



**CNBT**  
CETA National Board of Testing

# **Sterile Compounding Facilities**

## **Preparation Guide**

**for**

## **Multiple Choice Exam and Written Practical Exam**

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# **I Introduction**

The purpose of this document is to provide the information and references necessary to complete the Registered Cleanroom Certification Professional in Sterile Compounding Facilities (RCCP-SCF) credentialing examinations.

## **II Requesting the Exam**

### **Purpose of the Credential**

CETA National Board of Testing (CNBT) offers the Registered Cleanroom Certification Professional in Sterile Compounding Facilities credential to provide evidence of an individual's competence in the testing and certification of sterile compounding facilities.

### **Certification**

Members of the CNBT Committee along with psychometricians and examination development experts will determine the passing score upon the finalization of the last examination administration of that season.

Any and all Candidates who meet or exceed the determined passing score, based on validated procedures, will earn the RCCP-SCF credential.

Applicants who successfully pass both of the certification examinations (Multiple Choice and Written Practical) will receive a certificate describing their credential that is valid for sixty (60) months from the date of issuance.

### **Requirements for the Certification Examination**

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. An ideal candidate must have sufficient work experience to demonstrate expertise and a thorough understanding of controlled environment certification (customarily two (2) years) and provide the following supporting documentation:

Employment Verification letter which must:

- On the letterhead of the applicant's employer
- State the years which the applicant has worked for employer
- State the applicant's job responsibilities
- Contain the original signature of the applicant's supervisor
- OR
- signed certification reports proving active employment in the field
- OR

- other approved proof of active participation in sterile compounding facility certification activities.

## **Payment of Fees**

Payment of fees may be made by check, money order or credit card. Applicants must not have outstanding financial obligations to CETA. All expenses related to the examinations are the responsibility of the applicant. Candidates with complete applications will receive an authorization to test after the application has been approved.

## **Check Acceptance Policy**

When you pay by check you expressly authorize CETA, if your check is dishonored or returned for any reason, to electronically debit your account for the amount of the check plus a processing fee. The use of a check for payment is your acknowledgment and acceptance of this policy and its terms.

## **Testing Objectives**

The examinations developed and the credentials administered by CNBT are designed with the following objectives in mind:

1. Determine the fundamental knowledge of a professional working in the certification of sterile compounding facilities' clean rooms.
2. Promote a credential that represents those professionals who have met this fundamental knowledge.
3. Promote professional recognition in the field of sterile compounding facilities' clean room certification.

# **III Preparation for Taking the Exams**

## **Documents You Should Be Familiar with for the Exam**

In preparing for the examination, it is imperative you have a thorough understanding of and practical field experience in referencing the most current revision of the following documents:

- ISO 14644-1
- ISO 14644-2
- ISO 14644-3
- ISO 14644-4
- IEST RP's rev 1.5,
- IEST RP's rev 2.3
- IEST RP's rev 6.3

- IEST RP's rev 13.2
- IEST RP's rev 34.3
- USP<797>
- USP<800>
- USP<1116>
- CAG-001-2005 Applications Guide for The Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities (December 2008)
- CAG-002-2006 Compounding Isolator Testing Guide (Revised December 2008)
- CAG-003-2006 Certification Guide for Sterile Compounding Facilities (Revised December 2008)
- CAG-005-2007 Servicing Hazardous Drug Compounding Primary Engineering Controls (Revised May 2007)
- *Best Practice* questions may also be asked to help assess the examinee's knowledge and skills. Answers to these questions may not have specific support in any of the reference documents but are considered best practice and general industry knowledge by the CETA National Board of Testing subject matter experts.

## **Multiple Choice Exam Testing Format**

Each Multiple Choice examination contains 140 items which will be administered in a three (3) hour block.

The examination will be administered in the following format:

Pre-test tutorial	30 minutes
Examination	150 minutes (2.5 hours)

## **Written Practical Exam Testing Format**

Each Written Practical examination contains 50 items which will be administered in a three (3) hour block.

The examination will be administered in the following format:

Pre-test tutorial	30 minutes
Examination	150 minutes (2.5 hours)

## Examination Content Outline

The following table outlines the content and percentage of questions from each category that will make up the CNBT's RCCP-SCF examinations.

RCCP-SCF Blueprint	Multiple Choice Exam	Written Practical Exam
Performing Site Assessment		
1. Verify User Requirements		
2. Perform Safety Assessment		
3. Evaluate Cleanroom Devices	15%	4%
4. Evaluate Surface Finishes		
5. Manage Certification Equipment		
Counting Total Particles (14%)		
1. 1. Select Test Equipment		
2. 2. Determine Sample Plan	14%	10%
3. 3. Collect Air Samples		
4. 4. Analyze Sample Data		
Performing Environmental Monitoring		
1. Determine Sample Plan		
2. Collect Air Samples		
3. Collect Surface Samples	20%	10%
4. Collect Fingertip Samples		
5. Process Collected Samples		
6. Analyze Sample Data		
Determining Air Change Rate		
1. Determine Test Plan		
2. Setup Primary Test Equipment	13%	20%
3. Setup Alternative Test Equipment		
4. Collect Airflow Volumes		
Testing Airflow Velocity		
1. Determine Test Plan	7%	10%
2. Collect Air Velocity Data		
Proving Room Segregation		
1. Determine Test Plan		
2. Execute Primary Test Plan	9%	10%
3. Execute Secondary Test Plan		
Testing HEPA Air Filters		
1. Determine Test Plan	7%	14%
2. Perform Test Plan		
Performing Airflow Visualization		
1. Determine Test Plan	7%	18%
2. Perform Test Plan		
Preparing Certification Reports		
1. Document Implemented Procedures	8%	4%
2. Summarize Test Results		

## Multiple Choice Sample Question

Question. For ISO Class 7 environments, the maximum concentration of airborne particles equal to and larger than 0.5  $\mu\text{m}$  per cubic meter of air is

- a) 352,000
- b) 10,000
- c) 35,200
- d) 1,000

Answer: (a)

## Written Practical Sample Question

Fact: The letter A is long, thin and brown and the letter B is short, fat and orange in color.

Question: Name three differences between the letters A and B

Answer #1: One difference between the letters A and B is that the letter A is long and the letter B is short, a second difference between the letter A and letter B is that the letter A is thin and the letter B is fat and finally a third difference between the letter A and letter B is that the letter A is brown and the letter B is orange. (correct answer)

Answer #2

A	B
Long	Short
Thin	Fat
Brown	Orange

(also correct answer)

Fact: The area of a circle can be determined by geometric formulas.

Question: What is the area of a one-foot circle

Answer #1: 113 square inches or 0.785 square feet, pi times the radius squared (are correct answers)

Answer #2: 111.6 square inches or 0.775 square feet (is incorrect and will score no points)

Answer #3:  $3.1 \times (6 \times 6) = 111.6$  square inches (will receive partial credit because the grader can see that the number for pi is incorrect but the formula is correct)

## IV Day of the Examination

### Before the Examination Begins

#### Arrival:

The candidate should arrive at the testing location at least 15 minutes before the scheduled test time. **Any candidate who arrives at the room where the examination will be administered after the exam instructions have been given, will be treated as a no-show and will not be admitted.**

#### Identification:

Each authorized candidate must present a legal form of identification - which must be a government issued photo ID (e.g. driver's license, passport).

All candidates must bring to the RCCP-SCF test center the following:

- (1) your unsigned Admission Ticket. At the test center you will provide your signature at the check-in table.
- (2) one current, valid (NOT expired) government-issued ID.
- (3) Three or four sharpened No. 2 or HB pencils or mechanical pencils.

Use the restroom before entering the testing room.

Although the overall length of the test can be long—up to 2.5 hours; the actual starting time of the test may vary at different centers due to pre-administrative procedures. Dress in a manner that enables you to adapt to any room temperature.

Candidates must follow the proctor's instructions, test rules and regulations at all times.

The RCCP-SCF examination is confidential. All test materials, including test books, answer sheets, and writing response sheets are the property of the CETA National Board of Testing and must be returned to the test proctor before dismissal from the test center.

Under no circumstances may test content or any part of the test be removed, reproduced, and/or disclosed by any means (e.g., hard copy, verbally, electronically) to any person or entity. Legal action may be taken against anyone who removes test materials and/or reproduces or copies test materials in anyway, or shares test content.

#### Check-In:

After presenting a valid form of identification and the Admission Ticket, the candidate will sign a test center log.

Candidates ARE NOT allowed to have any personal or prohibited items at their testing station. The proctor reserves the final determination as to whether a questionable item will be allowed into the test center or at the candidates test station.



## Items Permitted in the Examination Room

Test takers may bring into the testing room the following items: Admission Ticket, valid ID, wallet, keys, hygiene/medical products, No. 2 or HB pencils or mechanical pencils, erasers, pencil sharpener, tissues.

## Prohibited Electronic Devices

Candidates may not bring any electronic devices to their testing station. All electronic devices must be surrendered to the proctor prior at time of entry.

Prohibited electronic items that test takers may **not** bring into the testing center include, but are not limited to, the following items:

- electronic timers of any kind
- beeping watches or watches with alarms
- calculators or watches with calculators
- cell phone
- personal computers
- beepers or pagers
- personal digital assistants (PDAs)
- photographic or recording devices
- listening devices like iPods with headsets
- media and electronic devices of any kind

## Prohibited Non-Electronic Devices

Prohibited non-electronic items that test takers may **not** take into the testing room include, but are not limited to, the following items:

- books,
- reference document
- papers of any kind
- earplugs
- rulers
- slide rules
- compasses
- weapons and firearms of any kind

Smoking is not permitted.

Hats/hoods may not be worn on the head (except items of religious apparel).

Test takers who take prohibited items into the testing room will be subject to the surrendering of such items to the proctor, until the conclusion of the exam.

Candidates who use or are in possession of prohibited electronic devices and/or prohibited non-electronic devices at their testing stations, will be issued a violation notice from the CNBT and will be dismissed from the test center. Such violations will be grounds for score cancellation. This policy will be enforced from the time candidates arrive at the test center until they leave at the conclusion of the test.

## **Special Accommodations**

CNBT proctor will provide, upon request, reasonable accommodations including auxiliary aids and services necessary to afford an individual with a disability an equal opportunity to participate in all services, programs and activities. To request such accommodations, a written letter of request and supporting documentation must accompany the examination application.

## **During the Examination**

- Only Proctors and Authorized Candidates will be admitted into the examination room.
- Instructions will be provided before the exam begins. If you do not understand the instructions, ask for clarification.
- The examination is closed book, no study materials or notes allowed.
- No examinee may leave the room without a proctor's permission.
- Questions concerning the content of the exam can not and will not be answered by the proctor.
- If you need assistance during testing for any reason, a proctor will assist you.

## **Calculations**

The candidate will be provided a calculator and writing instrument by the proctor prior to the start of the examination. Personal calculators are not permitted for use or allowed at the candidates test station.

## **Use of Scratch Paper**

Scratch paper is not permitted on the test, nor may pages or parts of pages be torn from the test book. You may, however, use the blank spaces available in the section on which you are working for any notes or calculations you wish to make for answering a test question.

## **Completing Your Answer Sheet**

If you encounter any problems with the recording of your answers on the answer sheet, you should raise your hand immediately for assistance and report any problems to the proctor. After the test is completed, be sure to report any problems to the proctor or on your comment form. Be sure to record accurately your correct biographical data on your answer sheet. Answers recorded in the test book will not be scored. All selected ovals must be completely blackened. Do not make any stray marks on your answer sheet.

## **Test Timing**

The RCCP-SCF allows you 2.5 hours of testing with no breaks. Once time has been called, all pencils are to be put down and no more marks or erasures are to be made on the answer sheet. You must put down your pencil immediately when instructed by the proctor to do so. You must keep your test booklet and answer sheet flat on the writing surface where you are seated. Failure to follow any of the proctor's instructions may result in your dismissal from the test center and the initiation of misconduct or irregularity proceedings.

## **Official Time**

The official time will be kept by the proctor. The proctor will announce that one hour, thirty (30) minutes and five (5) minutes remain before the end. At the conclusion of the test, you may not leave until all test materials have been collected and accounted for.

## **Behavior During the Examination**

Examination proctors shall monitor all examinees during examinations.

Proctors ARE NOT authorized to answer questions from candidates regarding examination content or scoring.

Inappropriate behavior during testing may result in termination of testing and the candidate's examination being declared invalid.

Candidates suspected of cheating will be referred to the CETA Board of Directors for further investigation and possible invalidation of examination results.

## **Inappropriate Behavior**

Inappropriate behavior is any act or attempt to subvert the processes of application, testing, or certification as administered by CNBT. Inappropriate behavior may occur prior to, during, or following the administration of an examination. CETA/CNBT considers any inappropriate behavior a threat to the integrity of its examination and certification processes.

Anyone who has information or evidence that any inappropriate behavior might have occurred should submit a written report to CNBT providing a detailed description of the inappropriate behavior, including copies of any supporting documentation or other evidence. In so far as possible, such written reports will be treated as confidential. Proctors at a test site may receive reports of inappropriate behavior at any time during testing.

CNBT proctor may take the following actions for inappropriate behavior discovered prior to or during an examination:

- Not allow Candidate to sit and/or continue with the examination
- Invalidation of examination results of the Candidate

CNBT proctor may take the following actions for inappropriate behavior discovered after an examination has been completed but before examination results are mailed:

- Invalidation of examination results of the Candidate

CNBT committee may take the following actions for inappropriate behavior discovered subsequent to certification:

- Revoking of certification
- Not allow Candidate to sit for CNBT examinations in the future.

Depending upon the severity and scope of a candidate's inappropriate behavior, CETA may take appropriate legal action.

## **Violations of Test Center Procedures**

If you engage in any violation of test center procedures during the examination including, but not limited to, taking prohibited items into the testing room; creating a disturbance; cheating; working on or reading the test during a time not authorized by the proctor; removing test materials or notes from the testing room; failing to follow the directions of test center staff; using any prohibited items and devices or other offenses you will be given a warning and/or be dismissed from the test center, and will be subject to an CNBT misconduct investigation. Proctors will report to CNBT any violation of test center procedures that occurs during the administration. A copy of a violation notice will be given to the test taker and submitted to CNBT

## **V After the Examination**

### **Emergencies or Exemptions**

If you experience and can substantiate an emergency that prevents your attendance on the day of your scheduled exam, then you may be permitted to apply all examination fees to a future scheduled examination. All such instances must be submitted by written request to CNBT. In the event the next exam cycle would cause the applicant's accreditation to lapse, a nonstandard exam administration may be requested. CNBT will consider each request for nonstandard examination administration once all necessary documentation has been received. CNBT's decision to accommodate any individual's request remains at the sole discretion of CNBT.

Candidates who fail to appear for a scheduled examination will be given an examination score representing failure to appear, and that score will represent one of the candidate's opportunities for examination and the payment submitted will be forfeited.

### **Examination Cancellation/Refund Policy**

If a candidate must cancel their scheduled exam date(s), all submitted payments will be applied towards a future examination date less a processing fee. No refunds will be issued.

## **Application Denial and Appeal**

Applicants may not appeal examination qualification criteria. Applicants or candidates may appeal decisions of CNBT pertaining to score reports or eligibility determination. Appeals must be made within 30 working days of the receipt of notification from CNBT.

CNBT has established the following categories for which an application for examination may be refused or for which already credentialed individuals may be disciplined:

**Category A:** Failure to:

- 1) complete the application properly,
- 2) submit all necessary and appropriate fees as required,
- 3) supply supporting or additional information as requested,
- 4) sign and date the application, and
- 5) abide by application financial policies.

**Category B:** Obtain or attempt to obtain certification by fraud, deception or artifice; or knowingly assist another person or persons in attempting to obtain certification credentials by fraud, deception or artifice.

**Category C:** Illegal use of credentials, unauthorized possession and/or distribution of any official CNBT testing or examination materials to include copying and/or reproduction of any part of the CNBT examination questions.

**Category D:** Conduct deemed harmful to the public or inappropriate to the discipline and breach of examination or examination security prior to, during or after examination administration.

### **Grievance**

The grievance process may vary according to the infraction and the manner by which it comes to the CETA National Board of Testing (CNBT).

**Category A:** Such denials and issues shall be adjudicated by the CETA National Board of Testing (CNBT) during the application process. Routine communication and correspondence will occur until the issue is resolved to the satisfaction of the applicant and CETA/CNBT.

**Category B-D:** Procedures related to these infractions will be fully investigated and the applicant or candidate will receive written notification of the decision. Resolution of these issues will be the responsibility of the CETA National Board of Testing (CNBT).

## **Non-discrimination Policy**

CETA abides by all federal and state laws prohibiting discrimination solely on the basis of a person's race, color, creed, national origin, religion, age, sex, marital status or physical disability, except where a reasonable, bona fide occupational qualification exists. CETA policy prohibits racial or sexual harassment of any kind. This policy applies to all professionals requesting examination

## **Affidavit**

You will be required to sign the following affidavit at time of check-in on exam day.

### **Affidavit**

I agree to provide any additional information in connection with my application, as may be required by CETA. I agree to read and abide by the CNBT Sterile Compounding Facilities Policies, the educational requirements, pay renewal fees and retest in five years to maintain my RCCP-SCF credential.

I hereby release, discharge and exonerate CETA, its officers, directors and agents from any and all liability of any kind arising out of procedures or action of CETA's National Board of Testing (CNBT) in approving or disapproving applicants to its stated policies. I, the undersigned, being duly sworn, upon my oath depose and say that I am the person making the foregoing statements and that they are made in good faith and true in every respect. I further authorize CETA in its discretion, to request information concerning matters relevant to this application and my certification or recertification.

**Print Name** \_\_\_\_\_ **Date** \_\_\_\_\_