Certification Submission Form

This form must be completed, signed and sent along with any required certification and/or viable sampling report submitted.

CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION

1. Have all cleanrooms, laminar airflow workbenches, BSCs, CAIs, CACIs, and barrier isolators been certified? ○ YES ○ NO Comments

2. Quantity of individuals documented as being present during dynamic comprehensive viable environmental monitoring. Ante Room IV Buffer Room HD IV Buffer Room

3. Does the pharmacy have an ISO Class 5 shielded laminar workflow area built in to the room? ○ YES ○ NO Comments

4. Is certification performed at least every six months, whenever the PECs are relocated or the physical structure of the buffer room or ante-area has been altered, or when any air flow is affected? ○ YES ○ NO Comments

4a. Are the certification reports available? ○ YES ○ NO Comments

4b. Note the date(s) of certification failures.

5. Is the person responsible for overseeing the certification reports familiar with required testing and interpretation of results? (List responsible person/parties) ○ YES ○ NO Comments

6. Is certification performed to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is it noted on the report? If not, indicate the standards used as indicated on the report. ○ YES ○ NO Comments

7. Is the equipment used by the certifier calibrated and is the calibration in date? ○ YES ○ NO Comments

8. Does each test on the certification report have a clear indication of pass or fail? ○ YES ○ NO Comments

9. Are the HEPA filtered air changes per hour (ACPH) measured for the compounding rooms?	○ YES	○ NO		Comments
10. Is the ISO Class 7 non-hazardous sterile compounding room certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources?	○ YES	○ NO		Comments
11. Is the ISO class 7 ante-room certified as having a minimum of 30 ACPH?	○ YES	○ NO	◉ N/A	Comments
12. Are the ISO class 8 ante-room ACPH measured? A minimum of 20 ACPH is commonly referred to by the FDA and others.	○ YES	○ NO	○ N/A	Comments
13. Is the ISO class 7 hazardous sterile compounding room certified as having a minimum of 30 ACPH?	○ YES	○ NO	◉ N/A	Comments
14. If a CACI is used, is the room in which it is located certified to maintain a minimum of 12 ACPH?	○ YES	○ NO	○ N/A	Comments
15. Was air pattern analysis using smoke testing performed?	○ YES	○ NO		Comments
15a. Is the smoke flow described in the report for the various tests such as turbulent, sluggish, smooth, etc.?	○ Acceptable	○ Unacceptable		Comments
16. Was air pattern analysis conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions?	○ YES	○ NO		Comments
17. Was air pattern analysis conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs?	○ YES	○ NO		Comments
18. Was air pattern analysis conducted around particle generating equipment while the equipment was in operation to confirm air flow?	○ YES	○ NO		Comments
19. Was differential pressure measured?	○ YES	○ NO		Comments

20. Was the differential pressure measured to be at least 0.02" water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed?	○ YES	○ NO	Comments	
21. Was the displacement airflow (for low and medium-risk non-hazardous rooms only) measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the ante-room. Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.	○ YES	○ N/A	Comments	
22. Were particle counts measured at greater than or equal to 0.5 micrometers?	○ YES	○ NO	Comments	
23. Were all particle counts taken during dynamic conditions and documented on certification reports?	○ YES	○ NO	Comments	
24. Are ISO Class 5 areas and hoods certified as having less than 3,520 particles per cubic meter of air?	○ YES	○ NO	Comments	
25. Are ISO Class 7 areas certified as having less than 352,000 particles per cubic meter of air?	○ YES	○ NO	Comments	
26. Are ISO Class 8 areas certified as having less than 3,520,000 particles per cubic meter of air?	○ YES	○ NO	Comments	
27. Was HEPA filter testing performed in the ISO certified rooms?	○ YES	○ NO	Comments	
27a. List the number of HEPA filters in each ISO certified room				
28. Were all room HEPA filters leak tested?	○ YES	○ NO	Comments	
28a. If leaks were identified were they repaired?	○ YES	○ NO ◉ N/A	Comments	
28b. Was the BSC/CACI exhaust HEPA filter leak tested?	○ YES	○ NO	Comments	
28c. Was a smoke study performed in front of the repaired area?	○ YES	○ NO	Comments	
29. Were viable air and surface sampling tests conducted?	○ YES	○ NO	Comments	

30. Is appropriate growth media used that supports both bacterial and fungal growth? List media used in note.	○ YES	○ NO		Comments
31. Was viable air sampling by active impaction using a volumetric air sampling device? NOTE: Passive air sampling is not compliant with USP Chapter <797>.	○ YES	○ NO		Comments
32. Was each air sample taken in the ISO areas/PECs at least 1000 liters in volume? If no, statistical analysis must be performed.	○ YES	○ NO		Comments
33. Was viable surface sampling performed on all direct compounding areas (inside of ISO 5 rooms or hoods), in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc., performed?	○ YES	○ NO		Comments
34. Did any of the viable samples exceed the USP recommended microbial action levels (or internal action levels if more restrictive)? Note: CFUs are TOTAL of bacterial plus fungal/mold plates.	○ YES	○ NO		Comments
35. Were all CFUs detected analyzed to determine the organism down to the genus? All CFUs detected must be identified even if the number of CFUs does not exceed an action level.	○ YES	○ NO	○ N/A	Comments
36. Were any mold, yeast, coagulase positive staphylococcus, or gram negative rods detected?	○ YES	○ NO		Comments
36a. If yes, was immediate remediation performed and was the root cause investigation conducted?	○ YES	○ NO	○ N/A	Comments
37. Did the testing report indicate that it included growth promotion testing and sterility quality control testing of the media plates? Positive and negative control tests important to validate results of viable testing.	○ YES	○ NO		Comments

38. Did the testing results report include media lot numbers, expiration dates, and a signature of the laboratory analyst and/or reviewer?

- ☐ Media type
- ☐ Media lot number
- ☐ Media expiration date
- ☐ Signature of the laboratory analyst and/or reviewer
- ☐ Temperature of incubation
- ☐ Date of incubation

Comments

39. Has a dynamic comprehensive viable environmental monitoring been performed within the last 6 months?

○ YES ◉ NO

Note: Performing incompetent or negligent work violates CGS Section 20-579(a)(15)

Name of Person Completing Review

Date