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The Joint Commission Requirements for Meeting USP <797> Standards
Frequently Asked Questions
GNYHA Webinar October 7, 2019

1. Please reiterate what is enforceable/surveyed to regarding IM Methotrexate, crushing or splitting Table 2 or Table 3 by nursing staff at bedside immediately before administration?
    A. *The removal of methotrexate from a vial and IMMEDIATELY administering the medication IV or IM considered administration. The crushing of a pill at the bedside is part of the administration process and is excluded from the requirements of USP 800.*

2. Can NIOSH Table 2 and 3 be AOR to compounded in a positive pressure PEC?
    A. Yes

3. If you have only compounding of group 2 and 3 --are you required to do risk assessment of all items compounded?
    A. Yes, if you wish to exclude them from the requirements of USP 800 based on the AOR.

4. For HZD handlings of group 2 and 3 do you also have to use the gloves ASTM D6978 like for Chemo compounding?
    A. If you have not completed an assessment of risk that shows you do not need to apply USP 800

5. Going back to the discussion regarding table 2/3 drugs (i.e. phenytoin) if the pharmacy is compounding a final preparation that is sterile, may we conduct an assessment of risk?
    A. Yes, you may.

6. For Long term care that are administering crushed tablets and oral suspension, does the nurse have to go to a special room (alternative containment or negative pressure room) or can the nurse crush the tablet or withdraw oral liquid from bulk bottle at patient's bedside?
    A. Not if it is done at the time of administration.

7. What is your recommendation for the institution that has decided to no longer compound or administer Antineoplastic Agents, to best handle compliance with the Hazardous Medications in the other NIOSH groups?
    A. They should conduct an assessment of risk to determine what components of USP 800 they may wish to adopt to protect their staff.

8. Does USP800 require PPE for administration except for immediate use situations? This exception is not noted in the current regs?
    A. The components of USP 800 that relate to administration are informational only. The organization should determine what components they should adopt for the safety of their staff.

9. Are pass-through refrigerators within anteroom: cleanroom prohibited in both 797 and 800?
    A. *They are prohibited in USP 800.*
    B. *USP 797 is silent.*

10. In USP 800 when the anteroom is for both entry to the USP 797 and 800 I thought the pressure in the anteroom could be positive? to accommodate both environments; (similar question → One of the slide shows ISO 7 ante room to HD compounding room as negative pressured. Want to clarify ante room serving HD compounding room can be positive pressured).
    A. *That is correct. The ante room is positive to the non-classified space only.*

11. Should pharmacy labels have both a "hang by" time and a "discard by" time for nursing reference? There is much confusion within our institution with this, especially with continuous infusions, when a bag must be taken down due to stability time if only a hang by time is written
    A. *Organizations should determine how they wish to label the products so that staff are clear on when a medication can no longer be utilized for a patient.*

12. Just spent a small fortune creating a 797 compliant room. However, limited space available to put HEPA filters in the wall in the buffer room. Are there any strategies that can be used to not have the HEPAs moved to the ceiling (which I have been told is not possible) for the new requirements. Currently, the HEPAs are high on the wall in the buffer room
    A. *Unfortunately, I do not have any strategies to assist you.*

13. Does revision require fungal testing or just bacterial for category 2?
    A. *It requires both fungal and bacterial testing, this includes the PEC regardless of category 1 or 2.*

14. If pharmacy is using BUD from revised chapter, will that be acceptable to Joint Commission?
    A. *No, it will not. The revised chapters have been suspended until further notice.*

15. In terms of 797, Can you speak to the master compounding formulas required? Is this for batched items only? Do you need one for every single product prepared?
    A. *Based upon section 11.1 of USP 797; A Master Formulation Record must be created for CSPs prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s)*

16. What would the BUD for an IV prepared [straight draw up] under a hood in a Pharmacy Satellite
    A. *An assumption is that this satellite is a SCA. Therefore, under the revision it would be 12 hours room temperature and 24 hours refrigerated. Currently it would be 12 hours for low risk items only.*

17. If the pharmacy has an automated program Simplifi is that acceptable to show competency
    A. *If all of the required competencies are listed as well as evidence they passed the competency evaluations. If the revision doesn't change, there will be additional documentation requirements that must be considered and either added to you program or stored in another location.*

18. Are TJC surveyors directly observing Pharmacists in compounding area?

A. *Yes*

19. Can a pneumatic tube system be in the room where the CSA is?
    A. *The issue is that if a tube system is present then it is a higher traffic area and therefore the area is not segregated.*

20. When is immediate use compounding with a 1hr beyond use date appropriate? Our pharmacists will mix something quickly in the time of an emergency outside of the clean room, but in a clean designated immediate use compounding area. The reason for this is because in some emergencies the time it takes to garb PPE is too long. Is this appropriate?
    A. *In the example you provide it is appropriate.*

21. How does TJC feel about preparing products for immediate use inside a satellite pharmacy
    A. *That is up to the organization. If it is felt the area is cleaner and less cluttered it would be appropriate.*

22. Should non-sterile hazardous C-SCA have dedicated exhaust, or it can be shared?
    A. *The chapter does not provide that level of specificity. However, they must be externally vented.*

23. Can we store HD drugs in the hazardous IV room?
    A. *I do not find anything in the chapter that would prevent it. ISO levels must be maintained.*

24. Hospitals with no 24 hour pharmacy may stock phenytoin, valproic acid, and oxytocin in ED pyxis for urgent use. In this case, do we need to have to formulate an assessment of risk? Does it have to be prepared in a negative pressure room and C-PEC? or can we prepare it in the patient's room with Proper PPE attire?
    A. *The answer to this question would depend upon the preparation type and assessment of risk.*

25. We are currently in our survey window. We have been working to update our policies to be in compliance with the revised 795 regulations. Do we need to try to reverse all these policies back to current 795 or can we keep moving forward with our revisions?
    A. *We will not assess compliant with 795 during a hospital survey, only during home care surveys. We will continue to survey against the current version of USP 797 that is in effect.*

26. If a hazardous drug is compounded from one facility and sent to another site for administration do they have to comply with USP 800 storage and negative pressure.
    A. *Please see the following which is section 11.3 of USP 800*
    B. *HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations. HDs must be transported in containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination. When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS. The entity must ensure*

that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.

27. If a 0.22 micron filter is being used in the preparation of a CSP that utilizes all sterile ingredients, does an integrity test "bubble test" need to be performed on the filter?
    A. *It depends on the use of the filter. If the filter is being used to complete "terminal sterilization" of the product then yes you would need to do so. If the filter is being used as part of the package insert instructions dues to particulate, ample opening, etc., then no.*

28. How often do employees have to be examined for chemotherapy exposure if mixing hazardous materials? Will the joint commission be looking for such documentation?
    A. *Those requirements are recommendations only. TJC will survey you to whatever policy you develop.*

29. How to scan barcodes of antineoplastics that are stored in negative pressure buffer room before compounding. Can we keep computer and scanner in the buffer room?
    A. *There is a section in USP 797 that addresses how to handle equipment in the buffer area.*

30. What is the expectation on Hazard Communication and having staff sign the acknowledgement of risk?
    A. *Those are recommendations. The organization should develop policy and may use USP 800 as a guiding tool if they choose.*

31. Does non-sterile compounding require us to have a negative pressure room for compounding?
    A. *Yes please see Table 2 in USP 800 that provides the requirements for non-sterile HD compounding.*

32. Will there be a guidance checklist to assist with mock surveys?
    A. *Yes once all appeals are completed and we know the final chapter content.*

33. How many years of sterile compounding room and staff requirements are reviewed?
    A. *The documents up to Jan 18 are reviewable. Moving forward nothing prior to the previous full accreditation survey 4.*

34. Please discuss scoring of any missing testing reports or staff requirements during survey review.
    A. *These items would be scored as appropriate with potential condition level deficiencies and follow up survey activity.*
    B. *Any missing certification of a PEC could lead to an immediate adverse decision.*

35. Can the institution implement the changes that benefit the institution, such as the BUD changes? Does this still hold true with the chapters being in flux as they are?
    A. *At this time, the revisions have been suspended so they should not be implemented related to USP 797 or 795.*

36. Is Medical Surveillance a mandate or a recommendation under USP 800?
    A. Recommendation