

FAQ for Division 45

1. Do I need to follow the rules set forth in division 45 if I do simple compounding (like magic mouthwash or mixing 2 creams) in my retail pharmacy?

OAR 855-045-0200

No. Simple and infrequent compounding using non-sterile commercial components to fill a single prescription for a non-sterile product is classified as Category 1 compounding. The Board states that Category 1 compounding is not considered compounding for all intensive purposes.

2. When does category 1 compounding become category 2?

When the compounding becomes complex (multiple ingredients, etc...), requires complex calculations, a scale is needed to weigh ingredients, if it requires alterations of the original dosing form (making capsules, etc...), or changes in the route of administration (making suppositories, etc...). Any of these requirements would result in a compound that is no longer classified as category 1.

3. Can you make a compound without a prescription?

OAR 855-045-0200

You may compound a reasonable amount of drug product without a prescription, but you must be anticipating prescriptions for what you are compounding or you must be distributing the product under the Shared Pharmacy Services agreement (as defined in OAR 855-006-0005).

4. Does division 45 apply to nuclear pharmacies?

OAR 855-045-0200

No. Radiopharmaceuticals have their own guidelines and are exempt from division 45. For information on nuclear pharmacies see division 19 and 42.

5. If compounding a non-sterile product, do I need to comply with division 45?

Yes. Division 45 applies to sterile and non-sterile compounding, unless the compound is classified as category 1.

6. Does division 45 incorporate USP chapters 797 and 795 rules?

No. The Board doesn't require strict application or adherence to all USP 795/797 guide-lines. It is expected that appropriate guidelines be followed based on individual settings.

7. What does CSP stand for?

OAR 855-045-0210

Compounded Sterile Preparation. It incorporates anything compounded in an IV room (prepared sterile products under manufacturers' guidelines in an environment with possible exposure to contamination) or preparing with non-sterile components and devices that must be sterilized before administration.

8. What are the training requirements for compounding in division 45?

OAR 855-045-0220

The PIC is responsible for training, testing, and assessing all employees involved in sterile and non-sterile compounding. The PIC must also implement policies and procedures for employees to follow that are reviewed at least annually. This includes a verification procedure for pharmacists to determine correct drug, dose, form, calculations, and label. For low to medium risk compounding retesting aseptic skills must occur at least annually and retesting for high risk compounding must occur at least semi-annually. Records must be kept to demonstrate training and testing.

9. Are we allowed to compound anything the doctor prescribes?

OAR 855-045-0230 and 855-045-0240

No. You may not compound products that are commercially available, unless the Board has given prior approval to compound a commercially available product that is temporarily in short supply/unavailable. For parenteral products a commercially available product may be compounded if there are multiple companies that provide the mixture (ex. KCl premixed IV bags) or if the premix IV admixture is commercially available as well as the premixed IV bags (ex. Using a commercially available vial of medication to make an IV bag, even though there is a commercially available premixed IV bag).

10. Are there specific policies and procedures for the compounding pharmacy?

OAR 855-045-0230 and 855-45-0270

If a pharmacy participates in compounding, the PIC must ensure that there are policies and procedures that provide at least the following: an organized index, product formula information, log book, conditions and surveillance of the compounding environment, compounding procedures and requirements, training requirements for all staff, cleaning, QA plan with a BUD (Beyond Use Date/expiration date), product labeling, shipping and delivery procedures, pharmacist final verification, and safety procedures. IV admixtures made for a specific patient does not need to comply with the worksheet or log book requirements if it can still be tracked for recall purposes. The pharmacy must keep records on site and organized for 3 years.

11. What additional policies and procedures are required for sterile compounding?

OAR 855-045-0230

You must follow the requirements described in question 10, but also ensure an appropriate BUD with end product testing and random sampling of the environment and CSPs when it's appropriate. The PIC needs to have a QA plan in writing with records requiring the cleaning, testing and calibration of all equipment.

12. Do I need to perform random end product testing?

OAR 855-045-0230

It depends, if you are mixing high level CSPs or wish to extend the BUD, you would be required to perform end product testing. The BUD must not exceed USP 797 guidelines unless quality is verified by end product testing.

13. Are there any requirements for purchasing bulk chemicals?

OAR 855-045-0230

Bulk chemicals need to be purchased from an outlet registered by the Board. The bulk chemicals must also have a certificate of analysis and labeling that shows the date obtained and the BUD. The BUD cannot be greater than 5 years from opening, unless tested to extend the BUD by no more than 1 year.

14. What needs to be on the label of sterile parenteral products?

OAR 855-045-0240

The labeling requirements include all of the regular items (patient name, etc...), but also require the following: Rate of infusion, BUD, storage requirements, ingredients information (name, quantity and concentration of all ingredients), and hand written initial of pharmacist who verified it.

15. Can I reassign a parenteral admixture to another patient?

OAR 855-045-0240

Yes, as long as it has been stored properly and the BUD has not lapsed.

16. What defines low risk conditions?

OAR 855-045-0250

An ISO Class 5 environment or better, no more than three commercially manufactured sterile products placed in 1 container, and limited manipulations

17. What is the expiration date of low risk sterile preparations?

OAR 855-045-0250

Without sterile testing; at room temperature the BUD can be up to 48 hrs, under refrigeration the BUD is up to 14 days and under frozen conditions (-20 degrees C) the BUD is up to 45 days.

18. What defines medium risk conditions?

OAR 855-045-0250

These conditions meet the same conditions as low risk conditions and include 1 or more of the following; multiple sterile products are combined, will be administered to multiple patients, will give to one patient multiple times, requires complex aseptic manipulations, and a long duration to compound.

19. What is the expiration date of medium risk sterile preparations?

OAR 855-045-0250

Without sterile testing; at room temperature the BUD can be up to 30 hrs, under refrigeration the BUD is up to 9 days and under frozen conditions (-20 degrees C) the BUD is up to 45 days.

20. What defines high risk conditions?

OAR 855-045-0250

CSPs are classified as high risk for any of the following reasons: compounded from non-sterile ingredients (manufactured products intended for other routes of administration) or a non-sterile device is used before terminal sterilization. If exposure to an environment that does not meet ISO 5 for greater than 1 hour and the product lacked effective antimicrobial preservatives. If the non-sterile procedures (mixing or weighing) occurred in an environment that does not meet ISO 7 or personnel is improperly gloved or gowned. If water containing preparations are stored for more than 6 hours.

21. What is the expiration date of high risk sterile preparations?

OAR 855-045-0250

Without sterile testing; at room temperature the BUD can be up to 24 hrs, under refrigeration the BUD is up to 3 days and under frozen conditions (-20 degrees C) the BUD is up to 45 days.

22. What are the requirements of an immediate use sterile preparation?

OAR 855-045-0250

It is classified as a low risk compound provided: It doesn't contain hazardous material, the compound has less than 3 sterile ingredients, involves simple manipulations, is completed in one sitting, and will be administered within the hour. They can be prepared in the following conditions; must use aseptic manipulation, use sterile ingredients and devices, but does not need to meet ISO 5 conditions and does not need to wear gloves or gown.

23. What are the requirements for same day use sterile preparations?

OAR 855-045-0250

The compounded product must be administered within 24 hours of preparation. The compound may be classified as low or medium risk classification if it is prepared using sterile ingredients and devices and has ISO 5 or better environment. Other environmental requirements are a mixing cabinet with restricted air flow, a partitioned area around the cabinet ("buffer zone") that is clearly identified and the area is cleaned daily with low particle counts and free of cardboard boxes/clutter. Preparations must be completed in 1 sitting, may not exceed 8 CSPs per batch, use gloves, appropriate gown and mask with hair and shoe covers, and single dose ampoules are not reused.

24. What is the expiration of a multi-dose vial?

OAR 855-045-0250

The BUD is 1 month from first usage or the manufacturer expiration date, whichever is earlier.

25. What equipment do I need to make a low-risk sterile preparation?

OAR 855-045-0260

Starting January 1st, 2009 an ISO 5 or better BSC (biological safety cabinet), CAI (compounding aseptic isolator) or LAF (laminar airflow hood).

26. What equipment is required to make a medium-risk sterile preparation?

OAR 855-045-0260

Starting January 1st, 2009 an ISO 5 or better BSC, CAI or LAF can be used. A BSC or LAF can be used in an ISO 7 or better buffered room that is attached to an anterior room with ISO 8 or better. CAI's may be used in an ISO 8 or better environment. These areas must have positive air flow pressure.

27. What equipment is required for high-risk sterile preparations?

OAR 855-045-0260

Starting January 1st, 2009 it will require the same standards as medium-risk sterile preparations (see above).

28. Are there requirements on how frequently the compounding room must be cleaned?

OAR 855-045-0260

All work surfaces and floors must be cleaned at least daily in ISO 7 and 8 areas. All other surfaces in these areas (shelving, walls, ceilings) must be cleaned monthly. The cleaning solution should be a high-level disinfectant or you may alternate regularly between medium-level disinfectants. These areas must be checked and certified by a qualified person at least every 6 months and when alterations have been made to the area.

29. *What needs to be documented on the formula worksheets?*

OAR 855-045-0270

All documents of preparation, verification and dispensing/transfer must be kept for 3 years and contain the following information; Drug name and strength, quantity made, date prepared, pharmacy unique lot number, ingredients, manufacturer lot numbers with their expiration dates, BUD, verification and the name of the verifying pharmacist, names of all technicians involved, copy of the label used for the compounded product (or a system to identify batches of prescriptions), mixing instructions, physical evidence of the proper weight of each drug used, and certification of completion of any additional testing that may be required.

30. *Are there specific requirements for using hazardous drug materials?*

You are required to follow state and federal laws, there are no additional stipulations specified in division 45. Contact the EPA (www.epa.gov/) and OSHA (www.osha.gov/) for further information.