



Cleanroom Testing and Certification Board

CLEANROOM TESTING

EXAMINATION

3.00pm till 5.00pm, 23rd June 2004

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 What were unidirectional cleanrooms previously called?
- 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 What air quantities should be measured when testing (a) a turbulently ventilated room and (b) a unidirectional airflow?

Air conditioning plant

- 4 Where does most of the air supplied to a cleanroom come from?
- 5 What are the advantages and disadvantages of an axial flow fan?

High efficiency filters

- 6 Define an ULPA filter.
- 7 What type of high efficiency filter and ventilation is normally used in cleanrooms of ISO Class 6 (Class 1000) and poorer quality in the operational state?
- 8 What are the two types of construction of high efficiency filters called?
- 9 How are mini-pleat filters constructed?

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

Standards

11 What is the approximate size of (a) a human hair and (b) a speck of surface dirt?

12 How many 0.5 μm particles per cubic foot are in a Federal Standard 209 Class 100 000 cleanroom?

13 What is the ISO 14644 standard called?

14 What information is contained in ISO 14644-1?

15 What information is contained in ISO 14644-2?

16 Give the equation used to classify rooms in ISO 14644-1. Do not define the variables used in the equation.

17 What are the two 'additional' tests given in ISO 14644-2 that can be used to demonstrate compliance with ISO 14644-1 and what is the maximum time between tests?

18 How many particles $\geq 5 \mu\text{m}/\text{m}^3$ is expected in Grade A 'at rest' and in 'operation', and Grade B 'at rest'?

19 The IEST of the USA produce Recommended Practices. What is the name of the IEST RP CC006?

Air supply and extract volumes

- 20 What should be measured in a turbulently ventilated cleanroom to show that it is receiving sufficient air (give units)?
- 21 Where would a Pitot-static tube normally be used?
- 22 How does a measuring hood work?
- 23 When measuring air velocity with an anemometer, what four inaccuracy problems should you consider?
- 24 What variables would influence your choice of the number of measuring points across a supply air filter?
- 25 Give examples of situations where the velocity across an air duct is uneven.
- 26 What is the law by which a rectangular air duct can be divided up to determine the average air velocity?
- 27 What methods can be used to determine the air supply volume in a turbulently ventilated cleanroom?

Pressure differences

- 28 What is an appropriate pressure difference between two cleanrooms?

- 29 What is the relationship between the following units of measurement: Pascals, inches of water, and millimetres of water?
- 30 What initial conditions must be satisfied with regards to the air conditioning plant and doors before measuring the pressure difference between cleanrooms?
- 31 Some ventilation systems measure the pressure difference between one fixed point and all the other cleanrooms. How would you find out the pressure difference between two cleanrooms?

Containment, visualisation and recovery tests

- 32 ISO 14644-2 lists four tests that are 'optional', and may have a test interval of two years. What are they?
- 33 What should be demonstrated in a containment leak test?
- 34 How could you check for infiltration of air into a cleanroom from dirty areas that are a higher pressure than an adjacent cleanroom?
- 35 What properties of threads, or sound recording tapes, are best for visualising air movement?

Filter installation leak testing

- 36 In terms of particle numbers, what test will determine if the *quality* of air supplied to a cleanroom is satisfactory?
- 37 A room-fitted filter may have two types of leaks that are difficult to distinguish between. What are these?
- 38 What test aerosol is most suitable for testing a microelectronic fabrication cleanroom?

- 39 Does a photometer measure the number, or mass, of particles?
- 40 What percentage concentration of test challenge is considered by a leak by PD6609-2000, if the clean area is ISO Class 6 and poorer?
- 41 Why is the speed of scanning a filter important?
- 42 Why is a filter more likely to fail the filter integrity test if a thermal generator is used in preference to a Laskin nozzle.
- 43 When testing a room inserted filter, how can you distinguish between a fault in the casing and a leak from the gasket?
- 44 What does standard PD6609-2000 suggest should be done if leaks are found in a filter medium?

Airborne particle tests

- 45 What time interval does ISO 14644-2 required for cleanrooms \leq ISO Class 5 to be tested for particle counts to show that they comply with ISO 14644-1?
- 46 Define the 'as built' occupancy state as given in ISO 14644-1.
- 47 In a cleanroom that requires very large samples, what is the name of the method given in Annexe F of ISO 14644-1 that might save you time when sampling particles?
- 48 If the ISO 14644-1 class limits are exceeded, what re-test options are there?

- 49 What spread of particle counts might cause a higher than expected UCL?
- 50 Give an example of where an 'outlier' count could be found, and cause the UCL to be too high.

Microbial counts

- 51 What is the major source of micro-organisms in cleanrooms?
- 52 What are the two general types of volumetric (active) air samplers that are used in cleanrooms to sample micro-organisms?
- 53 How does a centrifugal microbial air sampler work?
- 54 How does bud swabbing of surfaces, for micro-organisms, work?

Conduct

- 55 How should you enter a cleanroom?
- 56 What precautions should be taken with tools brought into a cleanroom?
- 57 When changing into cleanroom clothing, what street or factory clothing should normally be removed?

58 When working in a cleanroom what should you do to prevent unwanted air transfer?

59 Should face masks be worn so that they are positioned just below the nose?

60 Why are personal handkerchiefs a problem in cleanrooms?

Example