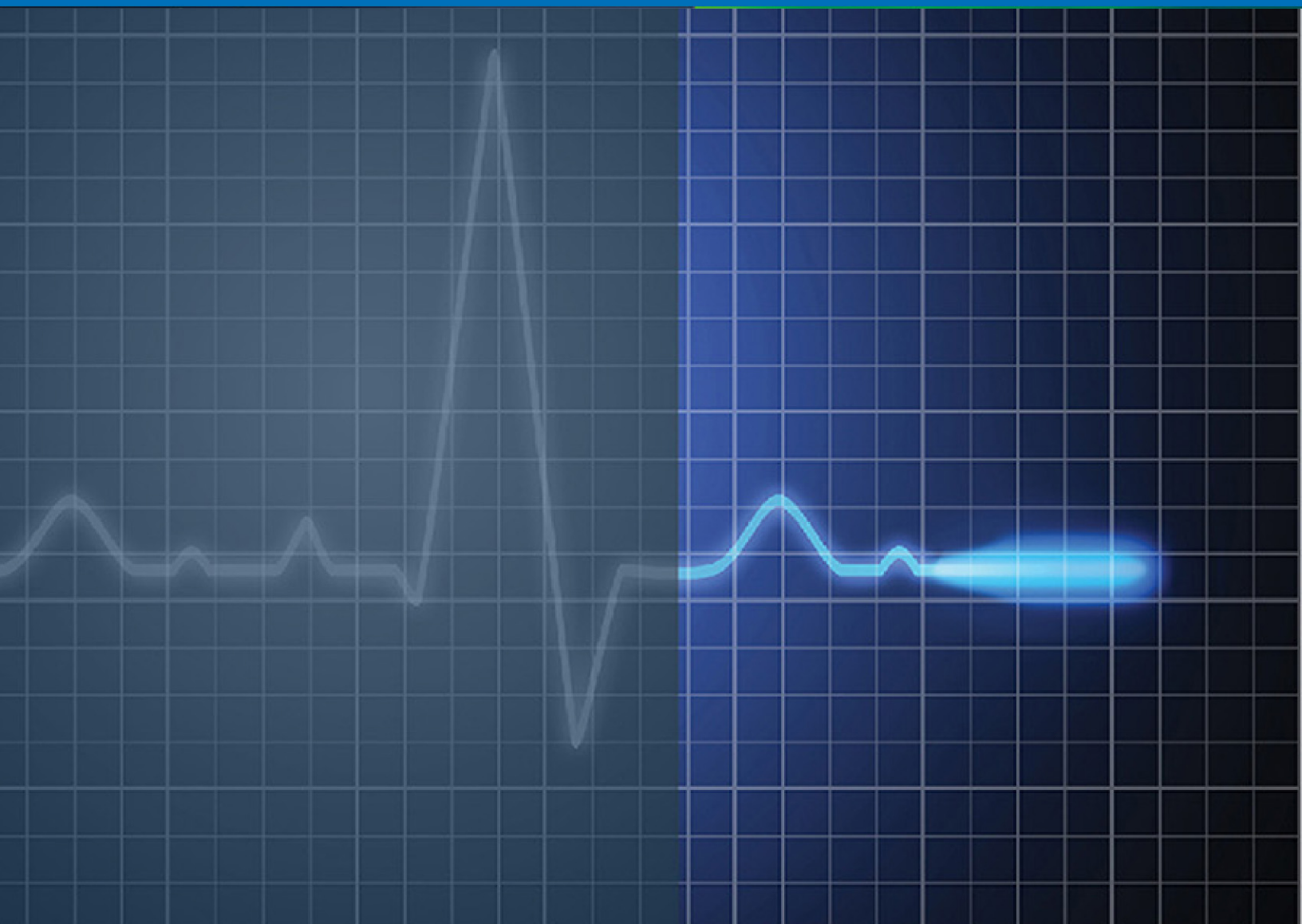
Certified Medical Device Reprocessing Manager/Supervisor (CMDRS)

Certification Guide



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Introduction

Purpose of this Guidebook

This Guidebook provides information on the requirements to achieve and renew a Certified Medical Device Reprocessing Manager/Supervisor (CMDRS) personnel certification.

This personnel certification guide is provided for informational purposes only. The most current version of this manual, as published on the CSA Group website, shall prevail in any case a discrepancy occurs between this version and the official released version of this guide.

About CSA Group

CSA Group is an independent, not-for-profit member-based association dedicated to advancing safety, sustainability and social good. We are an accredited standards development organization.

As technologies continue to grow and evolve, and as the labor force grows more mobile, so has the need for a method to consistently assess, certify and measure individual worker knowledge. In response to this growing need, CSA Group develops and manages personnel certification programs **guided by** ISO/IEC 17024:2012 General Requirements for Bodies Operating Certification Systems of Persons. Current operating programs include CNG (Compressed Natural Gas) Cylinder and Fuel System Inspector, P.I.P.E.S. Riggers, Medical Gas Piping and Systems Installation, Construction Electrician (NOC 7241) Solar Photovoltaic (PV) Systems Installation, and Certified Medical Device Reprocessing Technicians.

Certification Contact Information

CSA Group

Email: Traning@csagroup.org

Website: www.csagroup.org

About this Certification

The Certified Medical Device Reprocessing Manager/Supervisor (CMDRS) Personnel Certification program has been developed by CSA Group in conjunction with industry stakeholders to provide assurance that an individual possesses the competencies deemed necessary to perform the job function of a Medical Device Reprocessing Manager/Supervisor. The certification is designed to complement accreditation programs for verification bodies.

The development of this certification is guided by the ISO/IEC 17024 standard. ISO/IEC 17024 is the global benchmark for organizations operating personnel certification programs and outlines the methods and procedures required to ensure the objective and unbiased assessment of a candidate's knowledge, skills and abilities.

Passing the CMDRS examination will indicate that the candidate possesses the knowledge, skills and decision-making abilities necessary to practice the proper techniques for cleaning, disinfection and sterilization of medical instruments and devices, in order to properly supervise the MDR staff.

Certified Medical Device Reprocessing Manager/Supervisors will be periodically re-assessed to ensure they remain up-to-date on technical developments and industry changes.

The CSA Group website will contain a registry of Certified Medical Device Reprocessing Manager/Supervisors.

Qualifications of a Certified Medical Device Reprocessing Manager/Supervisor

The Medical Device Reprocessing Manager/Supervisor certification tests each candidate's knowledge to ensure the candidate possesses the knowledge and skills of the CMDRS known as the minimally qualified candidate (MQC). CSA's expert committee defines the minimally qualified candidate as follows:

The MQC can perform medical device reprocessing activities without assistance, including (but not limited to):

The Medical Device Reprocessing Manager/Supervisor certification tests each candidate's knowledge to ensure the candidate possesses the knowledge and skills of those who supervise Medical Device Reprocessing Manager/Supervisors known as the minimally qualified candidate (MQC). CSA's expert committee defines the minimally qualified candidate as follows:

The MQC can perform medical device reprocessing activities without assistance, and supervise those who perform the activities, including (but not limited to):

- Applying the principles of basic microbiology and infection prevention and control to decrease risk

to both patients and staff during routine reprocessing procedures

  - Use Personal Protective Equipment
  - Follow dress code/hand hygiene practices
  - Maintain traffic control and
  - Maintain one-way workflow
- Following written department policies and standard operating procedures
- Handling and transporting contaminated medical devices
- Decontaminating reusable medical devices
- Preparing and packaging medical devices
  - Identify common medical instruments and other medical devices by type and function
  - Use appropriate packaging material
- Inspecting instruments and devices for cleanliness, function, and damage
- Selecting and safely using reprocessing products (e.g., detergents, low and high-level disinfectants)
- Disinfecting medical devices
  - Chemical
  - Thermal
- Sterilizing medical devices via
  - Steam
  - Low temperature methods (gases and liquids)
- Monitoring and documenting quality
  - Recognizing non-compliant reprocessing outcomes,
  - Respond appropriately to non-compliant reprocessing events
- Storing and distributing medical devices

- Recognizing and responding to occupational health and safety hazards or events
- Troubleshooting common problems
- Using common reprocessing equipment (e.g., washer disinfectors, ultrasonic, pasteurizers, cart washers, steam sterilizers, low temperature sterilizers, automatic endoscopic reprocessors).

Certification Prerequisites

To apply to write the CMDRS exam toward the Supervisor certification, candidates must satisfy the following prerequisites:

1. Proof of Medical Device Reprocessing Manager/Supervisor role through letter from Manager or HR;

AND

2. Documented 100 hours of continuous learning in MDR in the past two years.

Please note: all information including references provided to CSA Group as part of the application process will remain confidential.

Training Resources

Medical device reprocessing (sterile processing) courses are available through a number of community colleges throughout Canada, full and part-time in-class and via distance education. Courses are also available through professional associations and may be available through private colleges or other training providers. For a list of training resources, please visit CSA Group's website at: www.csagroup.org. CSA Group does not endorse any organization and provides this list as a resource for individuals seeking additional information.

Certification Process

Application Process

To become a Certified Medical Device Reprocessing Manager/Supervisor an applicant must:

1. Purchase application and exam through the CSA Group website at store.csagroup.org,
2. Meet all prerequisites of the certification
3. Respond to purchase confirmation by completing the online application
4. Provide copies of all applicable documentation
5. Agree and adhere to the code of ethics and professional conduct and the certification terms and conditions, and
6. schedule and pass the written exam.

All fees are due prior to submitting the application

An e-mail address is mandatory and must be included as this will be the primary mode of communication regarding the steps in the certification process. Each candidate applying for certification must have their own unique, individual email address. One email address may not be used for multiple candidates.

CSA Group will process applications when received. If an application is incomplete, CSA Group will notify the applicant via e-mail of the deficiencies found in the application. Those deficiencies must be corrected before the candidate will be approved to take the certification exam.

All applicants will receive a confirmation e-mail with-in two (2) weeks of application regarding their registration and certification eligibility requirements.

Each new application has a life span of six (6) months from the time it is accepted. The applicant must fulfill all requirements of the certification process within that time period. If an applicant is unable to complete the certification process within that period of time, the application will expire and the applicant must restart the certification process including payment of any application or examination fees.

Program Fees

Program fees for the Certified Medical Device Reprocessing Manager/Supervisor Certification, including application, examination, and re-examination fees, may be found on the CSA Group Store. Please visit store.csagroup.org for more information.

Payment and Refund Policy

Payment of the fees must be submitted online at store.csagroup.org CSA Group accepts Visa, MasterCard and American Express as payment in US or Canadian dollars.

When the payment has been received, candidates will receive an email from training@csagroup.org with a log-in and password to CSA's eLearning system in order to complete the online application. Once the application is submitted, CSA will process the application and notification will be sent to the candidate by email regarding the next step. This email may:

- Request additional information if necessary, or
- Notify the candidate the application has been selected for audit (if selected), or
- Notice of approval to exam, and information for scheduling.

Application fees are non-refundable.

Exam fees may be refunded if a written request is submitted at least one month prior to a scheduled exam date and at least one month prior to the examination eligibility expiration date. CSA Group will retain a processing fee of $45 US or Canadian Funds.

Audit Process

The submission of an application indicates the applicant's agreement to comply with the terms of CSA Group's audit process. All applications are subject to an audit and a percentage of applications are randomly selected for audit. Please note that while the selection process for an audit is primarily random, CSA Group reserves the right to select any applicant to be audited at any time, including after the credential has been awarded. If the applicant fails to meet the audit requirements after attaining the credential, the applicant is not entitled to a refund.

The applicant will be notified when the application and fee is received if the submitted application is selected for audit. An audit notification will be sent to the applicant electronically and will provide detailed information on how to comply with the terms of the audit. During an audit, the applicant may be asked to submit supporting documentation required by the certification, such request may include, but is not limited to, the following:

- Copies of diploma or a global equivalent;
- Signatures from supervisor(s) or manager(s) for the skills, experience and/or responsibilities if required and documented in the experience section of the application and on the performance checklist;
- Copies of certificates and/or letters from the training institution(s) for any mandatory course;

- Copies of certificates and/or letters to demonstrate the required amount of professional development; and
- Other items required by the certification.

Once documentation is provided, the audit should take approximately two weeks to complete. The applicant may not continue with the certification process until the applicant has complied with the audit requirements.

Once the applicant has successfully completed the audit, the applicant will be permitted to continue the certification process and will be notified of his/her examination eligibility. If the applicant fails to meet the audit requirements, a refund may be given, dependent upon the stage of the certification process at the time of the audit. (Refer to the Payment and Refund Policy section of this guidebook for more details).

Examination Administration and Scheduling

The Certified Medical Device Reprocessing Manager/Supervisor certification is administered through CSA Groups' computer based testing network. Once a candidate has submitted all the required information and has been approved to take the certification exam, CSA Group will send the candidate approval to exam and scheduling information by email. Once the candidate receives their email notifications they will be able to register for the exam:

Testing may be scheduled for examination:

- At a proctored testing location (locations are typically a short drive for most candidates), or
- Via online proctoring, using the candidates own computer at home, work, or any location that meets the online requirements*.

Applicants should save all examination scheduling verifications for their records.

CSA Group uses computer-based testing (CBT) to deliver its certification examinations. However, in certain situations, paper-based tests may be offered following specific industry events or following selected training courses when an eligible exam proctor is available. Please contact CSA Group for paper-based test delivery. CSA Group reserves the right to cancel a scheduled paper-based test in the event that there are fewer than 10 candidates registered.

*Please contact CSA Group for a guide on computer and location requirements for online exam proctoring.

Examination Eligibility

The examination eligibility period is six (6) months from the time an application is approved by CSA Group. Applicants may take the examination up to three times within the six month period if they did not pass on the first attempt. (As noted below, re-examination fees apply to the second and third attempts to pass the examination.)

Re-examination

During the examination eligibility period, an applicant may take the written examination up to three times.

Re-examination fees apply to the second and third attempts to pass the examination, and re-examination fees must be paid in full in order to schedule an exam. If the eligibility period expires without achieving a passing score, the applicant must reapply for the certification.

Examination Language

The CSA Group certification examination for Medical Device Reprocessing Manager/Supervisor is administered in English and French.

Examination Special Accommodation

CSA Group adheres to the principles of accessibility and will accommodate any special needs upon request.

Certificate Issuance

Upon confirmation of application requirements and passing the certification exam, each Certified Medical Device Reprocessing Manager/Supervisor will be issued a certificate indicating the valid Certification Period.

The certificate is owned by CSA Group and may not be reproduced or modified in any way. Verification of certification should be done using the qualified personnel listing at https://www.csagroup.org/search-qualified-personnel/.

Replacement of Certificates

CSA Group may issue a replacement certificate if a Medical Device Reprocessing Manager/Supervisor certificate has been lost or destroyed, or if the Certified Medical Device Reprocessing Manager/Supervisor's name has changed, and the original certificate is returned to CSA Group.

Certification Period

CSA Group's' Certified Medical Device Reprocessing Manager/Supervisor (CMDRS) certification is valid for a period of 5 years from the date of issue.

Use and Requirements for Use of Certificates and Logos

Once an individual receives his/her certification letter and certificate the individual may represent themselves as a Certified Medical Device Reprocessing Manager/Supervisor (CMDRS) under CSA Group's Certified Medical Device Reprocessing Manager/Supervisor Certification Program.

Certification under this program does not authorize the certified individual any rights to the use of CSA Group's name or logo. All requests for use of the name or logo must be made in writing and expressly authorized by CSA Group. As part of the program monitoring, CSA Group routinely reviews advertisements, catalogs, websites and promotional material to confirm compliance. Unauthorized use of the CSA Group name or logo constitutes cause to initiate procedures for withdrawal of certification and in severe cases may constitute grounds for legal action.

Certification Terms and Conditions

By signing and submitting the electronic application candidates are agreeing to the following terms and conditions:

1. I agree to comply with the provisions of this certification as described in PCP-04 Certified Medical Device Reprocessing Manager/Supervisor Personnel Certification Guide, to only make claims regarding my certification with respect to the scope for which the certification has been granted, and not to use the certificate in a misleading manner.

2. I agree to notify CSA Group in a timely manner of changes concerning the information I have provided, including my current address, telephone number, and e-mail.
3. I have reported, and will continue to report, to CSA Group, within sixty (60) days of occurrence, any matters, proceedings, lawsuits, settlements and/or other agreements, administrative agency actions, or organizational actions relating to my profession or occupation, including all complaints relating to my professional activities, and matters or proceedings involving, but not limited to certification, credentialing, malpractice, disciplinary ethics or similar matters. I also agree to promptly report, within sixty (60) days of occurrence, any felony criminal charges, convictions, or plea agreements or other criminal charges, convictions, or plea agreements relating to acts of dishonesty or unethical conduct.
4. I agree that CSA Group has the right to communicate with any person, government agency or organization to review or confirm the information in this application or any other information related to my application for CSA Group certification. Further, I agree to and authorize the release of any information requested by CSA Group for such review and confirmation.
5. I understand that the CSA Group credential status does not imply licensure, registration or government authorization to practice any specific job function or to engage in related activities
6. I agree that all materials submitted to CSA Group become the property of CSA Group, and that CSA Group is not required to return any of these materials to me.
7. I agree that upon achieving the CSA Group credential, my name may be posted on the CSA Group website as part of an Online Registry to be created and maintained by CSA Group.
8. I agree that all disputes relating in any way to my application for a CSA Group certification and/or my involvement generally in a CSA Group certification program, will be resolved solely and exclusively by means of CSA Group policies, procedures and rules, including the stated appeals process.
9. CSA Group reserves the right to suspend or revoke my credential if it is determined I have failed to uphold, or otherwise breached this Agreement, or committed a violation of the CSA Group Code of Ethics and Professional conduct.
10. I agree to refrain from use or promotion of this certification should my certification be suspended, until notified of the suspension being resolved.
11. I agree to refrain from all use and promotion of this certification should this certification be withdrawn.
12. I release and indemnify CSA Group from all liability and claims that may arise out of, or be related to, my certification and related activities. This certification agreement may be revised periodically. I understand that it is my responsibility to obtain the most current copy of this certification agreement in the certification guide online at store.csagroup.org

Professional Code of Ethics

This code of ethics sets forth the expectation that credential holders will commit to conducting themselves in a professional, honest and impartial manner.

This code of ethics applies to all CSA Group Personnel Certification credential holders regardless of the certification designation, and includes the following professional conduct:

- Provide equitable, honest and impartial treatment of customers;
- Provide customers with accurate, objective, timely and understandable information
- Perform all services in a safe and professional manner;

- Stay informed of and comply with all relevant laws, codes, regulations, standards and industry practices;
- Protect proprietary and confidential information gained during the course of work; and
- Promote positive activities which raise the level of professionalism of the industry.

By signing and submitting the electronic application candidates agree to conduct themselves in a professional and thorough manner as a CSA Group Personnel Certification holder. Furthermore, they agree to the Certification Agreement terms and conditions, including adherence to the Code of Ethics and Professional Conduct.

Non-Discrimination

Participation in CSA Group's occupational certification programs are open on a non-discriminatory basis to all individuals and does not require membership in any association.

Impartiality

CSA Group and our employees, contractors and volunteers understand the importance of impartiality and the consideration of any potential conflict of interests in carrying out certification activities. CSA Group is committed to identifying and mitigating risks in every area of the certification process which may pose a threat to impartiality. Certification of individuals is based on objective evidence obtained by CSA Group through a fair, valid and reliable assessment process which is not influenced by other interests or parties.

Confidentiality

CSA Group is committed to protecting confidential and/or proprietary information related to applicants, candidates, certificates and examination development, maintenance, and administration process.

All information submitted and/or retained by CSA Group regarding each individual's program application, private information and communications, examination results and certification information are confidential and may not be disclosed, divulged or made accessible. Examination results will only be released to the candidate.

Information related to the design, development, administration and maintenance of the certification examination is confidential with confidential materials including, but not limited to, all examination development documentation, standard setting documentation, exam performance documents, individual examination items and exam forms, as well as examination scores and score reporting.

CSA Group maintains confidential information received from the individual and will not disclose such information to any third party without prior written approval by the individual, or as required by law. CSA Group will provide written notification to the individual at least five (5) business days prior to releasing such information.

Privacy Policy

CSA Group and its subsidiaries and affiliates (collectively CSA Group) are committed to respecting your privacy. Our Privacy Policy describes how we collect, use, disclose, store and otherwise process information through our website and its affiliated websites and other online products and services. In addition, this Policy states how you can control the collection, correction and/or deletion of information. We will not use or share your information with anyone except as described in this Privacy Policy.

We urge you to read our Privacy Policy so that you understand our commitment to you and your privacy, and how you can participate in that commitment by visiting https://www.csagroup.org/legal/privacy-policy/.

By providing your personal information to CSA Group in the ways described in this Privacy Policy, you agree that you are authorized to provide that information and are accepting this Privacy Policy and any supplementary privacy statement that may be relevant to you. You have the right at any point to revoke consent and CSA Group will stop using and processing your personal data. If you do not agree to our practices, please do not register, subscribe, create an account, or otherwise interact with our services, CSA Group's websites, or mobile-device applications.

Recertification

Medical Device Reprocessing Manager/Supervisor certifications expire every five (5) years. Generally, CSA Group will issue a recertification notice and application form 90 days prior to the date when the certificate expires, but is the responsibility of the applicant to ensure timely recertification. Certified Medical Device Reprocessing Manager/Supervisors who apply for recertification, meet the requirements, and pay the required fee will receive a new certificate containing the new expiry date.

Medical Device Reprocessing Manager/Supervisors may apply for recertification up to 6 months prior to their certification expiration date and no later than 3 months after expiration. Medical Device Reprocessing Manager/Supervisors applying for recertification more than 3 months after expiration of their certification must fulfill all requirements of the initial certification process.

Recertification Requirements

The following are requirements for recertification:

1. Proof of Medical Device Reprocessing Manager/Supervisor role through letter from Manager or Human Resources;

AND

2. Documented 100 hours of continuous learning in MDR in the past two years.

Writing the CSA exam is not required.

Please note: all information including references provided to CSA Group as part of the application process will remain confidential.

General Guidelines for Earning Continuous Learning (CL) Activities:

- CL activities shall be related to Medical Device Reprocessing.
- Each activity shall be a minimum of .5 hours (30 minutes).
- Each clock hour equals one CL Activity hour. Do not include time for breaks or lunch.
- Examples of CL activities include: conferences, workshops, seminars, employee in-services, formal courses (site-based or web based) at college or university, preceptorship, independent study, presentations, and writing articles or presentation of abstracts related to MDR at conferences/workshops/symposiums.
- No single activity can account for more than 50% of your total hours.

(Proof of attendance or publication is required. This may include a certificate of attendance or signature of supervisor/manager).

Please Note: All Activities are Subject to Audit by CSA

Specific Guidelines:

College or University courses:

- Course must be applicable to Medical Device Reprocessing.
- Includes distance education courses.
- Generally, college or university courses run for one semester (4 months) and each course is equal to 36 CL hours.
- If you are unsure of the hours allowed for a course, calculate one CL hour for every clock hour you spent attending the course.

Conferences, seminars, workshops:

- Calculate the total hours attended, not including lunch or breaks (it is not necessary to break down every individual conference session attended).

Employee in-services:

- Only sessions of .5 hours (30 minutes) or greater are eligible.
- Keep a running list of the sessions attended. Ask your supervisor or educator to sign the list prior to submitting.

Presentations:

- For presentations you make to co-workers on topics related to MDR.
- You can also count preparation time. To calculate preparation time, double the presentation time (i.e. 1 hour presentation + 2 hours preparation = 3 CL hours).
- If you repeat the exact presentation in the five-year period, it counts as a CL only once.
- For an oral presentation to a provincial or national conference, you may claim a maximum of 10CL hours for your preparation and presentation.
- For a poster presentation to a provincial or national conference, you may claim a maximum of 10 CL hours for your preparation and presentation.

Preceptorship (Mentorship):

- The maximum number of hours you can claim under this activity is **10 hours per year.**
- The preceptorship must be in an MDR area.
- The intent of preceptorship is to assist the novice in successfully adjusting to a new role. The novice may be a student or an already practicing MDR Supervisor moving into a new role or setting.
- Hours must be supervised by a competent technician or role model and must be signed- off prior to submitting.

Writing Articles:

- Can include publication of materials or research relevant to MDR.
- The publication may be in a recognized professional journal or newsletter.
- Include a copy of the publication with recertification application.
- For an article or paper, allot 15 CL hours.
- Research projects must have been completed during the five-year certification term.

Independent Study:

- You may include reading articles and answering the test questions that appear in professional journals (i.e., CEU articles) and must provide proof of successful completion.
- CL hours equals the number of hours as stated in the journal.

Refusal to Issue or Renew a Certified Medical Device Reprocessing Manager/Supervisor Certificate

CSA Group may refuse to issue or renew a Medical Device Reprocessing Manager/Supervisor's certification:

- For any of the circumstances under which CSA Group can revoke or suspend a certification; or
- the certification to be renewed was revoked or suspended by CSA Group.

Revocation or Suspension of a Certified Medical Device Reprocessing Manager/Supervisor's Certification

CSA Group reserves the right to withdraw the certification of any person found violating the Certification Terms and Conditions, Professional Code of Conduct or the policies and procedures of the certification.

CSA Group may revoke or suspend a Certified Medical Device Reprocessing certification for any of the following reasons including by not limited to:

- Violation of the Certification Terms and Conditions or Professional Code of Ethics;
- The application submitted was fraudulent or inaccurate;
- The person was discharged from his/her employment for incompetence, unless the person has not yet exhausted the rights of appeal available in his/her organization;
- The person has previously had a Certified Medical Device Reprocessing Manager/Supervisor Certification revoked; or
- The person has failed:
    - To exercise the level of care, diligence and skill that a reasonably prudent supervisor would be expected to exercise in a similar situation;
    - To act honestly, competently and with integrity; or
    - To meet or has contravened any condition that is set out in his or her certificate.

Upon a notice of termination of a CMDRS certification, the individual will cease all use of or reference to the CSA Group certification and the Certified Medical Device Reprocessing Manager/Supervisor designation. Individuals have the right to appeal as outlined in the appeals process below. The individual will be removed from the Qualified Personnel Listing on the CSA Group website.

Voluntary Withdrawal of Certification

Individuals wishing withdrawal of the Certified Medical Device Reprocessing Manager/Supervisor Certification must submit a request in writing to CSA Group. Once approved, the individual will be removed from the National Registry and must immediately cease any use of or reference to the CSA Group certification. Individuals wishing to reinstate their certification must apply for certification as outlined in the certification process.

Complaints and Disputes

CSA Group is committed to the value certification programs offers to industry, and the credibility that certification offers to individuals in their chosen field. It is the policy of CSA Group that all certification programs are of quality and that all applicants, certified persons, employers, and stakeholders, have a fair and impartial forum to bring forward complaints concerning the certification process, or to the conduct of individuals who are certified under this program.

CSA Group's policy is to provide a fair and impartial forum for complaints associated with the CSA Group Certification programs and the individuals certified under the programs. Anyone wishing to appeal a decision affecting their certified status, or having a complaint as to the performance of a certified person or candidate may file a complaint within thirty (30) calendar days of the occurrence which the complaint is about.

Information regarding the complaint process is available to the public on the CSA Group website and/or other published documents.

Actions taken under this policy do not constitute enforcement of the law, although referral to appropriate federal, state, or local government agencies may be made about the conduct of the certified person as warranted by the individual situation. Individuals bringing complaints are not entitle to any relief for damages by virtue of this process.

Complaints are to be submitted in writing and signed to the Manager, Product Development at CSA Group and include the full name, postal mailing address, and telephone number of the appellant/complainant and specifying the conditions and circumstances of the appeal/complaint, along with documentation supporting the complaint. All complaints will be reviewed by CSA Group within 30 days of receipt to determine merit. Written notice will be provided to the candidate/certified person if CSA Group determines the complaint is valid so they have opportunity to respond to the complaint.

Complaints under review by CSA Group will be will be completed in an appropriate amount of time, not to exceed 6 months, unless there are extenuating circumstances that require an extended period of time. The Manager, Product Development exercises general supervision over all inquiries. The Manager, Product Development and personnel certification staff may be assisted in the conduct of its review by other CSA Group staff or legal counsel. Both the individual submitting the complaint and the candidate/certificant who is the subject of the investigation (or his or her employer) may be contacted for additional information with respect to the complaint. CSA Group may at its discretion contact such other individuals who may have knowledge of the facts and circumstances surrounding the complaint.

All review inquiries and investigations are conducted in confidence and objectively, without any indication of prejudgment. An investigation may be directed toward any aspect of a complaint which is relevant or potentially relevant. Formal hearings are not held and the parties are not expected to be represented by counsel, although CSA Group may consult its own counsel.

Outcome of the complaint review may be a determination by CSA Group:

- For dismissal of the complaint;
- That a violation has occurred and provide the candidate/certificant with an opportunity to correct the violation and provide written assurance that issues will not continue or recur;
- That a violation has occurred with suspension of the certification for a designated period of time, or suspension of a candidate's eligibility for a designated period of time;
- That a violation has occurred and termination or revocation of a certification; or
- That a violation has occurred and termination of a candidate's eligibility for a designated period.

For outcomes that include suspension or termination publication of the information will only occur after any appeal and decision has been completed, or an appeal period has passed.

Certificants who have their certification terminated are not to be considered for certification in the future. If certification is revoked, any and all certificates or other materials requested by the CSA Group must be returned promptly the Manager, Product Development.

If the individual disputes the decision made by CSA Group after the appeal meeting, the individual has the right to appeal to an independent and impartial Appeals Board as outlined below.

Appeals

CSA Group's certification programs are administered and supervised by Canadian Standards Association. Challenges to the certification program are governed by CSA Groups' Complaints and Disputes and Appeals Procedures outlined in this certification guide.

Any individual has the right to appeal all decisions relating to CSA Group's personnel certification program including, but not limited to: testing, suspension, denial or termination of certification within 30 days of the date of the result or notice. A written notice of intent to appeal must be sent to CSA Group within thirty (30) business days of the individual's receipt of the decision, which forms the basis for appeal.

Upon receipt of a written request by the individual to appeal, CSA Group shall convene an Appeals Board and notify the individual and responding parties. CSA Group will arrange an appeal meeting with the individual at CSA Group's headquarters or other mutually agreed to location, within forty-five (45) business days of the receipt of the written request, with the appeal decision complete and final decision notice given to the appellant within ninety (90) days of the receipt of the written request.

The individual and the Appeals Board will attend and participate in the meeting. The appeal will not include a hearing or any similar trial-type proceeding. Legal counsel is not expected to participate in the appeal process, unless requested by the appellant at least five (5) business days prior to the meeting and approved by the Appeal Board. CSA Group and the Appeal Committee may consult legal counsel. When the individual has had a full opportunity to submit their case, the Appeals Board may declare the hearing closed and provide the individual and CSA Group with a decision, including a brief description of its reasons, within ten (10) business days. Decisions of the Appeals Board are by majority vote.

The decision of the Appeals Board either affirms or overrules the determination of the CSA Group Reviewer(s). The Appeal Committee decision is binding upon CSA Group, the candidate/certificant who is subject to the decision, and all other persons involved in the complaint. The Appeals Board will provide notice to the appellant at the end of the appeals-handling process.

Appeals Board

The Appeals Board will consist of at least three (3), but not more than five (5) members. No current member of the Review committee, or individual or agent or any person with any interest in the individual, directly or indirectly, is eligible to serve on the Appeals Board.

The Appeals Board hearing will be informal and private. The Appeals Board may only review whether the determination by the CSA Group Reviewer(s) was inappropriate due to material errors of fact, or failure of the Reviewer(s) to conform to published criteria, policies or procedures. Only evidence of fact and conditions up to and including the time of the Reviewer's determination are considered during an appeal. The appellant will be given a full opportunity to present any material or proof relevant to the issue. Formal rules of evidence are not applicable. The Appeals Board determines the relevance and materiality of any evidence presented.

All costs related to the Appeals Board are the responsibility of the individual and are due within thirty (30) business days of the billing, unless the Appeals Board sides with the individual's position, in which case CSA Group will be responsible for the costs.

Examination Preparation and Completion

General Description

The CMDRS certification exam consists of approximately 105 multiple-choice questions. Examination questions have only one correct answer. Each exam question is independent and does not rely on the correct answer to any other questions.

CSA Group may include an additional 10 questions in the exam for statistical evaluation of future examination questions. These additional questions are not included as part of the examination score. These questions will not be identified in the exam, so it is important that the candidate answer every question completely. The candidate's grade is based only on the number of scored items answered correctly, not the additional questions.

The candidate will have three hours (180 minutes) to complete the exam. Exams are closed book. No reference materials may be used during the course of the exam. Test centers may have additional requirements.

Exam Content

The exam is based on categories of tasks and knowledge required by a Medical Device Reprocessing Manager/Supervisor. The list below outlines the examination content by category for the CMDRS Certification.

Categories

- Quality Management Systems
- Infection Prevention and Control
- Occupational Health and Safety
- Decontamination Processes
- High-Level Disinfection
- Assembly
- Sterilization of Medical Devices
- Storage, Transportation and Distribution
- Flexible Endoscopes
- Ultrasound Transducer Probes

Pass-Fail Standard

CSA Group's Medical Device Reprocessing Manager/Supervisor certification examination passing standard is established utilizing standard psychometric guidelines and is determined using a criterion-reference technique that evaluates a candidate based on a predetermined standard of knowledge or skill. This predetermined standard is defined as the minimum score that would be expected from

candidates who have the level of knowledge and skills needed to competently conduct their work responsibilities.

Exam Delivery

The CMDRS certification exam will be delivered electronically at our computer-based testing center locations on demand, or through remote on-line proctoring using your own computer.

Examination General Instructions

During the exam, the proctor will be responsible for supervising the exam in such a way as to ensure that exam security is maintained. As such, all candidates are expected to adhere to the following guidelines during the test sessions.

A candidate's participation in any irregularities occurring during the examination, such as giving or obtaining unauthorized information or aid, as evidenced by an observation or subsequent statistical analysis, may be sufficient cause to terminate participation, invalidate the results of the examination, or other appropriate remedy.

To be admitted to the examination the candidate must:

- **Provide a proper valid identification. The candidate will NOT be admitted without proper identification.** If there are any questions concerning the type of picture ID, the candidate should contact CSA Group. Bring **two (2)** current forms of **non-expired photo** identification with **signature** from the following list that exactly match the first and last names on the certification application:
  - Driver's license
  - State or Provincial/Federal government ID card
  - Passport
  - Employee ID card
  - Military ID card
  - Student ID card
- Report on time.

During the Exam:

- Smoking is NOT permitted in the examination site.
- Food and beverages are NOT allowed in the examination area.
- All personal items including books, notebooks, other papers, all electronic equipment (i.e. cell phones, cameras, etc.), book bags, coats, etc. will NOT be allowed in the exam room and must be left outside of the exam room **AT YOUR OWN RISK.**
- Friends and relatives, including children, will NOT be allowed in the examination building.
- Computer-based testing facilities offer exam services to multiple agencies. There may be other individuals in the testing room with the candidate who are sitting for exams from different organizations. The rules for their exam may be slightly different than the rules for the CSA candidate's exam in terms of exam time, and what is and is not allowed at their station.

- Computer-based tests are delivered via secure Internet connections. Internet connections are subject to the local Internet providers in the area. While it is not the norm, Internet connections can, on occasion, be lost momentarily, requiring the proctor to log the candidate back into his/her examination. If this occurs, the candidate should inform the proctor that the connection has been lost and the proctor will assist the candidate in logging back into the exam. The exam time remaining will be exactly the same as it was when the Internet connection was lost.

Prohibited Items:

Candidates are expressly prohibited from bringing the following items into the exam room:

- Cameras, cell phones, optical readers, or other electronic devices that include the ability to photograph, photocopy or otherwise copy test materials
- Notes, books, dictionaries or language dictionaries
- Book bags or luggage
- Smart watches or other wearable devices with internet access
- iPods, mp3 players, headphones, or pagers
- Calculators (except as expressly permitted by the test sponsor), computers, PDAs, or other electronic devices with one or more memories
- Personal writing utensils (i.e., pencils, pens, and highlighters)
- Food and beverage
- Hats, hoods, or other headgear

If the proctor determines that the candidate has brought any such items into the exam room, the test session will immediately stopped and voided.

Environment

Examination room temperature can be unpredictable; therefore, we suggest that the candidate bring appropriate clothing (e.g. sweater or sweatshirt without pockets) to help to adapt to a cooler or warmer climate in the examination room. The candidate should bring ear plugs if he/she is sensitive to noise.

Exam Security

All CSA Group certification examination content and wording of examination questions constitute confidential information protected by copyright law. Any unauthorized receipt, possession, or transmission of CSA Group examination questions, content, or materials, either before the examination, on-site, or in the future is strictly forbidden.

The use of CSA Group examination materials for the purpose of examination preparation or training is also forbidden.

CSA Group reserves the right to take whatever measures are necessary to protect the integrity of its examinations. Violation of the CSA Group examination agreement and/or non-disclosure agreement, or the giving or receiving of aid in any CSA Group examination as evidenced either by observation at the time of the examination or by statistical analysis, or engaging in other conduct that subverts or attempts to subvert the examination or the CSA Group certification process, is sufficient cause for CSA to:

- Bar an individual from the examination
- Terminate participation in the examination

- Withhold and/or invalidate the results of the examination
- Withhold a certification
- Revoke a certification or
- Take appropriate other action.

Exam Results Notification

Approximately two weeks after completion of the exam, the candidate will receive official notification of the exam score from CSA Group. Candidates passing the exam and fulfilling all program requirements will also receive a certificate with the effective date of certification. In order to protect the candidate's confidentiality, under no circumstances will test scores be given by telephone.

Examination Body of Knowledge and Blueprint

Examination Knowledge Reference Documents

The CMDRS exam draws on concepts included in the following standards and materials. They are helpful reference materials to use in preparation for the exam:

Familiarity with Medical Device Reprocessing standards including, but not limited to:

- Tier 1 (Highly Recommended reading):
  - CSA Z314-23 Canadian medical device reprocessing in all health care settings

Exam Objectives

The following exam objectives were developed by a group of industry experts. The weighting of each objective was determined through industry survey. The following table outlines the knowledge and skills required for each objective.

		Percent of Exam
Section 1.0	**Quality Management System**	**4%**
Objective 1.01	Describe the elements of a quality system that apply to daily practice	
Objective 1.03	Recognize medical devices and minimum reprocessing requirements as per the spaulding classification system.	
Section 2.0	**Infection Prevention and Control**	**12%**
Objective 2.01	Describe basic microbiology concepts related to reprocessing of medical devices.	
Objective 2.02	Describe routine practices related to infection prevention and control.	
Objective 2.03	Describe how and when to practice hand hygiene.	
Objective 2.04	Describe how to select and use personal protective equipment (PPE).	
Objective 2.05	Describe safe management of sharps.	
Objective 2.06	Recognize potential risk of exposure to body fluids and describe how to take appropriate action following exposure.	
Objective 2.07	Describe how to prevent contamination and cross contamination.	
Objective 2.08	Given a scenario, identify breaks in good infection prevention and control	

	practice.	
Section 3.0	**Occupational Health and Safety**	**2%**
Objective 3.01	Describe relevant occupational health and safety practices.	
Section 4.0	**Decontamination Processes**	**18%**
Objective 4.01	Describe how to select and use appropriate cleaning agents and dosing equipment for decontamination.	
Objective 4.02	Describe the types, functions, and uses of decontamination equipment.	
Objective 4.03	Describe how to collect, transport, and receive soiled medical devices.	
Objective 4.04	Describe the steps for decontamination of soiled medical devices.	
Objective 4.06	Describe how to manually clean medical devices.	
Objective 4.07	Given a scenario, identify incorrect practices in decontamination.	
Objective 4.08	Describe frequency of routine monitoring of manual and automated decontamination equipment	
Objective 4.09	Describe how to select and use low-level disinfectant and intermediate level disinfectants.	
Section 5.0	**High-Level Disinfection**	**10%**
Objective 5.01	Identify devices that require high-level disinfection.	
Objective 5.02	Describe how to select and use appropriate chemicals for high-level disinfection.	
Objective 5.03	Describe how to manually high level disinfect semi-critical devices.	
Objective 5.04	Describe how thermal disinfection can be achieved.	
Objective 5.05	Describe the different types and functions of automated high-level disinfecting equipment.	
Objective 5.06	Describe minimum effective concentration (MEC) testing	
Objective 5.07	Describe documentation and tracking for high-level disinfected devices	
Section 6.0	**Assembly**	**17%**
Objective 6.01	Describe how to sort, inspect, and test medical devices.	
Objective 6.02	Distinguish between single-use, multi-use, and reposable medical devices.	
Objective 6.03	Describe how to assemble a set/tray.	
Objective 6.04	Describe how to identify, select, and place chemical indicators within a sterile barrier system, (i.e., tray, pouch, or container set)	
Objective 6.05	Describe how to function test assembly area equipment.	
Objective 6.06	Given a scenario, describe how to prioritize assembly workload.	
Objective 6.07	Describe how to properly package medical devices for sterilization.	
Objective 6.08	Given a scenario, describe appropriate assembly practices.	
Objective 6.09	Identify correct instrument care and handling.	
Section 7.0	**Sterilization of Medical Devices**	**19%**
Objective 7.01	Explain the importance of medical device compatibility and validation.	
Objective 7.02	Describe the different types of steam sterilizers and critical parameters needed for sterilization	
Objective 7.03	Identify correct placement of test packs in steam sterilizers	
Objective 7.04	Explain how to load, operate, and unload steam sterilizers.	
Objective 7.05	Describe the elements of a sterilization quality assurance program.	
Objective 7.06	Describe the different types of low temperature sterilizers and critical parameters needed for each method.	

Objective 7.07	Explain how to load and operate low temperature sterilizers.	
Objective 7.09	Given a scenario, identify appropriate responses to an adverse sterilization event.	
Objective 7.10	Describe devices most commonly reprocessed in low temperature sterilizers (heat or pressure sensors)	
Section 8.0	**Storage, Transportation, and Distribution**	**6%**
Objective 8.01	Describe elements of storage and inventory management of medical devices.	
Objective 8.02	Describe elements of transportation and distribution of medical devices.	
Objective 8.03	Given a scenario, identify best practices in storage and transportation of medical devices.	
Section 9.0	**Flexible Endoscopes**	**7%**
Objective 9.01	Describe how to reprocess flexible endoscopes and accessories.	
Objective 9.02	Given a scenario, identify best practice for reprocessing flexible endoscopes.	
Section 10	**Ultrasound transducer probes**	**5%**
Objective 10.01	Describe how to reprocess ultrasound transducer probes	
Objective 10.02	Given a scenario, identify best practice for reprocessing ultrasound transducer probes	
Objective 10.03	Describe the automated methods for disinfection of ultrasound transducer probes	
	Total	**100%**

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100%