

# **CETA National Board of Testing Policies for the Registered Certification Professional Cleanroom Testing Certification**

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## SECTION 1.0 CERTIFICATION CRITERIA

- 1.1 The *Registered Certification Professional – Cleanroom Testing* (RCP-CT) credentialing program is designed to ensure that the certificate holders possess the fundamental knowledge required to evaluate a controlled environment as functioning properly and within required industry standards and/or facility protocols. A successful candidate will be required to show an understanding of international standards (such as ISO-14644) and other regulatory guidelines; along with the ability to demonstrate the proper use of the equipment and procedures for evaluating the performance of the controlled environments and document the results following cGMP documentation practices. The examination for the RCP-CT will be administered multiple times a year.
- 1.2 Certification as a *Registered Certification Professional – Cleanroom Testing* requires:
  - 1.2.1. Successful completion of the Multiple Choice Examination and
  - 1.2.2. Successful demonstration of certification skills through a Written Practical Examination.
- 1.3 CETA National Board of Testing (CNBT) Certification for *Registered Certification Professional – Cleanroom Testing* shall be valid for a period of five [5] years from the date of successful completion of both the Multiple Choice and Written Practical exams, to be issued effective either January 1<sup>st</sup> or July 1<sup>st</sup>
- 1.4 A CNBT credentialed individual will be responsible to report to the CNBT Executive Committee any criminal or negligent behavior if that behavior affects patient care and/or public safety. The CNBT Executive committee reserves the right and authority to implement disciplinary action deemed appropriate, including revocation of credentials.
- 1.5 A CNBT credentialed individual is required to use their credentials in a professional and responsible manner.
  - 1.5.1 CNBT issues a trademarked certificate and a trademarked stamp to Registered Certified Professionals. The certificate and stamp bears the title of the applicable discipline, the expiration date of the credential and the name of the Registered Certified Professional
    - 1.5.1.1 Each certificate and stamp is discipline specific. A CNBT certificate or stamp may not be used by a Registered Certified Professional to validate work in a discipline other than what is signified on the certificate or stamp itself or for a co-worker's work not directly supervised in-situ.
    - 1.5.1.2 Expired certificates and stamps may not be used for any purpose.
    - 1.5.1.3 CNBT certificates and stamps are registered trademarks of CNBT and cannot be used by the Registered Certified Professional's company without the consent of the Registered Certified Professionals whose name it bears.

## **SECTION 2.0 APPLICATION PROCEDURE and Eligibility Requirements**

### **Application Submittal**

- 2.1. Applications can be completed online at the CNBT website at:  
<http://cetainternational.org/about-exams>  
An applicant may request an application be mailed by contacting the CETA Headquarters.
- 2.2. An application may be submitted electronically upon completion and all supporting documentation must be received by the CETA National Board of Testing at 701 Exposition Place, Suite 206, Raleigh, NC 27615, either electronically or by hard copy, before the application deadline for that examination cycle.
  - 2.2.1 It is the responsibility of the applicant to meet the application deadline. CETA National Board of Testing cannot be responsible for misdirected mail, lost mail, or other possible scenarios beyond the control of the CNBT.
  - 2.2.2 Late applications may not be accepted by the CNBT Administrator due to the lack of available examinee space.
  - 2.2.3 A late fee will be levied against all applications submitted after the published application deadline for that exam cycle.
  - 2.2.4 Incomplete applications cannot be considered. The applicant will be notified of the reason(s) that their application is considered incomplete. The applicant will remain responsible for complying with all application requirements including completion of the application by the deadline. Any application that is not complete by the application deadline will be declared void and the CNBT Administrator will notify the applicant that they have been withdrawn from the application process.
  - 2.2.5 If the re-submission of an application extends the application beyond the application deadline, then the applicant may not be eligible for the ensuing examination and a late fee, as per 2.2.3, may apply. Subsequent examinations will have their own application processes and fee schedules.
- 2.3. Payment should accompany the application submission, if not then payment must be completed on or before the application deadline of the examination for which the fee is being submitted.
  - 2.3.1 If any payment is returned, either by a bank or other financial institution, the applicant will be ruled ineligible for the examination and a returned payment fee will be charged, plus any additional penalties incurred by CNBT.
- 2.4. A completed application must include all of the following:
  - 2.4.1 Original application form with all sections completed and any supporting documents.

- 2.4.2 The applicant's legal signature on the application attesting to the completeness and correctness of all information and documentation being submitted and signifying their willingness to abide by the governance of the CETA National Board of Testing.

## **Work Experience**

- 2.5 Time of service does not guarantee an applicant's ability to prove competence but does provide an individual with exposure to specific equipment, regulations, guidelines and best practices.
  - 2.5.1 Ideally an examinee should have sufficient work experience to demonstrate expertise and a thorough understanding of controlled environment certification to have a reasonable chance of success.
  - 2.5.2 A Non-Member of CETA will need to provide documentation, in the form of a signed letter on corporate letterhead of active interest in controlled environment certification, describing current job responsibilities and other activities to be considered.
- 2.6 CETA National Board of Testing reserves the right to reject any applicant that cannot be verified.

## **Application Withdrawal**

- 2.7 Any examination applicant may withdraw from the examination process by notifying CNBT in writing (or by email at [info@cetainternational.org](mailto:info@cetainternational.org)), which must be received by the CETA National Board of Testing 701 Exposition Place, Suite 206, Raleigh, NC 27615, on or before the application withdrawal deadline, defined as the registration close date.
  - 2.7.1 Any examination applicant who voluntarily withdraws their application for an examination before the deadline, may receive a refund of their application fee minus a processing fee.
  - 2.7.2 Any examination applicant who voluntarily withdraws an application for an examination before the deadline, may re-submit their application for any subsequent examination. Subsequent examinations will have their own application processes, fee schedules, and rules and regulations.
  - 2.7.3 If the applicant cannot attend the scheduled examination after the withdrawal deadline; the applicant can, by notifying CNBT in writing (or by email at [info@cetainternational.org](mailto:info@cetainternational.org)), apply all application fees to the next examination cycle, a late fee as per 2.2.3 may apply.
- 2.8 Any examination applicant not present at the scheduled time of the exam administration will forfeit all fees.
- 2.9 If for any reason, the CNBT Administrator and/or proctor is unable to start, administer or complete the scheduled test cycle, immediate provisions will be administered for an expedient and successful completion of that test cycle.

## SECTION 3.0 EXAMINATION AND PERFORMANCE CRITERIA

### General

- 3.1 The content of the Multiple Choice and Written Practical examinations shall be derived directly from the current CNBT Cleanroom Testing Exam based on the *Job Task Analysis*.
- 3.2 The examination(s) shall be administered by a CNBT approved proctor(s).
- 3.3 If English is an examinee's second language or if the examinee has a documented learning disability, a written request to CNBT can be filed with the Administrator requesting an additional time allotment of 30-minutes for each exam, Multiple Choice and Written Practical.

### Multiple Choice examination

- 3.4 The Multiple Choice examination shall consist of one hundred twenty [120] multiple choice questions graded for pass/fail. When deemed necessary an exam may have as many as ten (10) additional questions for piloting that will not count towards the final grade, increasing the total exam content to as many as one hundred and thirty (130) questions. This is a closed book examination.
- 3.5 A maximum of two and one half hours (2.5) shall be permitted for completion of the Multiple Choice examination.
- 3.6 The Multiple Choice passing grade is targeted to be **xx%** based on previous exam cycles.

### Written Practical examination

- 3.7 The Written Practical examination shall consist of forty [40] essay questions graded for pass/fail. When deemed necessary an exam may have as many as seven (7) additional questions for piloting that will not count towards the final grade, increasing the total exam content to as many as forty seven (47) questions. This is a closed book examination.
- 3.8 A maximum of three hours (3.0) shall be permitted for completion of the Written Practical examination.
- 3.9 The Written Practical exam passing grade is targeted to be **x.xxx** on a scale of 0.000 to 4.000 points, based on previous exam cycles.
- 3.10 Each exam's final grade is based on the statistical analysis of three individual examiners.

## **SECTION 4.0 RE-CERTIFICATION CRITERIA**

- 4.1 A current credentialed individual, in good standing with the CNBT committee, can extend their current credentials for an additional 60 months (5 yrs) by completing all of the following requirements:
- 4.1.1 Attend a minimum of three (3) CETA Annual Meetings over the initial five (5) year period
  - 4.1.2 Apply for and pass the CNBT Multiple Choice (MC) exam, before the end of their 60th month (5yr) anniversary date.
    - 4.1.2.1 Should a re-certifying applicant fail to successfully pass the Multiple Choice (MC) exam, they will be required to re-apply for and successfully complete **both** the Multiple Choice (MC) **and** Written Practical (WP) exams
  - 4.1.3 If the requirement of 4.1.1 is not met, successful completion of **both** the Multiple Choice (MC) **and** (WP) Written Practical will be required to remain certified.
- 4.2 An individual's accreditation will expire on the last day of the 60th month (5 years) after issuance and their active listing of accreditation will be removed from the CNBT website, unless the requirements of 4.1 are successfully completed.
- 4.3 Once an individual's accreditation has expired there will be a 120 day grace period, to allow for scheduling difficulties, in which the lapsed accreditation can be reinstated by scheduling and successfully passing the Multiple Choice exam and submitting a one time administrative fee of \$500, or \$250 if the time lapse is held to less than 60 days.
- 4.4 After 10 years of **continuous** accreditation, applicants must apply for and pass **both** Multiple Choice (MC) **and** Written Practical (WP) examinations.

## **SECTION 5.0 RE-EXAMINATION CRITERIA**

- 5.1 Failure of the Multiple Choice examination by the criteria cited under Section 3.6 shall require re-examination on the entire Multiple Choice examination.
- 5.2 Failure of the Written Practical examination by the criteria cited under Section 3.9 shall require re-examination of the entire Written Practical examination.
- 5.3 When an applicant successfully passes only one of the two required examinations, the passing test result will remain effective for an 18-month period. During that 18-month period, the applicant must pass the remaining exam in no more than 3 attempts. Failure to pass both examinations within an 18-month window will result in the accreditation process concluding. Said applicant will need to complete a new application request as per Section 2.0 to continue.

## **SECTION 6.0            CNBT EXECUTIVE COMMITTEE DUTIES AND RESPONSIBILITIES**

- 6.1 CNBT Executive committee shall consist of three (3) to five (5) qualified persons appointed by the Committee Chair and approved by the CETA Board of Directors.
- 6.2 CNBT Executive committee shall approve the Subject Matter Experts (SME).
- 6.3 CNBT Executive committee shall approve the Written Practical Examiners.
- 6.4 CNBT Executive committee shall authorize approved facilities to conduct examination sessions for *Registered Certification Professional – Cleanroom Testing*
- 6.5 CNBT Executive committee shall oversee the administration of certifying examinees that satisfied the accreditation requirements.
- 6.6 CNBT Executive committee shall oversee the administration of issuing certification credentials by mail to successful examinees.

## **SECTION 7.0      SUBJECT MATTER EXPERT (SME) CRITERIA**

- 7.1 A Subject Matter Expert item writer shall as a minimum:
  - 7.1.1. Have five (5) years of experience in the controlled environment certification profession verified by documented industry recognition and leadership.
  - 7.1.2. Complete and submit a signed SME application on an approved CNBT application form, with an attached CV or resume, for review and approval.
  - 7.1.3. Sign a conflict of interest statement and affidavit of confidentiality
  - 7.1.4. Have access to all reference materials on the examination's approved reference list.
  - 7.1.5. Be willing to donate time spent working for CNBT with employer consent.
  - 7.1.6. Accept a requirement to periodically develop quality test items.
  - 7.1.7. Be available to attend item writing workshops, meeting at various locations within the United States.
- 7.2 CNBT Executive Committee will require a majority agreement to approve the SME item writers provided all of the conditions in Section 7.1 are deemed to be satisfied.
- 7.3 The length of service for an individual SME shall be based on the continuing ability of that individual to contribute to the knowledge assignment, determined by the majority agreement of the CNBT Executive Committee.
- 7.4 Any individual that currently, or within the previous 12 months, develops, manages or lectures in a 3rd party educational program that is designed and developed to provide specific preparation of the student for the CNBT Cleanroom Testing exam; that individual cannot item write as an Cleanroom Testing Subject Matter Expert for any cycle of Cleanroom Testing exams. The CNBT Committee will be responsible for determining if an educational program, or the individual, meets the criteria.
- 7.5 SME's can be removed with a majority vote of the CNBT Executive Committee.



## **SECTION 8.0 WRITTEN PRACTICAL EXAMINER (WPE) CRITERIA**

- 8.1 A Written Practical Examiner shall as a minimum:
  - 8.1.1. Have eight (8) years of experience in the controlled environment certification profession verified by documented industry recognition and leadership.
  - 8.1.2 Submit a completed and signed WPE application on an approved CNBT application form with an attached CV or résumé for review and approval.
  - 8.1.3 Sign a conflict of interest statement and affidavit of confidentiality
  - 8.1.4 Be willing to travel, at the expense of CNBT, and receive compensation for grading with employer consent.
  - 8.1.5 Be a full member in good standing with the Controlled Environment Testing Association (**CETA**).
- 8.2 CNBT Executive Committee will require a majority agreement to approve all Written Practical Examiners, provided all of the conditions in Section 8.1 are deemed to be satisfied.
- 8.3 All Written Practical Examiners shall be expected to maintain the integrity and guarded nature of the item bank during all examination grading sessions.
- 8.4 Any Written Practical Examiners that could have a possible conflicting interest such as, but not limited to, an examinee currently:
  - employed in the same organization or
  - employed by a customer/client, shall be excused from any grading responsibilities for that examinee.
- 8.5 A Written Practical Examiner will be required to successfully complete the Written Practical Examiner training process, which includes:
  - 8.5.1 Examiner correlation evaluation/exercise shall consist of questions scoring from 0 to 4 for the purpose of standardization and
  - 8.5.2 Participate in a full grading session, considered a dry run that does not impact the examinees overall scoring, in order to establish correlation compatibility for the WPE under consideration.

- 8.6 Written Practical Examiners are not allowed to define terms or interpret examination questions for the examinees or discuss the exam afterwards at anytime with any examinees.
- 8.7 Written Practical Examiners will grade performance based on the CNBT ideal answer sheets and the scoring rubric.
- 8.8 The length of service for a Written Practical Examiner shall be determined by the continuing ability of the individual to grade fairly and maintain an acceptable correlation with other graders, determined by the majority agreement of the CNBT Executive Committee.
- 8.9 Written Practical Examiners will be compensated per established rates as designated by CNBT Executive Committee
- 8.10 Any individual that currently, or within the previous 12 months, develops, manages or lectures in a 3rd party educational program that is designed and developed to provide specific preparation of the student for the CNBT Cleanroom Testing exam; that individual cannot grade any cycle of Cleanroom Testing exams as a WP Examiner. The CNBT Committee will be responsible for determining if an educational program, or the individual, meets the criteria.
- 8.11 Written Practical Examiners can be removed with a majority vote of the CNBT Executive Committee.

## **SECTION 9.0      EXAMINATION PROCTOR (EP) CRITERIA**

- 9.1 An Examination Proctor shall as a minimum:
  - 9.1.1. Submit a completed and signed Examination Proctor application on an approved CNBT application form with an attached CV or resume for review and approval.
  - 9.1.2 Sign a conflict of interest statement and affidavit of confidentiality
  - 9.1.3 Be willing to travel and work on behalf of CNBT at the discretion of the CNBT Executive Committee
  - 9.1.4 Be a full member or staff member in good standing with the Controlled Environment Testing Association (**CETA**).
- 9.2 CNBT Executive Committee will require a majority agreement to approve all Examination Proctors, provided all of the conditions in Section 9.1 are deemed to be satisfied.
- 9.3 An Examination Proctor shall be expected to maintain the integrity and guarded nature of the item bank during all examination sessions.
- 9.4 An Examination Proctor shall be expected to follow verbatim the Test Administration Manual during all examination sessions.
- 9.5 An Examination Proctor's selection will account for potential personal/professional conflicts with examinees. Any Examination Proctor with a possible conflicting interest in administration of an exam, is required to contact the CNBT Executive Committee to discuss a possible resolution.
- 9.6 Examination Proctors, while proctoring an exam, are not allowed to define terms or interpret examination questions for the examinees or discuss the individual exam items afterwards with any examinees.
- 9.7 The length of service for an Examination Proctor shall be determined by the continuing ability of the individual to proctor fairly and maintain an acceptable performance with other proctors, determined by the majority agreement of the CNBT Executive Committee.
- 9.8 An Examination Proctor traveling on behalf of the CNBT shall be reimbursed for reasonable travel expenses and entitled to a daily per diem as established by the CNBT Executive Committee
- 9.9 An Examination Proctor can be removed with a majority vote of the CNBT Executive Committee.

## SECTION 10.0 CNBT POLICY CHANGE LOG

**Pending** – Approved by the CNBT Executive Committee

Revision	Date	Section	Original Version	Revised Version	Status/Date
000	15 June 2020	N/A	New Document Created	N/A	Completed 7 July 2020
001					
002					