

SOP Section A



Information to be sent out before course starts and outline of course

The following Standard Operational Practice (SOP) list gives information on what documents should be sent out before the course starts, and an outline of the organisation of the course. The numbering of the paragraphs (A1 etc.) shows the computer file where information can be found.

A1 Information on course to be sent out on receiving an enquiry: an example document is given, which needs adaptation for use in each country. Information includes an application form.

NOTE: Cleanroom societies should note that national regulations about data storage and privacy must be complied with, notwithstanding the agreement of the candidate in the application form to having their photograph taken and their details placed on the web site.

A2 Outline of organisational pathway of course.

A3 Letter to Professionals, who have been certified for 5 years, and need to be re-certified.

A4 Email sent to two referees to obtain information about work experience of first-time professional candidates.

A5 Example of written exam to be sent to the candidates: This is best issued at same time as 'Course Notes' and 'Questions and Answers Handbook' i.e. immediately on registration.

A6 Examples of letters sent to candidates to confirm a place has been reserved on the course.

A7 Information about practical exam: Expectations and practical exam sheets are to be sent to candidates. The first page should be removed before being sent to a candidate. This information should be issued at least one month before exam and can often be conveniently issued when a place on the course is confirmed.

A8 Information to professional candidates about the particle counting test. This can be conveniently issued when a place on the course is confirmed.

A9 Letter given to candidates when they arrive at the course.

A10 Organisation of Annual Meeting CTCB-I

NOTE 1: A set of the CTCB-I 'Course Notes' and the 'Questions and Answers Handbook' should be sent to candidate on registration. These are not included in this SOPs documentation but available on Dropbox.

NOTE 2: A society that is a member of the ICCCS can apply for ICCCS Accredited Education certificates. When acquired, successful students will be placed in ICCCS register.



A1: Example of overall information about the course and application form to be sent when an initial inquiry is received:



CTCB- Cleanroom Testing Course and Examinations

When a cleanroom has just been built, and during its lifetime, it is necessary to test it to ensure that it is working correctly. The amount and quality of air supplied, the air movement between and within cleanrooms, and the particle and microbiological counts in the cleanroom, and other attributes, should be shown to be correct.

The testing of a cleanroom requires skill, and the following certified courses are provided to help acquire this. Teaching and certification is carried out by the Cleanroom Testing and Certification Board – International (CTCB-I), which is composed of international experts in cleanroom testing who oversee the content of the course, the teaching, and the examinations. This course has also been accredited by the Education Committee of the International Confederation of Contamination Control Societies (ICCCS). This course is held in the UK, Ireland, the Nordic countries, the Netherlands, Turkey and Belgium. See <http://www.ctcb-i.net/> for more information.

Registration

Candidates can register for either of two levels of certification. These are:

Professional certification: For people whose profession is cleanroom testing, and who routinely test all aspects of cleanroom testing. These people are examined at the end of the course to see if they have a satisfactory knowledge of cleanroom testing. At the time of their final exam, they will have a minimum of 2 years' experience. If you apply, and have suitable qualifications, you will be required to:



- Study the self-study course notes that will be sent to you, attend a revision lecture course, and then pass a written examination on Cleanroom Testing;
- Attend a one day course on practical aspects of cleanroom testing and be prepared for the practical exam;
- Pass a practical exam by demonstrating a high level of competence in (a) filter integrity testing and (b) measuring air velocities and volumes;
- Complete a particle counting exercise.

Associate certification: For people who are familiar with aspects of cleanroom testing and wish to gain a fuller knowledge of the subject, or, have been working less than two years as a cleanroom tester and wish to use the certification course as a basis of training to work towards professional status.

If you apply for the associate course, and have suitable qualifications, you will be required to:

- Study the self study course notes, attend a revision lecture course, and then pass a written examination;
- Attend a one day course on practical aspects of cleanroom testing;

The written exams are identical in both qualifications, the difference between the two certificates is that professional candidates will have 2 years experience and are examined on their practical competence. In the associate qualification, the practical aspects will be taught, but not examined. Students who obtained the associate qualification may convert to a professional certificate once they have a minimum of two years experience, but they must pass the practical exam.

On registration, the candidate will receive self-study course notes, a questions and answers handbook, an example of a written exam paper, and notification of the date of the next course and

examination. Prior to attending the course and exams, the professional candidates will be sent information on how the practical exam is run and the examiner's expectations. On satisfactory completion of the course, candidates receive a CTCB-I certificate, and entered onto the CTCB-I 'List of successful candidates' on the website. This registration applies to the person who passes the exam, and not their firm. A professionally-certified person will remain on the list for 5 years, at which time they must be re-certified. In order to update their knowledge, it is recommended that associate-certified people be recertified every 5 years.

The Course Notes and Syllabus

The candidate will receive over 100 pages of course notes. Also issued is a handbook containing a set of questions (and answers) for topics discussed in the notes, so that the candidate can assess their knowledge. The syllabus of the course is as follows:



- Introduction to cleanroom testing;
- How a cleanroom air conditioning plant works;
- High efficiency air filters;
- Standards for classification and certification;
- Air supply and extract volumes;
- Differential pressures;
- Containment, visualisation and recovery tests;
- Air filter integrity tests;
- Particle measuring methods according to ISO 14644-1;
- Microbiological measurements;
- Cleanroom conduct.

Revision Lectures, Practical Training and Examination

Professional candidates will and receive practical training, a lecture revision course and sit practical and written examinations. The Associate candidates will attend for shorter time and receive practical training, a lecture revision course and sit a written exam. The days will be organised as follows:



Practical Training: This course will demonstrate:

1. *Filter integrity testing:* An aerosol smoke generator and photometer, and how these are used to test filter integrity. The technique will be demonstrated and each student will have an opportunity to use the method.
2. *Air velocity and volume flow measurement:* An anemometer, hood capture method, averaging pressure flowmeter, and Pitot-static tube. The techniques will be demonstrated and there will be an opportunity for each student to use the methods.
3. *Other test methods:* Other testing techniques such as an airborne particle counter, microbial sampling methods and airflow visualisation techniques.

Revision Lecture Course: The lecture course will revise the course notes.

Written Theory Exam: This will examine the candidate's knowledge of the course notes. The questions will be short and of the type that can be answered by no more than 10 words; no essays are required. The questions will be similar, or identical, to those given in the question and answers handbook. The pass mark is 55%.

Practical Exam: The professional candidates will be examined on their competence to carry out the following important tests:

1. Determine the average air velocity and uniformity, as well as the volume of air passing through a HEPA fan/filter unit by use of an anemometer and the hood capture method.

2. Demonstrate that they can operate a smoke generator and photometer to find leaks in a filter/filter gasket.

The candidate will be required to competently write up reports on the results of the two tests.

The candidate will also be required to complete a written test on airborne particle counting and cleanroom classification according to ISO 14644-1.

The candidate's exam results are assessed by an Examination Board drawn from the CTCB-I Advisory and Examination Board. It is anticipated that about 70% of the candidates will pass their exams in the first attempt. The CTCB-I has an examination appeals procedure. Anyone failing an exam can re-sit it at the next examination in the UK, Ireland, Sweden and the Netherlands, although possible language difficulties should be discussed with the organisers.

The Cost

Costs are levied in two parts:

(1) Registration for associate and professional candidates, which includes:

- being entered as a candidate;
- receiving a set of self-teaching course notes;
- receiving a questions and answers handbook;
- receiving a past exam paper;
- a certificate on satisfactory completion of the course.

There is a fixed registration fee, which is the same at every CTCB-I member society €400 (or equivalent in local currencies)

(2) Lecture course and exam

(a) Professional three-day course which includes:

- one-day practical training course
- a revision lecture course;
- written and practical exams.

The course fees differ between societies, because of differing local costs structures (accommodation, catering and costs of teachers and examiners).

(b) Associate two-day course including:

- practical training course
- a revision lecture course;
- written exam.

The course fees differ between societies, because of differing local costs structures (accommodation, catering and costs of teachers and examiners).

Coffee, tea and lunch over the course will be included in the cost.

Exam Re-sit

Candidates can re-sit their exams. The cost will be [to be inserted] for one exam and [to be inserted] for the two. There is likely to be an opportunity every 4 months.

Note: Any costs required for accommodation and other meals are the responsibility of the candidate.

For current information and costs please contact the CTCB-I teaching centre of your choice. Alternatively, information may be available on the Internet at <http://www.ctcb-i.net/>

Application Form for CTCB-I Certification for Cleanroom Testing

1. Application for: Professional Certification <input type="checkbox"/> Associate Certification <input type="checkbox"/> Please tick only one box
2. Name:
3. Company:
4. Correspondence Address:
Tel: _____ Email: _____
5. Present position in your firm:
6. How many years work experience have you of cleanroom testing? Two years experience at the time of the practical exam is required for professional certification.
7. Do you routinely carry out: (a) filter integrity tests; (b) air velocity and air volume; (c) pressure differentials; (d) airborne particle counting? Associate applicants should have some experience with these tests, but professional applicants must be experienced at carrying out these tasks, <u>especially the filter integrity test by photometer</u> , or they will fail the practical exam.
8. Please give us the name and address of two people that we may contact to obtain their endorsement that you have sufficient time and experience of testing cleanrooms to be eligible for the Professional Certification. Associate applicants need not provide this information. Email addresses must be included.
Email address 1 : _____ Email address 2 : _____
9. Educational details at school, college or university (with any information on certificates received):
10. Is there anyone in your firm that may be able to act as an in-house tutor and assist you in your exam preparation? This person is likely to have at least 5 years' experience in testing cleanrooms? If so give their name.
11. The CTCB takes great care to ensure that examinations are conducted in a fair and legitimate manner. The Examination Board will advise unsuccessful candidates, <i>at their discretion</i>, why they have failed to meet the expected examination requirements. There is also an appeals procedure whose decision is final. Details of examination decisions are confidential and remain privileged information restricted to the Examining Board. All candidates registering for this course are deemed to have understood and accepted these conditions. Students by signing this form are also deemed to have accepted that they will be attentive and studious during all teaching periods, and to study efficiently. The candidate's photograph will be taken at the start of the course. This will be used during the course is to prevent impersonation and aid the examiners. On certification, the successful candidate's name and photograph will be placed on the CTCB-I web site to provide evidence that the person testing their cleanroom is CTCB-I certified. By signing this form, the candidate agrees to this. CANDIDATES SIGNATURE:
Office use only: Accepted by: _____ Inv. No. _____ Course notes, Q&A handbook, and sample exam paper sent:

