



# Oregon

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**2016 PHARMACIST-IN-CHARGE  
 PHARMACY SELF-INSPECTION REPORT  
 FOR STERILE AND NON-STERILE COMPOUNDING  
 OREGON BOARD OF PHARMACY  
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**All PICs of compounding pharmacies must complete this report in addition to the Retail, Home Infusion, or Long-Term Care inspection report and have it available for inspection within 15 days of becoming PIC or by 2/1/2016 (whichever is earlier). Note: This is not all-inclusive. DO NOT MAIL TO THE BOARD OFFICE.**

<u>Compounding and Sterile Parenteral Products</u>	<u>Rule Reference</u>
Compounding is separated into five categories (1-5):	OAR 855-045-0210
<b>Category 1</b> – Nonsterile- simple: the mixing of two or more commercial products for a patient-specific prescription (i.e. magic mouth wash, mixing two commercial creams together, antabuse suspension pursuant to a prescription)	
<b>Category 2</b> – 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)	
<b>Category 3</b> – 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)	
<b>Category 4</b> – Sterile- medium-risk. Multiple medications (2 or more) in an IV (i.e. TPNs - Total parenteral nutrition solutions with multiple additives)	
<b>Category 5</b> – 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)	
<u>Immediate-use</u> : 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.	
<u>Same-day –use</u> : 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**

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1.	Do you compound Category 2 through 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 use products? If yes, list which category: _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3.	Do you compound non-patient specific products WITHOUT a Shared Service Agreement?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.	Do you compound non-patient specific products for patients outside of Oregon?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5.	Do you participate in any Shared Service Agreements with another pharmacy or practitioner? If yes, please attach a copy of the required <b>Board approved</b> Shared Service Agreement.	OAR 855-045-0200(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	Do you understand that Shared Service Agreements are only valid between in-state pharmacies and in-state providers AND that the agreements may not be federally acknowledged?	OAR 855-060-0004(8)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	Do you provide non-patient specific controlled substance compounds? (Note: DEA requires a manufacturing license.)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	Do you provide sample(s) of compounded products to prescriber(s) or compound products to be sold OTC? <b>If yes, attach a copy of your FDA and Board of Pharmacy manufacturing registrations.</b>	OAR 855-060-0001
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	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.	OAR 855-045-0230(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	Do you have policies and procedures that contain protocols for initial <b>and ongoing</b> training and testing of all personnel, pursuant to their level of compounding? Where is the documentation? _____	OAR 855-041-0220(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	Are policies and procedures relevant to your practice setting reviewed annually and complied with by all staff?	OAR 855-045-0230(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	Do you have a QA plan and supporting documentation? What procedures are you performing to ensure the integrity of your products? _____	OAR 855-045-0230(2)(g)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	Does your QA plan include record keeping requirements for cleaning, testing and calibration of all equipment and devices? Where are your records kept? _____	OAR 855-045-0230(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	Do you have procedures for establishing a BUD for your products?	OAR 855-045-0230(2)(k)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	To extend any BUD, you must have the products tested for stability and sterility, to account for your facility's unique processes. Do you extend any BUD?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	Do bulk chemicals have the required certificate of analysis? Note location of the records: _____	OAR 855-045-0230(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	Are bulk chemical containers labeled with <b>the date pharmacy obtained the chemical and an expiration date of not more than 5 years from the date container was opened?</b> (Note, this is not required if you obtain an independent Certificate of Analysis.)	OAR 855-045-0230(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	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: _____	OAR 855-045-0270(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19.	Do formula worksheets include all of the following: (Note- this is not required for patient specific IVs but is required for batch and non-patient specific): -copy of the label used for the compounded product -drug name and strength -quantity prepared -date prepared -pharmacy unique lot number -manufacturers' lot numbers and expiration dates of all ingredients in compounded product <b>-BUD (make sure it does not extend beyond any specific ingredients' expiration date!)</b> -name of the verifying pharmacist -names of all technicians involved in the process -mixing instructions -physical evidence of the proper weight of each drug 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	OAR 855-045-0270(2)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20.	Is the pharmacist confirming the drug, dose, and dosage form are appropriate and the calculations, drug, and quantity of each drug are correct?	OAR 855-045-0220(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21.	Is there documentation of verification that includes the initials of the pharmacist responsible for the review and accuracy of compounded products?	OAR 855-045-0220(5)(b) OAR 855-045-0240(1)(E)

Nonsterile (NS)     N/A

Yes   No   N/A

Rule Reference

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22.	Is each product labeled with its physical description for compounds sold on a prescription?	OAR 855-045-0220(5) OAR 855-041-1130(1)(k)
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Compounded Sterile Products (CPS)     N/A

Yes   No   N/A

Rule Reference

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23.	Are CSP prepared in an ISO 5 certified or better Biological Safety Cabinet, or a Compounding Aseptic Isolator, or a Laminar Airflow Hood?	OAR 855-045-0260(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24.	Do you test <b>ALL</b> personnel involved in aseptic manipulative skills? How often (Category 5 -every 6 months; Category 3-4 -every 12 months)? _____ Where are the training records kept? _____	OAR 855-045-0220(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25.	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.	OAR 855-045-0250(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26.	Do you access single dose vials in an ISO 5 environment? BUD may not exceed 24 hours from time of initial entry.	OAR 855-045-0250(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27.	Do you label multi-dose vials with a BUD of 1 month of less from time of initial entry?	OAR 855-045-0250(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28.	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? Where are the records kept? _____	OAR 855-045-0260(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29.	Does your ongoing training require all compounding personnel to perform media fill transfers and are the results available? (Note: this applies to all employees including pharmacists who verify)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30.	Do your compounding procedures include requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks? (Note: no makeup, no jewelry, no fingernail polish, no skin exposed)	OAR 855-045-0230(2)(e)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	Do you have documentation of environmental monitoring to show that the compounding environment is properly maintained? Where is this located? _____	OAR 855-045-0230(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32.	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, <b>including primary solution</b> -Hand written initial of the verifying pharmacist <b>-Identification of the pharmacy</b> , patient name and location, auxiliary labels as needed and date mixed	OAR 855-045-0240(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33.	Do your policies and procedures specifically address product verification of finished CSPs?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34.	Are surfaces and furniture in buffer room/anteroom nonporous, smooth, non-shedding, impermeable, cleanable and resistant to disinfectants?	OAR 855-045-0260(4)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	In ISO 7 and 8 areas, are floors and work surface areas cleaned at least daily and are walls, ceilings, and empty shelving cleaned at least monthly either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant? Where is this documentation kept? _____	OAR 855-045-0260(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36.	If <b>Category 3</b> 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"/>	37.	Are <b>Category 3</b> manipulations limited to the following? -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 and dispensing	OAR 855-045-0250
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38.	Are <b>Category 3-5</b> CSP's properly stored and BUDs properly labeled?	OAR 855-045-0250
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39.	Does the buffer room contain a sink or drain (not permitted for Category 5)?	OAR 855-045-0260(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	40.	Do you have a positive pressure clean air room for preparing <b>Category 4 and Category 5</b> compounds which has an 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?	OAR 855-045-0260(3) OAR 855-045-0260(4)

Immediate Use  N/A

Yes No N/A

Rule Reference

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	41.	Does the administration of <b>immediate-use</b> compounded preparations begin within 1 hour of the time of preparation?	OAR 855-045-0250(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42.	Are <b>immediate-use</b> 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.	OAR 855-045-0250(4)

Same Day Use  N/A

Yes No N/A

Rule Reference

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	43.	Does the administration of <b>same-day use</b> compounded preparations begin within 24 hours of the time of preparation?	OAR 855-045-0250(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	44.	Does the environment in which the <b>same-day use</b> 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	OAR 855-045-0250(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45.	Do batch preparations of <b>same-day use</b> compounded preparations exceed 8 CSPs (not permitted)?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	Does the preparer of the <b>same-day use</b> compounded preparations complete the preparation without interruption and with no direct contact contamination?	