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Certification in the United States, Canada and Asia

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CERTIFIED BIOMEDICAL EQUIPMENT TECHNICIANS

The first certification in the US in the clinical engineering field was for biomedical equipment technicians (BMETs).¹⁻⁴ As biomedical equipment maintenance was developing in US hospitals in the late 1960s, there were no training programs for BMETs. A few 2-year technical schools initiated training programs based on their electronics curriculum, but there was no standardized curriculum. Even the electronic programs in these schools were not accredited nor had a standard electronic curriculum. There were also BMETs that had been trained in the military.

The Association for the Advancement of Medical Instrumentation (AAMI) had a task force to look at the BMET field and the maintenance of medical equipment in hospitals. The task force decided that something needed to be done to allow BMETs to demonstrate that they had a minimum level of expertise. Certification of BMETs became the tool to demonstrate this minimum level of expertise. A Board of Examiners was established by AAMI and the first exam was given in 1970. Individuals who passed the written exam became Certified Biomedical Equipment Technicians (CBETs).

Certification was not readily accepted by BMETs or by the institutions hiring them. There also was an issue of testing sites and dates to allow BMETs to readily be tested without considerable travel expenses.

The Department of Veterans Affairs (VA) wanted to have its BMETs certified, but funds were not available to provide travel for them to go to the AAMI meeting for testing. In 1973, the VA developed its own BMET certification program from its Engineering Training Center.⁵ The requirements to take the exam were the same as the

AAMI and the exam was similar since the director of the VA Training Center was on the AAMI Board of Examiners. The VA used the Human Resources Department at each hospital as a testing site since they were approved for giving other exams. The VA exam was developed by the VA Training Center faculty. In the VA, the technicians are called biomedical engineering technicians which is still BMET.

AAMI found a need to develop specialist exams for BMETs who worked on laboratory and radiological equipment. These BMETs might not be able to pass the general exam since they only worked on special equipment, but they need certification to demonstrate a minimum level of expertise in their specialty. AAMI developed specialty exams in these two areas and individuals that passed these exams became Certified Radiological Equipment Specialists (CRESSs) and Clinical Laboratory Equipment Specialists (CLESSs). These three certification programs still exist today.

The VA also found the need to establish the radiological specialty certification program and CRES. In 1984-5, the VA merged its certification program with the AAMI program. All VA certifications were accepted by the AAMI program and the VA allowed its Human Resources Offices to be used to give AAMI certification exams.

Individuals must meet the following qualifications to take the AAMI BMET certification exam:

- Associate's degree in biomedical equipment technology program and two years' full-time
- BMET work experience; OR
- Completion of a U.S. military biomedical equipment technology program and two years' full-time BMET work experience; OR

- Associate's degree in electronics technology and three years' full-time BMET work experience; OR
- Four years' full-time BMET work experience

The exam can be taken if a person has an associate degree in BMET or two-years' experience full time as a BMET. If they pass the exam, they have five years to complete the additional 2 years of full-time experience as a BMET to be certified. To take the CRES or CLES exam, a person must have worked at least 40% of the time in the past two years or 25% of the time in the past five years in the designated specialty area.

Each of the AAMI exams is 165 multiple-choice questions and is administered by a professional testing organization. The Board of Examiners creates questions for the exam bank and reviews new exams before they are used. The professional testing organization has responsibility for the exam security.

In the AAMI certification program over 3000 are CBETs, about 600 CRESs and around 100 CLESs. Every three years, individuals must renew their certification by demonstrating a certain amount of continuing education to be maintained as a CBET, CRES or CLES. Most of the CBETs are in the United States, but BMETs in several other countries have taken the exam and become CBETs.

AAMI has placed all of their certification programs in their AAMI Credentials Institute (ACI). In 2016 the CBET, CLES and CRES became ANSI accredited under ISO/IEC 17024 Personnel Certification.

Electronics Technicians Association International (ETA) also certifies BMET as both general medical equipment and radiological equipment technicians. They must be certified as Certified Electronics Technicians (CET) before they can take the journeyman certification exams. With six or more years of training and work experience in the field, the CET can take the journeyman exam. They must score 85% on the journeyman exam to be certified.⁶ If they pass the journeyman certification exam for medical equipment, they become CET-BMD. By passing the journeyman certification exam for radiological equipment, they become CET-BIET.⁷ Their programs are aligned with the ISO/IEC 17024 standards "*Conformity assessment – General requirements for bodies operating certification of persons*"

CERTIFIED HEALTHCARE TECHNOLOGY MANAGER (CHTM)

In 2015, the AAMI Credentials Institute (ACI) initiated the Certified Healthcare Technology Manager (CHTM) program.⁸ ACI defines a CHTM as

"The healthcare technology manager is a person responsible for planning and directing activities of other healthcare technology management professionals, monitoring their work, and taking corrective actions when necessary. This HTM certification covers two major areas in healthcare technology management: the management of healthcare technology operations; and, the management of personnel. The functions of the manager are to include the participation in the "leadership" of the business enterprise. The manager is also expected to have the skills and understanding needed to perform strategic, business, and change management as well as employee relation."

This certification is not currently ANSI accredited.

Individuals interested in pursuing the CHTM designation must meet one of the following paths to be eligible for the program.

Path 1: A current certification as a clinical engineer (CCE), biomedical equipment technician (CBET), radiology equipment specialist (CRES), or a laboratory equipment specialist (CLES) with at least three (3) years of work experience as a supervisor or manager in the last five (5) years.

Path 2: Successful completion of the Department of Defense's biomedical equipment maintenance technician (DOD BMET) training program with at least three years of work experience, military or civilian, as an HTM supervisor or manager in the last five years

Path 3: An Associate degree in biomedical technology, related health care discipline, information technology or business with at least three years of work experience as an HTM supervisor or manager in the last five years.

Path 4: A Bachelor's degree or higher in biomedical technology, engineering, related health care discipline, information technology or business with at least two years as a manager within the last five years.

Path 5: Work experience with or without a degree not related to biomedical technology, related health care discipline, information technology, or business management. Seven years of work experience in the HTM field with three years of management experience in the last five years

In any of the paths, if the individual does not have the title of supervisor or manager, he/she would have to confirm that he/she performs management duties either through self or third-party attestation.

Recertification requirements for this certification are a combination of work experience and continuing education to demonstrate sustained competency and knowledge in the healthcare technology management field.

CERTIFIED IN CLINICAL ENGINEERING (CCE)

Dr. Caesar Caceres, MD coined the term “Clinical Engineer” in 1967 for engineers working with physicians in the clinical setting. At that time, various types of engineers, physical scientists, and physiologists were performing engineering type work in the clinical setting in hospitals. As more medical instrumentation came into the hospital, more of this type of personnel came into the field as well. Also, as BMETs were hired to maintain the medical instrumentation, engineers and physical scientists were hired to manage clinical/biomedical engineering departments in hospitals.

AAMI thought that engineers should be certified in clinical engineering since there were no academic programs that trained clinical engineers. Some of the major people working in the field of clinical engineering were not engineers but held degrees in some other scientific field. It was decided that a program should be developed to certify people in the clinical engineering field and not as clinical engineers. An initial Board of Examiners was established with prominent people in the clinical engineering field. It was decided that for one year, individuals working in clinical engineering could be certified based on credentials. They had to have at least a BS degree in engineering or a physical science and at least three years experience working in the field of clinical engineering. These credentials were evaluated by the Board of Examiners. The AAMI certification program for clinical engineering

was established in 1975 and within a year about 200 individuals were certified in clinical engineering (CCE). After this first group of CCEs, the Board of Examiners developed a written exam and an oral exam to test future individuals for certification.

At this same time, another group of prominent individuals in the field decided that certification on credentials was the wrong approach to certifying people. They decided that people should take an exam to become certified in clinical engineering. As a result, five people self-certified themselves and developed an exam for certification in clinical engineering. This group became the American Board of Clinical Engineering (ABCE) and also started their certification program in 1975. Most of the initial individuals in this program were academic clinical engineers.

AAMI and the ABCE continued to certify individuals in clinical engineering until 1984. In 1983 the two groups began discussions on a possible merger of their programs. The merger was finalized in 1984 with all the ABCE CCEs being accepted into the AAMI certification program. As part of the merger the International Certification Commission for Clinical Engineering and Biomedical Technology (ICC) was established. Fifty individuals had been certified by the ABCE.

In 1979, AAMI started requiring CCEs to renew their certification every three years by demonstrating continuing education. In 1992, the renewal policy was that anyone certified after 1992 and not renewed would have their certification revoked. Anyone certified before 1992 that did not renew would become delisted. As of 2002, there were about 100 listed CCEs on the AAMI website. In 1999 AAMI discontinued accepting applications for certification because there were not enough applicants to support the program financially. However, they did continue to accept renewals. At the time AAMI discontinued accepting applications for certification, 474 had become a CCE by credentials or exam including 50 certified by the Canadian Board of Examiners for Clinical Engineering. This also included several individuals in other countries certified by the US Board of Examiners. However only about 200 had kept their renewal up-to-date.

In 2002, the Healthcare Technology Certification Commission (HTCC) was created under the Healthcare

Technology Foundation (HTF) to reestablish a CCE program. A US Board of Examiners was created to develop a written and oral exam. The written exam was based on the American College of Clinical Engineering (ACCE) Body of Knowledge (BOK) determined by an ACCE survey of practicing clinical engineers. This survey asked the clinical engineers about the work that they were doing and the knowledge requirements. The new certification program accepted anyone from a previous certification program who demonstrated that they were current in the field by continuing education for a one-year period. There were 112 individuals that were accepted in the new program from the previous program. The first exam was given in 2004 with three individuals taking the exam.

In 2013 the HTCC began looking for a new sponsoring body since new US tax policies were such that a non-profit foundation such as HTF could not have an income producing unit like the HTCC. They looked at various organizations as sponsors as well as considering becoming a stand-alone organization without a sponsor. Finally, AAMI and ACCE indicated an interest in becoming a sponsor and each presented their proposal. The ACCE was accepted as a sponsor since they guaranteed the exam process could continue to have the oral exam. AAMI was not sure they could continue to sponsor with the oral exam since they were trying to obtain ANSI recognition of their exam program. Thus, ACCE became the administrative sponsor for HTCC in 2014. At that time there were a little over 200 individuals certified by the HTCC from the US and the Canadian Board of Examiners.

Individuals must meet the following qualifications to take the CCE exam:

- Three years of clinical engineering experience plus
- Profession Engineer License or
- MS Eng or
- BS Eng plus 4 years total engineering experience or
- BSET in engineering technology plus 8 years total engineering experience.

They also must provide three professional references. The written exam is 150 multiple choice questions administered by a professional testing company. The questions

are developed by the Board of Examiners and are based on the BOK developed by the ACCE. The oral exam is about 2 hours and given by two members of the Board of Examiners and is based on practical knowledge needed to function on the job.

CANADA CERTIFICATION

Canada uses the ICC for certifying BMETs and they add the requirement that an individual must have a BS in biomedical technology to take the exam.⁹ The exam is developed by the Canadian Board of Examiners under the ICC

Under the laws of the Canadian provinces and territories, the use of the title “engineer” in a job description requires that the incumbent be licensed as a professional engineer in that jurisdiction. Canada has always taken the position that to be eligible to seek certification in clinical engineering; an applicant must first obtain licensure as a professional engineer. Once a person is licensed as a professional engineer and is working in the field of clinical engineering, then he or she can apply to the Canadian Board of Examiners for Clinical Engineering Certification.

By 1980, it was recognized that engineers working in the clinical engineering role required a distinct but unrecognized BOK to perform their tasks competently. Since there was no licensing process in place specifically for clinical engineering, leaders in Canada decided to establish a certification process that would be administered by competent members of the profession. In order to begin such an effort, discussions were held with colleagues in the United States who had undertaken a similar approach under the leadership of the (AAMI). Canadians with established track records working in the profession were grandfathered as certified and established the first Canadian Board of Examiners for Clinical Engineering Certification. They developed a written exam and an oral exam.

This process of certification continued for several years. However, the initial rush of applicants dwindled, and it remained a voluntary activity with limited visibility amongst the health care community. By the late 1990s, the work of the Board had effectively ceased with very few applicants coming forward.

Around 2008, there was a growing interest in certification in Canada as younger engineers entered the profession and the need for skilled staff continued to grow. Members of the former Canadian Board were asked by the Canadian Medical and Biological Engineering Society (CMBES) to restart a Canadian certification process and bring it up-to-date. It was apparent that with the small number of certification applicants, it would be difficult to launch and sustain a self-supporting certification process. Since there are many similarities in the practice of clinical engineering between Canada and the United States, they decided to approach the US Board about the possibility of sharing aspects of the enhanced US exam process.

Adding further credibility to the process, The US Board of Examiners is accountable to the Health Technology Certification Commission, which oversees the work of the Board and ultimately decides on recommendations from the Board to certify individuals.

Discussions between the Canadian and US Boards went well with good support and encouragement from US colleagues. The main issue of divergence of practice between Canadian and US clinical engineers relates to the country specific codes, regulations and standards, an important but relatively small part of the written exam. In discussion, it was agreed that members of the Canadian Board would review the US written exam, to identify those questions requiring specific knowledge of US codes, standards and regulations. Out of a full exam of 150 multiple-choice questions, the total number of exempted questions is typically no more than 30. These questions are not counted for Canadian examinees and the same percentage pass mark is used. To compensate for the lack of written exam questions on Canadian codes, standards and regulations, it was decided to put an additional (fourth) question into the Canadian oral exam process, specifically on these topics. The Canadian Board agreed to develop such a question using the same process as the US Board. In this way, Canadian candidates are examined through a slightly different but parallel process to their US counterparts.

It was agreed that Canadian applicants would register and be administered by the Secretariat to the US Board, to avoid setting up a parallel office in Canada. Sites are available in Canada to sit for the written exam, which is

made available in both countries on a single date and time each year, early in November. All policies and procedures are harmonized, and the Canadian Board assists the US Board in the generation of new written and oral exam questions. Members of the two Boards discuss their work on a regular basis, and the Chairs of each Board sit on the HTCC.

The harmonized process was established in 2010 and remains in place. There has been good communication between each Board, and a generally high level of support for this harmonized process.

COMMISSION FOR THE ADVANCEMENT OF HEALTHCARE TECHNOLOGY MANAGEMENT IN ASIA (CAHTMA)

CAHTMA was initiated in 2005 with the endorsement of the Asian Hospital Federation.¹⁰ The Asian Hospital Federation (AHF) is an international non-governmental organization, supported by members from 14 countries in the Asia Pacific Region. CAHTMA is a member of the International Federation of Medical and Biological Engineering (IFMBE) and initially had WHO advisers. It was established to provide a platform for health care professionals to discuss and exchange ideas on health care technologies and practices. Central to these objectives are the promotion of best technology management practices, the certification of clinical engineering practitioners and healthcare professionals and the dissemination of appropriate management tools through seminars and workshops.

CAHTMA has certified a few clinical practitioners, but there has been no major need for certification in Malaysia since it has not been required. When CAHTMA started certification, the government was planning legislation to require certification for maintenance of medical equipment. Technicians are certified as a level one clinical practitioner with a written exam and experience which is like the ICC BMET. Engineers are certified as level two clinical practitioners with a written exam and an oral exam and experience which is similar to the HTCC CCE. In order to encourage more engineers to become certified, CAHTMA is going to use the process of certifying individuals based on credentials similar to what has been with the initial program in the US and Taiwan.

CAHTMA is also certifying faculty for biomedical engineering technology programs which are developing with the increased need for technologists to maintain the medical equipment. The government is looking at requiring these technologists to be certified for certain work. In 2012, lecturers at one school were tested as assessors and certified by CATHMA with Certification for Clinical Engineering Assessors. Lecturers who completed five weeks of training and passed the exams were certified by CATHMA with Certification for Clinical Engineering Trainers.

CERTIFICATION IN TAIWAN

Certification in clinical engineering in Taiwan is performed by the Taiwan Society for Biomedical Engineering (TSBME).¹¹ In 2000, TSBME established the Certification Executive Committee for CE certification. During 2001, they certified clinical engineers by application. In 2003, they initiated a recertification program for CCE. The first testing for certification of clinical engineering and technologists of medical equipment was in 2007.

The TSBME provides certification for clinical engineers, medical equipment technicians and biomedical engineers. In 2010 they had certified 93 clinical engineers, 132 medical equipment technicians and 224 biomedical engineers. The clinical engineers and medical equipment technicians are for working in the hospitals and the biomedical engineers are for working in the medical device industry. This is the only certification that has separate certification for hospital and industry engineers.

To become certified an individual must be a member of TSBME. The requirements to take the certification exam are as follows:

- **Clinical Engineer:** MS degree in biomedical or related field plus at least one year of CE experience plus working in a hospital for more than 10 years.
- **Medical Equipment Technician:** BS degree in biomedical or related field plus at least one year of CE experience plus working in a hospital for more than 4 years.
- **Biomedical Engineer:** BS degree in Engineering plus at least two years of BME experience plus working in BME field for more than 4 years.

The content of the assessment exams by the TSBME for each of their certifications is as follows:

Clinical Engineer (core exam plus oral exam)

- Anatomy (24%)
- Medical Instrumentation (16%)
- Clinical Engineering (16%)
- Medical Imaging System (16%)
- Major Area: (Biomechanical or Biomaterial or Medical Electronics or Medical Information (28%)

Medical Equipment Technician (core exam)

- Anatomy (20%)
- Electronics & Electrical Safety (40%)
- Medical Instrumentation (40%)

Biomedical Engineer (core exam)

- Anatomy (20%)
- Medical Devices, Safety Regulation & GMP (10%)
- Major/Minor (Biomechanics plus Biomaterial or Medical Electronics plus Medical Instrumentation) Major 45% and Minor 25% (70%)

CERTIFICATION IN JAPAN

Clinical engineering in Japan is different from other parts of the world.^{12,13} It is the only country that the government certifies clinical engineering technologists (CETs). The CETs must graduate from a clinical engineering training school which can be a university, junior college or training school and pass a national exam to be certified. The CETs are also called clinical engineers. The CETs are paramedical staff and specialize in the medical equipment essentials in medical care. About 35% work in hemodialysis and about 20% in maintenance. Others work in respiratory, operating room, ICU, heart related, hyperbaric and other areas.

The clinical engineer system was established in 1987 by the Clinical Engineers Act. This act created the CET as a professional medical position responsible for the operation and maintenance of life-support systems under the direction of doctors. This act established a national qualification including passage of the 180-question exam in medicine, engineering and medical technology. In 2010 there were about 28,000 certified CETs and about 18,000

current working in the field. The certification of the CETs is most equivalent to the CBET in the ICC system in the US.

In addition to the CET certification by the government, the Japan Society for Medical and Biological Engineering (JSMBE) has a Biomedical Engineering Certificate program.¹⁴ The JSMBE has two classes of certification for biomedical engineers. The 1st class certification is for experienced clinical engineers and in 2008 the pass rate was 22.2% for 433 applicants. The 1st class exam covers basic aspects on medical engineering and medical device related subjects. The 2nd class exam is for students or recent graduates of clinical engineering and many take it as preparation for the national CET exam. In 2008 the pass rate on the 2nd class exam was 29.3% for 1398 applicants.

CERTIFICATION IN CHINA

In 2005, the international clinical engineer certification was introduced in China.¹⁵ The Medical Engineering Division of the Chinese Medical Association hosted the first international clinical engineering certification training courses and certification examination. From 2005 to 2016, eight sessions of lectures by international senior specialists and exams were done. A written exam based on the ACCE BOK with some adjustment for the practice of clinical engineering in China. The written exam is in English and is prepared by international senior specialists. Individuals that pass this 100-question multiple choice exam have to pass an oral exam in English to become certified. The oral exam is given by the international senior specialists. In the eight training sessions, there have been 700 clinical engineering personnel from hospitals and universities. There have been 219 individuals that have passed the two exams and been certified as international clinical engineers.

In the past 7 years, China has been working to establish its own certification program. In 2012, the Medical Engineering Division of the Chinese Medical Association carried out Chinese Registered Clinical Engineer Certification (RCEC) training and examination. The candidates were junior engineers in large hospitals or new graduates with majors in medical engineering. This exam is the basic admission exam to the occupational qualification of clinical engineering.

The RCEC exam consists of a theoretical exam and practical test. There is a Chinese exam question bank from which the theoretical questions are randomly selected. Candidates then take a practical test including repair, measurement and maintenance of medical devices. A committee of Chinese clinical engineering experts evaluates the ability of the candidates and determines if they are qualified to receive the RCEC. In 2012, there were 176 people who took the exam and 56 passed to become certified as RCEC.

In the future, the candidates for International Clinical Engineering Certification will be mostly senior clinical engineers with more than 10 years experience.

They are establishing a continuing education for both certification to maintain and improve the quality of the clinical engineers. The Medical Engineering Division plans to recommend to the government to officially authorize clinical engineer training and certification.

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