



Oregon

John A. Kitzhaber, MD, Governor

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002

E-mail: pharmacy.board@state.or.us

Web: www.pharmacy.state.or.us

**2012 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
www.pharmacy.state.or.us**

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 2/1/2012 (whichever is earlier). Note: This is not all-inclusive. DO NOT MAIL TO THE BOARD OFFICE.

Compounding and Sterile Parenteral Products : OAR 855-045-0210 Compounding is separated into five categories

Category 1- Nonsterile- simple: the mixing of two or more commercial products. This is not considered to be compounding. (i.e. miracle/magic mouth wash, mixing two commercial creams together, antabuse suspension pursuant to a prescription)

Category 2- Nonsterile- complex: compounding with bulk drug substances or when calculations are required. (i.e. making non-patient specific capsules, tablets, suppositories, antabuse suspension in anticipation of multiple prescriptions)

Category 3- Sterile- low-risk. No more than 3 sterile products, no more than two additives in an IV solution (i.e. antibiotic in an IV solution)

Category 4- Sterile- medium-risk. Multiple medications (2 or more) in an IV (i.e. TPNs - Total parenteral nutrition solutions with multiple additives)

Category 5- Sterile- high-risk, using non-sterile ingredients or non-sterile devices (i.e. non-sterile Morphine powder used to prepare solutions for IV pump infusions)

Immediate-use: generally considered low-risk if all criteria are met as outlined in OAR 855-045-0250(4): administration must begin within 1 hour of preparation

Same-day use: generally considered low or medium-risk if all criteria are met as outlined in OAR 855-045-0250(5): the administration of the preparation shall commence within 24 hours from the time of preparation.

General information

- | <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <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"/> | <input type="checkbox"/> | 2. Do you compound immediate-use or same-day products? If yes, which category?
_____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3. OAR 855-045-0200(4) Do you provide compounded medication to a prescriber for the prescriber to dispense in their practice or to another pharmacy for them to dispense to their patients in Oregon?
If yes, please attach a copy of the required Board approved Shared Service Agreement. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4. 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"/> | <input type="checkbox"/> | 5. OAR 855-045-0230(1) Are only products that are not commercially available compounded?
Note: You may compound commercial products that are temporarily in short supply or otherwise unavailable with Board approval. |
| <input type="checkbox"/> | <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 of all personnel? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7. OAR 855-045-0230(2) Are policies and procedures relevant to your practice setting reviewed annually and complied with by all staff? |

- | <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8. OAR 855-045-0230(2)(g) Do you have a QA plan and supporting documentation? What procedures are you performing to ensure the integrity of your products?
_____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9. OAR 855-045-0230(4) Does your QA plan include record keeping requirements for cleaning, testing and calibration of all equipment and devices? Where are your records kept?
_____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10. OAR 855-045-0230(2)(k) Do you have procedures for establishing a BUD for your products? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11. OAR 855-045-0230(5) Do bulk chemicals have the required certificate of analysis? Note location of the records _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. 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 ? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 13. 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 _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. OAR 855-045-0270(2) Do formula worksheets include the following: (Note- this is not required for patient specific IVs, but is required for batch compounding.) <ul style="list-style-type: none"> • 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 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 15. 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? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 16. OAR 855-045-0220(5)(b) and OAR 855-045-0240(1)(E) Is there documentation of verification that includes the initials of the pharmacist responsible for the review and accuracy of compounded products? |

Nonsterile (NS)

N/A

- | <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 17. OAR 855-045-0220 Has appropriate training been provided to all personnel involved in preparing compounded products? Where are the training records kept? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 18. OAR 855-045-0220(5) and OAR 855-041-0065(7)(k) Is each product labeled with its physical description for compounds sold on a prescription? |

Compounded Sterile Products (CSP)-

- N/A
- | <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 19. OAR 855-045-0260(2) Are CSP 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"/> | <input type="checkbox"/> | 20. OAR 855-045-0220(2) Do you test personnel in aseptic manipulative skills?
How often (every 6 months - category 5; every 12 months - Category 3-4)?

Where are training records kept? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 21. OAR 855-045-0250(6) Do you access single dose vials in <u>less</u> than an ISO 5 environment?
BUD may not exceed 1 hour from time of initial entry. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 22. 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 23. OAR 855-045-0250(7) Do you label multi-dose vials with a BUD of 1 month or less from
time of initial entry? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 24. 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"/> | <input type="checkbox"/> | 25. OAR 855-045-0230(2)(e) Do your compounding procedures including requirements for use
of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 26. OAR 855-045-0230(3) Do you have documentation of environmental monitoring to show
that the compounding environment is properly maintained? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 27. OAR 855-045-0240(1)/ OAR 855-041-0130(7)(c) In addition to regular labeling
requirements, does the label include: <ul style="list-style-type: none">• 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• Identification of the pharmacy, patient name and location, auxiliary labels as needed
and date mixed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 28. Does your facility only prepares immediate-use and/or same-day-use products? If so,
please skip to question # 39. |

Category 3 – 5

- N/A
- | <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 29. OAR 855-045-0260(4) Are surfaces and furniture in buffer room/anteroom nonporous,
smooth, non-shedding, impermeable, cleanable and resistant to disinfectants? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30. OAR 855-045-0260(7) Are floors and work surfaces in ISO 7 and 8 areas cleaned at least
daily with appropriate disinfectant solution? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 31. 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? Where are your cleaning
records kept? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 32. If Category 3 CSP are prepared in an ISO 5 environment without a separate buffer room,
is there a partitioned area to create a buffer zone (i.e. line of demarcation)? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 33. OAR 855-045-0250 Are Category 3 manipulations limited to the following? <ul style="list-style-type: none">• No more than 3 sterile products and no more than 2 entries into each sterile container• 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 & dispensing |

- | <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 34. OAR 855-045-0250 Are Category 3 CSP properly stored and BUDs established as follows? <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 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. OAR 855-045-0260 (4) Does the buffer room contain a sink or drain (not permitted for Category 5)? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 36. OAR 855-045-0250(2) Are Category 4 CSPs properly stored and BUDs established as follows? <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"/> | <input type="checkbox"/> | 37. OAR 855-045-0260(3),(4) Do you have a positive pressure clean air room for preparing Category 4 and Category 5 compounds 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"/> | <input type="checkbox"/> | 38. OAR 855-045-0250(3) Are Category 5 CSPs properly stored and BUDs established as follows? <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 |

Immediate-Use

- | <u>N/A</u> <input type="checkbox"/> | | | |
|-------------------------------------|--------------------------|--------------------------|--|
| <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 39. OAR 855-045-0250(4) Does the administration of immediate-use compounded preparations begin within 1 hour of the time of preparation? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 40. 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

- | <u>N/A</u> <input type="checkbox"/> | | | |
|-------------------------------------|--------------------------|--------------------------|--|
| <u>Yes</u> | <u>No</u> | <u>N/A</u> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 41. OAR 855-045-0250(5) Does the administration of same-day use compounded preparations begin within 24 hours of the time of preparation? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 42. OAR 855-045-0250(5) Does the environment in which the same-day use compound is prepared meet or exceed the following requirements: <ul style="list-style-type: none"> • 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 43. Do batch preparations of same-day use compounded preparations exceed 8 CSPs (not permitted)? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 44. Does the preparer of the same-day use compounded preparations complete the preparation without interruption and with no direct contact contamination? |