Cleanroom Training and Certification Board
Irish Cleanroom Society

CLEANROOM TESTING AND CERTIFICATION

EXAMINATION

Dublin 7 November 2012 1400-1600

***Candidates should read the following instructions*:**

1) **Candidates should not turn over the page of this examination script until asked to do so by the invigilator.**

2) **Write neatly, as marks will be lost if answers cannot be read.**

3) **No-one should leave the exam room before the first half hour has passed. All examination scripts must be handed to the invigilator before they leave. If the candidate has completed the exam before the end of the time they should hand in the script and leave quietly.**

4) **Candidates are allowed to bring in and consult, the following standards during the exam:**

   - **ISO 14644-1**
   - **ISO 14644-2**
   - **ISO 14644-3**
   - **PD 6609-2000**
   - **Annexe 1 of 'The Rules Governing Medicinal Products in the European Union. Volume 4. (2003). Good manufacturing practices - Medicinal products for human and veterinary use'. Called the European Union Guide to Good Manufacturing Practice (EU GGMP) in the CTCB course notes)**

5) **Candidates should use their own standards during the exam. However, these must be submitted to the CTCB Convenor at least 2 hours before the time of the exam. They must be clearly marked with the candidates name and will be returned immediately before the examination.**

6) **If candidates are uncertain as to the meaning of any question, they must interpret it as best they can, and write down what they think the question means. They should then answer the question.**

7) **Candidates are not allowed to bring into the examination room any electronic equipment, including programmable calculators, or any notebooks, folders or documentation (except the standards for consultation). All such material may be safely stored with the invigilators during the examination.**

8) **The pass mark is 55%.**

9) **The candidate should print their name in the box.**

Name =

Exam Questions

Introduction

QUESTION	ANSWER
1. How many air changes per hour would typically be found in a non-unidirectional ventilated cleanroom?	.
2. One of the principles of cleanroom testing is to make sure that '*The air supplied to the cleanroom is of a [ ] that will not add significantly to the contamination within the room'*. Supply the missing word..	

Air conditioning plant

3. Explain the function of the coiling coil in an air conditioning unit.	.
4. Explain the function of the ceiling diffuser in an air conditioning unit.	
5. What are typical percentages of fresh air supplied to a cleanroom?	
6. Where does most of the air supplied to a cleanroom come from?	.

High efficiency filters

7. What is 'ULPA' an abbreviation for?	
8. What type of high efficiency filter and ventilation type is typically used to obtain an ISO Class 5 cleanrooms, in the operational state?	
9. What is the nominal air velocity through a high efficiency filter?	
10. What is the typical pressure drop range across a new high efficiency filter?	
11. What is MPPS an abbreviation for?	

Standards

12. What is a 'micrometre'?	
13. What is the number given to the group of ISO standards called ' Cleanrooms and Associated Controlled Environments'?	
14. What information is contained in ISO 14644-1?	.
15. What information is contained in ISO 14644-2?	
16. In ISO 14644-1, what is the maximum concentration of 0.1 µm and 0.5µm particles in an ISO Class 5 cleanroom.	
17. Give the definition for 'operational' as given in ISO 14644-1 to describe the occupancy state of a cleanroom.	
18. What is the maximum time between particle counting given in ISO 14644-2 for a cleanroom of a standard *poorer* than ISO Class 5?	

Air supply and extract volumes

19. What air quantity should be measured in a non-unidirectional cleanroom to show that the room is receiving sufficient air? Give the units.	
20. What range of velocities do the FDA and EU GGMP suggest for unidirectional areas?	

21. When testing a cleanroom, in which three places might air velocities be measured?	
22. What three types of velocity-measuring instruments are commonly used in a cleanroom?	
23. How does a thermal anemometer work?	
24. What minimum distance from a filter face does ISO 14644-3 suggest for measuring velocity readings?	
25. What variation in the uniformity of velocity across a filter face is generally accepted in the cleanroom industry?	
26. How might you measure the average velocity of the air coming from a single filter	
27. The air supply to a non-unidirectional cleanroom is 2.4 m^3/s, and its size is 10m x 10m x 4m. What is the air changes/hour in the room? Write down your method of working this out	

Pressure differences

28. Why is there a pressure difference between clean areas, as well as between clean areas and uncontrolled areas	

29. What problems are associated with too high a pressure difference between cleanrooms?	
30. What is the fundamental SI unit for measuring pressure	

Filter installation leak testing

31. What test will ensure that the *quality* of air supplied to a cleanroom is satisfactory?	
32. What gasket seal method will largely prevent leaks between a filter and its housing?	
33. A room-fitted filter may have two types of leaks that are difficult to distinguish between. What are these?	
34. How is a high efficiency air filter system tested to make sure there are no leaks?	.
35. What is the name of the nozzle used to generate a cold-generated test aerosol used for filter integrity testing?	
36. What is the output of a hot type of generator (g/min), and approximately how large a ventilation system can be tested (in m^3/s) by a photometer?	
37. What two types of instruments are used to measure aerosols used to test filters?	
38. How does a photometer work?	
39. What is the equation that is used to determine the % leak through a filter system	

40. When might a particle counter be used in preference to a photometer	.
41. What class of cleanroom might a particle counter method of testing filters be more suited	
42. What percentage variation in the particle challenge to a filter, through time, is suggested by ISO 14644-3	

Containment, visualisation and recovery tests

43. What optional test is specified in ISO 14644-2 to ensure that no contamination infiltrates into the cleanroom from dirtier adjacent areas?	
44. What two 'optional' tests specified in ISO 14644-2 may be used to demonstrate that the air within a cleanroom dilutes or removes airborne contamination?	
45. What should the visualisation of air movement in critical areas show in a non-unidirectional airflow ventilated room?	
46. The time for a decay of particle concentration in a given volume of cleanroom air from 100,000 to 1,000 i.e. a 100 times drop was 13 minutes. Calculate the cleanliness recovery rate. Show your method of working	

Airborne particle tests

47. What is the only test that **must** be carried out in a cleanroom to show that it complies with ISO 14644-1?	
48. What is the lowest particle size that an airborne particle counters can sample?	

49. How is an airborne particle counter able to count and size particles?	
50. An airborne particle counter reports particle sizes in the same way as required by the class limits of ISO 14644-1. What is this type of count called?	
51. What are the three 'occupancy states' called in ISO 14644-1, in which particles may be counted?	

Microbial counts

52. What is the major source of micro-organisms in cleanrooms?	
53. Where are limits found of the microbial concentrations for pharmaceutical cleanrooms inspected by European regulators?	
54. What is the lowest concentration of airborne bacteria that is specified in the EU GGMP?	
55. How long would a settle plate be left exposed in a cleanroom to sample depositing microbe – carrying particles?	

Conduct

56. What precautions should be taken with tools brought into a cleanroom?	.
57. How would you deal with items with non-compatible cleanroom wrappings e.g. for light fittings, that have to be brought into a cleanroom?	
58. What is a 'crossover' bench in a changing room used for?	
59. How do the interlocks of a cleanroom airlock work?	
60. Approximately, how many particles ≥0.5µm per minute are produced by people sitting, moving and walking.	