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)]

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)

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

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)  
   a) POLICIES AND PROCEDURES FOR ALL ASPECTS OF PREPARATION, 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)  

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)  

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 MAINTAIN RECORDS OF PATIENT MEDICATIONS INCLUDING AT LEAST:  
   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)
25. REFERENCES INCLUDE: 11 B(4)(c)  
   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)  

IS THE PHARMacist 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  
VAILABLE AND NONVAILABLE ENVIRONMENTAL SAMPLING TESTING  
ENVIRONMENTAL NONVAILABLE PARTICLE TESTING PROGRAM  
TOTAL PARTICLE COUNTS  
PRESSURE MONITORING  
ENVIRONMENTAL VAILABLE AIRBORNE PARTICLE TESTING PROGRAM SAMPLING PLAN  
GROWTH MEDIA  
VAILABLE 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, ASEPITC WORK PRACTICES AND CLEANING/DISINFECTION PROCEDURES  
COMPETENCY EVALUATION OF GARBING AND ASEPITC WORK PRACTICES  
ASEPTIC WORK PRACTICE ASSESSMENT AND EVALUATION VIA PERSONNEL GLOVE FINGERTIP SAMPLING  
GARBING AND GLOVING COMPETENCY EVALUATION  
GLOVED FINGERTIP 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
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COMMENTS

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PHARMACIST-IN-CHARGE SIGNATURE       DATE