



**Cleanroom Testing and Certification Board
Irish Cleanroom Society**

**CLEANROOM TESTING
EXAMINATION**

DUBLIN 5 November 2008 1430- 1630

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. (1997). Good manufacturing practices - Medicinal products for human and veterinary use'. Called the 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 12 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) Candidates are not allowed to bring into the examination room any electronic equipment, including programmable calculators, or any notebooks, folders or documentation. All such material may be safely stored with the invigilators during the examination.
- 7) If candidates are uncertain as to the meaning of any question, they must interpret it as best they can, and put down what they think the question means. They should then answer the question.
- 8) The pass mark is 50%.
- 9) The candidate should print their name in the box.

Name =

Exam Questions

Introduction

- 1 How does the turbulent principle of ventilation work?
- 2 One of the principles of cleanroom testing is to make sure that: '*The air within the cleanroom suite moves from [] to minimise the movement of contaminated air.*' Supply the missing words.
- 3 Give three examples of additional tests that may be carried out in a cleanroom, but may also be carried out in rooms other than cleanrooms.

Air conditioning plant

- 4 Either draw, or write down, the various parts of a simple conditioning plant that uses 100% fresh air
- 5 Explain the function of the secondary air filters in an air conditioning plant.?

High efficiency filters

- 6 What two types of construction are found in high efficiency filters?
- 7 Describe the filter media used in high efficiency filters?
- 8 What is the size range of the most penetrating particles size (MPPS) of a high efficiency filter?

9 Describe how the EN 1822 test determines filter efficiency.

10 What is the disadvantage of the gasket type of housing?

Standards

11 What is ISO an abbreviation for?

12 What is the number of the group of ISO standards called 'Cleanrooms and Associated Controlled Environments'?

13 What information is contained in ISO 14644-3?

14 In ISO 14644-1, how many 0.1 μm and 0.5 μm particles define the class limit for an ISO Class 5 cleanroom.

15 How many occupancy states are defined in ISO 14644-1?

16 Give the definition for 'at rest' as given in ISO 14644-1 to describe the occupation state of a cleanroom

17 Give the equation used to describe a M descriptor, and define the variables.

18 What are the two 'additional' tests given in ISO 14644-2 to demonstrate compliance with ISO 14644-1, and what is the maximum time between tests?

19 What is the maximum number of particles $\geq 0.5\mu\text{m}/\text{m}^3$ is permitted in a EU GMP Grade A cleanroom, at rest?

Air supply and extract volumes

- 20 When testing a cleanroom, in which three places could air velocities be measured?
- 21 Give the equation (Bernoulli's) by which the velocity of the air can be determined from the velocity pressure. Define the variables
- 22 How does a thermal anemometer work?
- 23 If the air is unidirectionally supplied by a bank of ceiling filters, what approximate percentage decrease in velocity at the working height would you expect owing to the frame, housing and free space
- 24 What number of velocity measuring points does 14644-3 suggest for measuring velocity across the filter face of a unidirectional flow cleanroom?
- 25 What variables would influence your decision as to the number of points to be measured across a supply air filter in a unidirectional workstation?
- 26 In a perfect situation, what distance is required for the air velocity to become even in a duct *after* an obstruction?
- 27 How can the problem of a different hood reading caused by different diffuser types be solved??

Pressure differences

- 28 What range of pressure differentials does the FDA suggest should be used between adjacent rooms of different classification with doors closed?

- 29 How does an electronic manometer work, and what advantages does it have?
- 30 How would you manually measure the pressure difference between two cleanrooms using a manometer and tubing?
- 31 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?

Containment, visualisation and recovery tests

- 32 In a cleanroom supplied by an air plenum, where might dirty air from a supply plenum enter the room?
- 33 What should the visualisation of air movement in critical areas show in a turbulently ventilated room?
- 34 How could you visualise and record the airflow in a cleanroom?
- 35 What two tests does ISO 14644-3 suggest for investigating how quickly a contaminated area will recover from airborne contamination?

Filter installation leak testing

- 36 What test will ensure that the *quality* of air supplied to a cleanroom is satisfactory?
- 37 Where are the four places that filter leaks are likely to be found?
- 38 Where are the leaks more likely to be found in the glass fibre medium used in filters?

- 39 How is a filter system tested to make sure there are no leaks?
- 40 What is the name of the nozzle used to generate a cold-generated test aerosol used for filter integrity testing?
- 41 How many particles $\geq 0.5\mu\text{m} / \text{m}^3$ will be measured by a particle counter when concentration of test aerosol is $10 \mu\text{g}/\text{l}$, as measured by a photometer?
- 42 Why are oil test particle aerosols not generally used in semiconductor fabrication cleanrooms?.
- 43 What does ISO 14644-3 suggest as a suitable mass median diameter for the test aerosol?
- 44 What percentage variation in the particle challenge to a filter through time is suggested as acceptable in ISO 14644-3

Airborne particle tests

- 45 What time interval does ISO 14644-2 required for cleanrooms \leq ISO Class 5 to comply with ISO 14644-1 in terms of particle count?
- 46 An airborne particle counter reports particle sizes in a way that is required by the class limits of ISO 14644-1. What is this type of count called?.
- 47 Give the equation that is required to calculate the minimum volume of air that must be sampled when measuring particles in a cleanroom to show that it complies with ISO 14644-1. Define the variables in the equation

48 If a cleanroom is 4 metres x 5 metres in floor area, what is the minimum number of locations that must be sampled for airborne particles?

49 If the ISO 14644-1 class limits are exceeded, what re-test options does ISO 14644-1 suggest?

50 How might the problems associated with too high a 95% UCL be avoided?

Microbial counts

51 What is the major source of micro-organisms in cleanrooms?

52 What is the microbial 'colony'?

53 Why is a settle plates considered to be a good method of monitoring microbial contamination?

54 Describe a RODAC dish used for sampling surfaces in a cleanroom.

Conduct

55 What precautions should be taken with tools brought into a cleanroom?

56 What can be done to instructions that are printed on non-cleanroom paper, if they have to be taken into the cleanroom?

- 57 What is the overall principle for changing into cleanroom clothing? How would cleanroom management influence cleanroom changing methods?
- 58 Approximately, how many particles $\geq 0.5\mu\text{m}$ are produced by people sitting, moving and walking.
- 59 If you are working in an area that should not be contaminated, where should you be positioned?
- 60 Why are personal handkerchiefs a problem in cleanrooms?