



**Cleanroom Training and Certification Board  
Irish Cleanroom Society**

# **CLEANROOM TESTING AND CERTIFICATION EXAMINATION**

**Dublin 3 November 2010 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 50%.
- 9) The candidate should print their name in the box.

Name =

# Exam Questions

## Introduction

QUESTION	ANSWER
1. One of the principles of cleanroom testing is to make sure that: <i>'The air supplied to the cleanroom is of sufficient [ ] to dilute or remove the contamination generated in the room'</i> . Supply the missing word	
2. One of the principles of cleanroom testing is to make sure that: <i>'The air within the cleanroom suite moves from [ ] to minimise the movement of contaminated air.'</i> Supply the missing words	

## Air conditioning plant

3. Explain the function of the coiling coil in an air conditioning unit.	
4. Explain the function of the after-heaters in an air conditioning unit.	
5. What are typical percentages of fresh air supplied to a cleanroom?	
6. Describe the disadvantages of the pan type of humidifier.	

## High efficiency filters

7. What type of high efficiency filter and ventilation is typically used to obtain a cleanrooms for ISO Class 4, or lower, in the operational state?	
8. How are mini-pleat filters constructed?	

9. What are the four mechanisms by which particles are removed by air filters?	
10. Describe how the EN 1822 test determines filter efficiency.	
11. Does EN 1822 require the filter frame and gasket to be tested?	

## Standards

12. What is a 'micrometre'?	
13. What is the approximate size of (a) a human hair and (b) a speck of surface dirt that can be seen by a person?	
14. What is the ISO 14644 standard called?	
15. Give the equation used to classify rooms in ISO 14644-1. Do not define the variables used in the equation	
16. Give the definition for 'as-built' as given in ISO 14644-1 to describe the occupancy state of a cleanroom.	
17. According to Annex 1 of EU GGMP, what ISO standard should be referred to obtain the minimum number of sampling locations, sampling volume and method of evaluation of the data collected?	
18. The IEST of the USA produce Recommended Practices. What is the name of the IEST RP CC0034?	

## Air supply and extract volumes

19. What range of velocities (m/s) is generally used in a unidirectional cleanroom?	
20. What two pressures does a Pitot-static tube measure?	

21. What type of instruments would be used to measure pressures found by a Pitot-static tube?	
22. What would be a typical time between calibration of anemometers and what range of velocities should you check that are being tested.	
23. What minimum distance from a filter face does ISO 14644-3 suggest for measuring velocity readings?	
24. How might you measure the average velocity of the air coming from a single filter	
25. The air supply to a non-unidirectional cleanroom is 2.4 m <sup>3</sup> /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	
26. In a perfect situation, what distance is required for the air velocity to become even across a duct <i>after</i> an obstruction?	
27. How many 'lines of traverse' should ideally be taken across a circular duct to obtain the average air velocity, and at what angle should these lines be placed to each other?	

## Pressure differences

28. How does an electronic manometer work, and what advantages does it have?	
29. What 3 tests are manometers used for in cleanroom tests?	

<p>30. How many fold-increase in the differential pressure drop would be normally acceptable before a terminal high efficiency air filter is renewed because of soiling?</p>	
--	--

### Filter installation leak testing

<p>31. In what area are leaks more likely to be found in the glass fibre paper medium used in filters?</p>	
<p>32. Describe typical synthetic rubber gaskets used on high efficiency air filters.</p>	
<p>33. A room-fitted filter may have two types of leaks that are difficult to distinguish between. What are these?</p>	
<p>34. Give the names of three liquids (other than DOP) used to generate an artificial aerosol test challenge (the abbreviated chemical name may be given).</p>	
<p>35. How is a challenge of cold-generated test aerosol produced?</p>	
<p>36. How many particles <math>\geq 0.5\mu\text{m} / \text{m}^3</math> will be measured by a particle counter when the concentration of a test aerosol is <math>10 \mu\text{g}/\text{l}</math>, as measured by a photometer?</p>	
<p>37. What is the output of a hot type of generator (g/min), and approximately how large a ventilation system can be tested (in <math>\text{m}^3/\text{s}</math>) by a photometer?</p>	
<p>38. What concentration of test oil aerosol is suggested by ISO 14644-3, for testing filter integrity with a photometer?</p>	
<p>39. What variation between the filter face velocity and the probe intake velocity does ISO 14644-3 allow?</p>	

40. What techniques can be used to clean out test particles that have spread out from a gasket leak in a room-inserted filter so a leak can be found?	
41. What technique should be used to find the location of a leak in the filter medium?	
42. What would assist in preventing particles from a leaking gasket spilling over the filter face?	

### Containment, visualisation and recovery tests

43. What does the 'cleanliness recovery rate' test measure?													
<p>44. The following particle concentrations were measured in a cleanroom. What is the cleanroom's 'cleanliness recovery performance'</p> <table border="1" data-bbox="183 1568 782 1892"> <thead> <tr> <th>Particle concentration</th> <th>Time (min)</th> </tr> </thead> <tbody> <tr> <td>100 000</td> <td>0</td> </tr> <tr> <td>50 000</td> <td>2</td> </tr> <tr> <td>10 000</td> <td>6.5</td> </tr> <tr> <td>5000</td> <td>8.5</td> </tr> <tr> <td>1000</td> <td>13.00</td> </tr> </tbody> </table>	Particle concentration	Time (min)	100 000	0	50 000	2	10 000	6.5	5000	8.5	1000	13.00	
Particle concentration	Time (min)												
100 000	0												
50 000	2												
10 000	6.5												
5000	8.5												
1000	13.00												
45. The EU GGMP has a 'recovery requirement' in which the particulate conditions after completion of operations should achieve the 'at rest' unmanned state after a short 'clean up' period. What is the period of time?													

46. What EU GGMP Grades of cleanroom would the recovery test be carried out?	
--	--

### **Airborne particle tests**

47. If the class limit for a cleanroom is 1020 at a given particle size, what is the minimum sampling volume? Using a particle counter with a sampling volume of 28.3 l/min, how long should you sample?	
48. What particle counts might cause a higher than expected 95% UCL?	
49. Give an example of a sampling location where an 'outlier' count could be found, and cause the 95% UCL to be exceeded.	
50. How might the problems associated with too high a 95% UCL be reduced?	
51. What purpose is a photodiode used in an airborne particle counter?	

### **Microbial counts**

52. What sizes of Petri dishes would be used to measure the number of microbe-carrying particles that settle from the air of a cleanroom?	
53. What scientific units can be used to report the results from a settle plate?	
54. How is the contact sampling of surfaces for micro-organisms carried out?	
55. How is bud swabbing of surfaces for micro-organisms carried out?	

## Conduct

56. Does the most common method of putting on cleanroom clothing start at the 'head', or the 'feet'?	
57. When putting on a clean cleanroom coverall in the changing area, what common problem should be avoided?	
58. If work that generates particles must be carried out in a cleanroom e.g. drilling a hole, what can be done to prevent dispersion?	
59. If you are working in an area that should not be contaminated, where should you be positioned?	
60. Why should you be careful when touching surfaces in cleanrooms	