

**STERILE PRODUCTS COMPOUNDING  
SELF-ASSESSMENT REPORT  
16 NMAC 19.6.11  
2008**

INSTRUCTIONS

Each facility preparing parenteral and/or other sterile pharmaceuticals must complete this assessment. The pharmacist-in-charge is responsible for the report and must sign it. The completed report must be available for review by the New Mexico Board of Pharmacy during facility inspections. Regulation cites appear at the end of each statement. Please review any of these regulations prior to answering if you are unsure of a statement on this assessment report. Comments about specific statements can be recorded on the last page of this report. Please record the statement number with your comment.

FACILITY NAME: \_\_\_\_\_

DATE: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY, ZIP CODE: \_\_\_\_\_

PHARMACY LICENSE NUMBER: \_\_\_\_\_

EXP. DATE: \_\_\_\_\_

PHARMACIST-IN-CHARGE: \_\_\_\_\_

LICENSE NUMBER: \_\_\_\_\_

**PHYSICAL REQUIREMENTS [11 B (4); 11 C (1)]**

	<b>YES</b>	<b>NO</b>	<b>N/A</b>
1. CONTROLLED AREA (CLEAN ROOM) IS 100 SQ. FT. OR LARGER. 11 C (1) (c) (iii)	___	___	___
2. A PARENTERAL PHARMACY IS 240 SQ. FT. OR LARGER. 11 B (4) (a) (ii)	___	___	___
3. CONTROLLED AREA RELATIVE POSITIVE AIR PRESSURE FOR STERILE PROD. 11 C (1) (c)	___	___	___
3a. CONTROLLED AREA RELATIVE NEGATIVE AIR PRESSURE FOR CYTOTOXIC PROD. USP<797>	___	___	___
4. CONTROLLED AREA CERTIFIED ISO-5 EVERY SIX MONTHS. 11 C (1) (a)	___	___	___
5. CONTROLLED AREA USED FOR STERILE COMPOUNDING ONLY. 11 C (1) (c) (iv)	___	___	___
6. CONTROLLED AREA HAS NON-POROUS, WASHABLE FLOORS, WALLS, AND CEILING. 11 C (1) (c) (vii)	___	___	___
7. CONTROLLED AREA CONTAINS AN ISO-5 DEVICE OR ISOLATOR CERT EVERY 6 MONTHS. 11 C (1) (a)	___	___	___
8. CONTROLLED AREA CONTAINS APPROPRIATE CONTAINMENT DEVICE CERTIFIED EVERY 6 MONTHS FOR CYTOTOXIC DRUG PREPARATION. 11 C (1) (a)	___	___	___
9. CONTROLLED AREA LIGHTED AN AVERAGE 80-150 FOOTCANDLES. 11 C (1) (c) (ii)	___	___	___
10. REFRIGERATOR FOR STORAGE OF PREPARED PRODUCT. 11 B (4) (b) (ii)	___	___	___
11. FREEZER FOR BULK RECONSTITUTION ANTIBIOTICS, IF NEEDED. 11 B (4) (b) (iii)	___	___	___
12. BULK STORAGE OUTSIDE CONTROLLED AREA. 11 c (1) (d) (e) (f)	___	___	___

**TRAINING 11 C (2)**

	<b>YES</b>	<b>NO</b>	<b>N/A</b>
13. ALL PERSONNEL (RPh, INTERNS, TECHNICIANS) PREPARING OR SUPERVISING STERILE PRODUCT PREPARATIONS HAVE COMPLETED AN APPROVED COURSE AS DESCRIBED IN 11 C (2).	___	___	___
14. A RECORD OF INITIAL AND IN-SERVICE TRAINING FOR ALL PERSONNEL PERPARING STERILE PRODUCTS IS MAINTAINED FOR THREE YEARS. 11 C (2) (g)	___	___	___
15. THIS RECORD CONTAINS: TRAINEE NAME, DATE (S), TOPIC, TRAINING SUPERVISOR, TRAINEE AND SUPERVISOR SIGNATURES. 11 C (2) (e)	___	___	___
16. HOME STERILE PRODUCT PATIENTS AND/OR CAREGIVERS HAVE DOCUMENTED TRAINING. 11 C (3)	___	___	___

**QUALITY ASSURANCE**

	<b>YES</b>	<b>NO</b>	<b>N/A</b>
17. HOME STERILE PRODUCTS HAVE DOCUMENTED, ONGOING PROGRAM TO MONITOR PATIENT CARE AND PHARMACEUTICAL CARE OUTCOMES INCLUDING: 11 C (3)	___	___	___
a) PROSPECTIVE DRUG USE REVIEW BY A PHARMACIST	___	___	___
b) WRITTEN OUTCOME MEASURES	___	___	___
c) SYSTEMS FOR ROUTINE PATIENT ASSESSMENTS	___	___	___

18. PHARMACIES COMPOUNDING STERILE PRODUCTS HAVE A DOCUMENTED, ONGOING PERFORMANCE IMPROVEMENT PROGRAM MONITORING PERSONNEL PERFORMANCE, EQUIPMENT AND FACILITIES BY: 11C(4)	<b>YES</b>	<b>NO</b>	<b>N/A</b>
a) POLICIES AND PROCEDURES FOR ALL ASPECTS OF PERPARATION, STORAGE AND DISTRIBUTION OF STERILE PRODUCTS. 11 C (4) (a)	_____	_____	
b) FOR COMPOUNDING USING NON-STERILE CHEMICALS, APPROPRIATE END PRODUCT TESTING PRIOR TO RELEASE FROM QUARANTINE, 11 C (4) (a) (ii)	_____	_____	_____
c) REGULAR, PLANNED QUALITY ASSURANCE AUDITS. 11 C (4) (a) (iii)	_____	_____	
d) DOCUMENTED PLAN OR CORRECTIVE ACTION FOR IDENTIFIED PROBLEMS, 11 C (4) (a) (iii)	_____	_____	
e) MECHANISM FOR RETRIEVING/TRACKING RECALLED PRODUCTS, 11 C (4) (b)	_____	_____	
f) A WORKSHEET (LOG) OF ALL BATCH PREPARATIONS IS KEPT LISTING: 11(2) (d) (4)			
1) ALL SOLUTIONS AND INGREDIENTS AMOUNTS, VOLUMES, CONCENTRATIONS	_____	_____	
2) COMPONENT MANUFACTURER AND LOT NUMBER	_____	_____	
3) LOT OR CONTROL NUMBER ASSIGNED TO BATCH PRODUCT	_____	_____	
4) DATE OF PREPARATION	_____	_____	
5) BEYOND-USE DATE	_____	_____	
6) IDENTITY OF PERSON PREPARING AND PHARMACIST CHECKING FINAL PRODUCT	_____	_____	
7) SAMPLE LABEL	_____	_____	
19. ALL COMPOUNDING OF STERILE PHARMACEUTICALS IS PERFORMED BY UTILIZING APPROPRIATE ASEPTIC TECHNIQUE INCLUDING GARBING. 11 B (2) (f); 11 C (1) (c) (iv)	_____	_____	

**AUTOMATED COMPOUNDING DEVICES 11 C (4) (c)**

	<b>YES</b>	<b>NO</b>	<b>N/A</b>
20. SUCH DEVICES SHALL:			
a) HAVE ACCURACY VERIFIED ROUTINELY PER MANUFACTURER OR EVERY THIRTY DAYS	_____	_____	_____
b) HAVE OPERATOR OBSERVE FOR PROPER OPERATION EVERY THIRTY DAYS	_____	_____	_____
c) HAVE COMPUTER DATA ENTRY VERIFIED BY RPh PRIOR TO COMPOUNDING	_____	_____	_____
d) HAVE ACCURACY OF END PRODUCT DELIVERY VERIFIED	_____	_____	_____

**POLICIES AND PROCEDURES 11 B (5)**

	<b>YES</b>	<b>NO</b>	
21. THE FACILITY HAS WRITTEN POLICIES AND PROCEDURES FOR:			
a) CLEANING, DISINFECTION, EVALUATION, MAINTENANCE OF CONTROLLED AREA	_____	_____	
b) SURVEILLANCE OF PRODUCT FOR MICROBIOLOGICAL AND PARTICULATE CONTAMINATION	_____	_____	
c) PERSONNEL QUALIFICATIONS, TRAINING AND PERFORMANCE GUIDELINES	_____	_____	
d) FACILITY AND EQUIPMENT GUIDELINES AND STANDARDS	_____	_____	
e) DISPENSING SOP'S	_____	_____	
f) DISPOSAL SOP'S	_____	_____	
g) STABILITY, INCOMPATIBILITY AND INTERACTION SOP'S	_____	_____	
h) QUALITY CONTROL GUIDELINES AND STANDARDS	_____	_____	
i) QUALITY ASSURANCE GUIDELINES AND STANDARDS	_____	_____	

**RECORD KEEPING 11 C (6)**

22. EACH PHARMACY IS REQUIRED TO MAINTIAIN RECORDS OF PATIENT MEDICATIONS INCLUDING AT LEAST:	<b>YES</b>	<b>NO</b>	<b>N/A</b>
a) PRESCRIPTION RECORDS INCLUDING THE ORIGINAL PRESCRIPTION, REFILL AUTHORIZATIONS, ALTERATIONS OF ORIGINAL PRESCRIPTION, AND INTERRUPTIONS OF THERAPY.	_____	_____	_____
b) PATIENT HISTORY INCLUDING ALLERGIES AND DRUG REACTIONS	_____	_____	
c) DOCUMENTED PATIENT CONTACT	_____	_____	

**OTHER**

23. THE PRODUCT LABEL CONTAINS THE FOLLOWING INFORMATION: 11 C (4) (a) (iv)			
a) PATIENT NAME	_____	_____	
b) LOT OR CONTROL NUMBER FOR BATCH PROCESSING	_____	_____	_____
c) SOLUTION, INGREDIENT NAME (S) AND AMOUNT (S)	_____	_____	
d) BEYOND-USE DATE (AND TIME WHEN APPROPRIATE)	_____	_____	
e) DIRECTIONS FOR USE INCLUDING INFUSION RATE AND SCHEDULED TIMES	_____	_____	
f) NAME OR INITIALS OF PERSON PREPARING STERILE PRODUCT	_____	_____	
g) NAME OR INITIALS OF PHARMACIST PERFORMING FINAL CHECK	_____	_____	
h) ANCILLARY INSTRUCTIONS WHEN APPROPRIATE	_____	_____	
i) DEVICE INSTRUCTIONS WHEN APPROPRIATE	_____	_____	

24. FOR PRODUCTS USED OUTSIDE A HOSPITAL SETTING, THE PHARMACY PROVIDES THE PATIENT A 24-HOUR TOLL FREE TELEPHONE NUMBER TO THE PHARMACY/PHARMACIST 11 C (3) (b)	<b>YES</b>	<b>NO</b>	<b>N/A</b>
	_____	_____	_____

25. REFERENCES INCLUDE: 11 B(4)(c )	<b>YES</b>	<b>NO</b>	<b>N/A</b>
a) A DRUG MONOGRAPH REFERENCE	_____	_____	
b) A STABILITY AND COMPATIBILITY REFERENCE	_____	_____	
c) A PHARMACEUTICAL TECHNOLOGY AND COMPOUNDING REFERENCE	_____	_____	
d) A SUITABLE PERIODICAL	_____	_____	
e) A SPECIALTY REFERENCE FOR SCOPE OF PRACTICE 11 C (1) (h)	_____	_____	_____

**USP 797 STANDARDS FOR COMPOUNDED STERILE PRODUCTS (CSP)**

	<b>YES</b>	<b>NO</b>	<b>N/A</b>
IS THE PHARMCIST IN-CHARGE RESPONSIBLE FOR THE DEVELOPMENT, IMPLEMENTATION AND CONTINUING REVIEW OF THE WRITTEN STANDARD OPERATION PROCEDURE (SOP) CONSISTENT WITH USP/NF STANDARDS WHICH ARE USED BY THE OPERATION OF THEIR DAILY OPERATION? 11 B (3) B	_____	_____	
DO PERSONNEL HAVE THE POLICY AND PROCEDURE READILY AVAILABLE?	_____	_____	
INDICATE THE RISK LEVELS OF THE CSP			
IMMEDIATE USE	_____	_____	_____
LOW RISK	_____	_____	_____
MEDIUM RISK	_____	_____	_____
HIGH RISK	_____	_____	_____

**ARE THE FOLLOWING ADDRESSED IN THE SOP USING USP 797 STANDARDS?**

CSP MICROBIAL CONTAINMENT RISK LEVELS	_____	_____	_____
PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS	_____	_____	_____
IMMEDIATE-USE CSPS	_____	_____	_____
SINGLE AND MULTIPLE-DOSE CONTAINERS	_____	_____	_____
HAZARDOUS DRUGS AS CSPS	_____	_____	_____
RADIOPHARMACEUTICALS AS CSP	_____	_____	_____
ALLERGEN EXTRACTS	_____	_____	_____
VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY	_____	_____	_____
STERILIZATION METHODS	_____	_____	_____
STERILIZATION OF HIGH-RISK LEVEL CSPS BY FILTRATION AND/OR STEAM	_____	_____	_____
DEPYROGENATION BY DRY HEAT	_____	_____	_____
ENVIRONMENTAL QUALITY AND CONTROL ISSUES	_____	_____	_____
EXPOSURE OF CRITICAL SITES	_____	_____	_____
ISO CLASS 5 AIR SOURCES, BUFFER AREAS, AND ANTE-AREAS	_____	_____	_____
VIABLE AND NONVIABLE ENVIRONMENTAL SAMPLING TESTING	_____	_____	_____
ENVIRONMENTAL NONVIABLE PARTICLE TESTING PROGRAM	_____	_____	_____
TOTAL PARTICLE COUNTS	_____	_____	_____
PRESSURE MONITORING	_____	_____	_____
ENVIRONMENTAL VIABLE AIRBORNE PARTICLE TESTING PROGRAM SAMPLING PLAN	_____	_____	_____
GROWTH MEDIA	_____	_____	_____
VIABLE AIR SAMPLING	_____	_____	_____
AIR SAMPLING DEVICES	_____	_____	_____
AIR SAMPLING FREQUENCY AND PROCESS	_____	_____	_____
INCUBATION PERIOD	_____	_____	_____
ACTION LEVELS, DOCUMENTATION AND DATA EVALUATION	_____	_____	_____
FACILITY DESIGN AND ENVIRONMENTAL CONTROLS	_____	_____	_____
PLACEMENT OF PRIMARY ENGINEERING CONTROLS WITHIN ISO CLASS 7 BUFFER AREAS	_____	_____	_____
CLEANING AND DISINFECTING OF STERILE COMPOUNDING AREAS	_____	_____	_____
PERSONNEL CLEANSING AND GARBING	_____	_____	_____
PERSONNEL TRAINING AND COMPETENCY EVALUATION OF	_____	_____	_____
GARBING, ASEPTIC WORK PRACTICES AND CLEANING/DISINFECTION PROCEDURES	_____	_____	_____
COMPETENCY EVALUATION OF GARBING AND ASEPTIC WORK PRACTICES	_____	_____	_____
ASEPTIC WORK PRACTICE ASSESSMENT AND EVALUATION VIA PERSONNEL GLOVE FINGERTIP SAMPLING	_____	_____	_____
GARBING AND GLOVING COMPETENCY EVALUATION	_____	_____	_____
GLOVED FINGER TIP SAMPLING	_____	_____	_____
INCUBATION PERIOD	_____	_____	_____
ASEPTIC MANIPULATION AND COMPETENCY EVALUATION	_____	_____	_____
MEDIA-FILL TEST PROCEDURE	_____	_____	_____
SURFACE CLEANING AND DISINFECTION SAMPLING AND ASSESSMENT	_____	_____	_____
CLEANING AND DISINFECTING COMPETENCY EVALUATION	_____	_____	_____
SURFACE COLLECTION METHODS	_____	_____	_____
ACTION LEVELS, DOCUMENTATION AND DATA EVALUATION	_____	_____	_____
FINISHED PREPARATION RELEASE CHECKS AND TESTS	_____	_____	_____
INSPECTION OF SOLUTION DOSAGE FORMS AND REVIEW OF COMPOUNDING PROCEDURES	_____	_____	_____
STERILITY TESTING	_____	_____	_____
BACTERIAL ENDOTOXIN (PYROGEN) TESTING	_____	_____	_____
IDENTITY AND STRENGTH VERIFICATION OF INGREDIENTS	_____	_____	_____

