TRINU Corporation

1/23/15

Ms. Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
William P. Hobby Building
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701

Via facsimile transmission: (512) 305-8008, Via email Allison.Benz@tsbp.state.tx.us

Dear Allison:

I have reviewed the proposed rules revisions on sterile compounding (291.133) and have some comments for your consideration before final Board action at the upcoming meeting. I am the President of TRINU Healthcare (providing IV/797 training and ACPE activities) and the Chair of TSHP's Public Affairs and Advocacy Council.

First, thank you for making some of the adjustments per discussions with various practitioners and meetings with TSHP. Specifically, the sections providing clarity on media fill challenges and in-process checks are very much appreciated! It is truly a pleasure to have a state board so open to practice considerations while maintaining its mission of public safety.

Below is a list that includes four areas I'd like to draw your attention to, followed with detail on each section including actual passages and language from TSBP and USP to provide more complete information for your consideration of my recommendations.

1) Pg 18 -Laminar flow hood requirements relating to positive pressure differentials - the rules only discuss the buffer area having a min. differential positive pressure of 0.02-0.05 inches water column.

This is appropriate for separated rooms, but areas that are not separated by walls must use the principle of displacement airflow at a measure of 2 meters per second or 40fpm as per USP <797> (a pressure reading is not possible within the same space). I realize the proposed language is already in the rules in a different place and I surmise it was just an oversight initially.

2a) Pg 24, C. Personnel Cleansing and Garbing section -regarding the proposed removal of allowing electronic hand dryers to be used after handwashing.

I recommend the language remain as is, which is consistent with and still permissible in USP <797>. It is my understanding that there may have been an inspection which identified a trash can being erroneously placed under the dryer causing the proposed language, however, other language could be provided to ensure such improper placement does not occur and the allowance of electric hand dryers per <797> could remain. Many facilities have already gone through this expense to be in compliance with 797 standards.

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3 a) and 3b) Proposed rules regarding hazardous preparations/chemotherapy - 2 sections (Pg 19, (D) Compounding aseptic containment isolator AND Pgs 24-5, C. Personnel Cleansing and Garbing, (V) "....When preparing hazardous preparations, the compounder shall double glove..."

I recommend the language in these two proposed sections and any proposed language revision as related to hazardous preparations or chemotherapy be removed for reconsideration AFTER "USP <800> Hazardous Drugs—Handling in Healthcare Settings" is published. The public comment period concludes in May with rules to be finalized within months thereafter.

Should it be decided to go forth with the proposed revisions, I submit the following for your consideration:
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4) Pg 27, (iii) -High risk Preparations, regarding Bubble point testing.

I recommend the language be altered to reflect the category of filter integrity testing and not so specific to bubble point which limits the possibilities available to the pharmacy. There are other methods to test - USP <797> uses bubble point as an example, not the only one. Also, the sentence beginning with "The results should be compared...bubble point pressure" should be stricken because the range of PSIG or quite varied depending on method used. Finally, regarding the last sentence, "If a filter fails the ...test..." is of concern since a pharmacies SOP should reflect re-doing the test 2-3 times after more wetting has occurred (usual in manufacturing industry). Often results would reflect a false fail due to lack of appropriate filter wetting.

(III) Bubble Point Testing. Bubble point testing is an evaluation of the integrity of the filter(s) used to sterilize high-risk preparations. Bubble point testing is not a replacement sterility testing and shall not be interpreted as such. A bubble point test shall be performed after a sterilization procedure on all filters used to sterilize each high-risk preparation or batch preparation and the results documented. The results should be compared with the filter manufacturers bubble point pressure for the specific filter used (typically between 50 and 54 psig). If a filter fails the bubble point test, the preparation or batch must be sterilized again using new unused filters.

Thank you very much for your consideration. Feel free to contact me at any time.

Regards,

Aaron D. Reich, Pharm. D.
President

Detail using direct passages and language from proposed TSBP rules and USP <797>:

1) Pg 18, (A) Laminar air flow hood, (iv) regarding proposed minimum differential positive pressure of 0.02 to 0.05 inches water column

TSBP Excerpt:

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(ii) be certified by a qualified independent contractor according to the appropriate Controlled Environment Testing Association (CETA) standard (CAG-003-2006) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed;

(iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(iv) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

USP <797> Excerpt supporting displacement airflow principle as measure for combined buffer/ante spaces:

inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.

2a) Pg 24, C. Personnel Cleansing and Garbing section - regarding the proposed omission of the use of hand dryers

TSBP Excerpt:

(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels~~, an electronic hands-free hand dryer, or a HEPA filtered hands dryer~~.

USP <797> Excerpt supporting the use of electric hand dryers:

orous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer. After completion of hand washing, a nonshedding gown with sleeves that

2b) Pg 24, C. Personnel Cleansing and Garbing section -regarding the proposed use of sterile 70% IPA based surgical hand scrub

TSBP Excerpt:

(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a sterile 70% IPA ~~waterless alcohol~~ based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.

USP <797> Excerpt with proper wording "waterless alcohol-based surgical hand scrub":

Once inside the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity[12] following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

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3 a) Proposed rules regarding hazardous preparations/chemotherapy - **1st section**: Pg 19, (D) Compounding aseptic containment isolator, (I) "be vented to the outside..."

TSBP Excerpt:

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(I) be vented to the outside of the building in which the pharmacy is located;

USP <797> Excerpt with appropriate wording:

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3b) Proposed rules regarding hazardous preparations/chemotherapy - **2nd section:** Pg 24-5, C. Personnel Cleansing and Garbing section -regarding the proposed use double gloving when working with hazardous preparations

TSBP Excerpt (pg 24-5):

(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Sterile gloves shall be donned using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove ensuring that the outer gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

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Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.

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Thank you very much for your consideration. Feel free to contact me at any time.

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Randy Martin, Pharm. D.
Director of Pharmacy

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CAPS- Houston

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Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.

1/23/15

Ms. Allison Benz, R.Ph., M.S.
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Austin, Texas 78701

Via facsimile transmission: (512) 305-8008
Via email Allison.Benz@tsbp.state.tx.us

Dear Allison:

I have reviewed the proposed rules revisions on sterile compounding (291.133) and have some comments for your consideration before final Board action at the upcoming meeting. I am a licensed Pharmacist in Texas and work as a Director of Clinical Pharmacy Services for MedAssets. I currently serve as President of the Texas Society of Health-System Pharmacists (TSHP). The comments which follow were written by Aaron Reich. I fully endorse each statement.

First, thank you for making some of the adjustments per discussions with various practitioners and meetings with TSHP. Specifically, the sections providing clarity on media fill challenges and in-process checks are very much appreciated! It is truly a pleasure to have a state board so open to practice considerations while maintaining its mission of public safety.

Below is a list that includes four areas I'd like to draw your attention to, followed with detail on each section including actual passages and language from TSBP and USP to provide more complete information for your consideration of my recommendations.

1) Pg 18 -Laminar flow hood requirements relating to positive pressure differentials - the rules only discuss the buffer area having a min. differential positive pressure of 0.02-0.05 inches water column.

> *This is appropriate for separated rooms, but areas that are not separated by walls must use the principle of displacement airflow at a measure of 2 meters per second or 40fpm as per USP <797> (a pressure reading is not possible within the same space). I realize the proposed language is already in the rules in a different place and I surmise it was just an oversight initially.*

2) Pg 24, C. Personnel Cleansing and Garbing section -regarding the proposed removal of allowing electronic hand dryers to be used after handwashing.

> *I recommend the language remain as is, which is consistent with and still permissible in USP <797>. It is my understanding that there may have been an inspection which identified a trash can being erroneously placed under the dryer causing the proposed language, however, other language could be provided to ensure such improper placement does not occur and the allowance of electric hand dryers per <797> could remain. Many facilities have already gone through this expense to be in compliance with 797 standards.*

3) Pg 24, C. Personnel Cleansing and Garbing section -regarding the proposed use of sterile 70% IPA based surgical hand scrub.

> *I recommend the language remain as is, which is consistent with USP <797>. Requiring sterile 70%IPA based surgical hand scrub actually limits the practitioner from using available stronger disinfectant agents as documented in the literature (may be supplied upon request).*

4 a) and 4b) Proposed rules regarding hazardous preparations/chemotherapy - 2 sections (Pg 19, (D) Compounding aseptic containment isolator AND Pgs 24-5, C. Personnel Cleansing and Garbing, (V) "....When preparing hazardous preparations, the compounder shall double glove..."

I recommend the language in these two proposed sections and any proposed language revision as related to hazardous preparations or chemotherapy be removed for reconsideration AFTER "USP <800> Hazardous Drugs—Handling in Healthcare Settings" is published. The public comment period concludes in May with rules to be finalized within months thereafter.

Should it be decided to go forth with the proposed revisions, I submit the following for your consideration:
I recommend the first section regarding requiring CACI's to be vented to the outside be stricken to be consistent with USP <797>. The chapter states "optimally should" be vented to the outside during placement discussion of CACI's and BSC's, however, does not require it. The chapter further states that during QA monitoring, if contamination is discovered, the pharmacy employ increased measures to improve which may include venting of CACI's or BSC's to the outside. It is clear this is a recommendation and is stated as a "should" not a "shall" which is the language used by USP to denote 'may/could' versus 'must'.

I would also recommend the second section regarding the double-gloving be stricken as this is not consistent with USP <797> which clearly states double gloving "should" be used (versus "shall"). Currently, in practice, attempting to put a 'regular' sterile glove over or under a sterile chemo glove greatly reduces tactile ability and can increase needle sticks and increase the hazardous drug exposure risk that the proposed language aims to reduce. Utilizing a single, sterile, thicker mil chemo glove of nitrile construction provides greater tactile ability. USP <800> will likely address this inconclusive area.

Thank you very much for your consideration. Feel free to contact me at any time.

Regards,

Larry Egle
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Detail using direct passages and language from proposed TSBP rules and USP <797>:

1) Pg 18, (A) Laminar air flow hood, (iv) regarding proposed minimum differential positive pressure of 0.02 to 0.05 inches water column

TSBP Excerpt:

(A) Laminar air flow hood. If the pharmacy is using a laminar air flow hood as its PEC, the laminar air flow hood shall:

(i) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system;

(ii) be certified by a qualified independent contractor according to the appropriate Controlled Environment Testing Association (CETA) standard (CAG-003-2006) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed;

(iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and

(iv) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column.

USP <797> Excerpt supporting displacement airflow principle as measure for combined buffer/ante spaces:

inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.

2) Pg 24, C. Personnel Cleansing and Garbing section - regarding the proposed omission of the use of hand dryers

TSBP Excerpt:

(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels~~, an electronic hands-free hand dryer, or a HEPA filtered hands dryer~~.

USP <797> Excerpt supporting the use of electric hand dryers:

orous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer. After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer area use shall be worn, and pref

3) Pg 24, C. Personnel Cleansing and Garbing section -regarding the proposed use of sterile 70% IPA based surgical hand scrub

TSBP Excerpt:

(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a sterile 70% IPA ~~waterless alcohol~~ based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.

USP <797> Excerpt with proper wording "waterless alcohol-based surgical hand scrub":

Once inside the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity[12] following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

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4 a) Proposed rules regarding hazardous preparations/chemotherapy - **1st section**: Pg 19, (D) Compounding aseptic containment isolator, (I) "be vented to the outside..."

TSBP Excerpt:

(D) Compounding aseptic containment isolator.

(i) If the pharmacy is using a compounding aseptic containment isolator as its PEC for the preparation of low- and medium-risk hazardous drugs, the CACI shall be located in a separate room away from other areas of the pharmacy and shall:

(I) be vented to the outside of the building in which the pharmacy is located;

USP <797> Excerpt with appropriate wording:

All hazardous drugs shall be prepared in a BSC[5] or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5 (see *Table 1*) BSC or CACI shall be placed in an ISO Class 7 (see *Table 1*) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see *Table 1*) or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization. The BSC and CACI optimally should be 100% vented to the outside air through HEPA filtration.

4b) Proposed rules regarding hazardous preparations/chemotherapy - **2nd section:** Pg 24-5, C. Personnel Cleansing and Garbing section -regarding the proposed use double gloving when working with hazardous preparations

TSBP Excerpt (pg 24-5):

(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Sterile gloves shall be donned using proper technique to ensure the sterility of the glove is not compromised while donning. The cuff of the sterile glove shall cover the cuff of the gown at the wrist. When preparing hazardous preparations, the compounder shall double glove ensuring that the outer gloves are sterile powder-free chemotherapy-rated gloves. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever non-sterile surfaces are touched.

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