



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

**CLEANROOM TECHNOLOGY  
CERTIFICATION  
-EXAMINATION**

26 March 2008 1730 -1930

*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 your answers below or next to the questions in this examination paper. 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 allocated 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
  - 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'. Often called the EU GGMP
- 5) 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.
- 6) 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.
- 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%.. The number of questions is 73.
- 9) The candidate should print their name in the box.

Name =

## **Exam Questions**

### **Chapter 1 – Introduction**

1. What constructional materials should be used to build a cleanroom?
2. Why are clean rooms needed in a modern society?
3. What two major design types of cleanroom are differentiated by their method of ventilation?

### **Chapter 2 - History of Cleanrooms**

1. When did the ventilation of operating theatres become clearly associated with contamination control?
2. How effective was Sir John Charnley's work on ventilation of operating room between 1959 and 1970
3. What major advantage has a unidirectional flow in preventing contamination dispersal by a person working in the room?

### **Chapter 3 - Cleanroom Classification Standards**

1. What is a micrometre ( $\mu\text{m}$ )?

2. What size of particle can be seen on a surface?
3. How did the Federal Standard 209 versions, up to version D, classify cleanrooms?
4. What is the ISO 14644-1 cleanroom standard called, and when was it published?
5. What is the maximum number of 0.5  $\mu\text{m}$  particles to be found 'at rest' in the EU GGMP Grade B environments?
6. What does the EU GGMP Grade and B 'at rest' classification correspond approximately to in the ISO 14644-1 classification?

#### **Chapter 4 -Information Sources**

1. What is the name and number of the overall ISO standard that deals with particles in cleanrooms?
2. Where can the European Union Guide to Good Manufacturing Practice be obtained?

#### **Chapter 5 - The Design of Turbulently Ventilated and Ancillary Cleanrooms**

1. Do large cleanroom require a higher or lower percentage of fresh air than smaller rooms?
2. Typically, what level of particles  $\geq 0.5 \mu\text{m}$  is generated by an operator moving about in a laboratory coat?
3. Typically, what level of microbe containing particles is generated by an operator moving about in a laboratory coat?
4. In which direction should air move throughout the various cleanrooms within a cleanroom facility?

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

## **Chapter 6 – Design of Unidirectional Cleanrooms and Clean Air Devices**

1. What effect do ‘obstructions’ have on unidirectional airflow?
2. Give an example of one type of simple unidirectional air device..
3. By which other two names are ‘mini environments’ known?.
4. Briefly, describe a mini environment..

## **Chapter 7 – Construction Materials and Surface Finishes**

1. Name one type of modular cleanroom construction..
2. What dictates the use of suspended or supported ceilings in cleanrooms?
3. If static charge within the cleanroom is considered a problem, what properties should construction materials have?.

## **Chapter 8 – High Efficiency Air Filtration**

1. What does HEPA mean?
2. In the Military Standard 282, what is the average size of test particles?

3. What is the mass median size for test particles used in the Sodium Flame test?
4. Why are pinhole leaks in unidirectional flow systems **not** tolerated?

### **Chapter 9 – Cleanroom Testing and Monitoring**

1. If required, how often should air pressure differentials be measured?.
2. With regard to ongoing monitoring, what variables are likely to be checked?

### **Chapter 10 - Measurement of Air Quantities and Pressure Differences**

1. Why must a cleanroom have a sufficient supply of clean air?
2. What is the problem in measuring air quantities when air supply diffusers are used?

### **Chapter 11 - Air movement control between and within cleanrooms**

1. What characteristic do the best airflow visualisation streamers possess?
2. Give two forms of smoke or particle streams.
3. How can the airflow be checked in a conventionally ventilated cleanroom?

## **Chapter 12 - Filter Installation Leak Testing**

1. How are leaks detected?
2. In what situation would filter integrity testing not be necessary?
3. If acceptable, how can filter repairs be effected?

## **Chapter 13 - Airborne Particle Counts**

1. What is the typical sampling rate of a particle counter? - Give rate in metric and imperial units i.e. litres per minute and cubic feet per minute.
2. What is the basic method of detection of particles in a particle counter?
3. What size of particles can present a problem with sample systems using long lengths of tubing?
4. From 14644-1, give the formula for the minimum airborne sampling volume.

## **Chapter 14 - Microbial Counts**

1. What is agar?
2. A 9cm Petri dish ( $64\text{cm}^2$ ) is placed close to a filling process and the microbial count on the plate after 4 hours was 2. What is the contamination rate when the container with a neck area of  $1\text{cm}^2$ , is open for an average of 2 minutes..

3. In what circumstances is swabbing used?

### **Chapter 15 - Operating a Cleanroom – Contamination Control**

1. Give three examples of sources of contamination in cleanrooms
2. How can contamination from machines be reduced?
3. What is an 'action level'?

### **Chapter 16 - Cleanroom Disciplines**

1. Give 5 examples of personal items not allowed into the cleanroom.
2. How should personnel position themselves with regarding to working with the product in the cleanroom?
3. How would particle generating operations during maintenance be dealt with in cleanroom?

### **Chapter 17 - Entry and Exit of Personnel**

1. What is the minimum number of footsteps to be taken on the cleanroom mat

2. On leaving an aseptic pharmaceutical cleanroom what is done with the cleanroom clothing.
3. If garments are used again on re-entry to the change room, how should they be removed on leaving the cleanroom?

### **Chapter 18 – Materials, Equipment and Machinery**

1. List four examples of types of materials used in cleanrooms
2. What is the disadvantage of plastic materials?
3. Why does an airlock have interlocking doors?

### **Chapter 19 -Cleanroom Clothing**

1. How can contamination from operators be controlled?
2. What is the source of microbial contamination in a cleanroom?.
3. When choosing the type of cleanroom garment, what must one consider?
4. In a cleanroom laundry what is the 'soil area' used for?
5. What happens as a garment ages?

6. Why are antistatic properties of cleanroom clothing important?

## **Chapter 20 – Cleanroom Masks and Gloves**

1. How does a mask prevent the passage of particles to the environment?
2. Name the two general types of gloves used in cleanrooms
3. List four properties to be considered when choosing gloves.

## **Chapter 21 - Cleaning a Cleanroom**

1. Why is a wet vacuum system more efficient than a dry vacuum?
2. Of what material should buckets be constructed?
3. Why is it important to know a wiper's sorbency?
4. What are the four types of surfactants?

5. What is the benefit of using a disinfectant over a detergent?

6. . Only designated staff should clean - true or false?