Compounding Standards-Rule Hearing November 17, 2011-Consideration of comments

Comments from Jesse Rue:

Page 2: 1. Definitions; e); (4); (ii); a.; (1); V.

"V. Must be immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer."
-The concern in the language is that large volume IVs may continue passed the shift of the preparer or if the IV may begin in the ED and the patient may be transferred to the floor while still on the IV to different care.

-In <USP 797> on p 343 it states under the '5. ': "Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, ***the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time."***
The Board agrees that it would be appropriate to add the bolded portion into the language as to recognize the 'real world' setting of shift/staff care changes in order to accommodate the proper administration of Immediate-Use CSPs.

Page 11: 4.Compounding Process for Compounded Sterile Preparations; e); (2)

"(2) Don proper garb including shoe covers, head and facial covers, face mask, and non-shedding gown"
-The concern is there may be some leeway in the recommendations of appropriate garb according the what the manufacturer may recommend (i.e. a CAI the manufacturer may not require face mask or shoe covers.)

-In <USP 797>, it does state on page 344, "PPE should include gowns, face masks, eye protection, hair coves, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.

The board agrees and language has been added to allow for evidence from the manufacturer of the primary engineering control that this is not necessary. **If the manufacturer of the primary engineering control has research and documentation demonstrating that some of these things are not necessary, they are not required.**

Page 14: 6. Equipment Specific for Sterile Compounding; b); (3) concerning Environmental Monitoring:
" Where High Risk sterile preparations are being compounded air sampling via sterile nutrient agar plates or suitable electric air samplers must be performed semi-annually at locations judged by compounding personnel to be the most prone to contamination during compounding activities."
-The question is if he is correct in saying the passage applies only to high risk compounding areas?

-Yes. This particular passage labeled (3) pertains to the high-risk CSPs. However, ALL areas that are compounding sterile preparations must have the air quality re-certified every 6 months as indicated elsewhere in the draft and media-fill testing must be performed annually for low and medium risk compounding and every six months for high risk compounding, as indicated in those sections.

Page 15: 11. Hazardous drugs as compounded sterile products (CSPs): e); (1).

(1) When closed-system vial-transfer devices (CSTDs) are used, they shall be used within the ISO class 5 environment of a BSC or CACI. This may be done in a non-negative pressure room when this two tier containment method is used.
-The question asks if that means one may use a CSTD if our BSC is not in a negative pressure room or ISO 7 room and still be compliant.

According the <USP 797> p 348 under "Placement of Primary Engineering Controls" it states "PECs shall be located within a restricted access ISO Class 7 buffer area." Additionally, on pg 343 under "Hazardous Drugs as CSPs" it states, "When CSTDs are used, they shall be used within the ISO Class 5 environment of a BSC or CACI. The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

-Therefore, it is the board's interpretation that you would still be compliant if a CSTD is used in a BSC that is in a non-negative pressure room. However, one would not be compliant using a CSTD in a BSC that is not in an ISO Class 7 environment or better. Remember that some BSCs have the ISO Class 7 chamber built unto them.

Comments from Jocelyn Mohs

Page 15: 11. Hazardous drugs as compounded sterile products (CSPs):

1. Is the term "Hazardous Drugs" defined elsewhere in the rules?

The Board agrees this definition is need and one has been added under definitions.

2. Under 12 (b) Hazardous drugs shall be stored and prepared separately from other ~~(inventory)~~ non-hazardous drugs in a manner to prevent contamination and personnel exposure.

Maybe this is already addressed in section (e), but I just think it's important to not be making pre-meds and other non-chemo drugs in the same hood as we make chemotherapy because we are likely contaminating those non-chemo drugs. It's been a concern of mine where I currently work. I think it needs to be stressed.

The board agrees and this change has been made.

Comments from Joel Aukes

(2) f) (4) (on page 9) – Pre-packing

Now 2 g); (3); ii

ii. " If a component is transferred from the original container to another, the new container must be identified with the component name, weight or measure, the lot or control number, the expiration or beyond-use date, and the transfer date."

Would splitting tablets, for pre-packaging, be considered "manipulation" ? If so, there should be some wording added to differentiate "splitting" from "manipulation".

Board Comments:

Tablet splitting is not considered compounding and therefore is not addressed here. We have added "tablet splitting" under the "compounding" definition at 1. e) compounding does not include: tablet splitting, prepackaging …….

3) a) through k) (on page 11) Non-sterile compounding.

Should be deleted. This is standard practice not defined in the NDBOP rules for filling other types of prescriptions.

Board Comments

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to leave the section intact except to delete ~~the facility and~~ under k)

4) a) through c) (on page 11) – Sterile compounding.

Should be deleted. This is standard practice not defined in the NDBOP rules for filling other types of prescriptions.

Board Comments

It was moved by Pharmacist Thom and seconded by Pharmacist Ziegler to leave this section intact as the Board feels the reinforcement is valuable.

4) d) (on page 11) – Sterile compounding.

The number and type of Primary Engineering Controls are already specified in the rules. If a facility installs operates and maintains these controls according to the manufacturer's standards this wording is not necessary. The manufacturers should set these standards of practice for their products as the NDBOP can not possible be familiar with or keep up-to-date on all the available products and their associate specifications.

Board Comments

Pharmacist Ziegler stated that she feels the language is reasonable and makes the rule clearer. The Board concurred.

4) e) (2) (garbing) and 4) e) (3) (donning gloves) (on page 11) – sterile compounding.

It is my professional opinion that the gloving and garbing wording be deleted from the rules. I have not seen any studies showing that taking these steps increases public safety or decreases morbidity / mortality over using "standard aseptic technique" when compounding low / medium risk parenterals with the appropriate primary engineering controls. My professional opinion is that the improvement to public safety is negligible, if at all. Therefore, this requirement would add unneeded cost and time burden on pharmacies with little, if any, benefits to public safety.

Gloving and gowning should be dependent on each specific facility's configuration risk level, configuration and type(s) of Primary Engineering Controls used. Therefore, should be developed and set by each facility in their Policies and Procedures.

Board Comments

Pharmacist Ziegler stated that this procedure is intended to reduce particles and microbial counts and studies are why USP adopted this procedure. A change has been made to accommodate BSCs if the manufacturer of the primary engineering control has research and documentation demonstrating that some of these things are not necessary, they are not required.

4) f) (1) through (2) (sterile isopropyl alcohol) (on page 11) – Sterile compounding.

It is my professional opinion that the use of sterile isopropyl alcohol **not** be required for the cleaning of compounding surfaces. There is no evidence, scientific or anecdotal, that contamination has been caused by the use of standard non-sterile, 70% isopropyl alcohol. The mandate of utilizing sterile isopropyl alcohol would again, unnecessarily, increase the costs and barriers to sterile compounding without any beneficial effect on public safety.

Board Comments

Although there is some disagreement, the majority of North Dakota Compounding Pharmacists have come to accept sterile isopropyl alcohol as evidence has shown, that spores can survive in non-sterile isopropyl alcohol.

5) a) (2) (on page 12) Facilities for Sterile Compounding.

The number and type of Primary Engineering Controls are already specified in the rules. If a facility installs operates and maintains these controls according to the manufacturer's

standards this wording is not necessary. The manufacturers should set these standards of practice for their products as the NDBOP can not possible be familiar with or keep up-to-date on all the available products and their associate specifications.

Board Comments:

Pharmacist Ziegler stated that she feels the language is reasonable and makes the rule clearer. The Board concurred.

5) a) (3) i. (on page 12)) Facilities for Sterile Compounding.

Should be deleted. This is standard of practice and not defied in NDBOP rules for filling other types of prescriptions.

Board Comments:

The Board feels the language is reasonable and each facility must be familiar with the equipment they have purchased.

5) a) (3) i. a. through d. (on page 12)) Facilities for Sterile Compounding.

Should be deleted. This is standard of practice and not defied in NDBOP rules for filling other types of prescriptions.

Board Comments:

The Board feels this is a reasonable standard and probably will not be done unless specifically required here.

(6) a) (on page 13) – Equipment specific for sterile compounding.

> "Primary Engineering Controls such as: Laminar Airflow Workbenches, Biological Safety Cabinets, Compounding Aseptic Isolators, and Compounding Aseptic Containment Isolators; must be used to prepare all sterile preparations except those compounded for immediate-use and must be capable of maintaining ISO Class 5 or superior air quality during normal compounding activity."

Should be changed to just "Primary Engineering Controls" all the rest of the wording is covered in other parts of the rule.

Board Comments:

The Board agrees that the rule will be best served by a single definition and the specific language has been removed here and is available in the definition at 1. p).

(7) (on page 14)

This should be deleted as it has already been stated in the rules for both sterile and non-sterile compounding.

Board Comments:

The Board agrees and this, which is actually section 6. has been deleted.

Additional Points

1. I would request that wording be added indicating that pharmacies have at least 3-years, from the time of final rule adoption, to comply with any of these new rules.

Board Comments:

The Board agrees and although this has already been a three year process, giving pharmacies an opportunity to begin their planning process, a provision has been added to require compliance by January 1, 2015.