Cleanroom Testing and Certification Board
Irish Cleanroom Society

CLEANROOM TECHNOLOGY CERTIFICATION -EXAMINATION

10th April 2014 19:30 -21:30

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

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

Write your answers below or next to the questions in this examination paper. Write neatly, as marks will be lost if answers cannot be read.

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 allocated they should hand in the script and leave quietly.

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

- **ISO 14644-1,**
- **ISO 14644-2,**
- **ISO 14644-3**
- **Annex 1 of 'The Rules Governing Medicinal Products in the European Union. Volume 4. (1997). Good manufacturing practices - Medicinal products for human and veterinary use'. Often called the EU GMP**

Candidates should provide their own standards for consultation during the exam. However, these must be submitted to the invigilator before the exam for inspection. They must be clearly marked with the candidates name and will be returned immediately before the examination.

If candidates are uncertain as to the meaning of any question, they must interpret it as best they can, and put down on the exam paper what they think the question means. They should then give an answer to what they think the question means.

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.

The pass mark is 50%. The number of questions is 80

The candidate should print their name in the box.

Name :

Chapter 1 – Introduction

Q1: Give four examples of cleanroom industries where bacteria are a problem?

Q2: What constructional materials should be used to build a cleanroom?

Q3: What should people in a cleanroom do to minimise their dispersion of contamination?

Q4: Broadly speaking, what principles determine why a cleanroom is tested and monitored?

Chapter 2 - History of Cleanrooms

Q1: Where were the first types of cleanrooms established?

Q2: What was the accepted mode of dress for a surgeon in an operating room before about 1900?

Q3: Describe an operating theatre in, and around, the 1890s?

Q4: When did the ventilation of operating theatres become clearly associated with contamination control?

Chapter 3 - Cleanroom Classification Standards

Q1: How are cleanrooms classified?

Q2: The classification of a cleanroom, according to ISO 14644-1, can be carried out in three occupational states. What are these?

Q3: What is the definition of the 'as built' occupancy state in ISO 14644-1?

Q4: What is the definition of the 'at rest' occupancy state in ISO 14644-1?

Q5: What is the definition of the 'operational' occupancy state, according to ISO 14644 - 1?

Q6: What air filters types should be provided for Grade A, B and C pharmaceutical cleanrooms, according to the EU GGMP?

Q7: What air changes per hour do the FDA Guideline suggests for controlled areas?

Q8: What is the size of a human hair?

Q9: What size of particle can be seen on a surface?

Chapter 4 -Information Sources

Q1: What is the name and number of the overall ISO standard that deals with particles in cleanrooms?

Q2: Where can ISO standards on cleanrooms be purchased?

Chapter 5 – Non Unidirectional Airflow and Ancillary Cleanrooms

Q1: What sources of contamination *within* a cleanroom determine its cleanliness?

Q2: Why is it necessary for air to move from the clean to less-clean areas in a clean facility?

Q3: Typically, what is an acceptable differential pressure between a cleanroom and less-clean adjacent rooms?

Q4: What typically divides a changing area into two zones?

Q5: What consideration must be given to cleanroom garments intended for re-use?

Chapter 6 –Unidirectional Airflow Cleanrooms

Q1: In unidirectional systems, in which direction does the air flow?

Q2: What effect do 'obstructions' have on unidirectional airflow?

Chapter 7 – Separative Clean Air Devices & Containment Zones

Q1: Briefly, describe a mini environment?

Chapter 8 - Construction and Clean Build

Q1: What room construction design feature aids cleaning?

Q2: Give advantages of having windows in a cleanroom?

Chapter 9 – High Efficiency Air Filtration

Q1: What does HEPA mean?

Q2: What is the minimum efficiency of a HEPA filter in removing particles approximately equal to 0.3µm?

Q3: Name two types of construction of HEPA filters?

Q4: From what material is the HEPA filter media made?

Q5: When would pinhole leaks not be acceptable in air filters?

Chapter 10 – Cleanroom Testing and Monitoring

Q1: To what airborne standard should the cleanroom be tested to show that it is designed correctly?

Q2: Outline the principles of cleanroom testing?

Q3: What is the one test that must be carried out to show that a cleanroom complies with ISO 14644-1?

Q4: List three states of occupancy in which testing can be carried out?

Chapter 11 - Measurement of Air Quantities and Pressure Differences

Q1: Why is a positive pressure difference required between cleanrooms?

Q2: What is the unit of measurement for pressure?

Q3: To ensure pressure differentials are measured accurately, what must first be done?

Chapter 12 - Air Movement Control: Containment, Visualisation & Recovery

Q1: How can contamination enter a cleanroom from adjacent areas?

Q2: How can the direction of airflow through doors be checked?

Q3: In which areas of the cleanroom is it important to demonstrate good mixing?

Chapter 13 - Filter Installation Leak Testing

Q1: How do high efficiency air filters operate?

Q2: How can filters be damaged after manufacture?

Q3: What is used as a challenge for testing filters?

Chapter 14 - Airborne Particle Counts

Q1: What information does a particle counter display or printout?

Q2: What size of particles can present a problem with sample systems using long lengths of tubing?

Q3: Name the three occupancy states defined in ISO 14644-1.

Q4: Which occupancy state would normally have the lowest particle count?

Chapter 15 - Microbial Counts

Q1: What is the major source of micro-organisms within a cleanroom?

Q2: What is agar?

Q3: Explain the difference between 'active' air sampling and settle plate sampling?

Q4: Name two common methods of microbial surface sampling?

Q5: In what circumstances is swabbing used?

Chapter 16 - Operating a Cleanroom – Managing the Risk from Contamination

Q1: Give three examples of sources of contamination in cleanrooms?

Q2: What is an alert level?

Q3: Define the term 'validation'?

Chapter 17 - Cleanroom Disciplines

Q1: Why should personnel refrain from supporting material against their cleanroom clothing?

Q2: Give examples of personnel who might disperse significantly greater levels of contamination?

Q3: Give 5 examples of personal items not allowed into the cleanroom?

Q4: Should maintenance personnel be given free access to a cleanroom?

Chapter 18 - Entry and Exit of Personnel

Q1: Why is it necessary for personnel working in a cleanroom to change into cleanroom clothing?

Q2: In the change area, when selecting the new cleanroom garments, what should be checked prior to use?

Q3: If garments are used again on re-entry to the change room, how should they be removed on leaving the cleanroom?

Chapter 19 – Materials, Equipment and Machinery

Q1: Why should wood be avoided?

Q2: Why should the supplier of cleanroom materials be audited?

Q3: List two ways of transferring materials needed in a cleanroom in and out of cleanrooms.

Chapter 20 -Cleanroom Clothing

Q1: How can contamination from operators be controlled?

Q2: Through which routes can microbes be transferred from personnel and into the cleanroom environment?

Q3: What is the main source of microbial contamination in a cleanroom?

Q4: When choosing the type of cleanroom garment, what must one consider?

Q5: Sterilisation of garments can be carried out by several methods. List two?

Chapter 21 – Cleanroom Masks and Gloves

Q1: How does a mask prevent the passage of particles to the environment?

Q2: Discuss two problems associated with the use of cleanroom gloves?

Chapter 22 - Cleaning a Cleanroom

Q1: Why does a cleanroom need to be cleaned?

Q2: Why should string mops not be used in cleanrooms?

Q3: Is alcohol effective against spores?

Q4: What is the benefit of using a disinfectant over a detergent?