Certification Candidate Handbook

✓ Program Overview
✓ Policies & Procedures
✓ Exam Application
2023

<table>
<thead>
<tr>
<th>Testing Windows*</th>
<th>Application Deadline</th>
<th>Late Registration Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 1-15, 2023</td>
<td>April 14, 2023</td>
<td>April 21, 2023</td>
</tr>
<tr>
<td>November 1-15, 2023</td>
<td>October 13, 2023</td>
<td>October 20, 2023</td>
</tr>
</tbody>
</table>

*CABT Exam is proctored online and can be applied for and taken at any time.

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10/28/2022
# Table of Contents

ACI Objective ................................................................................................................... 3  
ACI Statement of Fairness ............................................................................................... 3  
Impartiality .......................................................................................................................... 3  
Code of Conduct .................................................................................................................. 3  
Types of Certification ......................................................................................................... 3  
Scope of Certification ......................................................................................................... 3  
  Certified Associate in Biomedical Technology ............................................................... 3  
  Certified Biomedical Equipment Technician ................................................................. 4  
  Certified Radiology Equipment Specialist ..................................................................... 4  
  Certified Healthcare Technology Manager .................................................................... 4  
  Certified Industrial Sterilization Specialist ................................................................... 4  
Candidate Eligibility .......................................................................................................... 5  
CABT Eligibility .................................................................................................................. 5  
CBET and CRES Eligibility ............................................................................................... 5  
  Full Certification ........................................................................................................... 5  
  Candidate Status .......................................................................................................... 5  
CHTM Eligibility ................................................................................................................ 5  
CISS Eligibility ................................................................................................................... 6  
Application Process .......................................................................................................... 7  
  Eligibility Appeals ......................................................................................................... 7  
  Accommodations ........................................................................................................... 7  
  Registration ..................................................................................................................... 7  
  Scheduling a Computer-based Test .............................................................................. 7  
Preparing for the Exam ...................................................................................................... 7  
  Exam Content Outlines ................................................................................................. 8  
  References ....................................................................................................................... 8  
Exam Day ........................................................................................................................... 8  
  Candidate Check-in ....................................................................................................... 8  
  Policies During Exam Administration .......................................................................... 8  
  Policies After Exam Administration ............................................................................. 8  
Inclement Weather ............................................................................................................ 8  
Security ............................................................................................................................... 8  
  Security Violations/Cheating ......................................................................................... 8  
Scoring and Results .......................................................................................................... 9  
  Scoring Process .............................................................................................................. 9  
  Notification of Results ................................................................................................... 9  
  Appeal of Exam Results ............................................................................................... 9  
  Appeal of Exam Administration .................................................................................... 9  
Rescheduling an Exam ....................................................................................................... 9  
Cancellation Policy ........................................................................................................... 10  
Withdrawing an Application ............................................................................................ 10  
Failure to Appear for an Exam ........................................................................................ 10  
Retaking the Exam ........................................................................................................... 10  
Change of Contact Information ....................................................................................... 10  
Use of Certification Marks and Designations ................................................................... 10  
  Introduction ................................................................................................................... 10  
  Acceptable Use .............................................................................................................. 10  
  Certificate ..................................................................................................................... 10  
Maintaining Certification ................................................................................................. 11
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale</td>
<td>11</td>
</tr>
<tr>
<td>Introduction</td>
<td>11</td>
</tr>
<tr>
<td>Recertification Policy (After January 1, 2017)</td>
<td>11</td>
</tr>
<tr>
<td>Recertification Cycle</td>
<td>11</td>
</tr>
<tr>
<td>Recertification Procedures (After January 1, 2017)</td>
<td>11</td>
</tr>
<tr>
<td>Late Renewal Submittal &amp; Reactivation</td>
<td>12</td>
</tr>
<tr>
<td>Certified on or After January 1, 1992</td>
<td>12</td>
</tr>
<tr>
<td>Certified on or Before December 31, 1991</td>
<td>12</td>
</tr>
<tr>
<td>CCE Certificate Holders</td>
<td>12</td>
</tr>
<tr>
<td>Multiple Certifications</td>
<td>12</td>
</tr>
<tr>
<td>Military Active Duty</td>
<td>12</td>
</tr>
<tr>
<td>CEU Audits</td>
<td>13</td>
</tr>
<tr>
<td>CEU Audit Reinstatement Policy</td>
<td>13</td>
</tr>
<tr>
<td>Change Scope of Certification</td>
<td>13</td>
</tr>
<tr>
<td>Leave of Absence</td>
<td>13</td>
</tr>
<tr>
<td>Emeritus Status</td>
<td>13</td>
</tr>
<tr>
<td>Complaint of Disciplinary Violation</td>
<td>14</td>
</tr>
<tr>
<td>Withdrawal/Revocation</td>
<td>14</td>
</tr>
<tr>
<td>Suspension</td>
<td>14</td>
</tr>
<tr>
<td>Appeals</td>
<td>15</td>
</tr>
<tr>
<td>Filing an Appeal</td>
<td>15</td>
</tr>
<tr>
<td>Appeals Body</td>
<td>15</td>
</tr>
<tr>
<td>Fees</td>
<td>15</td>
</tr>
<tr>
<td>ACI Board Consideration of the Appeal</td>
<td>15</td>
</tr>
<tr>
<td>Complaint Form</td>
<td>15</td>
</tr>
<tr>
<td>Certified Associate in Biomedical Technology Detailed Content Outline (2020)</td>
<td>16</td>
</tr>
<tr>
<td>Certified Biomedical Equipment Technician Detailed Content Outline (2018)</td>
<td>17</td>
</tr>
<tr>
<td>Certified Radiology Equipment Specialist Detailed Content Outline (2018)</td>
<td>19</td>
</tr>
<tr>
<td>Certified Healthcare Technology Manager Detailed Content Outline (2022)</td>
<td>20</td>
</tr>
<tr>
<td>Certified Industrial Sterilization Specialist Detailed Content Outline</td>
<td>22</td>
</tr>
<tr>
<td>CISS Specialties (EO, Moist Heat, Radiation) Detailed Content Outline</td>
<td>23</td>
</tr>
<tr>
<td>Exam Resources</td>
<td>26</td>
</tr>
<tr>
<td>CABT References</td>
<td>26</td>
</tr>
<tr>
<td>CBET and CRES References</td>
<td>26</td>
</tr>
<tr>
<td>CHTM References</td>
<td>27</td>
</tr>
<tr>
<td>CISS References</td>
<td>28</td>
</tr>
<tr>
<td>Study Guides and Review Courses</td>
<td>28</td>
</tr>
<tr>
<td>Certification Exam Pricing</td>
<td>31</td>
</tr>
<tr>
<td>ACI Recertification Categories (After January 1, 2017)</td>
<td>33</td>
</tr>
<tr>
<td>Definitions</td>
<td>34</td>
</tr>
<tr>
<td>Appendix A: Online Proctored Exam Conditions &amp; Requirements</td>
<td>35</td>
</tr>
<tr>
<td>Exam Registration Form</td>
<td>36</td>
</tr>
</tbody>
</table>
ACI Objective

ACI’s objective is to be the trusted source for quality professional development and credentials for healthcare technology-oriented professionals, industry, and healthcare delivery.

ACI Statement of Fairness

The ACI adheres to principles of fairness and due process and endorses the principles of equal opportunity. In administering the credentialing programs, ACI shall not discriminate or deny opportunity to anyone on the grounds of gender, age, religion, national or ethnic origin, marital status, veteran status, sexual orientation, or disability.

Impartiality

ACI understands the importance of impartiality in carrying out its certification activities, manages conflict of interest and ensures the objectivity of its certification activities.

Code of Conduct

The Code is designed to provide both appropriate ethical practice guidelines and enforceable standards of conduct for all ACI applicants, certificants, and candidates. The Code also serves as a professional resource for healthcare technology practitioners, as well as for those served by ACI certificants and candidates in the case of a possible ethical violation.

All ACI applicants, candidates, and certificants must agree to comply with the ACI Code of Conduct as outlined below:

1. I will conduct my professional activities with honesty and integrity.
2. I will uphold my professional conduct to the highest ethical standards.
3. I will represent my certifications and qualifications honestly and provide only those services for which I am qualified to perform.
4. I will maintain and improve my professional knowledge and competence through regular self-assessments, continuing practice, continuing education or training.
5. I will act in a manner free of bias and discrimination against clients, colleagues, or customers.
6. I will maintain the privacy of individuals and confidentiality of information obtained in the course of my duties unless disclosure is required by legal authority.
7. I will obey all applicable laws, regulations, and codes.
8. I will follow all certification policies, procedures, guidelines, and requirements of the ACI.
9. I will not use the certificate in a misleading manner.
10. I will discontinue use of the certificate and certification marks upon suspension, revocation, or withdrawal by decision of the certified body.

Types of Certification

The AAMI Credentials Institute (ACI) maintains the certification programs for associates in biomedical technology (CABT), biomedical equipment technicians (CBET®), radiology equipment specialists (CRES®), healthcare technology managers (CHTM), and industrial sterilization specialists (CISS). Each certification requires a separate, complete application and a separate examination. Applicants may test in only one discipline per testing window, except for CISS. Candidates for CISS may take the core and specialty exams in one testing window.

AAMI membership is not a prerequisite for certification.

Scope of Certification

The certification programs recognize healthcare technology management professionals whose practice reflects a high degree of knowledge about medical devices and clinical practice as well as skill in implementing electro-mechanical talent in the repair and maintenance of devices used in the delivery of healthcare. Achieving ACI certification indicates that certification candidates have demonstrated a broad knowledge skill-set in the specific certification area.

Exams are offered in English only.

Certified Associate in Biomedical Technology (CABT)

A certified associate in biomedical technology is an individual who is planning to enter the HTM field and looking to earn an entry level certification to kick-start their career.

In a work setting, this professional will be responsible for scheduled technology maintenance, supporting senior technicians, incoming/routine inspections on new
equipment, and minor troubleshooting. Characteristics of a CABT include, but are not limited to: strong communication skills, problem solving abilities, resourcefulness, strong time management skills, technology acumen, highly motivated, and resilience.

The CABT certification is non-renewable and is active for five years. If an individual wishes to maintain the designation, they will need to take and pass the exam again. At the five year expiration date, the candidate will have the necessary experience to sit for the CBET or CRES exam.

Certified Biomedical Equipment Technician (CBET)
Healthcare technology management professionals that desire a CBET certification are expected to have experience in a wide-range of electromechanical devices, computers, networks and software used in the delivery of healthcare. Generally, candidates desiring for this certification may work for medical device manufacturers, hospitals, clinics, home healthcare providers, medical device repair companies, regulatory bodies/agencies, and software manufacturers – such as EMR or device integration providers.

CBET candidates typically perform some of the following duties on a daily basis:
• Test and calibrate medical devices (preventive maintenance)
• Troubleshoot medical devices in a clinical setting and/or bench/depot setting (corrective maintenance)
• Manufacture software, parts or devices for use in patient care
• Ensure compliance with all regulatory processes necessary (i.e. CMS, FDA GMP, etc.)
• Manage medical software/hardware systems (i.e. PACS Administrator, Integration Specialist, etc.)
• Perform corrective and preventive maintenance on steam systems
• Educate the proper use, care and maintenance of medical devices
• Review technical manuals
• Document any and all maintenance and repairs and maintain records of maintenance activities
• Troubleshoot medical device networks

Certified Radiology Equipment Specialist (CRES)
Healthcare technology management professionals that desire a CRES certification are expected to have experience in a wide-range of medical imaging modalities, electromechanical devices, computers, networks and software used in the delivery of healthcare. Generally, candidates desiring for this certification may work for medical device manufacturers, hospitals, clinics, medical device repair companies, regulatory bodies/agencies, and software manufacturers – such as EMR or device integration providers.

CRES candidates typically perform some of the following duties on a daily basis:
• Test and calibrate medical devices (preventive maintenance)
• Troubleshoot medical devices in a clinical setting and/or bench/depot setting (corrective maintenance)
• Manufacture software, parts or devices for use in patient care especially imaging systems
• Ensure compliance with all regulatory processes necessary (i.e. CMS, FDA GMP, etc.)
• Manage medical software/hardware systems (i.e. PACS Administrator, Integration Specialist, etc.)
• Educate the proper use, care and maintenance of medical devices
• Review technical manuals
• Document any and all maintenance and repairs and maintain records of maintenance activities
• Troubleshoot medical device networks

Certified Healthcare Technology Manager (CHTM)
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 relations.
Certified Industrial Sterilization Specialist (CISS)

An industrial sterilization specialist is a person who understands the principles of sterilization process development, validation, control, and management as part of the manufacture of healthcare products.

CISS has expertise in the science of sterilization (including but not limited to microbiology, physics, and chemistry), knowledge of sterilization processing, quality management systems, risk management and regulatory requirements. The CISS program is a two-test process including a:

- Sterilization core exam including 75 multiple-choice questions
- A choice of one of the following specialty exams listed below:
  - Ethylene Oxide
  - Moist Heat
  - Radiation

The specialty exam consists of 50 multiple-choice questions.

Candidate Eligibility

CABT Eligibility

Individuals interested in earning the CABT designation must have a high school diploma or GED to sit for the exam. This can be waived for current high school students who have parent permission.

IMPORTANT: A copy of the applicant’s high school diploma or GED documentation must be submitted with the completed application.

CBET and CRES Eligibility

Full Certification

Certified Biomedical Equipment Technician (CBET), Certified Radiology Equipment Specialist (CRES)

Applicants must meet ONE of the following minimum eligibility requirements as of the application deadline:

1. Associate degree or higher in biomedical equipment technology program and two years’ full-time BMET work experience; OR
2. Completion of a U.S. military biomedical equipment technology program and two years’ full-time BMET work experience; OR
3. Associate degree or higher in electronics technology and three years’ full-time BMET work experience; OR
4. Four years’ full-time BMET work experience.

*CRES Applicants for full certification: At least 40 percent of work experience over the last two years or 25 percent over the last five years must be in the designated specialty area.

Candidate Status

Applicants desiring full certification, but do not yet meet the eligibility requirements (as listed above), may apply through candidate status. Successful candidates are given five years to meet the minimum eligibility requirements and be awarded full certification.

To test as a candidate for any of the certifications, an applicant must meet ONE of the following minimum eligibility requirements as of the application deadline:

1. Associate degree or higher in biomedical equipment technology program; OR
2. Completion of a U.S. military biomedical equipment technology program; OR
3. Associate degree or higher in electronics technology and one-year full-time BMET work experience; OR
4. Two years of full-time BMET work experience.

IMPORTANT: If claiming eligibility based in full or in part on an Associate’s or Bachelor’s degree, a copy of the diploma MUST be included with the application and fees. A copy of the diploma is required for individuals applying under the completion of a U.S. military biomedical program. Official college transcripts may be requested at the discretion of the application reviewer, but required from international applicants. NOTE: A Bachelor’s degree does not replace work experience requirements.

CHTM Eligibility

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. 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.

**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. 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.

**Path 3:** An Associate’s degree in biomedical technology, related healthcare discipline, information technology or business with at least three years of work experience as an HTM supervisor or manager in the last five years. If the individual does not have the title of HTM supervisor or manager, he/she would have to confirm that he/she performs management duties either through self or third party attestation.

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

**Path 5:** Work experience with or without a degree not related to biomedical technology, related healthcare 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. 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.

**APPROVED DISCIPLINES**
The following list of engineering, healthcare, and business disciplines is a preliminary list. Please contact the ACI office if you have a degree that is not listed.


**CISS Eligibility**
Candidates must meet one of the following options to be eligible to sit for the CISS exams:

1) Bachelor's degree (BS or BA in science or engineering field) AND 3 years of full-time, post baccalaureate work experience within the past 5 years in the appropriate exam specialty area.

2) Bachelor's degree (BS or BA) with 20 semester hours or 30 quarter hours of course work in microbiology or related field AND 3 years of full-time, post baccalaureate work experience within the past 5 years in the appropriate exam specialty area.

3) High school graduate with 20 academic credits awarded for participation in workshops sponsored by AAMI or other appropriate organizations in the sterilization area AND 7 years of full-time work experience within the past 10 years in the appropriate exam specialty area.

Individuals can take the core and specialty exam in the same testing window.

**Work Experience**
The candidate must have experience relevant to the area in which certification is being sought. Relevant experience is experience in which a majority of the candidate's duties are in the area in which he/she is seeking certification. This experience must contribute to the candidate's ability to perform the effective operation and/or validation of a sterilization process. Please submit as many references as needed to document the amount of time required under your preferred eligibility path. If
experience from more than one employer is needed, references from former direct supervisors may be submitted in conjunction with the reference from your current supervisor.

APPROVED DISCIPLINES

The following list of engineering and healthcare disciplines are illustrative of the disciplines acceptable for candidacy. Please contact the AAMI Credentials Institute (ACI) office if you have a degree that is not listed.

Biology, Microbiology, Chemistry, Physics, Engineering, Environmental Engineering, Chemical Engineering, Nuclear Science, Biomedical Engineering, Industrial Engineering, Packaging, Environmental Engineering, Biomedical Technology, Medicine, or other appropriate discipline

Application Process

The candidate must submit the completed application, registration form and appropriate fees at least 15 days in advance of the exam date. Exams are delivered through computer-based testing at testing centers nationwide during the two testing windows. Outside of the September 1-15, 2020 window, the CABT exams can ONLY be taken via online proctoring. Completed application forms should be sent to the ACI at 901 N. Glebe, Suite 300, Arlington, VA 22203, emailed to aci@aami.org, or faxed to 703-276-0793.

The application forms can be found on ACI’s website, www.aami.org/certification. Applications are reviewed to verify information and documentation to determine eligibility and will be kept confidential. Candidates will not be discriminated against based on race, religion, creed, age, gender or national origin or ancestry.

Candidates who meet the program requirements will receive confirmation of their acceptance into the program via email. They will then be able to register for a specific exam site and time to take the test. Candidates who do not meet the program requirements will receive a status letter indicating the month and year they will be eligible to take the exam(s).

If the application is incomplete, the candidate will receive a letter or e-mail explaining what is missing and will have a 30-day time period to respond. If the candidate does not respond, the candidate must then submit in writing a request for a refund minus the application fee. The application may be deemed incomplete for reasons such as:

- Application is not completely filled out
- Application is not signed
- Appropriate fees are not submitted
- Proper documentation is not submitted

If the application is denied, the candidate will receive a letter or email stating the reason for the denial. Candidates will have 30 days to respond. The application may be denied for reasons such as:

- Failure to demonstrate eligibility in academic, work experience, or specialized training
- Falsification of any information on the exam application

Eligibility Appeals

Candidates will be notified in writing or electronically their status in the certification program. If a candidate fails to meet the eligibility requirements for the exam, the candidate has 30 days to appeal the decision. The candidate must submit his or her request in writing to the ACI staff. The request will then be sent to the ACI Board for review.

Accommodations

ACI complies with the provisions of the Americans With Disabilities Act and Title VII of the Civil Rights Act, as amended (42 U.S.C. 2000e. et seq.) in accommodating disabled candidates who need special arrangements. The request must be submitted in writing with supporting documentation from a physician or other qualified professional reflecting a diagnosis of the candidate’s condition and explanation of exam aids or modifications needed a minimum of 60 days before the testing window. Please contact the ACI, at aci@aami.org, if the candidate has any questions concerning ADA arrangements.

Registration

To register for a certification exam, the candidate must meet the specific requirements for the exam. The registration forms and fees can be found at the back of this handbook. Candidates must register at least 15 days prior to the exam window.
Scheduling a Computer-based Exam
After the application has been approved, and the exam registration fee has been paid, the candidate will receive two e-mails with logon information and instructions on how to schedule his or her exam at a testing center. Exams must be scheduled at least 24 hours in advance.

Preparing for the Exam
Candidates should register at least 15 days in advance of the exam testing window. All certification programs are self-study. Education courses are not required to sit for any of the ACI’s certification exams.

Exam Content Outlines
Exam content outlines are available for every exam. Candidates can find the outlines at the back of this handbook. The content outline provides information such as the number and type of questions; how long the candidate will have to complete the exam; what materials the candidate may bring to the exam; and percentage of questions per category.

References
References for each exam are listed at the back of this handbook.

Exam Day
Candidate Check-in:
Computer-based testing candidates are required to provide the exam proctor two (2) forms of identification (one must be a photo government issued ID). Secondary identification would be a credit card, bank debit card, employee identification card. NOTE: In the United States a Social Security card is “not” an acceptable form of identification. Candidates should also bring their confirmation email that contains the exam launch code with them on testing day in order to begin the test. The confirmation email will include the test date, time, testing center location and exam the candidate is taking. If the candidate loses or does not receive his/her confirmation email after scheduling the exam, please contact the ACI at 703-525-4890.

The candidate must arrive at the exam location at least 15 minutes prior to the exam starting time. Late arrivals will not be admitted to the room and will be considered “no shows” and lose all exam fees paid.

Online proctored exams for CABT will have a set of rules and requirements (Appendix A) that test takers must abide by that address the test environment, the computer/devices used, the tester’s behavior, and consequences of rule violations. All testers MUST have an active camera during the exam session.

Policies During Exam Administration
The following list is the policies that will be maintained during the testing session:

- Candidates are admitted only to their assigned test center at their assigned time.
- No guests are permitted in the exam room.
- No reference material, books, papers, translation aids, personal items are allowed in the exam room.
- No electronic devices, such as pager, cell phone or “smart” watches, any device with internet access or camera, or google glasses are allowed in exam room.
- No weapons may be brought into the exam room.
- No test materials, documents, memos of any sort are allowed to be taken from the exam room.
- Candidates are not allowed to communicate with others test takers. Proctors are authorized to maintain a secure and proper test administration.
- Candidates will be given the opportunity to write comments about exam items during the exam.
- Candidates are provided scratch paper and a pencil during the exam.
- Breaks are not allowed during the exam.
- Food and beverage is not allowed in the exam room.
- Candidates may not copy in writing, transmit or record exam questions and/or answers of any exam material.

Policies After Completing the Exam
A candidate who completes the exam may leave the testing room after turning in all related exam materials. Please try to do this as quietly as possible so that those still working on the exam will not be disturbed. The administrator will make sure that the candidate returns all materials.

Inclement Weather
If a candidate in unable to arrive at the designated exam site because of inclement weather, terrorist acts, natural disasters, or other unforeseen emergencies beyond the control of the candidate as determined by ACI, the
candidate will be allowed to take the next regularly
scheduled exam without being charged the retesting fee.

If for any reason the exam is unable to be administered,
then the exam will be rescheduled within a reasonable
period of time. Candidates may take the exam at the next
testing window without any additional cost. Candidates
are responsible for their own associated expenses.

Security

Security Violations/Cheating
No spouses, children, parents, friends, or other outside
parties are permitted near the testing room. Upon
completion of the exam, candidates must leave the
testing area immediately.

Any candidate who gives or receives help during the
exam will be asked to leave and his/her exam will not be
scored. Exam fees will not be refunded and the
candidate may be prohibited from taking ACI exams for a
specified period of time.

The performance of all candidates is monitored and may
be analyzed to detect fraud. At any time after the exam
administration should there be a question about score
validity or the identity of an exam candidate, the ACI staff
will investigate and determine whether it is appropriate to
void the exam score. The ACI Board maintains and
adheres to a security policy which is available to board
members and staff for the administration of exams and
maintaining the certification program.

Scoring and Results

Scoring Process
Exams are scored making every effort to ensure that the
score is reported within a reasonable time period and
that the score accurately reflects the points received by
the candidate. This may involve hand scoring exams to
verify results and/or reviewing candidate comments.
Candidates are encouraged to write comments in the
comment section of the exam.
Comments can be related to a specific question; the
administration of the exam; or the exam site conditions.
Comments that would affect whether a candidate passes
or fails an exam will be reviewed before the exam is
scored. All other comments are reviewed by the ACI
Board at their regularly scheduled meetings.

Notification of Results
Preliminary results will be reported for immediately
following the completion of the exam and with 24 hours
of completing their exam via email. Results will be
reported as “pass” or “fail.” If the exam is using a new
test form, results will be delayed up to sixty days after the
testing window closes for exam committees to review
and confirm passing score.

Candidates who pass an exam and achieve a
certification will be notified of their passing status within
30 days. They will receive an official ACI certificate and a
wallet card that they may carry with them.

Candidates who fail an exam will be provided with
diagnostic information. The “analysis of performance”
identifies the knowledge areas in which the candidate’s
performance is deficient and is intended to help the
candidate become better prepared before sitting for the
exam again.

Please note: When new exam forms are added to the
program, results will be delayed up to 60 days for ACI
exam committees to review.

Apologies of Exam Results
Candidates may request a verification of their score
which may involve hand scoring and/or a review by the
ACI Board. Any scoring alteration found as a
consequence of an appeal of exam results will be applied
to all candidates whose pass-fail status was affected; not
just the candidate requesting the appeal. All requests
should be made in writing within 30 days of receiving
exam results to ACI and can be emailed to
aci@aami.org.

Apologies of Exam Administration
Testing conditions should be such that each candidate
has an equal opportunity to be successful. Test sites
should be comfortable, accessible, well-lit and free of
distracting noise. Proctors should provide clear and
uniform instructions and monitor testing conditions
throughout the entire session. If conditions of the exam
administration do not meet these standards, notify ACI as
soon as possible. Any special considerations made for
testing conditions that are deemed unacceptable as a
consequence of an appeal will be applied to all
candidates whose pass-fail status was affected; not just
the candidate requesting the appeal.
Rescheduling an Exam

All ACI exam candidates are allowed to reschedule an exam once. Certification exams rescheduled within five business days of their scheduled exam date will forfeit all exam fees and must notify ACI in writing by email at aci@aami.org. Exams rescheduled outside five business days of their scheduled exam will be charged a rescheduling fee in order to sit for the exam. These rules are universal for all ACI exams, including those that are proctored online.

Cancellation Policy

A cancellation fee will be assessed to the candidate who fails to cancel a scheduled exam at least five business days before the exam date. This policy includes both testing center and online proctored exams. Cancellations must be made in writing and sent to the attention of ACI by email at aci@aami.org.

Withdrawing an Application

All application changes must be made in writing and sent to the attention of ACI by email at aci@aami.org.

Failure to Appear

If a candidate does not appear to take a scheduled exam, whether it’s at a testing center or online proctored, the candidate will forfeit all fees. All fees will need to be paid again if the candidate decides to reschedule at a later date.

Retaking the Exam

No retake exam may be scheduled by anyone in the exam process until the candidate has been officially notified of the results of his/her previously taken exam. Candidates must wait at least 60 days to retake an exam. There is no refund for failed exams. A candidate will be allowed to take the exam no more than three times within a two-year period. If unsuccessful on the third attempt, the candidate must wait one year before he/she will be allowed to re-apply to the program and take the exam.

Change of Contact Information

It is the certified professional’s responsibility to ensure that AAMI has their most current contact information including mailing address, phone number and email address. Payments and journals are due by December 31 of their expiration year.

Use of Certification Marks and Designations

Introduction

After receiving notification of earning an ACI designation, the credential(s) granted may be used only as long as the individual’s ACI certification remains valid and in good standing.

Individuals may not use the credential(s) until they have received specific written notification that they have successfully completed all requirements, including passing the required exam(s). Certificants must comply with all recertification requirements to maintain use of the credential(s).

The use and/or display of the official ACI acronyms or designation names, except as permitted by this policy, is prohibited. Individuals who fail to maintain ACI certification / recertify or whose ACI certification is suspended or revoked must immediately discontinue use of the certification mark(s) and must return any certificates or renewal cards issued by the certification body. They are also prohibited from stating or implying that they hold the ACI certification.

Acceptable Use

Individuals who have earned the credential(s) may identify themselves as an “ACI Certified Professional.”

The name and official acronym may be used only as long as the individual’s certification is valid and in good standing. ACI certification is a non-transferable, revocable, limited, non-exclusive license to use the certification designation and is subject to compliance with the policies and procedures of the ACI Board. Certified individuals may not make misleading, deceptive, or confusing statements regarding their ACI certification status.

Certificate

Each certificant will receive a certificate for each credential granted. Each certificate will include, at a minimum, the following information:
Recertification Policy Beginning January 2017

As of January 1, 2017, to retain an ACI certification, a certified professional must accumulate a minimum of 30 Continuing Education Units (CEU) over a three-year period and submit a continuing practice journal with the applicable fees. CEUs can be accumulated through a wide range of professional activities, including attending educational meetings, classes, and seminars, leadership roles, presenting, teaching or developing educational content, and continual work in the HTM field as a few examples.

ACI’s recertification program is flexible to accommodate the diverse learning styles and approaches to professional involvement. At least 30 CEUs must be accumulated in activities directly related to the HTM or sterilization field during the three year cycle.

The structure includes continuing practice activities for the following major categories:

- **Category I:** Earn an additional HTM-related certification
- **Category II:** Leadership roles
- **Category III:** Development of educational content
- **Category IV:** Professional development
- **Category V:** College or university courses
- **Category VI:** Work experience

The complete recertification breakdown can be found at the end of this handbook.

Recertification Cycle Beginning January 2020

The journal is to be used to record professional activities achieved throughout the three-year cycle. Initial certification covers the remaining year of original certification and expires December 31 of that year (i.e., May 10, 2020 through December 31, 2020). In the year your certification is to expire (i.e., 2020) you will receive a notice reminding you that, by December 31, renewal fees are due, which will extend certification through the next three-year cycle (i.e., 2021, 2022, 2023). Thereafter, renewal fees and a continuing practice journal, with a record of professional activities during previous three years, are due December 31 of the third year after the initial certification period.

Recertification Procedures

Certified professionals holding CBET, CRES, CHTM, and CISS designations are required to submit documentation for all activities they are submitting for
their renewal. Acceptable documentation is considered but not limited to: certificates, transcripts, letters from class sponsors or badges or onsite programs for conference attendance.

Upon receipt of the Continuing Practice Journal and renewal payment, the journal will be reviewed. When approved, a wallet card showing the new certification expiration date will be issued and mailed out with a letter of renewal confirmation.

When the journal does not meet the minimum required for approval, the certification holder will be asked to update his journal by the reviewer. If the certification holder does not comply with the requirements, he/she will be notified by ACI that the renewal was denied.

The CABT designation is NOT renewable through the normal recertification process. To renew, the exam must be retaken and passed.

Late Renewal Submittal and Reactivation
A $100.00 reactivation fee applies if materials are submitted after the renewal due date. This fee should be paid along with the current renewal fees and a Continuing Practice Journal must be submitted for the current triennial period. Failure to pay the reactivation fee will result in the certification remaining in an inactive status, even if the renewal fees and Journal have been submitted.

Certified professionals must immediately inform ACI of matters that affect his/her capability to continue to fulfill the certification requirements.

A. Certified on or after January 1, 1992
Individuals certified in an ACI program on or after January 1, 1992 are required to submit their continuing practice journals and recertification fees by December 31 of their certification expiration year. Certified candidates will be allowed a 90-day grace period after the date of certification expiration date but will be considered inactive during that time. At the end of the 90 days, if the journal and the fees, including the reactivation fee, have not been received, the certification will be revoked. Once certification has been revoked, it will be necessary to take the certification examination again to regain certification.

B. Certified on or before December 31, 1991
Individuals certified on or before December 31, 1991 who choose not to submit the required continuing education and renewal payments to renew their certification will be given the designation of CBET-I, CRES-I and CLES-I to show that their certification is inactive and that they are not maintaining the continuing education requirements. These individuals will not be listed in the directory of active certified individuals.

C. CCE Certificate Holders
Individuals certified in the U.S. CE program under the ICC/USCC on or before January 1, 1992 are not required to renew their certification, and will not have their certification revoked if they do not comply with the renewal requirements of submitting a Journal. However, their certification will be considered inactive. If the CE certification is ever revoked or lost, there currently is no means of regaining the certification under the ACI.

D. Multiple Certifications (after January 1, 2017)
If certified in more than one discipline (CBET, CRES, CLES, CHTM, CCE, CQSM, CISS), certificants will be charged an additional fee for each certification every three years for each certification beyond the primary one to maintain active status in each certification.

There is no need to complete a Continuing Practice Journal for each certification. Thirty continuing education hours are required for each three-year period, regardless of the number of certifications earned.

E. Military Active Duty
Individuals who are deployed, while US military forces are involved in hostile activities, will be handled on a case-by-case basis. The certificant is to contact the ACI to inform them of the military status and the proposed duration, and should present a copy of his/her military assignment.

The general policy is: the person who will be on active duty within 60 days of the actual deadline for renewal, the recertification deadline be postponed until 180 days after discharge from their active duty or return to their standard responsibilities. If the certificant will not be performing his military assignment in the HTM field, the certification(s) should be placed on leave of absence until the certificate is released from his/her assignment and back to working in the field. ACI would then work
with the certificant to determine what information is needed to continue to keep the certification active.

The information above only applies to those either deployed to an assignment or called to active duty while the country’s military forces are on alert, and they need to provide the ACI with a copy of their military assignment. Those certified and on standard military assignments in the HTM field are expected to follow all recertification policies and procedures.

**CEU Audits**

At the end of each CEU cycle, random CEU audits consisting of ten percent of all certified individuals within the cycle will be conducted. The ACI Board may add additional certified individuals, at their discretion, to the randomly chosen list of certified individuals to investigate claims or suspicion of impropriety.

Individuals chosen to participate in the CEU audit will be notified that their renewal submission is being audited to ensure compliance with the recertification policies. Individuals will be notified of their status upon completion of the audit and will be notified of any deficiencies that they may have. Individuals will have an opportunity to resolve any issues by submitting additional hours or further documentation to prove attendance in an event.

Status letters from ACI will be mailed and emailed on a weekly basis. There are two possible CB responses:

- The individual is in compliance and no action is required. Status letter will be mailed regular mail.
- The individual is not in compliance and will be given 45 days from the date of their status letter to take corrective action.

For those people who do not respond to the corrective action letter, second notices will be mailed requiring a signature. These individuals will have an additional 15 days to respond to the request. There are two possible ACI Board responses after the second letter is sent. They are:

- Documentation is received, and the individual is in compliance and no further action is required.
- Documentation is received and the individual is not in compliance and will be given 30 days from the date of their letter to take corrective action.

For those individuals who don't respond to the corrective action letter, their certifications will be revoked on *March 31 of the year following their deadline*. This letter will be mailed and emailed requiring a signature receipt to the individual. These individuals will need to retake all exams, at full price, in order to become certified again. Renewal fees are non-refundable.

**CEU Audit Reinstatement Policy**

Any person who was audited but did not respond to the corrective action letter but submits information prior to *March 31 following the certification deadline* can be reinstated to the program. This late submittal needs to be complete and have no deficiencies in order to be accepted. A late submittal fee will be required for processing. If there are deficiencies in the submission and the individual ends up with less than the required CEUs for certification renewal, they will lose their certifications. These individuals will need to successfully retake all exams, at full price, in order to become certified again. This letter will be mailed requiring a signature receipt.

**Changing Scope of Certification**

In the event that a certificant is no longer able to meet the requirements of the certification, the certified person must inform ACI, without delay, of matters that can affect the capability of the certified person to continue to fulfil the certification requirements.

**Suspension/Leave of Absence Status**

A certificant may apply for a suspension of their certification for one of the two following reasons:

- Health reasons
- Military deployment

Candidates must submit the application and the following documentation with request.

- Doctor or deployment orders
- All CEUs, including documentation, earned to that point in their recertification cycle.

If a suspension is granted, it may not extend beyond two years. The certificant’s certification will be marked as inactive during the suspension.
When the candidate is ready to return to active status, the certificant will be required to submit the necessary CEUs to complete their cycle and submit their renewal fee. Once the fee and necessary CEUs are submitted and approved, the certificant’s certification will be returned to active status. The certification cycle may be adjusted depending on the return of the suspension.

**Retired Status**
Retired status may be granted in accordance with ACI Board requirements to individuals who are retired from employment in the HTM profession and do not meet the requirements for emeritus status. Individuals who qualify for retired status will be required to submit a $25 renewal fee to maintain the status.

Individuals under the retired status may not work in the field in any capacity. They will be listed in the directory with a “-R” after their designation. If it is determined that the person is still working in the field, they will lose the designation and will need to retest to earn the designation again.

**Emeritus Status**
1. Purpose: To recognize a demonstrated effort through continuing practice, in order to reach new levels of knowledge in the HTM field.
2. Qualifications for Emeritus Status: Eligible candidates must submit the status change request form and meet one of the following requirements:
   - Retired from employment in the HTM profession, whose number of years certified, when added to their years of work experience in the HTM field, is greater or equal to 30 years; or;
   - Retired from employment in the HTM field and held at least 15 years of continuous years of active certification status.

Individuals earning the Emeritus status will no longer be required to submit a continuing practice journal or recertification fee, and they will be listed in the on-line registry as "Emeritus".

**Complaints of Disciplinary Violation**
The ACI Board chair, vice-chair and one other ACI Board member will be responsible for implementing disciplinary policies and procedures as established by the ACI Board. Grounds for disciplinary action shall include, but are not limited to the following:

- Evidence of falsification of information provided on documents submitted to the ACI or its agents.
- Cheating on certification exams or audits.
- Evidence of non-compliance with the Code of Conduct.
- Evidence of improper use of the ACI certification status, logos and/or acronyms.
- Violation of established ACI certification policies, rules and requirements.
- Conviction of a felony or other crime of moral turpitude under federal or state law.
- Gross negligence, willful misconduct, or other unethical conduct in the performance of services for which the individual has achieved certification from ACI.

The ACI Board will establish procedures to fairly and consistently address alleged violations. Disciplinary procedures are designed to ensure that valid and actionable complaints are investigated and considered, and that all parties involved in the complaint have an opportunity to document circumstances warranting the complaint and to respond to the complaint.

All complaints will first be reviewed by the ACI staff who will then report the complaint to the ACI Chair. If the complaint can be verified and resolved without further documentation or investigation, staff will notify the Board chair and the complaint will be closed.

If the complaint requires additional information, the complainant will be required to submit a signed ACI complaint form with supporting documents within 30 days of request for further actions to be considered. Upon receipt and review of the complaint form and supporting documentation, the ACI staff may inform, in writing, the accused and/or complainant of the official opening of an investigation.

ACI staff will acknowledge receipt of complaint form and supporting documentation. The accused will have the opportunity to respond to the complaint made against him/her within 30 days of notification of the investigation.

Following the investigation, the ACI Chair will inform the complainant of the decision in writing. The complainant will be notified in writing that a decision was reached. If disciplinary action is imposed, the complainant may submit an appeal of the decision to the full ACI Board.
This appeal must be submitted in writing to the ACI Chair. A signed appeal must be submitted in writing within 60 days from receipt of the written notification that a disciplinary action is imposed and must clearly state the grounds for appeal.

Below are two possible decisions that the ACI board may make in regards to a complaint.

Withdrawal/Revocation
When a complaint is received by ACI which upon investigation by the policies and processes laid out appears to be due to negligence or intentional malpractice or violation of the code of conduct, the ACI Board may withdraw certification. In the event of withdrawal, the certified professional must refrain from further use of all references to certified status.

Suspension
When a complaint is received by ACI which upon investigation by the policies and processes laid out appears to be due to accidental causes, unintentional negligence or oversight, the ACI Board may suspend the certificant’s certification for a specific period. The ACI Board may establish monitoring procedures during the suspension which the certificant must conform to. During the time of suspension the certificant must refrain from further promotion of his or her certification. If the certificant does not remedy the conditions of the suspension, the certificant’s certification may be withdrawn.

Appeals
In addition to appeals of disciplinary action, an individual or certificant who was denied certification or had his/her certification revoked may file an appeal within 60 days of receipt of notice of the action taken that is eligible for appeal.

Filing of Appeal
The appeal shall state the nature of the objection, including the details, and the specific remedial action that the appellant is requesting. Upon the filing of a properly executed appeal, the original action will be suspended until final action is taken on the appeal. ACI staff makes an initial determination of whether the appeal has been properly filed and includes all needed documentation and rationale. Appellants will be notified within 60 days of ACI’s receipt whether the appeal has been filed properly for an appealable action.

Appeals Body
The ACI Board is the appeals body that hears appeals. The full ACI Board is the final body to hear an appeal and there are no further appeals once the full ACI Board has acted. The ACI Board ruling is final.

Fee
The fee for an appeal with the ACI Board is $750 (U.S.D.) payable by the individual filing the appeal. The fee for a subsequent appeal to the full ACI Board is an additional $1,000 (U.S.D.). Fees are payable with the filing of the appeal. An appellant may request that ACI to reduce these fees and must provide a rationale for this request (e.g., demonstrable financial hardship). The decision to reduce any appeal fee will be made by the ACI Board Chair after review of the request and rationale.

ACI Board Consideration of the Appeal
The ACI Board reviews all properly filed and documented appeals to determine if significant evidence exists of a substantive error or omission in the certification process or outcome. Decisions require a (2/3) two-thirds vote by committee members. When the ACI Board reaches a decision, the appellant will be notified in writing within 60 days of such decision being made. The appellant may request a hearing on the appeal, but is responsible for paying all administrative expenses of the ACI associated with such a hearing (including but not limited to travel expenses of the ACI Board, if the appellant wishes to have a hearing in person).

Complaint Form
Certificants or other individuals within the industry can request a complaint form by contacting ACI at aci@aami.org.
Certified Associate in Biomedical Technology

Content Outline

Anatomy & Physiology
1. Understand the basic functions and interactions of the physiological systems (e.g., Respiratory, Nervous, Circulatory)
2. Identify the basic function of the major organs (e.g., Heart, Lungs, Kidneys, Brain, Skin, Blood)

Medical Devices as Related to Patient Care
1. Understand the purpose and basic function of diagnostic medical equipment (e.g., otoscope, ophthalmoscope, thermometer, scales, centrifuges, bladder scanners, EKG cart, microscopes)
2. Understand the purpose and basic function of patient monitoring equipment (e.g., non-invasive blood pressure, pulse oximetry, telemetry, EtCO₂, ECG)
3. Understand the purpose and basic function of therapeutic medical equipment (e.g., infusion pumps, suction pumps, syringe pumps, PCA pumps, physical therapy equipment, defibrillator, patient warming and cooling)
4. Understand the proper use of hand tools (e.g., graduated cylinder, stopwatch, Allen and torque wrenches, channel locks, needle-nose pliers, diagonal cutters, wire stripper, vice grips)
5. Understand the proper use of biomed test equipment (e.g., multimeter, electrical safety analyzer, patient simulator, tachometer, scale)

Safety in Healthcare
1. Understand safety concepts and symbolism (e.g., lock out tag out (LOTO), safety data sheets (SDS), color coding for gases, signage)
2. Identify potential safety hazards (e.g., environmental, electrical (micro- and macro-shock), chemical)
3. Follow universal precautions and infection control procedures
4. Understand the safety risks when working with various medical equipment (e.g., imaging devices, defibrillator, lab equipment, PPE)

Fundamentals of Electricity and Electronics
1. Understand Ohm’s Law and how it applies to electrical safety and testing
2. Understand basic concepts of electricity and symbols (e.g., fuses, circuit breakers, capacitors, batteries, transformers)
3. Understand direct and alternating current principles
4. Understand basic electronics terminology (e.g., electrostatic discharge (ESD), wiring, color-code wire standards, ground, voltage, current, resistance, LED)
5. Interpret basic operation of a simple circuit (e.g., power supply, switch, load)
6. Identify open and short circuits within a simple circuit

Reasoning and Problem Solving
1. Perform unit conversions and unit readings within the metric system (e.g., visual measurement, wave forms, tolerance)
2. Read and interpret visual representations of information (e.g., graphs, tables)
3. Use provided information and resources to determine next steps (e.g., flowchart, process of elimination, service manual)

Healthcare Information Technology
1. Use basic computer and smart-phone applications (hardware and software)
2. Understand basic concepts of computer architecture and systems/schema (e.g., RAM, hard-drive, solid-state drive, CPU, GPU, power supply, printers (local and network))
3. Understand computer connectors (e.g., video output, USB-types, network cables)
4. Understand basics of local and wireless networks (e.g., LAN, WAN, Bluetooth, Radio Frequency Identification (RFID), data closet, server rack, VPN, VLAN)
5. Understand basic HIPAA regulations as they apply to device integration and electronic medical record (EMR)
6. Understand the importance of network security (e.g., firewalls, phishing, patches, passwords)

The CABT exam is a two-hour closed book exam consisting of 100 multiple choice questions.

Candidates will have access to a simple calculator during the exam. Cell phones, iPads or other electronic devices that have internet capabilities or cameras are not allowed into the testing room.

Score required to pass: The minimum score required to pass the CABT examination is 75/100.
Certified Biomedical Equipment Technician Content Outline

Anatomy & Physiology – Approximately 12%
1. Understand the functions, abnormal functions, and interactions of the physiological systems (e.g., Respiratory, Gastrointestinal, Nervous, Circulatory, Musculoskeletal, Endocrine).
2. Identify components and function of the major organs (Heart, Lungs, Liver, Kidneys, Brain, Gallbladder, Pancreas, Skin, Blood).

Public (employee, patient, visitor) Safety in the Healthcare Facility – Approximately 14%
1. Understand and apply NFPA99 to the use of medical equipment.
2. Interpret information from safety data sheets, apply PPE, and identify standard hazard symbolism and signage.
3. Identify blood-borne pathogen hazards, follow universal precautions, and determine appropriate infection control procedures.
4. Apply expectations from relevant accrediting organizations (Joint Commission, DNV, CMS, etc.) as applicable to healthcare environments.

Fundamentals of Electricity & Electronics – Approximately 10%
1. Understand and apply foundational electronic theories as they apply to voltage, resistance, current, resistors, active and passive devices, transducers, capacitors, and inductors including the utilization of schematics.
2. Understand the purpose and usage of various power conditioning, distribution, and storage systems (Transformers, Batteries).

Healthcare Technology and Function – Approximately 25%
1. Understand physiological concepts as applicable to healthcare technology (e.g., PEEP sphygmomanometer, manometer, Korotkoff sounds, Einthoven’s triangle, 10-20-10 EEG pattern).
2. Understand normal function, use, and underlying technology of test equipment (electrical safety analyzer, defibrillator analyzer, electro surgical analyzer, physiologic simulators, DVM, meters).

Monitoring Equipment
3. Understand normal function and underlying technology of monitoring systems (e.g., EtCO2, ECG, EEG, non-invasive blood pressure, invasive blood pressure, pulse oximetry, fetal monitor, respiration).

Diagnostic Equipment
4. Understand normal function and underlying technology of laboratory equipment (e.g., centrifuges, water baths, analyzers, cryostats, microlomes).
5. Understand normal function and underlying technology of imaging devices (e.g., Ultrasound, Radiographic/Fluoroscopy).
6. Understand normal function and underlying technology of diagnostic equipment (e.g., otoscope, ophthalmoscope, audiometer, uroflow meter).

Therapeutic Equipment
7. Understand normal function and underlying technology of infusion equipment (e.g., feeding pumps, infusion devices, syringe pumps, PCA pumps).
8. Understand normal function and underlying technology of life support equipment (e.g., defibrillators, anesthesia machines, ventilators, balloon pumps, external pacemakers).
9. Understand normal function and underlying technology of therapeutic equipment (e.g., infant warmers, ultrasound therapy, hypo/hyperthermia, aspirators, SCD, Bilirubin light).
10. Understand normal function and underlying technology of operating room equipment (e.g., electro surgical generators, video equipment, lasers, tourniquets, sterilizers, warmers).

Healthcare Technology Problem Solving – Approximately 25%
1. Identify and resolve fault conditions of modules/subsystems including power supplies.
2. Prioritize repairs of medical devices based on level of risk and/or urgency.
3. Differentiate between a device error and a use error (User Training, Applications) to determine appropriate action.

Monitoring Equipment
4. Differentiate between an issue with a localized monitoring device on a network and a system-wide problem.
5. Identify the fault conditions and apply appropriate corrective action for monitoring systems (EtCO2, ECG, EEG, non-invasive blood pressure, invasive blood pressure, pulse oximetry, fetal monitor, respiration).

Diagnostic Equipment
6. Identify the fault conditions and apply appropriate corrective action for laboratory equipment (Centrifuges, Water Baths, Analyzers, cryostats, microtomes).
7. Identify the fault conditions and apply appropriate corrective action for diagnostic equipment (otoscope, ophthalmoscope, audiometer, uroflow meter).

Therapeutic Equipment
8. Identify the fault conditions and apply appropriate corrective action for infusion equipment (feeding pumps, infusion devices, syringe pumps, PCA pumps).
9. Identify the fault conditions and apply appropriate corrective action for therapeutic equipment (infant warmers, ultrasound therapy, hypo/hyperthermia, aspirators, SCD, Bilirubin light, defibrillators, external pacemakers).
10. Identify the fault conditions and apply appropriate corrective action for operating room equipment (electro surgical generators, video equipment, tourniquets, sterilizers, warmers).

Healthcare Information Technology – Approximately 14%
1. Understand and apply protective standards and regulation for protected data (HITECH, Medical Device Data Systems [MDDS], IEC 80001 – Application of Risk Management for IT Networks, Health Insurance Portability and Accountability Act [HIPAA], Manufacturer Disclosure Statement for Medical Device Security, Digital Millennium Copyright Act [DMCA]).
2. Identify and troubleshoot PC hardware and networking components (wired and wireless) with use of appropriate diagnostic tools (e.g., cable tracers, cable testers, PING).
3. Understand the interrelatedness of computer applications.
4. Understand and apply the fundamentals of network configuration.

The CBET exam is a three-hour closed book exam consisting of 165 multiple choice questions.

Candidates will have access to a simple calculator during the exam. Cell phones, iPads or other electronic devices that have internet capabilities or cameras are not allowed into the testing room.

Score required to pass: The minimum score required to pass the CBET examination is 116/165.
Certified Radiology Equipment Specialist
Content Outline

Anatomy & Physiology – Approximately 10%

1. Identify the characteristics and functions of organs (e.g. Heart, Lungs, Liver).
2. Identify the characteristics and functions of systems (e.g. Gastrointestinal, Circulatory, Musculoskeletal).
3. Understand the relationship between anatomy and the technique to be used across all imaging modalities.
4. Understand and use medical terminology correctly.

Public (employee, patient, visitor) Safety in the Healthcare Facility – Approximately 10%

1. Understand the appropriate electrical and mechanical safety protocols to ensure patient, visitor, and staff safety.
2. Understand the hazards associated with the magnetic environment associated with the MRI.
3. Understand the effect of radiation on patients, visitor and staff, as well as policies, procedures and physical activities to help reduce its impact.
4. Understand regulations and applicable standards from relevant accrediting organizations (e.g. Joint Commission, CMS, OSHA, FDA, etc.), including appropriate documentation.

Fundamentals of Electricity & Electronics – Approximately 10%

1. Understand and apply fundamental electronic theories as they apply to voltage, resistance, current, including the utilization of schematics.
2. Understand fundamental theories of electronic components.
3. Understand facility power distribution (3 phase, 480, VAC).
4. Understand the fundamentals of imaging system power distribution and storage devices, including UPS/Line Conditioning and high voltage generation.

Healthcare Technology and Function – Approximately 25%

1. Identify all parts of the specialty components and describe their function (e.g. X-Ray tubes, digital detectors, flat panel displays).
2. Identify systems and subsystems, their function, and how they are connected (e.g. X-Ray machine - tables, generator, controls, console).
3. Understand and apply preventive/corrective maintenance procedures in accordance with manufacture’s specifications, regulatory standards, or local policy.
4. Understand and use applicable terminology correctly.

Healthcare Technology Problem Solving – Approximately 25%

1. Identify faulty operation of systems or subsystems using schematic diagrams, manuals, diagnostic software and vendor support.
2. Understand how to systematically and logically troubleshoot and repair equipment to manufacturer’s specifications.
3. Prioritize repairs of medical devices based upon level of risk.

Healthcare Information Technology – Approximately 20%

1. Understand the principles of system and network security and actions necessary to regulatory compliance.
2. Understand the fundamentals of hardware and software as it applies to imaging systems, networking, communications, and healthcare information systems.
3. Troubleshoot assorted hardware and software components and communication issues.

The CRES exam is a three-hour closed book exam consisting of 165 multiple choice questions. Candidates will have access to a simple calculator during the exam. Cell phones, iPads or other electronic devices that have internet capabilities or cameras are not allowed into the testing room.

Score required to pass: The minimum score required to pass the CBET examination is 118/165.
Certified Healthcare Technology Manager
Content Outline

Financial Management – Approximately 20%
3 – Recall Questions
13 – Application Questions
3 – Analysis Questions

A. Manage financial planning for HTM resources of the organization
   1. Analyze the financial details of past, present, and expected operations to identify development opportunities and areas where improvement is needed.
   2. Develop business justifications and return on investment (ROI)

B. Develop and manage HTM annual budgets
   1. Manage HTM department revenue and expense general ledger (e.g., supplies, payroll, parts, consumables, contracts, training)
   2. Analyze and explain financial statements, business activity reports, financial forecasts

C. Manage and advise procurement activities
   1. Assist in determining life expectancy for medical equipment and systems (i.e., capital planning)
   2. Assure compliance with organizational policies and procedures and generally accepted accounting principles [GAAP] (e.g., accounts payable, accounts receivable)

   3. Evaluate and manage vendor service and support contracts
      a. Cost
      b. Compliance
      c. Terms and conditions

   4. Review sourcing options for parts, service, training, and test equipment/tools.

   5. Advise management on actions regarding the fair market value of purchase, lease, or asset recovery value of disposed healthcare technology.

Risk Management – Approximately 16%
2 – Recall Questions
8 – Application Questions
2 – Analysis Questions

A. Identify and evaluate key risks associated with the use of healthcare technology (e.g., patient safety, operations, financial impact, emergency preparedness, regulatory).

B. Recommend processes, procedures, or policies to control or mitigate risk.

C. Apply risk-assessment models or methodologies (e.g., root cause analysis [RCA], incident investigations, Failure Modes and Effects Analysis [FMEA])

D. Produce reports that outline findings, explain risk positions, or recommend changes (e.g., Safe Medical Devices Act of 1990 [SMDA], Sentinel Event alerts).

E. Assure integrity of data collection, data storage, and data security associated with healthcare technology (e.g., PACS, EMR, networked devices, etc.).

F. Support the evaluation and mitigation risk of networked/integrated devices (e.g., cybersecurity, physical security, patching, hardening of systems, Wireless Medical Telemetry Service [WMTS], network segmentation)

G. Manage recalls, hazards, and safety advisories in use in healthcare technology.

Operations Management – Approximately 40%
11 – Recall Questions
11 – Application Questions
24 – Analysis Questions

A. Manage activities directly related to providing HTM services (e.g., work orders, project management, customer satisfaction)

B. Ensure appropriate documentation in CMMS regardless of equipment ownership (e.g., asset inventory information, parts, work orders, service history, recalls and end-of-life).

C. Coordinate the internal and external activities of service providers (e.g., planning acquisition, contracting, installation, training, sustainment/lifecycle management).
D. Review performance data to measure productivity and goal achievement (e.g., financials, activity reports, KPIs, staffing, competencies, cost reduction, program improvement).

E. Develop departmental and/or team policies and procedures, goals, and objectives:
   1. Maintain departmental policies and procedures (e.g., MEMP, SOPs, EOC manual).
   2. Measure and report goals and objectives (e.g., KPIs, EOC metrics, compliance).
   3. Determine departmental staffing and scheduling requirements.
   4. Report performance to appropriate committees/stakeholders (e.g., EOC, patient safety, risk management, performance improvement, radiation safety, infection control, cost of service ratio [COSR], benchmarking).

F. Comply with federal, state, and local regulatory requirements, accreditation requirements, and deemed status organizations (e.g., CMS, FDA, FCC, HIPAA, NRC).

G. Ensure resources are available to complete departmental activities (e.g., PPE, tools, test equipment, supplies, technical information, and training).

H. Participate in capital planning to evaluate healthcare technology requests
   1. Assess project feasibility and requirements (e.g., space, site prep, power, network)
   2. Evaluate sustainability and service strategy (e.g., parts, training, service manuals, life expectancy, Maude reports)
   3. Advocate for standardization
   4. Support oversight of cyber-security and vulnerability (e.g., operating system life expectancy, network security, antivirus, patching)

I. Engage in project management activities (e.g., create/review project plans, coordinate project activities, engage with stakeholders, implement sustainment plan, participate in construction planning meetings)

J. Lead departmental and/or team meetings and communications.

K. Communicate with department leaders, vendors, and stakeholders, encouraging cooperation, identifying issues, and resolving problems (e.g., scheduled meetings, rounding, daily huddles)

L. Collaborate with stakeholders (e.g., IT, nursing, vendors, informatics, technicians, senior leadership, facilities)
   1. Consult with users, management, vendors, and technicians to assess healthcare technology needs and requirements.
   2. Collaborate with other departments on utility maintenance and interruption (e.g., network, telecom, electrical, plumbing, mechanical systems, change management, downtime procedures).
   3. Maintain device and systems interoperability

M. Ensure electronic data management of computerized healthcare technology assets occurs (e.g., backups, security, patching, updates)

Education & Training – Approximately 11%

A. Analyze training needs based on cost, ROI, operations, technical requirements, competency, customer requirements, resources, asset inventory, etc.

B. Evaluate the effectiveness of training programs (e.g., cost, failure rates, total time to repair, staff competencies/skill set, user satisfaction).

C. Manage training and professional development for staff members.
   1. Safety
   2. Soft skills
   3. Technical skills
   4. Regulatory requirements/code compliance
   5. Internal department and facility policies and procedures
   6. Orientation and initial training (e.g., assign mentor, SOP, facility and shop)

D. Facilitate operator training to address failure trending and use error

E. Collaborate with user departments and facilitate operator training to address staff and inventory changes
(e.g., database management, new equipment, new clinical applications, new employees/staff)

F. Collaborate with non-clinical departments (e.g., infection prevention, facilities management, materials management, IT).

G. Assure availability of training manuals (e.g., service manuals, operations manuals, training media, and other educational materials).

**Human Resources – Approximately 13%**

- 3 – Recall
- 9 – Application
- 0 – Analysis

A. Lead job description development, employee selection, retention, and termination process.

B. Conduct performance evaluations of departmental and/or team staff.
   1. Evaluate staff performance to determine appropriate compensation
   2. Evaluate staff observance of organizational values
   3. Evaluate staff engagement
   4. Develop performance development plans
   5. Provide appropriate recommendations to human resources

C. Perform personnel management activities.
   1. Write and communicate periodic evaluations
   2. Document improvement opportunities
   3. Set employee goals
   4. Provide coaching/mentoring
   5. Deliver recognition
   6. Manage employee conflict
   7. Facilitate change
   8. Participate in personnel-related hearings and investigations on behalf of the organization
   9. Ensure competency of HTM department staff

D. Ensure department and team practices comply with federal, state, and local labor laws (e.g., ADA, EEOC, FMLA, and NLRA).

E. Ensure a safe work environment (e.g., OSHA compliance, PPE utilization)

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The CHTM exam is a two-hour closed book exam consisting of 100 multiple choice questions.

Candidates will have access to a simple calculator during the exam. Cell phones, iPads or other electronic devices that have internet capabilities or cameras are not allowed into the testing room.

*Score required to pass: The minimum score required to pass the CHTM examination is 72/100.

*The May 2023 CHTM exam will be given on a new form. Scores will take 60-90 days to be assessed and the passing score may differ from the previous form.*
Certified Industrial Sterilization Specialist
Core Exam Content Outline

Quality Management Systems – Approximately 11%
A. Adhere to compliance regulations
B. Assemble sterilization data to support regulatory requirements
C. Audit sterilization providers
D. Establish procedures for incoming sterilization supplies (e.g. gas, dosimeters, biological indicators, chemical indicators)
E. Interface with contract organizations (e.g. laboratories, sterilizers)
F. Interface with internal departments (e.g. R&D, regulatory, packaging)
G. Interpret regulatory requirements
H. Perform GAP analyses to reflect changes in regulatory requirements and standards
I. Process technical agreements
J. Support regulatory inspections
K. Update internal documents to reflect changes in regulatory requirements and standards
L. Write technical rationales

Sterilization Agent, Process, and Equipment Characterizations – Approximately 10%
A. Assess the adequacy of the calibration program for sterilization equipment
B. Assess the adequacy of the preventive maintenance program for sterilization equipment
C. Select the proper sterilization agent for the target device
D. Ensure the microbiologic methods are appropriate
E. Identify the equipment to be used in the process
F. Perform process characterization
G. Adhere to safety requirements

Product and Process Definition – Approximately 25%
A. Ensure assessment of the sterilization process for impact on product safety, functionality, quality, and performance
B. Identify the steps of sterilization
C. Assess the adequacy of manufacturing environmental controls
D. Assist in the design of products/packaging for sterilization
E. Design sterilization processes
F. Determine the microbiological qualification method
G. Develop Process Challenge Devices (PCDs)
H. Establish a load configuration
I. Establish parameters of the sterilization process
J. Establish product groups
K. Establish the rationale for the product sterility assurance level
L. Establish tolerances of the sterilization process
M. Interpret bioburden data
N. Qualify microbiological effectiveness of the process (radiation)
O. Select biological indicators
P. Select the correct sterilization process for the product

Validation – Approximately 25%
A. Analyze validation results
B. Determine the locations of routine process monitors (e.g. biological indicators, dosimeters, chemical indicators)
C. Determine the placement of validation process monitors
D. Develop sterilization procedures for validation
E. Ensure equipment is calibrated prior to use
F. Establish a validation process
G. Ensure the microbiologic methods are validated
H. Establish acceptance criteria for validation
I. Perform sterilization validation
J. Qualify microbiological effectiveness of the process (non-radiation)
K. Assess that the process does not adversely affect the product functionality
L. Qualify the equipment
M. Qualify the process is reproducible
N. Review sterilization residuals for adverse levels
O. Review validation data
P. Write sterilization validation protocols
Q. Write validation reports

Routine Monitoring, Control and Product Release – Approximately 15%
A. Develop a sterilization procedure that can be followed by sterilization personnel
B. Ensure equipment is calibrated prior to use
C. Ensure processed and non-processed product segregation
D. Ensure sterilization procedures are followed
E. Establish acceptance criteria for routine sterilization process
F. Interpret environmental data
G. Investigate microbiology issues
H. Assess the impact of process non-conformance
I. Review routine process records
J. Troubleshoot process anomalies

Maintaining Process Effectiveness – Approximately 14%
A. Assess change to process
B. Assess change to product/package
C. Assess process equivalence
D. Document rationale for product adoption
E. Establish requalification criteria
F. Evaluate sterilization process anomalies (e.g. residuals, wet packs, blown-seals)
G. Investigate product complaints (e.g. sterility, functionality)
H. Perform periodic process requalification
I. Perform periodic process review
J. Recognize opportunities to optimize the process

The CISS Core exam is a two-hour closed book exam consisting of 75 multiple choice questions.

Candidates will be allowed to bring a scientific, non-printing calculator to use during the exam. Cell phones, iPads or other electronic devices that have internet capabilities or cameras are not allowed into the testing room.

Score required to pass: The minimum score required to pass the CISS-Core examination is 60/75.
Certified Industrial Sterilization Specialist
Specialty Exam Content Outline

Each specialty has the same content outline but
candidate should relate the content to the specialty
they are taking.

Sterilization Agent, Process, and Equipment
Characterizations – Approximately 10%
A. Assess the adequacy of the calibration program
   for sterilization equipment
B. Assess the adequacy of the preventive
   maintenance program for sterilization equipment
C. Select the proper sterilization agent for the
   target device
D. Ensure the microbiologic methods are
   appropriate
E. Identify the equipment to be used in the process
F. Perform process characterization
G. Adhere to safety requirements

Product and Process Definition – Approximately 24%
A. Ensure assessment of the sterilization process
   for impact on product safety, functionality,
   quality, and performance
B. Identify the steps of sterilization
C. Assess the adequacy of manufacturing
   environmental controls
D. Assist in the design of products/packaging for
   sterilization
E. Design sterilization processes
F. Determine the microbiological qualification
   method
G. Develop Process Challenge Devices (PCDs)
H. Establish a load configuration
I. Establish parameters of the sterilization process
J. Establish product groups
K. Establish the rationale for the product sterility
   assurance level
L. Establish tolerances of the sterilization process
M. Interpret bioburden data
N. Qualify microbiological effectiveness of the
   process (radiation)
O. Select biological indicators
P. Select the correct sterilization process for the
   product

Validation – Approximately 26%
A. Analyze validation results
B. Determine the locations of routine process
   monitors (e.g. biological indicators, dosimeters,
   chemical indicators)
C. Determine the placement of validation process
   monitors
D. Develop sterilization procedures for validation
E. Ensure equipment is calibrated prior to use
F. Establish a validation process
G. Ensure the microbiologic methods are validated
H. Establish acceptance criteria for validation
I. Perform sterilization validation
J. Qualify microbiological effectiveness of the
   process (non-radiation)
K. Assess that the process does not adversely
   affect the product functionality
L. Qualify the equipment
M. Qualify the process is reproducible
N. Review sterilization residuals for adverse levels
O. Review validation data
P. Write sterilization validation protocols
Q. Write validation reports

Routine Monitoring, Control and Product Release –
Approximately 20%
A. Develop a sterilization procedure that can be
   followed by sterilization personnel
B. Ensure equipment is calibrated prior to use
C. Ensure processed and non-processed product
   segregation
D. Ensure sterilization procedures are followed
E. Establish acceptance criteria for routine
   sterilization process
F. Interpret environmental data
G. Investigate microbiology issues
H. Assess the impact of process non-conformance
I. Review routine process records
J. Troubleshoot process anomalies
Maintaining Process Effectiveness – Approximately 20%

A. Assess change to process
B. Assess change to product/package
C. Assess process equivalence
D. Document rationale for product adoption
E. Establish requalification criteria
F. Evaluate sterilization process anomalies (e.g. residuals, wet packs, blown-seals)
G. Investigate product complaints (e.g. sterility, functionality)
H. Perform periodic process requalification
I. Perform periodic process review
J. Recognize opportunities to optimize the process

The CISS Specialty exams are a one-hour closed book exam consisting of 50 multiple choice questions.

Candidates will be allowed to bring a scientific, non-printing calculator to use during the exam. Cell phones, iPads or other electronic devices that have internet capabilities or cameras are not allowed into the testing room.

Score required to pass: The minimum score required to pass the CISS Specialty exams are:
- EO – 39/50
- MH – 40/50
- Rad – 39/50
**Exam Resources**

The following is not intended to be a complete listing of every source available, nor should applicants feel they must purchase and study every item on this list. Most texts in a particular category are redundant. The list is purposely long to increase the probability that everyone will have access to at least some of the sources listed. Other generally accepted texts may be of equal value in preparation for the examinations.

**CABT References**

AAMI Study Courses and Products:


**CBET and CRES References**

AAMI Study Courses and Products:

CBET Study Course (Online): 8-session online training held in April and October. Registration for future sessions at www.aami.org/store.

CBET Study Course (eLearning): Self-paced online course that covers each of the 6 topic areas of the CBET exam with multiple post-module practice exams, including a 165-question final practice exam. Can be purchased at www.aami.org/store.

CBET Adaptive Test Prep: CBET & CRES study guide that is delivered on an adaptive learning platform built based on cognitive science and proven to reduce study time and increase retention. Interested testers can purchase this at www.aami.org/store.

**Anatomy, Physiology, and Medical Terminology**


**Safety and Regulatory-Public and Patient Safety in the Health Care Facility**


MQSA: Mammography Quality Standards Act http://www.fda.gov/cdrh/mammography/


NEMA Standards (Publication No. XR 8, XR9, XR11, XR12): National Electrical Manufacturers Association http://nema.org/


OSHA: Occupational Safety & Health Administration http://www.osha.gov/
**Electronics and Devices**


**Biomedical Instrumentation (General)**


**Health Care Information Technology**


**Radiology**


**CHTM References**


Wang, Binseng: *Medical Equipment Maintenance: Management and Oversight* (Synthesis Lectures on Biomedical Engineering) 2012 Articles


Janssen, Martin and Schrenker, Rick: *Guidelines From 80001 Maintaining a Medical IT Network Biomedical Instrumentation & Technology*, Jul 2011, Vol. 45, No. 4, pp. 295-29


**Links**

- [Association for the Advancement of Medical Instrumentation (AAMI)](http://www.aami.org)
- [80001-1 Managing Medical IT-Networks: 2012](http://www.aami.org)

**Federal Communications Commission**

- [WMTS](http://www.fcc.gov)

**U.S. Department of Labor (DOL)**

- [Americans with Disabilities Act](http://www.dol.gov)
- [Disability Resources](http://www.dol.gov)
- [Fair Labor Standards Act](http://www.dol.gov)
- [Family and Medical Leave Act](http://www.dol.gov)
- [Federal Wage Garnishments](http://www.dol.gov)
- [Wage and Hour Division](http://www.dol.gov)

**U.S. Food and Drug Administration (FDA)**

- [Safe Medical Devices Act Family](http://www.fda.gov)
- [FDA 21 CFR 800 and 1000 series](http://www.fda.gov)

**Various Links**

- [AHA Healthcare Data Viewer](http://www.aha.org)
- [American National Standards Institute ANSI](http://wwwansi.org)
- [ASHE: Registration of Equipment Operating in WMTS Band](http://www.ashe.org)
- [CMS Categorical Waiver for Power Strips Use in Patient Care Areas](http://www.cms.gov)
- [CMS Medical Equipment Standards](http://www.cms.gov)
- [Code of Federal regulations CCPA 29CFR 870](http://www.cfr.gov)
- [HIPAA](http://www.hhs.gov)
- [IEC](http://www.iec.ch)
- [MQSA Mammography Quality Standards Act](http://www.mqsa.org)
- [MRI Facility Design Guide](http://www.mri.org)
- [NFPA 70, 99, 101](http://www.nfpa.org)
- [NLRB: Rights We Protect](http://www.nlrb.gov)
- [OSHA](http://www.osha.gov)
- [U.S. EEOC](http://www.eeoc.gov)

**CISS References**

- ISO 10993-7
- ISO 11135
- ISO 11137-1,-2,-3
- ISO 11138-1,-2 (for EO), -3 for moist heat
- ISO 11139
- ISO 11607-1,-2
- ISO 11737-1,-2
- ISO 17665-1,-2,-3 for moist heat
- ISO 14161
- ISO 14937
- TIR 14, 15, 16, 17, 28, 39, 52, 56, 67

For the Moist Heat Specialty exam:

- PDA TR 1, PDA TR 48, TIR 12

For the Radiation Specialty exam:

- TIR 29, 33, 35, 37, 40
Study Guides and Review Courses

It is considered a conflict of interest for any certifying organization or commission to help individuals attain the credential it issues. The ACI does not sponsor or endorse any refresher course, study guides, or study materials of any kind. Contact a local biomedical society or ask colleagues about organizing study groups or arranging for review courses.
# Certification Exam Pricing

<table>
<thead>
<tr>
<th></th>
<th>Member Fee</th>
<th>Non-member Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exam Fees</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABT Exam Fee</td>
<td>$200</td>
<td>$250</td>
</tr>
<tr>
<td>CABT Retake Fee</td>
<td>$175</td>
<td>$225</td>
</tr>
<tr>
<td>CBET &amp; CRES Exam Fee</td>
<td>$350 ($100 is non-refundable)</td>
<td>$400 ($100 is non-refundable)</td>
</tr>
<tr>
<td>CBET &amp; CRES Retake Fee (non-refundable)</td>
<td>$275</td>
<td>$325</td>
</tr>
<tr>
<td>CHTM Exam Fee</td>
<td>$420 ($100 is non-refundable)</td>
<td>$500 ($100 is non-refundable)</td>
</tr>
<tr>
<td>CHTM Retake Fee (non-refundable)</td>
<td>$300</td>
<td>$350</td>
</tr>
<tr>
<td>CISS Exam Fee – Core</td>
<td>$250 ($100 is non-refundable)</td>
<td>$300 ($100 is non-refundable)</td>
</tr>
<tr>
<td>CISS Exam Fee – Specialty (each)</td>
<td>$250</td>
<td>$300</td>
</tr>
<tr>
<td>CISS Retake Fees (non-refundable)</td>
<td>$225</td>
<td>$275</td>
</tr>
<tr>
<td>International Exams (outside domestic USA &amp; Canada)</td>
<td>$100 additional</td>
<td>$100 additional</td>
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<tr>
<td>Late Registration Fee (non-refundable)</td>
<td>$50 additional</td>
<td>$50 additional</td>
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<tr>
<td>Rescheduling Fee (outside of 5 business days)</td>
<td>$50</td>
<td>$50</td>
</tr>
<tr>
<td>Rescheduling Fee (inside of 5 business days)</td>
<td>Forfeit all exam fees</td>
<td>Forfeit all exam fees</td>
</tr>
<tr>
<td>No Show Fee</td>
<td>Forfeit all exam fees</td>
<td>Forfeit all exam fees</td>
</tr>
<tr>
<td><strong>Recertification</strong></td>
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<tr>
<td>Recertification Fees (non-refundable)</td>
<td>$100</td>
<td>$150</td>
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<tr>
<td>Additional Fee for multiple certification</td>
<td>$50 (per additional certification)</td>
<td>$75 (per additional certification)</td>
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<tr>
<td>Reactivation Fee (received after December 31)</td>
<td>$100</td>
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<tr>
<td><strong>Miscellaneous</strong></td>
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<tr>
<td>Upgrade Fee</td>
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</tr>
<tr>
<td>New Certificate</td>
<td>$25</td>
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</tbody>
</table>
ACI RECERTIFICATION CATEGORIES (Beginning January 1, 2017)
(related to current content outline for designation held by certificant)

**Category I: Earn an additional HTM-related certification (maximum CEUs allowed in this category is 15)**

<table>
<thead>
<tr>
<th>Certifications</th>
<th>CEUs/certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTM related certifications including ACI certification programs (CBET, CHTM, CISS), and CCE</td>
<td>5 CEUs/certification</td>
</tr>
<tr>
<td>Healthcare-related Certifications (such as CHSP, CQSP, CMLT, dialysis certifications)</td>
<td>2 CEUs/certification</td>
</tr>
<tr>
<td>Technology-related Certification (such as A+, NET+, S+, MSCE, CET)</td>
<td>2 CEUs/certification</td>
</tr>
<tr>
<td>Business Certifications (such as CPM)</td>
<td>2 CEUs/certification</td>
</tr>
</tbody>
</table>

**Category II: Leadership roles (maximum CEUs allowed in this category is 15)**

<table>
<thead>
<tr>
<th>Leadership Role</th>
<th>CEUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paid or volunteer positions on HTM-related and healthcare committees, workgroups, or appointments (outside your position description) such as the following:</td>
<td>30+ hours per year: 4 CEUs</td>
</tr>
<tr>
<td>ACI Certification Board</td>
<td>Less than 30 hours per year: 2 CEUs</td>
</tr>
<tr>
<td>ACI Exam Committees (non-item writing committees)</td>
<td></td>
</tr>
<tr>
<td>HTM Society Role</td>
<td></td>
</tr>
<tr>
<td>Hospital Committee</td>
<td></td>
</tr>
<tr>
<td>Hospital/healthcare association roles (such as AHA, ACHE)</td>
<td></td>
</tr>
<tr>
<td>Engineering or technical association roles (such as ASHE, HIMSS, ASCP)</td>
<td></td>
</tr>
<tr>
<td>Volunteer activities (missions)</td>
<td></td>
</tr>
</tbody>
</table>

**Category III: Development of educational content (maximum CEUs allowed in this category is 15)**

<table>
<thead>
<tr>
<th>Educational Content</th>
<th>CEUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Write Items for ACI</td>
<td>5 items = 1 CEU</td>
</tr>
<tr>
<td>Write an opinion based article -published (minimum of 500+ words)</td>
<td>1 CEU</td>
</tr>
<tr>
<td>Write a peer-reviewed published article (minimum of 1,200-1,500 words)</td>
<td>3 CEUs</td>
</tr>
<tr>
<td>Write a published technical article (minimum of 1,200-1,500 words)</td>
<td>3 CEUs</td>
</tr>
<tr>
<td>Write book</td>
<td>1 chapter = 3 CEUs</td>
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</table>

**Category IV: Professional Development (minimum CEUs needed in this category is 15 – No Maximum)**

<table>
<thead>
<tr>
<th>Professional Development</th>
<th>CEUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attending education class (such as AAMI course)</td>
<td>1 CEU per hour of attendance</td>
</tr>
<tr>
<td>Attending an in-service (documented), vendor presentation or vendor school</td>
<td>1 CEU per hour of attendance</td>
</tr>
<tr>
<td>Attending a webinar (live or recorded)</td>
<td>1 CEU per hour of attendance</td>
</tr>
<tr>
<td>HTM Conferences (seminars/sessions)</td>
<td>1 CEU per hour of attendance</td>
</tr>
<tr>
<td>Presenting a webinar</td>
<td>2 CEU per hour of presentation</td>
</tr>
<tr>
<td>Teaching an education class/seminar</td>
<td>2 CEU per hour of teaching</td>
</tr>
<tr>
<td>Presenting a technical paper</td>
<td>2 CEU per hour of presentation</td>
</tr>
</tbody>
</table>
Courses indirectly related to HTM field (such as communication, management, accounting) 0.5 CEU per hour of attendance

Category V: College or university courses (maximum CEUs allowed in this category is 15)

Courses must be directly related to obtaining an accredited degree (AA, BS, MBA, PHD, etc) and directly related to the HTM profession (included on the exam content outlines) to receive credit. Students must receive a grade of "C" or above and must supply a copy of their transcript as proof of attendance to submit college course.

| Attending a course | 1 CEU for 10 hours of class time |
| Teaching a course  | 3 CEU for 10 hours of teaching time |

Category VI: Work experience (maximum CEUs allowed in this category is 6)

| Full-time employment (working in the HTM field) | 1.5 CEU per year |
| Part-time employment/Military Reserve Duty (working in the HTM field) | 0.5 CEUs per year |
Definitions

Business
Business is any discipline that teaches the application of financial and management principles to an organization of people and resources with the goal of delivering goods and/or services that satisfy customers. Some examples are academic degrees in business administration, accounting, finance, and management.

Engineering
Any discipline that teaches the application of scientific and mathematical principles to practical ends such as the design, manufacture, support, and operation of efficient and economical structures, machines, processes, and systems. Some examples are academic degrees in mechanical engineering, electrical/electronic engineering, biomedical engineering, manufacturing engineering, and computing engineering.

Healthcare Technology Management Professional
A person who applies engineering, business, and healthcare principles to design, construct, maintain, or manage medical devices or systems.

Healthcare Technology Manager
Healthcare technology manager is a person who is responsible for planning and directing the activities of other healthcare technology management professionals, monitoring their work, and taking corrective action when necessary.

Healthcare Related
Any discipline that teaches the organization, procedures, and methods of services associated to the diagnosis, treatment, prevention, and management of disease. Some examples are academic degrees in medicine, nursing, healthcare administration, public health, dentistry, pharmacy, and health informatics.

Quality System
Quality system means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management (FDA 21 CFR 820.3(v)).

Quality System Manager
A quality system manager oversees all aspects of quality assurance including: establishing metrics, applying industry best practices, and developing new tools and processes to ensure quality goals are met. A quality system manager also manages the process and resources for identifying, correcting, and improving non-conformities in product specific policies, procedures, and protocols as well as product specifications. Additionally, all of this is accomplished in a manner that ensures compliance to all relevant regulatory requirements. Finally, the quality system manager controls, directs and/or leads the establishment and maintenance of an acceptable quality system and who reports on the performance of the quality system to executive management.

Science
Science is the intellectual and practical activity encompassing the systematic study of the structure and behavior of the physical and natural world through observation and experiment.
Appendix A: Online Proctoring Conditions & Requirements
Candidates participating in an online proctored exam must have a functioning camera linked to their computer that can track them during the duration of the exam. Participants must show photo ID prior to the start of the exam to verify identity.

Below are a list of condition violation actions that will be strongly enforced during online proctored exams:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Pause &amp; Send Warning</th>
<th>Terminate</th>
<th>No Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test taker left area</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Camera out of position</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audio problem</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Camera out of focus</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talking non-test related</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Poor lighting</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unauthorized test aid</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Invalid keystroke</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Video signal problem</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Multiple people in view</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inappropriate environment</td>
<td>1 Warning prior to start</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading exam aloud</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talking about the exam</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glasses (Reading glasses only)</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Pan the room</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test item theft</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Leaning out of view</td>
<td>1 Warning followed by Termination</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell phone being used</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Using camera on cell phone to take picture</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Wearing headphones</td>
<td>1 Warning prior to start</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>