



2019 Candidate Handbook
for
Certification in Clinical Engineering
by the
Healthcare Technology Certification Commission

Program sponsored by the
American College of Clinical Engineering

Examination conducted by the
US Board of Examiners for Certification in Clinical Engineering
or the
Canadian Board of Examiners for Certification in Clinical Engineering

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Nov. 02 thru Nov. 16, 2019

¹ Testing site within the United States & Canada
² Testing site outside the United States & Canada

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Certification Program

The Healthcare Technology Certification Commission (Commission), the United States Board of Examiners for Certification in Clinical Engineering (US Board), and the Canadian Board of Examiners for Certification in Clinical Engineering (Canadian Board) endorse the concept of voluntary certification by examination for all clinical engineers and manage a program for certification in clinical engineering. Certification is one part of a process called credentialing. It focuses specifically on the individual and is an indication of current competence in a specialized area of engineering practice. Board certification in clinical engineering is highly valued and provides formal recognition of the knowledge base of clinical engineers.

Definition of Clinical Engineer

The Commission, US Board, and Canadian Board (Boards) have adopted the definition of a clinical engineer as set forth by the American College of Clinical Engineering (ACCE):

A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

Clinical engineers generally have backgrounds in engineering applied to the healthcare industry. They have completed a period of defined education in engineering or related disciplines, in addition to defined experience as practicing clinical engineers leading to mastery of a defined core of knowledge.

Purposes of Certification in Clinical Engineering

The purpose of certification is to promote healthcare delivery improvement through the certification and continuing assessment of competency of professionals who support and advance patient care by applying engineering and management skills to healthcare technology. The certification process includes:

1. Establishing and measuring the level of knowledge required for certification as a clinical engineer.
2. Providing a standard of knowledge requisite for certification; thereby assisting the employer, public, and members of the health professions in the assessment of the clinical engineer.
3. Recognizing formally those individuals who meet the eligibility requirements of the Boards and pass the Examination Certification for Clinical Engineering.
4. Requiring continued personal and professional growth in the practice of clinical engineering to maintain certification.

Certification Process

Certification in Clinical engineering is a three-step process: (1) application review by the Boards; (2) written examination; and (3) oral examination.

The application review consists of the assessment of information contained in the application in comparison to defined eligibility requirements, review and verification of college or university transcripts, and review of three references that attest to the candidate's clinical engineering experience and abilities. All exams and communication for the certification process will be conducted in American English.

Eligibility Requirements

To be eligible for certification in clinical engineering a candidate must hold appropriate professional or educational credentials and have achieved the associated levels of engineering and clinical engineering practice shown in the tables below. Years of engineering and/or clinical engineering practice must be met at time of application.

For U.S./International candidates, one (or more) of the following options:

Option	Professional Credentials Educational Credentials	Engineering Experience ^A Clinical Engineering Experience ^B
1	Licensure in the United States as a Professional Engineer (PE) ^C	3 or more years of clinical engineering practice ^{E,F}
2	BS or higher degree in engineering (EAC/ABET accredited program) ^D	4 or more years of engineering practice, including 3 or more years of clinical engineering practice ^{E,F}
3	BSET degree in engineering technology (TAC/ABET accredited program) ^D	8 or more years of engineering practice, including 3 or more years of clinical engineering practice ^{E,F}

For Canadian candidates:

Professional Credentials Educational Credentials	Engineering Experience ^A Clinical Engineering Experience ^B
Licensure as a Professional Engineer in the province in which the candidate practice	3 or more years of clinical engineering practice ^F

A. For purposes of eligibility, “engineering practice” is defined as “any service or creative work, the adequate performance of which requires engineering education, training, and experience in the application of special knowledge of the mathematical, physical, and engineering sciences to such services or creative work in consultation, investigation, expert technical testimony, evaluation, planning, design and design coordination of engineering works and systems, planning the use of land and water, teaching of advanced engineering subjects, performing engineering surveys and studies, and the review of construction for the purpose of monitoring compliance with drawings and specifications; any of which embraces such services or work, either public or private, in connection with any utilities, structures, buildings, machines, equipment, processes, work systems, projects, and industrial or consumer products, or equipment of a control systems, communications, mechanical, electrical, hydraulic, pneumatic or thermal nature, insofar as they involve safeguarding life, health, or property, and including such other professional services as may be necessary to the planning, progress, and completion of any engineering services” (NCEES Model Law, revised August 1999, National Council of Examiners for Engineers and Surveying).

The Boards may accept the following as representing up to two years of engineering practice each:

- *Serving on the teaching staff of, and teaching advanced engineering subjects for, an academic institution providing engineering degrees at or above the BS level.*

- *MS or higher degree in engineering.*
- B. For purposes of eligibility, “clinical engineering practice” is defined as engineering practice (defined above) within the clinical environment (the healthcare delivery system) or in support of clinical activities (healthcare delivery and patient care). The Boards shall refer to the current ACCE definition of clinical engineering, which states “A clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology”. This definition is discussed further in the next section. The Boards shall distinguish clinical engineering practice from technician-level activities such as routine assembly, installation, testing, and maintenance of medical equipment.
- C. The US Board may accept equivalent professional engineering licensure from countries other than the United States. The cost (if any) required to establish equivalency shall be paid by the applicant.
- D. The US Board may accept degrees from programs in the United States that are accredited by other agencies or are unaccredited. The cost (if any) required to establish equivalency shall be paid by the applicant.
- E. The US Board may accept equivalent degrees from countries other than the United States. The cost (if any) required to establish equivalency shall be paid by the applicant.
- F. The Boards shall require applicants to provide clear evidence of engineering practice and clinical engineering practice. This evidence shall be verified by written statements from professional colleagues who have direct knowledge of the applicants’ professional activities.

For purposes of eligibility, “clinical engineering practice” is considered to be “engineering practice.” Therefore, an applicant’s time in clinical engineering practice shall be applied toward the engineering requirement (in options 2 and 3) *and* the three-year clinical engineering experience requirement (in all options). An applicant’s time in engineering practice other than clinical engineering shall be applied only toward the engineering experience requirement (options 2 and 3).

Application Procedure

To obtain additional Handbooks for Candidates and Applications for the Examination for Certification in Clinical Engineering contact the Healthcare Technology Certification Commission, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298 or call (610) 567-1240 or e-mail the CCE secretariat at certification@accenet.org or visit our website at <http://accenet.org/CECertification/Pages/Default.aspx>

Read and follow the directions on the Application and in this Handbook for Candidates.

The completed application with the appropriate fee and the required documentation **must be received by the board by the application deadline. Please ensure your application is signed and dated.** Transcripts must be mailed directly from the College or University. **Your references must email the completed form *directly* to the Healthcare Technology Certification Commission. Reference statements received from the candidate will not be accepted and can further delay the application review process.** Email the application and required documentation to: certification@accenet.org

NOTE: Applications received after the application deadline CANNOT be considered for the upcoming examination.

The Commission will notify the applicant of his/her eligibility status within 1 month prior to the scheduled examination. Any applicant deemed ineligible may appeal this decision in writing to the Commission.

Exam Administration

Written Examination

The Certification Program is sponsored by the American College of Clinical Engineering and managed by the Healthcare Technology Certification Commission. The Examination for Certification in Clinical Engineering is administered for the Commission by the Professional Testing Corporation (PTC), 1350 Broadway - Suite 800, New York, New York 10018, (212) 356-0660, www.ptcny.com. The Examination is available during a two-week testing period on a daily basis, Monday through Saturday, excluding holidays, at computer-based testing facilities managed by PSI. PSI has several hundred testing sites in the United States as well as Canada. Scheduling is done on a first-come first-serve basis. To find a testing center near you, visit <http://www.ptcny.com/cbt/sites.htm> or call PTC at (212) 356-0660. Please note: hours and days of availability vary at different centers. You will not be able to schedule your examination appointment until you have received an email from notices@ptcny.com with your Scheduling Authorization

The written examination consists of 150 multiple choice questions with 4 hours of allotted time. For Canadian candidates, written exams questions specific to US standards and regulations will be removed from the evaluation.

TESTING SOFTWARE DEMONSTRATION

A Testing Software Demonstration can be viewed online.

- Go to <http://www.ptcny.com/cbt/demo.htm>

This online Testing Software Demonstration can give you an idea about the features of the testing software.

Oral Examination

1. The oral examination can be arranged once the written exam is passed.
2. The objective of the examination is to assess candidate's oral presentation of clinical engineering ideas in an organized and professional manner as well as their application of practical knowledge to solve problems.
3. For a more detailed explanation of the Oral examination process refer to pages 12-13.

Scheduling Your Examination Appointment

Written Exam

Within six weeks prior to the first day of the testing period, you will be emailed a Scheduling Authorization from notices@ptcny.com. If you do not receive this email with your Scheduling Authorization at least three weeks before the beginning of the testing period, contact the Professional Testing Corporation by telephone at (212) 356-0660 for a duplicate.

The Scheduling Authorization will indicate how to schedule your examination appointment as well as the dates when testing is available. Appointment times are first-come, first-serve, so schedule your appointment as soon as you receive your Scheduling Authorization in order to maximize your chance of testing at your preferred location and on your preferred date.

It is your responsibility as the candidate to schedule the examination appointment.

It is highly recommended that you become familiar with the testing site.

Arrival at the testing site at the appointed time is the responsibility of the candidate. Please plan for weather, traffic, parking, and any security requirements that are specific to the testing location. Late arrival may prevent you from testing.

After you make your test appointment, PSI (PSI Services, LLC, www.psonline.com) will send you a confirmation email with the date, time and location of your exam. Please check this confirmation carefully for the correct date, time and location. Contact PSI at (833)207-1288 if you do not receive this confirmation or if there is an error.

Oral Exam

To schedule the oral exam please contact the HTCC Secretariat via email, certification@accenet.org. The oral examination will be offered at no charge at professional meetings where two Board members are in attendance. Oral examination times will be scheduled with each individual candidate. Late comers may be admitted to the examination at the discretion of the examiner but examination times will not be extended such that later oral examination schedules are affected.

Requests for International Special Testing Centers

Written Exam - International Testing

Candidates outside of the United States and Canada must complete and submit the Request for International Special Test Center Form found on the www.ptcny.com homepage. This form must be uploaded to your application no later than 8 weeks prior to the start of the chosen testing period. Fees for testing at an international computer test center (outside of the United States and Canada) are \$100.00 in addition to the examination fee. PTC will arrange a computer-based examination at an international test center for you.

Special Needs Individuals:

Special testing arrangements will be made for individuals with special needs. Submit the Application, Examination Fee, and a completed and signed Request for Special Accommodations Form, available from www.ptcny.com or by calling PTC at (212) 356-0660. Requests for special testing for individuals with special needs must be received at least EIGHT weeks before the testing date. Please notify PTC at least two weeks prior to your examination appointment if you need to bring a service dog, medicine, food, or beverages needed for a medical condition with you to the test center.

Oral Exam

For testing at other sites or times beyond professional meetings, the candidate is responsible for associated travel costs for the Examiners and conference room fees. Efforts will be made to arrange testing locations to minimize the cost to the applicant.

Changing Your Examination Appointment

Written Exam

If you need to cancel your examination appointment or reschedule to a different date within the two-week testing period, you must contact PSI at (833) 207-1288 no later than noon, Eastern Standard Time, of the second business day PRIOR to your scheduled appointment.

Oral Exam

If you need to cancel your examination appointment or reschedule to a different date, you must contact the HTCC Secretariat by email, certification@accenet.org.

Rules for the Examinations

Written Examination Rules

1. All electronic devices that can be used to record, transmit, receive or play back audio, photographic, text or video content, including but not limited to: cell phones, Bluetooth type devices, MP3 players (iPods), cameras, and voice recorders, laptop computers, and tablets cannot be used during the examination and must be turned off. All types of watches and Fitbit type devices cannot be worn during your examination. We suggest that you do not bring them with you to the test center. Please do not bring any other items with you to the test center, other than what is needed for your examination.
2. No papers, books or reference materials may be taken into or removed from the testing room.
3. Simple, nonprogrammable calculators are permitted. A calculator is also available on screen if needed.
4. No questions concerning content of the examination may be asked during the examination session. The candidate should read carefully the directions that are provided on screen at the beginning of the examination session.
5. You must present your current driver's license, passport or U.S. military ID at the test center. Temporary paper copies of driver's license WILL NOT be accepted.
6. Candidates are prohibited from leaving the room while their exam is in session, with the sole exception of using the restroom.
7. Bulky clothing, such as sweatshirts (hoodies), jackets, coats and hats, except hats/head coverings worn for religious reasons, may not be worn while taking the examination.

Oral Examination Rules

1. The candidate is encouraged to bring a pen or pencil to the examination site.
2. All electronic devices that can be used to record, transmit, receive or play back audio, photographic, text or video content, including but not limited to: cell phones, Bluetooth type devices, MP3 players (iPods), cameras, and voice recorders, laptop computers, tablets and wearable tech gear such as smart watches, cannot be used during the examination and must be turned off. Please do not bring any other items with you to the test center, other than what is needed for your examination.
3. No papers, books or reference materials may be taken into nor removed from the testing room.
4. All other materials and belongings may enter the examination site but must be left at the door.
5. Paper will be provided to the candidate in the examination site and will be left in the examination site upon exam completion.

Admission to Testing

Oral examination times will be scheduled with each individual candidate. Late comers may be admitted to the examination at the discretion of the examiner but examination times will not be extended such that later oral examination schedules are affected. Additionally, positive photo identification must be presented

Report of Results

Candidates will be notified within eight weeks whether they have passed or failed the written examination. Scores on the major areas of the examination and on the total examination will be reported. Successful candidates will be permitted to take the oral examination leading to certification.

Reexamination

An applicant who is approved to take the written exam must take the exam within two years of the original notification of eligibility for the written exam. If an applicant does not pass the written or the oral examination, one retest will be allowed under the current application. If the applicant does not pass the written examination, one retest is allowed after a six-month waiting period but before 2 years from the date of the initial examination. There is an additional written examination fee for retesting the written examination. If the applicant does not pass the oral examination, one retest is allowed after a period of one year, but before 3 years of the date of original notification of eligibility for the written examination. There is an additional fee for retesting the oral examination.

Appeals Process

The Appeals Committee of the United States Board of Examiners for Certification in Clinical Engineering, the Canadian Board of Examiners for Certification in Clinical Engineering and the Healthcare Technology Certification Commission provides the appeal mechanism. It is the responsibility of the individual to initiate this process. Please submit your letter of appeal to the CCE Secretariat at certification@accenet.org within 60 days of receiving written notification from the Commission regarding the status of your application review.

Attainment of Certification and Renewal

A registry of individuals certified in Clinical Engineering is maintained by the Commission and is posted on its website at <http://accenet.org/CECertification/Pages/Default.aspx>. Persons who take and pass the examination acknowledge and agree that their names will be posted on the website.

Certification in Clinical engineering is for a period of three years at which time the candidate must demonstrate continuing practice or development as a clinical engineer. After three years, renewal is required to continue to be certified in clinical engineering. It is the responsibility of the certificant to keep track of their renewal date and notify ACCE/HTCC of any change in contact information (certification@accenet.org).

Revocation of Certification

Certification will be revoked for any of the following reasons:

1. Falsification of an Application.
2. Misrepresentation of certification status.
3. Other activity deemed by the Board or Commission to be contrary to the Purposes of Certification in Clinical Engineering

Fees

1. Application fee for the Examination for Certification in Clinical Engineering\$475
2. Retesting fee for applicants that fail the written examination.....\$175
3. Retesting fee for applicants who fail the oral exam.....\$150
4. International Special Testing Center Fee\$100

NOTE: Pay the International Special Testing Center Fee ONLY if you are requesting to test outside the U.S. and Canada

5. Fees for determining professional licensure or educational equivalency (if necessary) will be passed along to the candidate at prevailing market rates. The candidate will be notified of the estimated extra fee eight (8) weeks in advance of the examination to allow the applicant to authorize activity and to allow the Board, Commission, and PTC to coordinate application and testing processes.

MAKE CHECK OR MONEY ORDER PAYABLE TO:

ACCE

Visa, MasterCard, Discover, and American Express are accepted online securely through PayPal®. Please visit our website at <http://accenet.org/CECertification/Pages/Default.aspx> to submit payment.

The oral examination will be offered at no charge at professional meetings where two Board members are in attendance. For testing at other sites or times, the candidate is responsible for associated travel costs for the Examiners and conference room fees. Efforts will be made to arrange testing locations to minimize the cost to the applicant.

Refunds

Applicants found ineligible for testing will be refunded \$325.00.

Applicants that fail the examination are not entitled to a refund.

Special Testing Center Fees will NOT be refunded. Fees will NOT be transferred to another testing date.

Confidentiality

1. The Commission will release the individual test scores ONLY to the individual candidate.
2. Any questions concerning test results should be referred to the Commission or the Professional Testing Corporation.
3. Any questions concerning the oral test results should be referred to the Commission.

Content of Examination

Written Examination

1. The Examination for Certification in Clinical Engineering is a written examination composed of a maximum of 150 multiple-choice, objective questions with a total testing time of four (4) hours.
2. The content for the examination is described in the below and sample written examination questions are in the following section. The content for both examinations is based on a “body of knowledge” survey that is periodically performed by ACCE to determine the current knowledge and skill sets needed for competent clinical engineering practice.
3. The Board, with the advice and assistance of the Professional Testing Corporation, prepares the written examination using questions developed and reviewed by the Board for construction, accuracy and appropriateness.
4. The questions for the written examination are also obtained from practicing clinical engineers and are reviewed for construction, accuracy, and appropriateness by the Board.
5. The distribution of questions in the written examination for Certification in Clinical Engineering will be weighted in approximately the following manner:

I.	Technology Management.....	31.7 %
II.	Service Delivery Management.....	19.9 %
III.	Product Development, Testing, Evaluation, & Modification	4.3 %
IV.	IT / Telecom	6.8 %
V.	Education of Others	8.0 %
VI.	Facilities Management.....	5.7 %
VII.	Risk Management / Safety	10.2 %
VIII.	General Management.....	13.4%
IX.	Other	0 %
6. Some sections of the written examination may include questions on basic underlying knowledge including ones from anatomy, physiology, and the management and engineering sciences (see outline on pages 14-15)

Oral Examination

1. Following notification of successful completion of the written examination, applicants will be contacted to schedule the oral examination.
2. The objective of the examination is to assess candidate’s oral presentation of clinical engineering ideas in an organized and professional manner as well as their application of practical knowledge to solve problems.
3. The oral examination for US candidates will consist of questions related to three clinical engineering scenarios. The oral examination for Canadian candidates will include a fourth scenario that relates to Canadian codes and standards.
4. For the United States examination, 75% of the score will be based on information from the candidate’s responses, and 25% will be based on based on verbal presentation of clinical engineering ideas in an organized and professional manner.
5. The scenarios will be presented in writing. Candidates will be given a period of time to collect their thoughts about each scenario before being questioned by the examiners. This period is 30 minutes for the U.S. exam and 40 minutes for the Canadian exam. The review time may be used to make notes regarding all scenarios.
7. A series of 5-7 questions for each scenario will then be asked orally by the examiners. The candidate will have 20 minutes per scenario to answer the questions pertaining to that scenario.

8. Candidates may request for questions to be repeated while answering that question. Questions will not be rephrased or expanded upon.
9. Examiners can only repeat the question; they cannot expand on or request the candidate to clarify their answers.
10. If the candidate completes a scenario's examination session before the 20 minute allotted time, the remaining additional time will not be extended to any of the remaining examination times. Candidates are encouraged to manage their time wisely and take all the time available for each scenario to present comprehensive answers to the questions.
11. Examiners will take notes during the candidate's responses and may take up to 5 minutes to compile their comments. After that the process will repeat for the remaining scenarios.

Content Outline

- I. Technology Management
 - A. Product Selection / Vendor Selection
 - B. Technology Assessment
 - C. Project Management
 - D. Capital Planning
 - E. Interpretation of Codes and Standards
 - F. Usability/Compatibility Assessment
 - G. Healthcare Technology Strategic Planning
 - H. Clinical Device Use and/or Application
 - I. Device/System Upgrade Planning
 - J. Device Integration Planning
 - K. Clinical Systems Networking
 - L. Life Cycle Analysis
 - M. Coordinating Device Interoperability/Interfacing
 - N. Other Technology Management Responsibilities
 - O. Return on Investment (ROI) Analysis
 - P. EMI/RFI Management
 - Q. Pre-clinical Procedure Set-up/Testing
 - R. Clinical Trials Management (Non-investigational)
 - S. Water Quality Management
 - T. Participation in Clinical Procedures (e.g., surgery)
- II. Service Delivery Management
 - A. Technician / Service Supervision
 - B. Equipment Repair and Maintenance
 - C. Equipment Acceptance
 - D. Service Contract Management
 - E. Equipment Performance Testing
 - F. Maintenance Software (CMMS) Administration
 - G. Develop Test/Calibration/Maintenance Procedures
 - H. Parts/Supplies Purchase and/or Inventory Management
 - I. Other Service Delivery Responsibilities
 - J. Technical Library / Service Manuals Management
- III. Product Development, Testing, Evaluation, & Regulatory Compliance
 - A. Regulatory Compliance Activities
 - B. New Product Testing & Evaluation
 - C. Documentation Development/Management
 - D. Human Factors Engineering
 - E. Product/Systems Quality Management
 - F. Device Modifications
 - G. Medical Device Design
 - H. Product Research and Development
 - I. Medical Device Concept Development/Invention
 - J. Other Product Development Responsibilities
 - K. Product Sales/Sales Support
- IV. IT / Telecom
 - A. Integration of Medical Device Data
 - B. Information Technology (IT) Management
 - C. Help Desk / Dispatching / Call Tracking
 - D. Other IT / Telecommunications Responsibilities
 - E. Telecommunications Management
 - F. Installation Management
 - G. Configuration and Change Management
 - H. ISO/IEC 80001 (Risk Management of Medical Devices on a Network)
 - I. Continuity and Capacity Management
 - J. ISO/IEC 20000 (Information Technology Service Management – ITSM)
 - K. Release Management
 - L. ITIL (Information Technology Infrastructure Library)
- V. Education of Others
 - A. Technician Education
 - B. Device User / Nurse Training
 - C. Develop/Manage Staff Training Plan
 - D. Engineering Education
 - E. Other Education Responsibilities
 - F. International Healthcare Technology Management
- VI. Facilities Management
 - A. Facility Emergency Preparedness Activities
 - B. Emergency Electrical Power
 - C. Building Plan Review
 - D. Medical Gas System Testing
 - E. Building Design
 - F. Other Facility Management Responsibilities
 - G. Facility/Utility Remediation Planning
 - H. Supervise/Manage/Direct Facilities Management

VII. Risk Management / Safety

- A. Patient Safety
- B. Product Safety / Hazard Alerts / Recalls
- C. Incident / Untoward Event Investigation
- D. Engineering Assessment of Medical Device Failures
- E. Risk Management
- F. Root Cause Analysis
- G. Medical Device Incident Reporting (SMDA)
- H. Infection Control
- I. Failure Mode and Effect Analysis
- J. Workplace Safety Practices (OSHA)
- K. Fire Protection/Safety (Life Safety Code)
- L. Radiation Safety
- M. Hazardous Materials
- N. Industrial Hygiene
- O. Other Risk Management / Safety Responsibilities
- P. Expert Witness
- Q. Investigational Research (Human Use)
- R. Forensic Investigations

VIII. General Management

- A. Budget Development/Execution
- B. Personnel Management/Supervision
- C. Staffing
- D. Staff Skills / Competency Assessment
- E. Policy/Procedure Management/Development
- F. Performance Improvement / CQI
- G. Business/Operation Plan Development/Management
- H. Committee Management
- I. Other General Management Activities
- J. Revenue Producing Activities

IX. Other

References

For examination preparation, applicants are encouraged to review standards, publications, and journals that are normally referenced in clinical engineering practice, such as the Safe Medical Devices Act, NFPA99, JCAHO guidelines, and the Journal of Clinical Engineering. Additionally, any general text dealing with the subject matter contained in the content outline is appropriate.