



Oregon

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**2009 PHARMACIST-IN-CHARGE
PHARMACY SELF-INSPECTION REPORT
FOR STERILE AND NON-STERILE COMPOUNDING
OREGON BOARD OF PHARMACY
TEL: 971-673-0001 FAX: 971-673-0002
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All PICs of compounding pharmacies must complete this report in addition to the Hospital, Retail, Home Infusion, or Long-Term Care inspection report and have it available for inspection within 15 days of becoming PIC or by 2/1/2009 (whichever is earlier). DO NOT MAIL TO THE BOARD OFFICE.

Compounding and Sterile Parenteral Products

Compounding is separated into five categories (1-5).

Examples of each category are:

Category 1- Miracle/magic mouth wash, mixing two creams together

Category 2- Making capsules, tablets, suppositories, Antabuse suspension

Category 3- Antibiotic in an IV solution, Two additives in an IV solution. No more than 3 commercial products.

Category 4- Multiple medications (2 or more) in an IV, TPNs - Total parenteral nutrition solutions with multiple additives

Category 5- Non sterile Morphine powder used to prepare solutions for IV pump infusions.

- | <u>Yes</u> | <u>No or
Needs
Correcting</u> | |
|--------------------------|--|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Do you compound Category 2, 3, 4, 5 products? If yes, list which categories: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. OAR 855-045-0200(4) Do you provide compounded medication to a prescriber for the prescriber to dispense in their practice?
If yes, please attach a copy of the required Board approved Shared Service Agreement. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. OAR 855-060-0001 Do you compound products to be sold OTC?
If yes, attach a copy of your FDA and Board of Pharmacy manufacturing registrations. |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. OAR 855-045-0230(1) Are only products that are not commercially available compounded?
Note: You may compound multi-source products or single source compounds in short supply |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. OAR 855-045-0220 Has appropriate training been provided to all personnel involved in preparing compounded products that includes training in theoretical principles and practical skills of aseptic manipulations?
Where are the training records kept? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. OAR 855-045-0220(2) Do you have policies and procedures that contain protocols for initial training and testing or all personnel? |
| <input type="checkbox"/> | <input type="checkbox"/> | 7. OAR 855-045-0220(2) Do you test personnel in aseptic manipulative skills?
How often (every 6months - category 5; every 12months - Category 2-4)? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | 8. OAR 855-045-0220(5) and OAR 855-041-0065(6)(k) Is each product labeled with its physical description for compounds sold on a prescription? |
| <input type="checkbox"/> | <input type="checkbox"/> | 9. OAR 855-045-0220(5) and OAR 855-045-0240(1) Is there documentation of verification that includes the handwritten initials of the pharmacist responsible for the review and accuracy? |
| <input type="checkbox"/> | <input type="checkbox"/> | 10. OAR 855-045-0260(7) Are all ISO classified areas checked and certified at least every 6 months and whenever LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered? |
| <input type="checkbox"/> | <input type="checkbox"/> | 11. OAR 855-045-0220(5) Is the pharmacist confirming the drug, dose, and dosage form are appropriate and the calculations, drug, and quantity of each drug are correct? |

Yes No or
Needs
Correcting

12. OAR 855-045-0230(2) Are policies and procedures reviewed annually and complied with by all staff?
- An organized index
 - Product formula information
 - Specifications for a compounding log book in compliance with OAR 855-045-0270
 - Conditions and surveillance of the compounding environment
 - Compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks
 - Cleaning and equipment maintenance procedures
 - QA plan and documentation
 - Shipping and delivery procedures
 - Product labeling
 - Procedures for final product verification by the pharmacist
 - Compounded product quality procedures including procedures for establishing a BUD
 - Training requirements for all staff
 - Safety procedures and training for personnel handling hazardous materials
 - Requirements for availability of reference materials

 13. OAR 855-045-0260(7) Are floors and work surfaces in ISO 7 and 8 areas cleaned at least daily with appropriate disinfectant solution?

 14. OAR 855-045-0260(7) Are walls, ceilings, and empty shelving in ISO 7 and 8 areas cleaned at least monthly with appropriate disinfectant solution?

 15. OAR 855-045-0230(4) Does QA plan include record keeping requirements for cleaning, testing and calibration of all equipment and devices?

 16. OAR 855-045-0230(5) Do bulk chemicals have the required certificate of analysis?
 Note location of the records _____

 17. OAR 855-045-0230(6) Are bulk chemical containers labeled with the date pharmacy obtained the chemical and an expiration date of not more than 5 years from the date container was opened?

 18. OAR 855-045-0270(1) Are compounding logs, formula worksheets and documentation of the preparation, verification, dispensing or transfer of compounded products stored in an organized manner? Note location of the records _____

19. OAR 855-045-0270(2) Do formula worksheets (not required for patient specific IV) include:
- Drug name and strength
 - Quantity prepared
 - Date prepared
 - Pharmacy unique lot number
 - Manufacturers' lot numbers and expiration dates of all ingredients in compounded product
 - BUD
 - Name of verifying pharmacist
 - Names of all technicians involved in the process
 - Copy of the label used for the compounded product
 - Mixing instructions
 - Physical evidence of the proper weight of each dry chemical or drug used
 - Pharmacist verification that the correct formula and the correct weights or volumes of chemical or drugs were used
 - Certification of completion of any additional testing that might be required in your policies and procedures

Sterile Parenteral

 N/A 20. OAR 855-045-0230(3) and (4) Do you have policies and procedures and QA plan for establishment of BUD, end product testing, and random sampling of both the environment and Compounded Sterile Products (CSPs).

21. OAR 855-045-0240(1) In addition to regular labeling requirements, does the label include:
- Rate of infusion (if applicable)
 - BUD
 - Storage requirements or special conditions

- Name, quantity and concentration of all ingredients contained in the products, including primary solution
 - Hand written initial of the verifying pharmacist
- ORAR 855-041-0130(7)(c)
- Identification of the pharmacy, patient name and location, auxiliary labels as needed and date mixed

Yes **No or**
Needs
Correcting

Category 3 (Low Risk)

- | | | | | | |
|--------------------------|------------------------------|-----|---------------------|--|--|
| | N/A <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 22. | OAR 855-045-0260(2) | Are Category 3 compounds prepared in an ISO 5 certified or better Biological Safety Cabinet, or a Compounding Aseptic Isolator, or a Laminar Airflow Hood? | |
| <input type="checkbox"/> | <input type="checkbox"/> | 23. | OAR 855-045-0250 | Are manipulations limited to the following? | |
| | | | | <ul style="list-style-type: none"> • Aseptically opening ampoules • Penetrating sterile stoppers on vials with sterile needles and syringes • Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing | |
| <input type="checkbox"/> | <input type="checkbox"/> | 24. | OAR 855-045-0250 | Are Category 3 compounds properly stored? | |
| | | | | <ul style="list-style-type: none"> • BUD of less than or equal to 48 hours stored at a controlled room temperature • BUD up to 14 days stored under refrigeration • BUD up to 45 days stored in a solid frozen state at -20°C | |

Category 4 (Medium Risk)

Category 5 (High Risk)

- | | | | | | |
|--------------------------|------------------------------|-----|----------------------|---|--|
| | N/A <input type="checkbox"/> | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | 25. | OAR 855-045-0260(3) | Are Category 4 and 5 compounds prepared in an ISO 5 certified or better BSC, CAI, or LAF? | |
| <input type="checkbox"/> | <input type="checkbox"/> | 26. | OAR 855-045-0260(3) | Is BSC and LAF in an ISO 7 certified or better buffer room or area and connected to an ISO 8 certified or better anteroom or area? | |
| <input type="checkbox"/> | <input type="checkbox"/> | 27. | OAR 855-045-0260 (4) | Does buffer room contain a sink or drain (not permitted for Category 5)? | |
| <input type="checkbox"/> | <input type="checkbox"/> | 28. | OAR 855-045-0260(4) | Are surfaces and furniture in buffer room/anteroom nonporous, smooth, nonshedding, impermeable, cleanable and resistant to disinfectants for Category 5 compounds? | |
| <input type="checkbox"/> | <input type="checkbox"/> | 29. | OAR 855-045-0250(2) | Are Category 4 compounds properly stored? | |
| | | | | <ul style="list-style-type: none"> • BUD of less than or equal to 30 hours stored at a controlled room temperature • BUD up to 9 days stored under refrigeration • BUD up to 45 days stored in a solid frozen state at -20°C | |
| <input type="checkbox"/> | <input type="checkbox"/> | 30. | OAR 855-045-0260(4) | Do you have a positive pressure clear air room which has a ISO 8 certified or better anteroom, ISO 7 or better buffer room which contains a certified ISO 5 or better compounding cabinet or equivalent environment. | |
| <input type="checkbox"/> | <input type="checkbox"/> | 31. | OAR 855-045-0250(3) | Are Category 5 compounds properly stored? | |
| | | | | <ul style="list-style-type: none"> • BUD of less than 24 hours stored at a controlled room temperature • BUD up to 3 days stored under refrigeration • BUD up to 45 days stored in a solid frozen state at -20°C | |

Yes No or
Needs
Correcting

Immediate-use

N/A

32. OAR 855-045-0250(4) Does the administration of immediate-use compounds begin within 1 hour of the time of preparation?
33. OAR 855-045-0250(4) Are immediate-use compounds prepared by someone other than the person who will administer the drug? If yes, labeling must include patient name, name and quantity of ingredients, name of person who prepared compound, and exact one hour BUD.

Same-day use

N/A

34. OAR 855-045-0250(5) Does the administration of same-day use compounds begin within 24 hours of the time of preparation?
35. OAR 855-045-0250(5) Does the environment in which the same-day use compound is prepared meet or exceed the following requirements:
- The mixing cabinet (ISO 5 or better) is located in an area that restricts airflow to prevent drafts and reduce particle counts;
 - There is a partitioned area around the mixing cabinet, which is at least the width of the hood in front of the mixing cabinet;
 - The buffer zone is clearly identified to prevent cardboard or outer packing material from intruding;
 - The environment is cleaned daily.
36. Does the preparer use gloves, shoe covers or dedicated shoes, hair covers, gown and mask?
37. Do batch preparations exceed 8 CSPs (not permitted)?
38. Does the preparer complete the preparation without interruption and with no direct contact contamination?

Single-dose/Multi-dose vial

N/A

39. OAR 855-045-0250(6) Do you access single dose vials in less than an ISO 5 environment? BUD may not exceed 1 hour from time of initial entry.
40. OAR 855-045-0250(6) Do you access single dose vials in an ISO 5 environment? BUD may not exceed 24 hours from time of initial entry.
41. OAR 855-045-0250(7) Do multi-dose vials have a BUD of 1 month or less?

DO NOT SEND ANY PART OF THIS REPORT TO THE BOARD OFFICE! KEEP IN THE PHARMACY. COPIES SENT TO THE BOARD WILL BE DISCARDED.

I hereby certify that I have verified this outlet is in compliance with all laws and rules, have read and verified that written polices and procedures reflect current practices, have documented training of technicians, and the answers marked on this report are true and correct.

Pharmacist-in-charge Signature

License #

Date