



2011 Candidate Handbook

for

Certification in Clinical Engineering

by the

Healthcare Technology Certification Commission

Program sponsored by the

Healthcare Technology Foundation

Examination conducted by the

US Board of Examiners for Clinical Engineering Certification

5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Phone: 610-567-1240
Fax: 815-642-0658
E-mail: certification@thehtf.org

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November 5, 2011

¹ Testing site within the United States & Canada

² Testing site outside the United States & Canada



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Table of Contents

Certification Program	p. 3
Definition of Clinical Engineer	p. 3
Purposes of Clinical Engineering Certification	P. 3
Certification Process	p. 3
Appeals Process	p. 4
Eligibility Requirements	p. 4
Administration	p. 5
Attainment of Certification and Renewal	p. 5
Revocation of Certification	p. 6
Application Procedure	p. 6
Regional Testing Center Information	p. 7
Requests for Special Testing Centers	p. 7
Fees	p. 8
Refunds	p. 8
Schedule for Written & Oral Examination	p. 9
Rules for the Examination	p. 9
Admission to Testing	p. 10
Report of Results	p. 10
Confidentiality	p. 10
Content of Examination	p. 11
Content Outline	p. 12
Sample Questions	p. 13
References	p. 14

Certification Program

The Healthcare Technology Certification Commission (Commission) and United States Board of Examiners for Clinical Engineering Certification (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* and Board 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 Clinical Engineering Certification

The purpose of certification is to promote healthcare delivery improvement in the United States 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 Board 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

Clinical engineering certification is a three-step process: (1) application review by the US Board of Examiners for Clinical Engineering Certification; (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.

The written examination consists of 150 multiple choice questions with 3 hours of allotted time.

The oral examination consists of 3 questions with 1 3/4 hours of allotted time. The written examination must be passed before taking the oral examination.

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.

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 for one (or more) of the five options shown in the table below.

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 ^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 ^F
4	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 ^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 United States Board of Examiners for Clinical Engineering Certification (the Board) 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 Board 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 Board shall distinguish clinical engineering practice from technician-level activities such as routine assembly, installation, testing, and maintenance of medical equipment.
- C. The 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 Board may accept degrees from programs in the United States that are accredited by other agencies or are unaccredited. To confirm the school’s accreditation, please visit www.abet.org. The cost (if any) required to establish equivalency shall be paid by the applicant.
- The 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.
- E. The Board 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&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&3).

Administration

The Certification Program is sponsored by the Healthcare Technology Foundation 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 - 17th Floor, New York, New York 10018, (212) 356-0660, www.ptcny.com. Questions concerning the examination should be referred to the Secretariat of the Commission at (610) 825-6067 or by e-mail at Secretariat@thehtf.org

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 www.thehtf.org/certification. Persons who take and pass the examination acknowledge and agree that their names will be posted on the website.

Clinical engineering certification 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.

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.

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 secretariat at certification@thehtf.org or visit our website at <http://www.thehtf.org/certification>

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 secretariat by the application deadline. Transcripts must be mailed directly from the College or University. Confidential reference statements must be mailed directly from the reference. Mail the application and required documentation to:

Healthcare Technology Certification Commission
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

NOTE: Applications received after the application deadline can NOT 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.

Regional Testing Center Information

The following areas will serve as testing centers for the examination on **November 5, 2011**. Indicate your choice of center on your Application in the space provided.

ARKANSAS

234 – Little Rock

CALIFORNIA

255 – Los Angeles area

262 – San Francisco area

COLORADO

276 – Denver area

FLORIDA

313 – Orlando

GEORGIA

334 – Savannah

ILLINOIS

368 – Chicago

INDIANA

388 – Indianapolis

IOWA

405 – Des Moines

KENTUCKY

434 – Lexington

LOUISIANA

452 – New Orleans

MARYLAND

477 – College Park

MASSACHUSETTS

486 – Boston

MICHIGAN

508 – Detroit area

MINNESOTA

534 – Minneapolis

MISSOURI

566 – St. Louis

NEBRASKA

594 – Lincoln

NEVADA

607 – Las Vegas

NEW YORK

668 – New York City

NORTH CAROLINA

703 – Greensboro

OHIO

732 – Columbus

PENNSYLVANIA

788 – Philadelphia

SOUTH CAROLINA

823 – Columbia

TENNESSEE

851 – Memphis

TEXAS

890 – San Antonio

892 – Ft. Worth

VIRGINIA

912 – Richmond

WASHINGTON

929 – Spokane

WISCONSIN

962 – Madison

NOTE: Requests for change of testing center location must be received **SEVEN** weeks before the testing date.

Requests for Special Testing Centers

1. Distance:

If a candidate lives over 500 miles from an established testing center, arrangements for a special testing center may be possible for an additional fee of \$150 USD. Arrangements can be made for a special testing center outside the United States and Canada for an additional fee of \$250 USD. A written request must accompany the candidate's application specifying the preferred test center and must be received by the application deadline.

2. Sunday:

Sunday testing is permitted **ONLY** for those candidates submitting satisfactory evidence that their religious convictions prevent them from taking the examination on Saturday. The Special Testing Center Fee is not required for Sunday Testing. Requests for Sunday Testing must be made in writing at the time the Application is submitted, and must be received by the application deadline.

3. Special Needs Individuals:

Special testing arrangements may be made for special needs individuals submitting the Application, examination fee, and a letter describing the nature of the disability and the special accommodations needed for testing. Requests for special testing needs individuals must be received by the application deadline.

4. Groups:

Groups of ten or more candidates may request a special group testing center **PROVIDED** all ten Applications and fees are sent in one group and received by the application deadline. The Special Testing Center Fee is **NOT** required for candidates requesting special group testing centers.

Fees

Note: All fees are listed in US Dollars (USD)

1. Application fee for the Examination for Certification in Clinical Engineers.....\$450
2. Retesting fee for applicants that fail the written examination.....\$175
3. Retesting fee for applicants who fail the oral exam.....\$150
4. Special Testing Center Fee (test sites in the US).....\$150
5. Special Testing Center Fee (international test sites).....\$250

NOTE: Pay the Special Testing Center Fee ONLY if a special testing center for distance is being requested. See Special Testing Center instructions on page 7.

6. 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:

Healthcare Technology Certification Commission

Visa, MasterCard, Discover, and American Express are accepted online securely through PayPal®. Please visit our website at <http://www.thehtf.org/certification> 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.

Schedule for Written & Oral Examination

The following schedule will be observed at all testing centers (testing center local time):

8:30 A.M. - Report to testing center

9:00 A.M. - Examination begins

1:00 P.M. - Examination ends (approximate)

All candidates should report to their assigned centers at 8:30 A.M. on the examination date. Latecomers may be admitted to the examination at the discretion of the examiner but will NOT be permitted to write beyond the time scheduled for completion of the examination.

Oral examination times will be scheduled with each individual candidate. Latecomers 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.

Rules for the Examination

Written Examination Rules

1. Candidates must bring several sharpened Number 2 pencils with erasers with them to the testing center.
2. Simple calculators are permitted, but no personal digital assistants, books, or other reference materials may be taken into the examination room. Calculators must be small (hand-held or smaller), noiseless, cordless, and tapeless, and must have no printing capability, expansion capability, or alphanumeric keyboards or displays. Calculators' make and model numbers must be registered at the time of application.
3. No signaling devices, including pagers, cellular phones, and alarms, may be operative during the examination.
4. Scrap paper for calculations will be included as part of the test booklet.
5. No test materials, documents, or memoranda of any sort are to be taken from the examination room.
6. The examination will be held only on the day and at the time scheduled.
7. No questions concerning content of the examination may be asked during the testing period. The candidate should listen carefully to the instructions given by the Examiner and should read carefully directions in the test booklet.
8. Payment of required fee.

Oral Examination Rules

1. The candidate is encouraged to bring a pen or pencil to the examination site.
2. All other materials and belongings may enter the examination site but must be left at the door.
3. 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

The Professional Testing Corporation will notify candidates approximately three weeks before the testing date of final assignments for testing centers by means of an Admission Notice showing exact address to which candidates should report.

This Admission Notice **PLUS** positive photo identification must be presented in order to gain admission to the testing center. A candidate not receiving an Admission Notice at least one week before the test date should contact the Professional Testing Corporation by telephone at (212) 356-0660.

Positive photo identification must be presented in order to gain admission to the testing center for the oral examination.

Changes in assignments to testing centers inside or outside the United States **CANNOT** be made later than **SEVEN (7)** weeks before the examination date.

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 have passed the written exam will be permitted to take the oral examination leading to certification.

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

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 three (3) 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 questions for the oral examination are developed by the Board.
6. The distribution of questions in the written examination for Certification in Clinical Engineering will be weighted in approximately the following manner:

I.	Technology Management.....	32 %
II.	Service Delivery Management.....	17 %
III.	Product Development, Testing, Evaluation, & Modification	5 %
IV.	IT / Telecom	8 %
V.	Education of Others	10 %
VI.	Facilities Management.....	5 %
VII.	Risk Management / Safety	11 %
VIII.	General Management.....	11 %
IX.	Other	1 %
7. 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 below)
8. Following notification of successful completion of the written examination, applicants will be contacted within approximately a month to schedule the oral examination.
9. The oral examination will consist of questions related to three clinical engineering situations. Scenarios for each question will be presented in writing. A series of questions will then be asked orally by the examiners. Follow-up questions may also be asked.

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
- 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

Sample Examination Questions

1. Capnography measures which of the following?
 1. Blood SaO₂
 2. Heart rate
 3. Airway CO₂
 4. Tidal volume

2. Which of the following NFPA codes deals the most directly with hospital electrical distribution systems?
 1. NFPA 70
 2. NFPA 99
 3. NFPA 110
 4. NFPA 517

3. If an infant patient monitored on an apnea/ECG monitor suffers a 10-second period of obstructive apnea, which of the following is characteristic?
 1. The monitor will yield a false positive alarm
 2. The monitor will yield a false negative alarm
 3. The ECG will show a large change within the 10-second period of apnea
 4. The obstructive apnea may go undetected by a transthoracic impedance monitor

4. Which of the following is the standard format for exchange of digital radiographic images in a PACS system?
 1. JPEG
 2. HTML
 3. DICOM
 4. IEEE 802.11

CORRECT ANSWERS TO SAMPLE QUESTIONS:

1.3; 2.2; 3.4; 4.3

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