be extended based on storage at room temperature when it is thawed.

163. Can the BUDs of Category 2 CSPs be extended beyond those in *Table 13. BUD Limits for Category 2 CSPs*?

The chapter states that BUDs for Category 2 CSPs must be established in accordance with *Table 13*. However, if there is a compounded preparation monograph for a particular CSP formulation, that BUD may be assigned if the CSP is prepared according to the monograph and all monograph requirements are met (e.g., Specific Tests). *General Notices 3.10* states that where the requirements of a monograph differ from the requirements in an applicable general chapter, the monograph requirements apply and supersede the general chapter.

Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in *Table 14*, if compounded in accordance with all applicable requirements for Category 3 CSPs.

BUDs must be assigned conservatively and must take into account factors such as validated stability-indicating analytical methods and testing for sterility, endotoxins, container closure integrity, and particulate matter.

164. Why is the BUD for aseptically prepared Category 2 CSPs using only sterile ingredients 4 days when stored at controlled room temperature?

The previous version of <797> specified a storage time of 48 hours and 30 hours at controlled room temperature for low- and medium-risk level CSPs, respectively. The longer BUD in the revised chapter is based on a risk-based approach to balance the need for quality CSPs and to facilitate patient access. Further, the revised chapter contains additional requirements (e.g., facility and engineering controls and surface sampling) to help mitigate risks of inadvertent contamination.

165. Is mixing MVI vial 1 and vial 2 compounding? What is the BUD?

No. Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer. Refer to the approved labeling for use of MVI once mixed.

166. If the compounding facility meets the requirements for compounding Category 3 CSPs, can a CSP still be given a Category 2 BUD to avoid sterility testing that particular CSP?

Yes. The chapter does not prohibit a compounder from assigning a shorter BUD than is specified in the BUD Limits tables (*Table 14* for Category 3 CSPs). As these are BUD limits, they are the date and time after which a CSP must not be used, stored, or transported, and a BUD shorter than the limit may be assigned to a CSP.

167. What is an example of a CSP requiring a shorter BUD based on stability and sterility?

Shorter BUDs must be assigned when the CSP's stability and/or sterility is less than the hours or days established in BUD limits for each CSP Category. For example, per guidelines, parenteral nutrition compounded as a total nutrient admixture (TNA) at a final concentration of amino acid > 4%, monohydrated dextrose > 10%, and lipid injectable emulsion > 2% are more likely to remain stable for up to 30 hours at room temperature or for 9 days refrigerated followed by 24 hours at room temperature.

168. Are there special considerations for CSPs that contain lipid emulsions?

Manufacturer recommendations regarding administration times and filtering must be followed for CSPs containing lipid emulsions. Some lipid-containing products should not exceed an administration hang time exceeding 12 hours and many require the use of a 1.2-micron filter.

169. Do Category 3 CSP BUDs have to be based on published stability studies?

The USP Compounding Expert Committee has compiled the Stability Study Reference Document posted here to help compounders understand when a stability study is suitable for assigning Category 3 BUDs to CSPs. While every CSP must meet release testing requirements for each batch to ensure sterility, evidence to prove the physicochemical stability of a CSP may be obtained from any stability-indicating assay method study, either published or unpublished, and does not have to be repeated for each batch as long as the formula, procedures, and container closure systems in the study are exactly the same for the CSP being prepared.

170. Describe when <51> testing is necessary

An aqueous multiple-dose CSP must pass antimicrobial effectiveness testing in accordance with <51> *Antimicrobial Effectiveness Testing*.

171. Is <51> testing required for stock solutions?

No. When a CSP stock solution is used as a component to compound additional CSPs, the original CSP stock solution must be entered or punctured in ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). The CSP stock solution may be used for sterile compounding for up to 12 h or its assigned BUD, whichever is shorter, and any remainder must be discarded.

172. Must antimicrobial effectiveness testing results be provided by an FDA-registered facility?

The compounder may rely on antimicrobial effectiveness testing 1) conducted (or contracted for) once for each formulation in the particular container closure system in which it will be packaged or 2) results from an FDA-registered facility or published in peer-reviewed literature sources, provided that the CSP formulation (including any preservative) and container closure system are exactly the same as those tested, unless a bracketing study is performed. Outside of the United States, facilities must comply with the laws and regulations of the applicable regulatory jurisdiction.

173. The conversion from high, medium, and low-risk compounding to Category 1 and Category 2 CSPs means that CSPs previously categorized as low-risk (48 hours at room temperature; 14 days refrigerated), now categorized as Category 2 (4 days room temperature; 10 days refrigerated) would increase the BUD at room temperature but decrease the BUD if refrigerated. Why is that?

The Compounding Expert Committee replaced risk levels with categories based on criteria other than just starting ingredients and number of manipulations. In addition to starting ingredients, BUDs are also based on environmental quality, personnel hygiene and garbing, physicochemical stability, and requirements for release testing.

174. If I only compound Category 3 CSPs occasionally, do I still have to follow the Category 3 requirements at all times?

Yes, if a compounder desires to assign a BUD longer than those allowed in *Tables 12* and *13*, then the requirements outlined in Section *14.4 Additional Requirements for Category 3 CSPs* must be met at all times.

175. What BUD should we use if there is no stability data available for the exact concentration of a CSP?

In this case, the maximum allowable BUD limits in <797> must not be exceeded.

176. May a plastic luer lock vial be stored after access?

No. The container closure system must remain intact in order to store a single-dose container after opening. Opened plastic luer lock vials are treated like ampules and must not be stored for any time period.

177. May a vial that has the septum or metal septum ring removed be stored after access?

No. The container closure system must remain intact in order to store a single-dose container after opening. Vials that have the septum or metal septum ring removed are treated like ampules and must not be stored for any time period.

Use of Conventionally Manufactured Products as Components

178. Is a conventionally manufactured single-dose container required to be stored in an ISO Class 5 PEC in order for it to be allowed to be used for up to 12 hours?

No, opened or punctured conventionally manufactured single-dose containers may be stored outside of an ISO Class 5 PEC. However, the chapter does require that the conventionally manufactured single-dose container be entered or punctured inside of an ISO Class 5 PEC. These containers may be used up to 12 hours after initial entry or puncture provided that the storage requirements (e.g., controlled room temperature, cold temperature) are maintained. Opened single-dose ampules must not be stored for any period of time.

179. Are conventionally manufactured sterile topical ophthalmic products considered multiple-dose containers?

No, <659> *Packaging and Storage Requirements* defines multiple-dose containers as a container closure system that holds a sterile medication for parenteral administration (injection or infusion) that has met antimicrobial effectiveness testing requirements, or is excluded from such testing requirements by FDA regulation. Therefore, the requirement that multiple-dose containers not be used for more than 28 days unless otherwise specified on the labeling does not apply to conventionally manufactured sterile topical products.

180. If the approved labeling of a pharmacy bulk package describes a long storage time (e.g., 14 days), can the pharmacy bulk package be stored and used for that period of time?

Users should carefully review the manufacturer's approved labeling for pharmacy bulk packages. Some approved labeling may provide a storage time based on stability (e.g., 14 days) as well as a shorter time (e.g., 4 hours) based on the risk of microbial contamination. Users must use the shorter storage time specified in the manufacturer's approved labeling. The pharmacy bulk package must be used according to the manufacturer's approved labeling.

Use of CSPs as Components

181. How is the BUD of a CSP affected by pH-modifiers or other stock solutions that are used as components?

For CSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted.

182. What is an example of assigning a BUD to compounded stock solutions and their subsequent CSPs?

A compounder wants to reconstitute a conventionally manufactured sterile product and further dilute it to prepare a subsequent CSP (see *16.2 Use of Compounded Single-Dose CSPs and CSP Stock Solutions*).

- Day 1: a 2-gram single-dose conventionally manufactured container of powder for solution is reconstituted with 8 mL of a conventionally manufactured diluent, yielding 10 mL of 200 mg/mL of drug (CSP-A, original CSP). CSP-A is assigned a BUD of 10 days because it is aseptically processed, has not passed sterility testing, was prepared from only sterile starting components, and will be stored in a refrigerator (see *Table 13*).

- Day 3: CSP-A is entered or punctured in an ISO Class 5 PEC, where 10 mL of CSP-A solution is further diluted with 40 mL of diluent, yielding 50 mL solution of 40 mg/mL of drug (CSP-B, a finished CSP). CSP-B is aseptically processed, has not passed sterility testing, was prepared from only sterile starting components, and will be stored in a refrigerator. The BUD of a CSP prepared from one or more compounded components may not exceed the shortest BUD of any of the individual starting components. Therefore, the assigned BUD for CSP-B will be 7 days (10 days minus the 3 lapsed days of CSP-A), because that is the shortest BUD of all of its individual components.

- Additionally, CSP-A must be used within 12 hours of initial entry/puncture or its originally assigned BUD, whichever is shorter, and the remainder must be discarded.

183. What BUD must be assigned to Category 2 or Category 3 CSPs made using a CSP stock solution?

The BUD assigned to a CSP, whether compounded from conventionally manufactured components or from compounded stock solutions, follows the same standards in Section *14. Establishing Beyond-Use Dates*. The one difference found in Section *14.3 Establishing a BUD for a CSP,* is that the BUD of CSPs made from compounded components may, at times, exceed the BUD of compounded components. For example, if a compounded pH-altering solution with a short BUD is used to compound a CSP, the resulting CSP would likely have greater stability, and thus a longer BUD than the pH-altering solution. Another example would be a Category 2 CSP that was not sterility tested and used to make a Category 3 CSP that will be sterilized and sterility tested. If the physical, chemical, and microbiological stability is not negatively impacted, the BUD of the resulting CSP may exceed that of the component. This exception does not exist for commercially available components. It is important to note that the BUD of the final CSP should not be further restricted by the time limits for entering or puncturing components found in Sections *15* and *16*.

184. Once punctured, can a CSP or conventionally manufactured product still be used for the length of its BUD?

Compounders may utilize both conventionally manufactured and compounded components. The chapter specifies the time in which each of these components can be stored and used after first entered. This is often called in-use time, although this term is not used in the chapter. The BUD is not the same as in-use time. A multiple-dose vial may have a BUD of 60 days but must still be discarded no later 28 days after first puncture.

185. The chapter states, "After a multiple-dose CSP is initially entered or punctured, the multiple-dose CSP must not be used for longer than the assigned BUD or 28 days, whichever is shorter. This time limit for entering or puncturing is not intended to restrict the BUD of the final CSP." Can you clarify what the last sentence means?

Each component, whether conventionally manufactured or compounded, must have a time limit for entering or puncturing after first use. For example, a conventionally manufactured multiple-dose vial may not be used after 28 days of first puncture. This 28-day time limit for use is not the same as the BUD of the component and is not intended to restrict the BUD of the resulting CSP. If a CSP is prepared from a multiple-dose vial either 1 day or 10 days after first puncture, the BUD of the resulting CSP would remain the same. For example, let's assume a conventionally manufactured multiple-dose vial with a one-year expiration date is used to compound a CSP with a 60-day BUD. The multiple-dose vial component may be punctured on day 1 to make the CSP and a BUD of 60 days would be given. Now, 27 days later the same multiple-dose vial component is punctured to make the CSP, and still, a 60-day BUD is assigned. In this instance, the time limit for entering or puncturing the MDV component does not further restrict the CSP being compounded.

186. Please provide guidance as to the appropriate BUD for a reconstituted single-dose vial. For example, a reconstituted vial of daptomycin is stable for 2 days in the refrigerator. Can this vial be saved and reused for multiple preparations if kept in the refrigerator?

See Section *15* of <797> which describes the different types of components that could be part of a CSP. When using a single-dose vial, <797> says: "If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 12 h after initial entry or puncture as long as the labeled storage requirements during that 12-h period are maintained." Using the example listed, you could maintain the punctured single-dose vial inside the ISO 5 PEC (as long as the manufacturer's information supports that long a time), but you could not move it between the PEC and the refrigerator for use on multiple patients. You would be able to use it for more than one dose or more than one patient if it remained in the PEC and was stable for up to 12 hours.

Quality Assurance and Quality Control

187. What does "the overall QA and QC program" entail?

A quality assurance program is guided by written procedures that define responsibilities and practices that ensure compounded preparations are produced with quality attributes appropriate to meet the needs of patients and healthcare professionals. The authority and responsibility for the quality assurance program should be clearly defined and implemented and should include at least the following nine separate but integrated components: (1) training; (2) standard operating procedures (SOPs); (3) documentation; (4) verification; (5) testing; (6) cleaning, disinfecting, and safety; (7) containers, packaging, repackaging, labeling, and storage; (8) outsourcing, if used; and (9) responsible personnel.

CSP Handling, Storage, Packaging, Shipping, and Transport

188. <797> states that the temperature in the storage area must be monitored each day, either manually or by a continuous recording device. ("The results of the temperature readings must be documented in a temperature log per facility SOPs or stored in the continuous temperature recording device and must be retrievable.") Does this mean that it would be acceptable to record temperatures on Monday if closed on weekends?

Yes.

189. Do all personnel who "touch" a CSP need to have training?

Yes, but not all personnel require the same training. <797> is specific about training for compounding, but leaves requirements for other personnel up to the organization. Personnel who receive sterile products and preparations, enter orders but do not compound or check CSP preparation, clean compounding areas, transport CSPs, or other activities must have documented competence as defined by the organization.

See related question in Personnel Training and Evaluation.

Compounding Allergenic Extracts

190. What are allergenic extracts?

Allergenic extracts are biological substances used for the diagnosisand/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy. Allergenic extract prescription sets are combinations of licensed allergenic extracts which would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved biological license application (BLA) for the licensed biological products.

191. Does *21. Compounding Allergenic Extracts* apply to physician and pharmacy settings?

Yes, the provisions in *21. Compounding Allergenic Extracts* apply regardless of where the allergenic extract is compounded when:

1. The compounding process involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances, and

2. Manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials.

192. Why are the BUDs for compounded allergenic extracts longer than those required for Category 1 and Category 2 CSPs?

Because of certain characteristics of allergenic extracts and allergy practice (e.g., preservative systems and risk of anaphylaxis), preparation of allergenic extract for individual patient prescription sets is not subject to the requirements in this chapter that are applicable to other sterile CSPs. Further, FDA provides additional information for preparation of allergenic extracts in the FDA Guidance for Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.

193. Does gloved fingertip and thumb sampling need to occur after media-fill testing for personnel who compound allergenic extracts?

No. Unlike personnel training for other CSPs, the goal of gloved fingertip and thumb sampling for personnel who compound allergenic extracts is to evaluate hand hygiene and garbing but not aseptic technique, due to the nature of the CSPs they compound. Therefore, personnel perform gloved fingertip and thumb sampling three times initially before compounding; thereafter gloved fingertip and thumb sampling is performed immediately after donning gloves at least once every 12 months. The action level for these samples is anything greater than 0 CFU per each hand.

194. Can allergenic extracts be prepared for immediate-use?

Yes.

195. Can this section apply for vials that are made for multiple patients?

No. Compounding allergenic extracts is per individual patient prescription set only.

Agenda Item 7.4

Advisory committee updates
- informational only

BRN Nursing Practice Committee | January 26, 2023

BOARD OF REGISTERED NURSING
Nursing Practice Committee Meeting
Agenda Item Summary

AGENDA ITEM: 7.4
DATE: January 26, 2023

ACTION REQUESTED: **Advisory committee updates – informational only**

- Nurse Practitioner Advisory Committee (NPAC)
- Nurse-Midwifery Advisory Committee (NMAC)
- Nurse Education and Workforce Advisory Committee (NEWAC)

REQUESTED BY: Elizabeth (Betty) Woods, RN, FNP, MSN
Nursing Practice Committee Chair

BACKGROUND:

Loretta Melby, Executive Officer, will provide updates on the activities of the NPAC, NMAC, and NEWAC.

RESOURCES:

NEXT STEPS:

FISCAL IMPACT, IF ANY: None

PERSON(S) TO CONTACT: McCaulie Feusahrens
Chief of the Licensing Division
California Board of Registered Nursing
Mccaulie.feusahrens@dca.ca.gov

Agenda Item 7.5

Information only: Update on the implementation of Assembly Bill 890 (Reg. Session 2019-2020)

BRN Nursing Practice Committee | January 26, 2023

BOARD OF REGISTERED NURSING
Nursing Practice Committee Meeting
Agenda Item Summary

AGENDA ITEM: 7.5
DATE: January 26, 2023

ACTION REQUESTED: **Information only:** Update on the implementation of Assembly Bill 890 (Reg. Sess. 2019-2020)

REQUESTED BY: Elizabeth (Betty) Woods, RN, FNP, MSN
Nursing Practice Committee Chair

BACKGROUND:

Loretta Melby, Executive Officer, will provide updates on the implementation of Assembly Bill (AB) 890 Nurse practitioners: scope of practice: practice without standardized procedures.

RESOURCES:

AB 890: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB890

AB 890 Status Updates including FAQs: https://www.rn.ca.gov/practice/ab890.shtml

December 30, 2022, News Release: New Nurse Practitioner Certifications Coming to California in 2023: https://www.rn.ca.gov/pdfs/regulations/ab890_news_release.pdf

NEXT STEPS:

FISCAL IMPACT, IF ANY: None

PERSON(S) TO CONTACT: McCaulie Feusahrens
Chief of the Licensing Division
California Board of Registered Nursing
Mccaulie.feusahrens@dca.ca.gov

Agenda Item 7.6

Discussion and possible action: Regarding the appointment of committee member to the NMAC

BRN Nursing Practice Committee | January 26, 2023

BOARD OF REGISTERED NURSING
Nursing Practice Committee Meeting
Agenda Item Summary

AGENDA ITEM: 7.6
DATE: January 26, 2023

ACTION REQUESTED: **Discussion and Possible Action:** Regarding the appointment of committee member to the NMAC

REQUESTED BY: Elizabeth (Betty) Woods, RN, FNP, MSN
Nursing Practice Committee Chair

BACKGROUND:

In accordance with BPC Section 2746.2(b)(1), the Board shall appoint a committee of qualified physicians and surgeons and nurses called the NMAC. NMAC will make recommendations to the Board on all matters relating to midwifery practice, education, appropriate standard of care, and other matters specified by the Board. Additionally, NMAC shall provide recommendations or guidance on care when the Board is considering disciplinary action against a Certified Nurse-Midwife (CNM). Additionally, BPC Section 2746.2(b)(3) requires NMAC to be composed of four qualified CNMs, two qualified physician and surgeons, including, but not limited to, obstetricians or family physicians, and one public member.

In October 2022, Misa Perron-Burdick, a Physician/Surgeon member, resigned from the NMAC.

APPOINTMENTS FOR CONSIDERATION:
Below are the names of the candidates being put forward for appointment to the NMAC. The Board will vote on candidates for appointment to fill behind Misa's term which expires on February 28, 2024.

Name	Title	Role	Location
Kenneth James	MD	Physician/Surgeon	Southern

RESOURCES:

NEXT STEPS:

FISCAL IMPACT, IF ANY: None

PERSON(S) TO CONTACT:
McCaulie Feusahrens
Chief of the Licensing Division
California Board of Registered Nursing
Mccaulie.feusahrens@dca.ca.gov

Agenda Item 7.7

Discussion and possible action: Regarding review and approval of the charters and the appointment process for the Clinical Nurse Specialist Advisory Committee and the Certified Registered Nurse Anesthetist Advisory Committee

BRN Nursing Practice Committee | January 26, 2023

BOARD OF REGISTERED NURSING
Nursing Practice Committee Meeting
Agenda Item Summary

AGENDA ITEM: 7.7
DATE: January 26, 2023

ACTION REQUESTED: **Discussion and Possible Action:** Regarding review and approval of the charters and the appointment process for the Clinical Nurse Specialist Advisory Committee and the Certified Registered Nurse Anesthetist Advisory Committee.

REQUESTED BY: Elizabeth (Betty) Woods, RN, FNP, MSN
Nursing Practice Committee Chair

BACKGROUND:

Loretta Melby, Executive Officer, will provide an overview of the appointment process for non-statutorily mandated advisory committees. Additionally, the committee members will review, make recommendations, if needed, and approve the charters for the following new advisory committees:

- Clinical Nurse Specialist Advisory Committee
- Certified Registered Nurse Anesthetist Advisory Committee

RESOURCES:

NEXT STEPS:

FISCAL IMPACT, IF ANY: None

PERSON(S) TO CONTACT: McCaulie Feusahrens
Chief of the Licensing Division
California Board of Registered Nursing
Mccaulie.feusahrens@dca.ca.gov

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The California Board of Registered Nursing's
Clinical Nurse Specialist Advisory Committee

The mission of the California Board of Registered Nursing (Board or BRN) is to protect the health, safety, and well-being of the public through the fair and consistent application of the statutes and regulations governing nursing practice and education in California. The Board values include effectiveness, integrity, transparency, collaboration and equity.

Background

On November 14, 2018, the Board appointed the initial members to the Advanced Practice Registered Nurse Advisory Committee (APRNAC). The APRNAC was structured on request of the Senate Committee on Business, Professions and Economic Development and the Assembly Business and Professions Committee with a goal to survey existing laws and regulations to determine what is lacking for regulation of Advance Practice Registered Nurses (APRNs) including the direction to seek legislation, promulgate regulations, and develop advisories to ensure APRNS have sufficient guidance in all practice settings. This committee was comprised of four Nurse Practitioners (NP), two Certified Nurse-Midwifes (CNM), two Certified Registered Nurse Anesthetists (CRNA), and two Clinical Nurse Specialists (CNS).

In September 2020, Governor Newsom signed both Senate Bill (SB) 1237 and Assembly Bill (AB) 890 into law which created the Nurse-Midwifery Advisory Committee and the Nurse Practitioner Advisory Committee, respectively. To address the statutorily required activities of these new advisory committees and to eliminate duplicity of work, the APRNAC was brought to the Board for discussion and possible action regarding the continuation and the role of this committee. At the August 2021 Board meeting, the motion was made to maintain the APRNAC with focus on Certified Registered Nurse Anesthetists (CRNA), Clinical Nurse Specialists (CNS) and issues that affect all APRN groups to exclude Nurse Practitioner (NP) and Certified Nurse-Midwife (CNM) issues.

During the November 2022 Board meeting, the members completed their annual review of non-statutory advisory committees and voted to sunset the APRNAC and develop two new advisory committees, one committee for CNSs and one for CRNAs and to move the CNS and CRNA members of the APRNAC to the prospective new advisory committees.

Clinical Nurse Specialist Advisory Committee (CNSAC) Purpose/Charge

The CNSAC provides a mechanism for nurses and other members of the public to advise and make recommendations to the Board on all matters relating to clinical nurse specialist practice, including but not limited to, education, appropriate standard of care, and other matters specified by the Board. This committee will focus on Business and Professions Code section 2838.2 and make recommendations to the Board to establish categories of clinical nurse specialists and the standards required to be met for nurses to hole themselves out as clinical nurse specialists in each category. The standards shall take into account the types of advanced levels of nursing practice that are or may be performed and the clinical and didactic education, experience, or both needed to practice safety at those levels. In setting the standards, the board shall consult with clinical nurse specialists, physicians and surgeons appointed by the Medical Board of California with expertise with clinical nurse specialist, and health care organizations that utilize clinical nurse specialists.

DRAFT

Relationship to the Board

CNSAC is an advisory committee of the Board. CNSAC meetings are conducted pursuant to the Bagley-Keene Open Meeting Act as set forth in Government Code (GOV) sections 11120-11133. CNSAC information and recommendations may be forwarded to the Nursing Practice Committee, where Board members assigned to that committee will hear and refer the information to the full Board. The Board's Executive Officer (EO) or CNSAC staff liaison will facilitate the referral of CNSAC recommendations. If time does not allow information and recommendations to be forwarded to the Nursing Practice Committee, referral may be made to the full Board. Referral to the Nursing Practice Committee or the full Board will depend on the relevance of the topic/issue to laws and regulations, the Board's public protection mandate, time-sensitivity, and other factors. Referred recommendations may be information-only or may request Board action in some instances.

Membership

In accordance with the Board's motion during the meeting, on the CNSAC shall be composed of the following:

- Four (4) qualified CNSs, and
- One (1) public member.

Except as provided below, all appointments shall be for a term of four years and vacancies shall be filled for the unexpired term. No person shall serve more than two consecutive terms.

The initial appointments shall be for the following terms:

- Two of the four licensed CNSs shall serve a term of four years. One licensed CNS shall serve a term of three years and the remaining CNS shall serve a term of two years.
- The public member shall serve a term of four years.

CNSAC members will identify and vote on a committee Chair and Vice-Chair to facilitate CNSAC meetings in collaboration with the Board's EO or CNSAC staff liaison. The CSNAC Chair will develop the meeting agendas in collaboration with the Board's EO, staff liaison, and other Board support staff. Only appointed CNSAC members vote on meeting agenda items when a vote is required. This may include items such as approval of minutes and specific recommendations to be moved forward to Board Committees or the full Board. The CNSAC Vice-Chair has the authority to perform the committee Chair's duties in the Chair's absence and is knowledgeable regarding issues that impact CNSAC and the policies and procedures by which the committee must be run. Members must be available for telephone and email consultation with BRN staff relative to program work and other program issues.

A listing of CNSAC members will be maintained by the BRN and include appointment start and end dates. A public listing of the CNSAC members will be posted on the BRN website. Appointed members resigning before their appointed term ends are asked to submit a letter of resignation directed to the attention of the CNSAC Chair and the Board's EO. The Board's EO or designee will facilitate the application process to fill committee vacancies and submit for Board appointment, as needed. Committee members may be removed by the Board prior to expiration of their term for dereliction of duties as a committee member, misconduct, or other good cause.

Meetings

The CNSAC meets twice per year. The meetings will typically be scheduled for 90 minutes and will be held virtually and/or at various locations throughout the state. All CNSAC meetings will be open to the public and will adhere to the Bagley-Keene Open Meeting Act requirements.

Special meetings may be held at such times as the board may elect, or on the call of the Board President or the Board's EO. The CNSAC agenda and materials are posted on the BRN website per GOV section 11125. Committee members will be asked to provide agenda items, a brief agenda item summary, and meeting materials in advance of meetings according to the requested submission timelines established by BRN staff. Meeting materials will be posted on the BRN website in the same location as the specific meeting agenda, meeting location, minutes etc. Meeting materials received during or after a meeting will subsequently be posted on the BRN website along with other already posted meeting materials and will be labeled as addenda/supplemental materials.

Meeting agenda items will be discussed using standard meeting management procedures. Members of the public and other interested parties will be provided opportunities to speak during public comment periods or as requested by committee members during meetings. Time allocated for public comment may be limited by the CNSAC meeting chair to facilitate effective meeting time management consistent with GOV section 11125.7.

CNSAC meeting minutes are prepared by the designated BRN staff. The Board EO or designee, Legal Counsel and CNSAC Chair will review meeting minutes for accuracy and needed edits in advance of submission to the CNSAC members. The Committee will vote to approve draft minutes at CNSAC meetings. Finalized meeting minutes will be signed and dated by the EO or designee and CNSAC Chair and subsequently posted on the BRN website in the same section as the meeting agenda and the meeting materials.

Quorum:
Three (3) CNSAC members at any CNSAC meeting constitutes a quorum.

Board Staff:
BRN staff will regularly support the committee by providing meeting assistance, advice, consultation, reports/presentations and other forms of help as requested. Such staff include: the Board EO, the Assistant EO, the Chief of Licensing, the Chief of Enforcement, the CNSAC staff liaison, Nursing Education Consultants (NEC)/Supervising NECs, and other staff as needed.

Review of CNSAC Advisory Committee:
All advisory committees of the Board are required to engage in a self-evaluation annually. Annual review of the original goals of the committee should be completed to ensure the work of the committee continues to be relevant to the BRN, licensees, and the public. The terms of the committee members and the Chair and Vice-chair should be reviewed, and the committee should vote on an election process and determine if any exceptions are applicable based on the original mandate of the committee.

Additionally, the CNSAC shall periodically review and update this document to ensure the document remains relevant to current statutes, regulations, the Board's mission and strategic plan, NP practice and workforce changes/updates, etc. At minimum, it will be reviewed and re-approved by the CNSAC membership at least every four years from the last effective approval date. This document will include a signature page for the Board's EO and the CNSAC Chair and Vice-Chair to sign and date once this document is approved by the membership in each review cycle.

Advanced Practice Registered Nurse Advisory Committee
Review and Approval Signature Page

Loretta Melby, RN, MSN
Board Executive Officer

Signature | Date

TBD
CNSAC Chair

Signature | Date

TBD
CNSAC Vice-Chair

Signature | Date

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The California Board of Registered Nursing's
Certified Registered Nurse Anesthetist Advisory Committee

The mission of the California Board of Registered Nursing (Board or BRN) is to protect the health, safety, and well-being of the public through the fair and consistent application of the statutes and regulations governing nursing practice and education in California. The Board values include effectiveness, integrity, transparency, collaboration and equity.

Background

On November 14, 2018, the Board appointed the initial members to the Advanced Practice Registered Nurse Advisory Committee (APRNAC). The APRNAC was structured on request of the Senate Committee on Business, Professions and Economic Development and the Assembly Business and Professions Committee with a goal to survey existing laws and regulations to determine what is lacking for regulation of Advance Practice Registered Nurses (APRNs) including the direction to seek legislation, promulgate regulations, and develop advisories to ensure APRNS have sufficient guidance in all practice settings. This committee was comprised of four Nurse Practitioners (NP), two Certified Nurse-Midwifes (CNM), two Certified Registered Nurse Anesthetists (CRNA), and two Clinical Nurse Specialists (CNS).

In September 2020, Governor Newsom signed both Senate Bill (SB) 1237 and Assembly Bill (AB) 890 into law which created the Nurse-Midwifery Advisory Committee and the Nurse Practitioner Advisory Committee, respectively. To address the statutorily required activities of these new advisory committees and to eliminate duplicity of work, the APRNAC was brought to the Board for discussion and possible action regarding the continuation and the role of this committee. At the August 2021 Board meeting, the motion was made to maintain the APRNAC with focus on Certified Registered Nurse Anesthetists (CRNA), Clinical Nurse Specialists (CNS) and issues that affect all APRN groups to exclude Nurse Practitioner (NP) and Certified Nurse-Midwife (CNM) issues.

During the November 2022 Board meeting, the members completed their annual review of non-statutory advisory committees and voted to sunset the APRNAC and develop two new advisory committees, one committee for CNSs and one for CRNAs and to move the CNS and CRNA members of the APRNAC to the prospective new advisory committees.

Certified Registered Nurse Anesthetist Advisory Committee (CRNAAC) Purpose/Charge

The CRNAAC provides a mechanism for nurses and other members of the public to advise and make recommendations to the Board on all matters relating to CRNA practice, including but not limited to, education, appropriate standard of care, and other matters specified by the Board. This committee will concentrate on Article 7 Nurse Anesthetist in the Business and Professions Code (BPC) with a focus on BPC section 2826 and make recommendations to the Board.

Relationship to the Board

CRNAAC is an advisory committee of the Board. CRNAAC meetings are conducted pursuant to the Bagley-Keene Open Meeting Act as set forth in Government Code (GOV) sections 11120-11133.

CRNAAC information and recommendations may be forwarded to the Nursing Practice Committee, where Board members assigned to that committee will hear and refer the information to the full Board. The Board's Executive Officer (EO) or CRNAAC staff liaison will facilitate the referral of CRNAAC recommendations. If time does not allow information and recommendations to be forwarded to the Nursing Practice Committee, referral

may be made to the full Board. Referral to the Nursing Practice Committee or the full Board will depend on the relevance of the topic/issue to laws and regulations, the Board's public protection mandate, time-sensitivity, and other factors. Referred recommendations may be information-only or may request Board action in some instances.

Membership

In accordance with the Board's motion during the meeting on the CRNAAC shall be composed of the following:

- Four (4) qualified CRNAs, and
- One (1) public member.

Except as provided below, all appointments shall be for a term of four years and vacancies shall be filled for the unexpired term. No person shall serve more than two consecutive terms.

The initial appointments shall be for the following terms:

- Two of the four licensed CCRNAs shall serve a term of four years. One licensed CRNA shall serve a term of three years and the remaining CRNA shall serve a term of two years.
- The public member shall serve a term of four years.

CRNAAC members will identify and vote on a committee Chair and Vice-Chair to facilitate CRNAAC meetings in collaboration with the Board's EO or CRNAAC staff liaison. The CRNAAC Chair will develop the meeting agendas in collaboration with the Board's EO, staff liaison, and other Board support staff. Only appointed CRNAAC members vote on meeting agenda items when a vote is required. This may include items such as approval of minutes and specific recommendations to be moved forward to Board Committees or the full Board. The CRNAAC Vice-Chair has the authority to perform the committee Chair's duties in the Chair's absence and is knowledgeable regarding issues that impact CRNAAC and the policies and procedures by which the committee must be run. Members must be available for telephone and email consultation with BRN staff relative to program work and other program issues.

A listing of CRNAAC members will be maintained by the BRN and include appointment start and end dates. A public listing of the CRNAAC members will be posted on the BRN website. Appointed members resigning before their appointed term ends are asked to submit a letter of resignation directed to the attention of the CRNAAC Chair and the Board's EO. The Board's EO or designee will facilitate the application process to fill committee vacancies and submit for Board appointment, as needed. Committee members may be removed by the Board prior to expiration of their term for dereliction of duties as a committee member, misconduct, or other good cause.

Meetings

The CRNAAC meets twice per year. The meetings will typically be scheduled for 90 minutes and will be held virtually and/or at various locations throughout the state. All CRNAAC meetings will be open to the public and will adhere to the Bagley-Keene Open Meeting Act requirements.

Special meetings may be held at such times as the board may elect, or on the call of the Board President or the Board's EO. The CRNAAC agenda and materials are posted on the BRN website per GOV section 11125. Committee members will be asked to provide agenda items, a brief agenda item summary, and meeting materials in advance of meetings according to the requested submission timelines established by BRN staff. Meeting materials will be posted on the BRN website in the same location as the specific meeting agenda, meeting location, minutes etc. Meeting materials received during or after a meeting will subsequently be posted on the BRN website along with other already posted meeting materials and will be labeled as addenda/supplemental materials.

Meeting agenda items will be discussed using standard meeting management procedures. Members of the public and other interested parties will be provided opportunities to speak during public comment periods or as requested by committee members during meetings. Time allocated for public comment may be limited by the CRNAAC meeting chair to facilitate effective meeting time management consistent with GOV section 11125.7.

CRNAAC meeting minutes are prepared by the designated BRN staff. The Board EO or designee, Legal Counsel and CRNAAC Chair will review meeting minutes for accuracy and needed edits in advance of submission to the CRNAAC members. The Committee will vote to approve draft minutes at CRNAAC meetings. Finalized meeting minutes will be signed and dated by the EO or designee and CRNAAC Chair and subsequently posted on the BRN website in the same section as the meeting agenda and the meeting materials.

Quorum:
Three (3) CRNAAC members at any CRNAAC meeting constitutes a quorum.

Board Staff:
BRN staff will regularly support the committee by providing meeting assistance, advice, consultation, reports/presentations and other forms of help as requested. Such staff include: the Board EO, the Assistant EO, the Chief of Licensing, the Chief of Enforcement, the CRNAAC staff liaison, Nursing Education Consultants (NEC)/Supervising NECs, and other staff as needed.

Review of CRNAAC Advisory Committee:
All advisory committees of the Board are required to engage in a self-evaluation annually. Annual review of the original goals of the committee should be completed to ensure the work of the committee continues to be relevant to the BRN, licensees, and the public. The terms of the committee members and the Chair and Vice-chair should be reviewed, and the committee should vote on an election process and determine if any exceptions are applicable based on the original mandate of the committee.

Additionally, the CRNAAC shall periodically review and update this document to ensure the document remains relevant to current statutes, regulations, the Board's mission and strategic plan, NP practice and workforce changes/updates, etc. At minimum, it will be reviewed and re-approved by the CRNAAC membership at least every four years from the last effective approval date. This document will include a signature page for the Board's EO and the CRNAAC Chair and Vice-Chair to sign and date once this document is approved by the membership in each review cycle.

DRAFT

Advanced Practice Registered Nurse Advisory Committee
Review and Approval Signature Page

Loretta Melby, RN, MSN
Board Executive Officer

Signature | Date

TBD
CRNAAC Chair

Signature | Date

TBD
CRNAAC Vice-Chair

Signature | Date