Regulatory Compliance Certification:

Medical Devices (RCC-IVDR)

Candidate Guide 2023-2024

November 2023

Contents

Welcome and Overview

Introduction

Congratulations on pursuing the Regulatory Compliance Certification for In Vitro Diagnostics (RCC-IVDR). RAPS commends your commitment to your career and the regulatory profession.

This document contains information about:

- Meeting eligibility requirements
- Applying to the program
- Preparing for the exam
- Scheduling the exam
- What to expect at the testing center
- What to expect after the exam
- Recertification requirements

This document pertains to the RCC-IVDR certification only. For information about the RCC-IVDR certification, see the RCC-IVDR Candidate Guide.

The RCC is a leading credential for regulatory professionals in the healthcare product sector. It is intended for individuals employed in regulatory agencies, industry, consultancies, and other settings involved with the regulation of healthcare products. Success on the RCC exam requires knowledge of:

- Conformity of the Devices
- Technical Documentation
- Post-marketing Surveillance
- Vigilance
- Clinical Investigation/Performance Study

About Certification

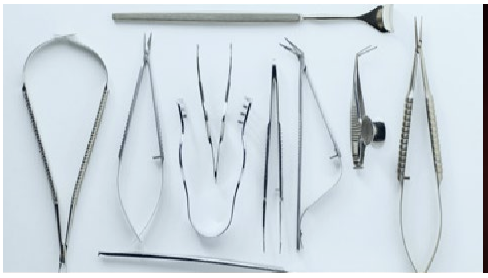
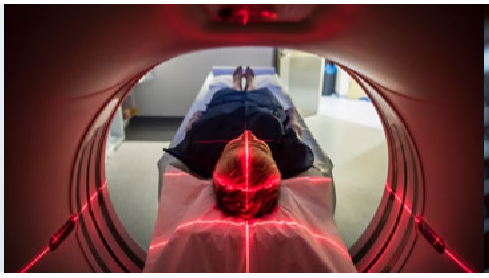
Certification is a process by which an entity grants formal recognition to individuals that meet predetermined, standardized criteria. The certification process involves a determination of eligibility, an assessment of demonstration of competence, and requirements for regular recertification. Certification is usually voluntary and established by a non-governmental entity.

The primary purpose of a professional certification program is to provide an independent assessment of the knowledge and skills required for the successful performance of a professional role. This assessment is typically accomplished by the successful completion of an exam.[1]

Certification Value[2]

In general terms, a high-quality certification validates an individual's knowledge, skills, and abilities in a defined profession, occupation, skill, or role. Certified individuals in the workforce reduce risk and enhance consumer protection and public safety. In addition, these certifications allow employers and other stakeholders to identify individuals with the competencies needed to perform a role or task.

[1] Defining Features of Quality Certification and Assessment-Based Certificate Programs. (2010) The Institute for Credentialing Excellence.
[2] A Look at the Value of Professional Certification. (2012). The Institute for Credentialing Excellence.


Certification holders benefit from:

- Increased recognition by peers and respect of colleagues in the profession
- Improved opportunities for employability and advancement
- Greater confidence in their professional competence
- Increased professional trust from employers or the public
- Increased autonomy in the workplace
- Better compensation and career longevity

Consumers benefit from:

- Objective, independent, third-party evaluation and assessment of professional competence
- Commitment to public safety and/or consumer protection
- Accountability through ethical conduct standards and/or a disciplinary process
- Recertification requirements for continued or enhanced competence

Employers benefit from:

- Qualified individuals for employment or advancement
- Recertification requirements for continued or enhanced competence
- Commitment to public safety and/or consumer protection
- Reduced risk of errors, accidents, and/or legal liability
- Reduced employee turnover and increased job satisfaction
- Justification for potential compensation differential[2]

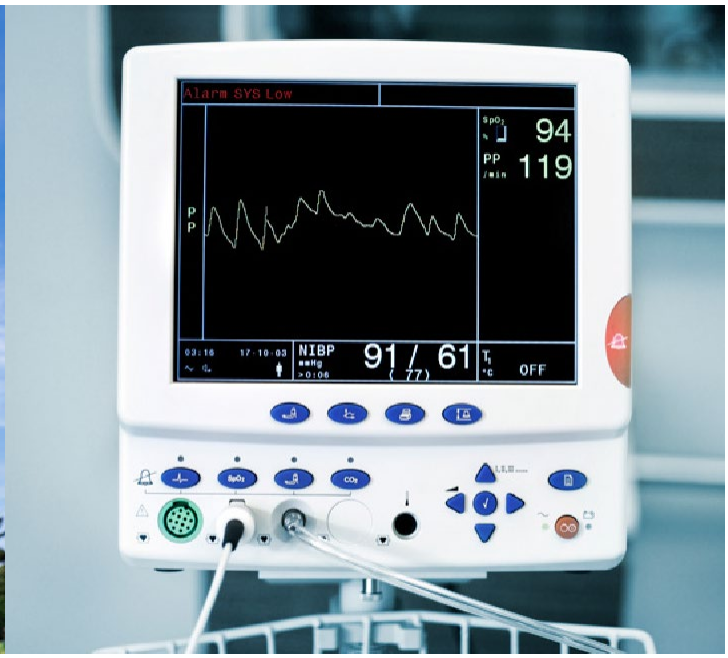
The RCC demonstrates to employers, clients, and colleagues that a regulatory professional has the essential knowledge required for regulatory compliance in the healthcare products sector. As the demand for competent regulatory professionals increases globally, RCC-credentialed professionals are well- positioned to be effective team members and contributors in every work setting.

Exam Overview

Each exam will be reviewed and revised annually. The current exam content is based on IVDR regulations that went into effect in May 2022. Each exam is designed to assess the knowledge and skills of a regulatory professional through a valid and defensible method, ensuring that the content assessed is reflective of current practice.

Knowledge Required and Regulatory Basis

- Knowledge and comprehension of the IVDR
- Knowledge and responsibilities required of a regulatory professional with at least four years of pertinent regulatory experience or equivalent



What it is…

The RAPS Regulatory Compliance Certifications (RCC) will provide individuals and organizations with an option for obtaining an internationally recognized credential. Employers and peers will know, through third-party validation, that certification holders understand European regulations related to In Vitro Diagnostics (IVDR) and Medical Devices (MDR), respectively.

As with the Regulatory Affairs Certification (RAC), this new program provides successful participants with distinguished credentials with either an IVD or Medical Device focus to help advance their careers! Inspired by the requirements under the IVDR and MDR respectively, this program covers knowledge specifically required in the new European regulations.

What it isn't…

These are voluntary certifications and are not mandated by law or regulation.

While the examination criteria were inspired by section 3 of Article 15 of the MDR and IVDR, these certifications are merely one part of an individual's career journey.

These designations do not qualify individuals to serve in the PRRC role, nor do they guarantee that an individual meets all the requirements necessary to practice as a qualified PRRC.

Preparing for the Exam

The RCC exams are challenging, so it is important to develop a study plan. Here are some things to consider:

- Review the exam content outline—The content outline in the Appendix contains the content domains, competency statements, and the number of questions in each domain.
- Assess knowledge and experience scope and depth— Use the content outline as a checklist to evaluate areas of strength and weakness; it will help focus studying.
- Build and implement a plan—Allow sufficient time to build a knowledge base in areas of limited experience to expand knowledge in more familiar areas. Use reference materials to supplement your knowledge.

Question Types

The exam consists of 120 multiple-choice questions that must be answered within a two hour and thirty-minute time limit.
There are two question formats used in the RCC exams.

- Recall questions ask for recognition and comprehension of specific information from the IVDR regulations
- Application questions require relating specific knowledge to a situation that may be encountered by a regulatory professional

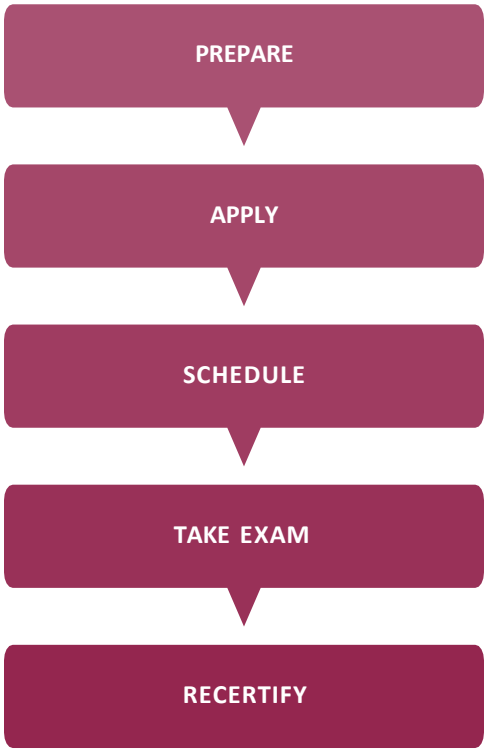
Preparing for the Exam

Computer-Based Testing and Testing Modality

All exams are computer-based. Testing can occur at selected testing centers, confirmed by the testing vendor, or online at a suitable location of the candidate's choosing. Candidates **do not** need to choose their preferred testing modality when applying. Modality is selected when scheduling the exam.

The Journey

Check the RAPS website at RAPS.org for additional resources. Some resources are free of charge; others are available for purchase. RAPS's resources are not required.



Key Exam

- EU content
- Content is updated annually
- 120 questions
- Two and a half hours
- Computer-based
- Two question formats—recall, application
- Can be taken at testing facility or online

Applying for the Exam

Application Process

Apply online or submit the printable application form. Testing windows, application deadlines, and fees are listed in the Appendix.

Eligibility Requirements

One of the following educational and professional experience requirement combinations is required to apply:

- IVDR – Bachelors, Masters, or Doctorate Degree in medicine, pharmacy, engineering, or relative sciences + 1 year of regulatory-related* experience with in vitro diagnostics medical devices,

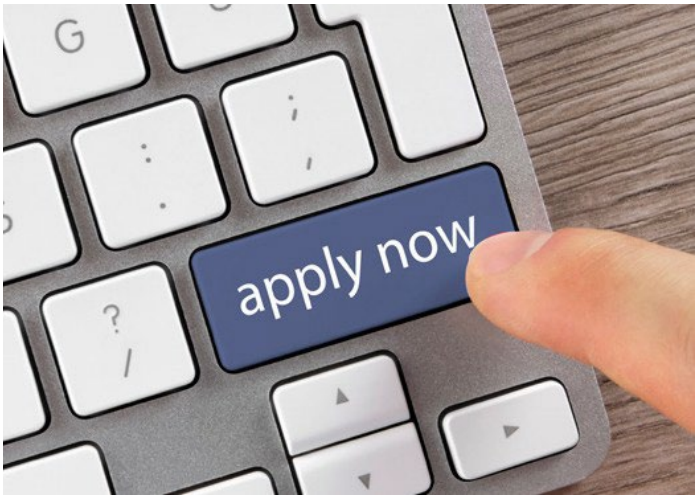
  OR
- 4 years of regulatory-related experience with in vitro diagnostics medical devices.

*Regulatory-related experience may include quality assurance, quality control, clinical research related to the approval of health products, or health product project management.

General Application Instructions

Include your name on the application as it appears on a government-issued photo identification (ID). If the name on the application does not match the government ID, you will not be allowed to sit for the exam.

1. Provide a valid email address. If using a work email address, please keep in mind that any change in employment during the application process could affect access to that e-mail account. All communications about the exam, including scheduling and results information, are electronic. Please contact the RAPS Program Office with email address changes.
2. Complete the exam application fully. As part of the application process, you must attest to the following:
   - I have read, understood, and agree to comply with all policies outlined in the RCC Candidate Guide.
   - I acknowledge and agree to RAPS examination policies and certification policies.



- The information in my RAPS account is complete and accurate.
- I meet all eligibility requirements for the RCC exam, and I authorize RAPS to make any inquiries deemed necessary to verify my credentials.
- I understand that false information may provide cause for denial of this application or loss of the RCC credential.
- I allow RAPS to use information from my application and from the exam for the purpose of aggregate statistical analysis, provided that any personal information or identifiers are removed.
- I authorize RAPS to publish my name in the public certification directory if I successfully complete my examination.
- I understand and agree to the policies related to withdrawing from the exam.
- I acknowledge that I have read and understand the tenets outlined in the RAPS Code of Ethics.

See the Appendix for the Code of Ethics for Regulatory Professionals.

Incomplete applications will delay processing and may lead to rejection minus an administration fee.

Application Tips

- Make sure name on application matches the provided government-issued ID
- Use an e-mail with long-term access; personal e-mails are often more effective than work emails
- Read the Candidate Guide
- Read and agree to abide by the RAPS Code of Ethics
- Review the eligibility rules prior to applying

Submitting Payment

The correct payment must accompany applications.

Application Receipt Confirmation

Receipt of a "thank you" email signifies application receipt. The RAPS Program Office will contact candidates with application questions or if an application is selected for audit.

Application Audit

RAPS may audit a percentage of applications for completeness and accuracy. If selected for audit, the candidate will receive an email detailing additional documentation requirements. Noncompliance by the stated deadline will result in the candidate not being allowed to test. The candidate will be issued an exam refund minus the administration fee.

Incomplete Applications

Any application deficiency must be corrected by the application deadline. Noncompliance by the stated deadline is grounds for application rejection. A candidate will be issued an exam refund minus the administration fee.

Application Rejection

Applications will be rejected for failure to meet eligibility requirements or falsification of application information. Applicants rejected on these grounds will be issued an exam refund minus the administration fee. Penalties and sanctions may also apply.

Application Cancellation and Refunds

To cancel your application, submit a written request to the RAPS Program Office before the application deadline (prior to any transfers). There is an administrative fee for canceled applications. Candidates are ineligible for refunds following a transfer. Requests to cancel after the deadline will be rejected.

Transferring to Another Testing Cycle

A request to transfer to the next testing window may be made without charge by contacting the RAPS Program Office before the application deadline. Only two transfers are permitted. Additional transfers will require re-applying to the program at full price.

Requests to transfer to the next testing window are free if they are made before the application deadline. Transfer fees apply if the transfer is made after the application deadline until the final day of the exam window. Transfers will not be permitted after the final day of the testing window. Applicants who request to transfer after the final day of the testing window must re-apply to the program at full price.

For candidates seeking transfers because of an emergency, consult the "Emergency Situations" section.

Appeals Process

Candidates have the right to request for reconsideration any adverse decision made by the RAPS Program Office.

1. A request for reconsideration must be submitted to the RAPS Program Office within 30 days after adverse decision notification using the form provided in the Appendix.
2. RAPS will acknowledge such requests in writing within 10 days.
3. The Regulatory Affairs Certification Board (RACB) will address the reconsideration.
4. Reconsideration outcome notifications will be provided within 90 days of receipt. RACB decisions are final.

Nondiscrimination Policy

The RCC program does not discriminate based on age, gender, race, religion, national origin, disability, sexual orientation, or marital status.

Exam Scheduling

Notice to Schedule Email

Exams are scheduled directly with the contracted testing vendor, Meazure Learning, who will send "Notice to Schedule" emails approximately 10 days before the testing window starts. This email provides important exam scheduling instructions.

Applicants should add candidatesupport@meazurelearning.com to their email safe list.

The email will contain a website link, unique login ID, and password. Use the link to choose the test date, time, and modality (the choice is between in-person and online testing).

Exam Scheduling

Log in to the Meazure Learning scheduling site and choose between in-person and online testing.

Candidates should schedule their exam as soon as possible to receive the most date, time, and location options. Scheduling requests must be submitted at least two days before the preferred testing date. All exams must be scheduled two days before the testing cycle closes.

Measure Learning will email exam scheduling confirmation, a copy of which candidates must present at the testing center on test day.

Meazure Learning reserves the right to cancel any testing site. Meazure Learning will send notifications and instructions for fee-free rescheduling if it cancels a site.

Scheduling an Online Exam

When choosing an online exam, candidates must confirm their demographic information, attest to Meazure Learning's privacy policy, and test their computers for exam delivery system requirements. Meazure Learning strongly encourages applicants to performance check their systems during appointment scheduling. Candidates whose computers fail the check will receive feedback on the hardware or software issues. Candidates must correct the issue, update the computer, or obtain another computer to test.

The system requirements check is included in the confirmation email. Candidates are reminded to perform the check prior to testing. Following these administrative tasks, the candidate selects "schedule" to proceed.

The candidate's computer must have webcam capability as well as a microphone and speakers. Candidates must have an adequate internet connection to ensure that the proctor can access the candidate's computer and that the session can proceed without internet disruption on exam day.

See the "Computer Requirements" section for full details on specifications needed for online testing.

International Testing

Applicants looking to schedule an exam outside of the US or Canada should follow the instructions to schedule through the Meazure Learning scheduling site.

Candidates should consider locations they may visit for business or pleasure if they cannot find a location near their home or office. Meazure Learning cannot guarantee availability of any international site/date during the designated testing period.

Within five business days, Meazure Learning will issue a confirmation notice for one of the preferred sites/dates. If none of the preferred sites or dates are available, Meazure Learning will offer an alternate site or date for candidate approval. Upon approval, Meazure Learning will issue a confirmation notice.

Changing an Onsite Testing Appointment

Candidates should use the link provided in their appointment confirmation emails if they wish to change the date, time, or location of the appointment within the same exam window.

Tests may be rescheduled with the same testing window up to two days before the scheduled appointment. To move to a different testing window, consult the "Transferring to Another Testing Cycle" section.

Meazure Learning charges a rescheduling fee for each request. Meazure Learning's e-mail is: candidatesupport@MeazureLearning.com. Contact Meazure Learning by telephone at +1 919 572 6880 if online rescheduling is problematic.

Changing an Online Testing Appointment

Access the online testing system via the scheduling link provided in the "Notice to Schedule" email to change appointments.

The rescheduling fee does not apply to online testing candidates who are rescheduling to another online testing slot or switching to in-person testing. The fee does apply to candidates rescheduling from in-person testing to another in-person time, location or to an online testing appointment.

Changing the Exam Type or Modality

A candidate requesting to change the exam they wish to take (e.g. from RCC-MDR to RCC-IVDR or vice versa) or the testing modality (e.g. from online to onsite testing or vice versa) must submit the request by the application deadline. Changes to the exam type should be directed to the RAPS Program Office. A change fee will apply.

Emergency Situations

Under certain emergency situations as outlined, the Program Office may, at its discretion, transfer an applicant's exam to the next testing window and waive the transfer fee.

If an applicant cannot take the RCC exam for one of the following reasons the applicant may request to transfer to the next testing cycle:

- Serious illness (either the candidate or an immediate family member)
- Death in the immediate family
- Disabling accident
- Court appearance or jury duty
- Unexpected military deployment
- Mandatory quarantines
- Geopolitical event (e.g., breakout of war)

In such circumstances, the applicant must contact the RAPS Program Office no more than three days after the end of the window. The appropriate documentation must be submitted. Work-related emergencies do not qualify for this exception.

Failure to Schedule or Keep an Appointment

Such failures are considered a no-show and result in all exam fees being forfeited. The following are no-show situations:

- Failure to schedule an exam appointment during the
- testing cycle
- Failure to fulfill a scheduled appointment
- Arriving at the testing site more than 15 minutes late
- Failure to produce appropriate government-issued ID at the exam appointment

No-shows must reapply to take the exam at the full price.

Special Accommodations for the Exam

Candidates who require special accommodations under the Americans with Disabilities Act (ADA) must send the completed "Special Accommodations Request" with "Disability-Related Needs" forms completed by a qualified professional, to the RAPS Program Office at the time of application. The request must indicate the nature of the disability and specify the type of accommodation requested. Candidates will be notified in writing if their request is approved. Consult the Appendices for more information.

On Exam Day (Onsite Testing)

What to Bring to the Testing Center

1. Arrive at the testing center at least 15 minutes early with a copy of the exam confirmation email and a valid government-issued ID. IDs must include name (in English characters or translation to compare with RCC application information), photograph, and signature. Make sure the name on the ID EXACTLY matches that on the scheduling screen. If the ID lists more than one last name, the same last name must be reflected in the confirmation email.

   The following are acceptable ID forms:

   - driver's licenses
   - military IDs
   - passports
   - national identification cards

2. In case of a mismatch or incorrect name, contact RAPS immediately at +1 301 770 2920, ext. 200. Candidates who cannot produce ID or exact matching ID forfeit their exam fees and will not be permitted to take the exam.

Items Prohibited at the Testing Center

Candidates are prohibited from bringing the following items to the test center:

- 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, luggage, purses, or handbags
- iPods, mp3 players, tablets, headphones, or pagers
- calculators, computers, PDAs, or other electronic devices with one or more memories
- personal writing utensils (i.e. pencils, pens, and highlighters)
- watches and other jewelry except for wedding or engagement rings
- food and beverages
- coats and jackets
- weapons
- hats, hoods, or other headwear are not permitted in the exam room unless required for religious purposes; all items are subject to inspection by the proctor if suspicious behavior is detected
- sweaters and sweatshirts without pockets or hoods are permitted
- Google and smart glasses (any glasses with electronics)
- medicine (except as expressly permitted in advance)

You will be provided with an:

1. abbreviations table

Meazure Learning testing centers administer exams for multiple organizations. Others in the testing room may be taking different exams and have different rules for their exam, including time allocation and permitted items.

Other Considerations

- Smoking is prohibited
- Questions about exam content are allowed
- Exam sessions are monitored and recorded in both audio and video formats
- If breaks are allowed, the clock keeps running

Inclement-Weather Cancellations

In the event of dangerous weather, a natural disaster, or other emergencies, Meazure Learning will post the information on its website. Candidates scheduled at a site operating on a delay will receive an email from Meazure Learning. Should the site be closed entirely, Meazure Learning will contact the candidate to reschedule.

Exam Security and Confidentiality

The RCC exams are the sole and exclusive property of the RAPS Program Office. These materials are confidential and not available for review by any person or organization other than the RACB and the exam committees. Copying, publishing, or disclosing exam content in any form is considered a violation of the exam security and confidentiality policy, and subject to disciplinary action, which may include termination of a testing session, invalidation of test results, and/or revocation of an RCC credential.

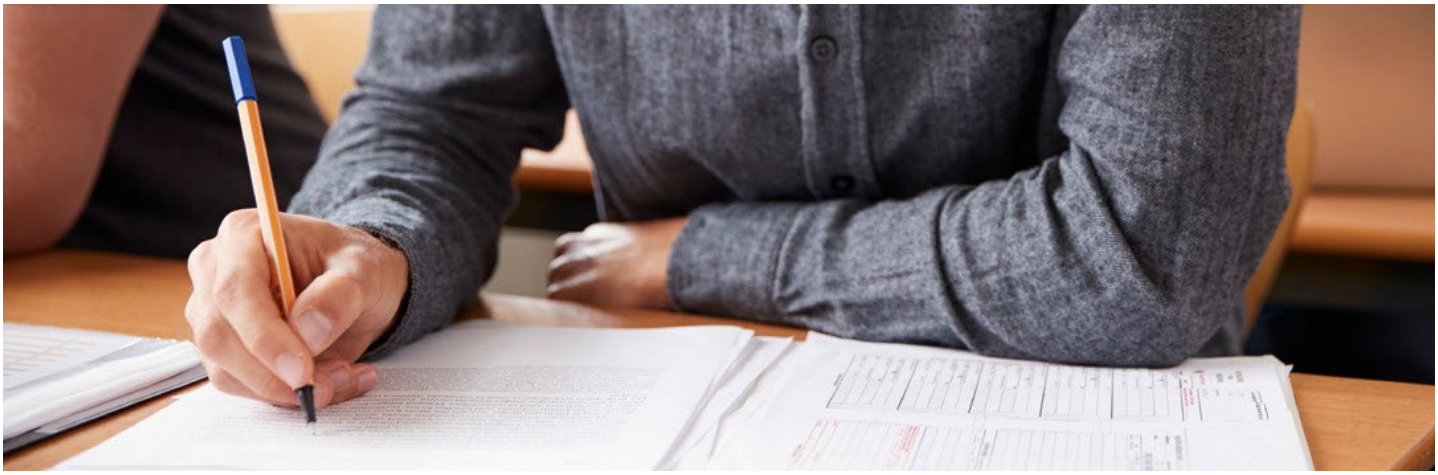
Termination of Exam/Dismissal

Candidates are expected to always conduct themselves in a professional manner at the testing center. The test center administrator or proctor is authorized to dismiss anyone and/or request that a test score be nullified under the following circumstances:

- Using or attempting to use someone else to take the examination.
- Using notes or other study materials during the testing process.
- Creating a disturbance. Disruptive behavior in any form is not tolerated. The test administrator has sole discretion to determine what constitutes disruptive behavior.
- Communicating in any manner with anyone other than the administrator or proctor during the testing process.
- Leaving the testing room without permission.
- Tampering with a computer.
- Removing or attempting to remove any material from the testing room.
- Failing to follow any examination policies or requirement explained in this Candidate Guide.

Problems at the Testing Center

The RAPS Program Office and Meazure Learning take steps to assure that the exam process is effective. However, sometimes there are irregularities. Contact the proctor immediately about any technical difficulties during the exam. Candidates may reschedule their exam appointment if a delay lasts longer than 30 minutes.



On Exam Day (Online Testing)

Authentication

- Show government-issued photo ID with a signature exactly matching the name used for registration
- Username, password, and exam password from "Notice to Schedule" email

Before Beginning

Before and after the exam, candidates will be asked to open their task manager (PC) or activity monitor (Mac) and ensure that all programs not needed for the exam are shut down.
Candidates will also be asked to open and clear their clipboards.

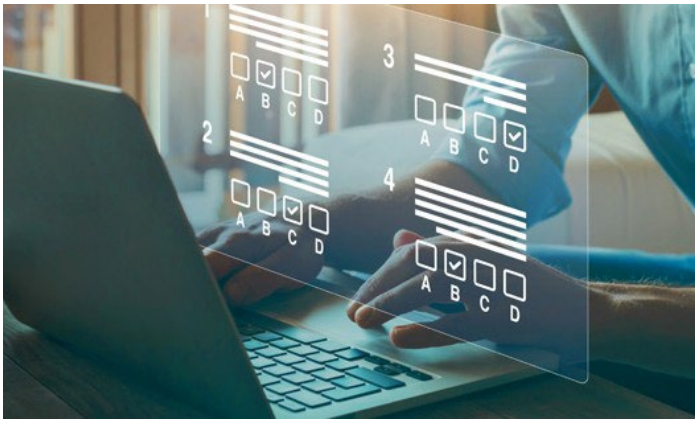
Candidates are required to pass the systems' requirements check prior to testing. After the systems' requirements check, the proctor verifies the identity of the candidate by examining the candidate's government-issued ID. The candidate may communicate with the proctor via chat features available within the online testing launch site.

If a computer fails the check of systems' requirements, candidates must correct the issue or obtain another computer to complete the testing appointment.

If directed by the proctor, or in case of technical difficulties, the candidate may contact the proctor by telephone.

As part of the login process, the candidate shows the proctor a 360-degree view of his or her environment, including the desk, by holding and moving the webcam or laptop with a webcam as directed by the proctor. After the environment check, the proctor enables the monitoring software, which allows the proctor to watch the candidate via the candidate's webcam and record video and audio during the testing appointment.

When the proctor has completed the necessary steps to ensure monitoring, the candidate clicks a link to launch the exam login process.



During the Exam

The environment should be quiet to avoid distractions and to ensure that the online proctor can hear everything at the candidate's location.

The proctor has complete access to the candidate's computer to monitor for unauthorized activities, such as accessing other software applications, using multiple monitors, letting someone else take the exam, and allowing anyone other than the proctor remote access to the computer.

The proctor can terminate the testing appointment for integrity reasons at any time.

During the exam login process, the proctor and candidate complete a dual login, in which candidates verify their information, complete the candidate-attestation statement, and review the testing rules and policies. In addition, prior to launching the exam, the candidate can review the online tutorial of ProctorU.

Testing time for candidates begins when the exam is launched. When a candidate completes the exam, they click "submit exam" and confirm their readiness to submit the exam. If a candidate does not submit the exam before the time limit, the exam will automatically be submitted at that time.

A "thank you" message will be presented to candidates after the submission.

Room Environment

- Quiet location
- Only candidates in the room
- Working, powered, and connected computer matching requirement specifications
- Clear desk/test-taking surface
- Remain seated
- No food or drink
- No hats, hoods, or other headgear, other than for religious purposes
- No coats or jackets

Other Considerations

- All exam sessions are monitored and recorded in both audio and video formats
- Breaks are not permitted for online exams
- No note board or scratch paper is permitted

Online Testing Log-In Issues

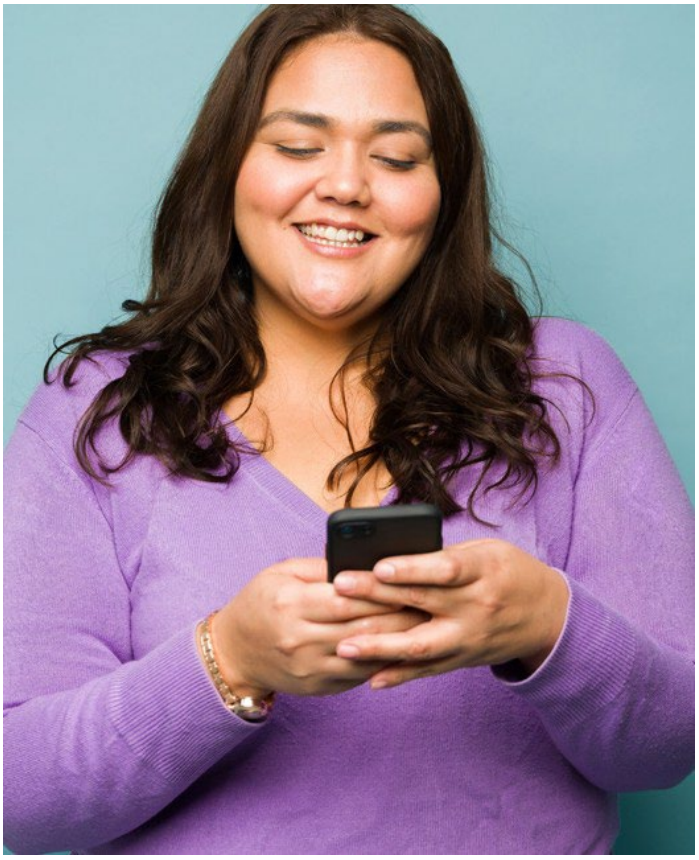
Log-in issues for online tests occur very rarely.

However, if a candidate is unable to begin the exam within 30 minutes of the scheduled exam start time, the candidate shall be provided the opportunity to reschedule to another date within the same exam window. In such an event, candidates must call Meazure Learning to reschedule, no later than close of business of the next available business day. If a candidate can log into the exam but is unable to complete the exam because of technical issues, the candidate will be permitted to re-test during the next testing window.

Online Testing Privacy Statement

By taking the online exam, candidates attest that they understand the exam session, including video, is recorded and may be saved for up to one year. The recordings will be deleted no later than one year after the exam date. By agreeing to take the exam online, the candidate agrees to exam session recording and review by the testing agency and testing program owners.

After the Exam



Exam Scoring

Exams are scored by Meazure Learning after the close of the testing cycle. Exams are not scored at testing centers. A statistical report of scoring is reviewed by a statistician and the exam committee to assure ongoing quality of the exams.

All scores will be reported on a scale of o to 550. The scaled score is neither the number of questions answered correctly nor the percentage of questions answered incorrectly. One cannot look at the scaled score and determine the number of correctly answered questions needed to pass the exam.

Notification of Exam Results

Exam results are typically available six weeks after the close of the testing cycle. Results will be sent via email. No results will be reported over the telephone. Results are released only to candidates.

RCC Recognition

A list of all active RCC-credentialed professionals is available online at RAPS.org. Newly credentialed professionals are added after all candidates are notified of their status. Anyone not wishing to be included in the online listing should contact the RAPS Program Office.

Use of the RCC Designation

After passing, candidates may use the "RCC-IVDR" designation as a professional credential after their names, as well as on resumes, curriculum vitae, employment, and other professional records. This designation cannot be used by individuals who do not recertify. See RAPS.org for more information on the proper usage of the designation.

Retaking the Exam

Candidates who fail the exam are eligible to retake the exam in the following window. Candidates cannot retake the exam during the same window. To apply to retake the exam, candidates must submit a new application. There is no limit on the number of times a candidate may retake the exam.

Release of Information

The RAPS Program Office maintains strict procedures for ensuring the confidentiality of all candidate records. Information about candidates is released only to the candidate.

Recertifying

Maintaining the Credential

Continual learning, knowledge enhancement, and professional development are vital to regulatory professionals. Once certified, holders maintain their RCC credentials through continued learning and involvement in professional activities. Holders must renew their RCC every three years by earning 24 RCC recertification credits. Credits may be accumulated in many ways, including participation in continuing education, public speaking on regulatory topics, professional writing, and involvement with professional organizations.

Individuals who hold more than one RCC designation are only required to submit a single recertification application with a total of 24 credits. The recertification cycle is based on the initial RCC certification and the related recertification cycle.

Contact Information

Regulatory Affairs Professionals Society
RCC Program Office
Tel: +1 301 770 2920, ext. 200
Email: certification@raps.org

Meazure Learning
Tel: +1 855 772 8678
Chat: https://auto.proctoru.com/chat
Email: candidatesupport@meazurelearning.com

Appendix A

RCC-IVDR Exam Content Outline

Domain weighting percentages in the exam content outline are approximate and may be +/-2%. Exam content for the RCC-IVDR exam is based on regulations and guidelines in:

Domain I: Conformity of the Devices– Exam Weighting Approximately 21%

1. Ensure all devices placed on the market have a valid declaration of conformity.
   a. ANNEX I
   b. ANNEX II
   c. ANNEX III
   d. ANNEX IV
   e. Article 17
   f. Article 7 through 9

2. Ensure, where applicable, devices have a valid European Conformity (CE) notified body certificate.
   a. Notified body website or EUDAMED to check the validity of the CE certificate (scope, valid dates, authenticity)
   b. ANNEX XII
   c. Article 51

3. Ensure that a management system for packaging material is in place or the device is properly CE marked.
   a. Article 18
   b. ANNEX V

4. Ensure the manufacturer or the authorized representative complies with the requirements of the IVDR.
   a. Articles 10, 11, 12
   b. MDCG 2022-16 Guidance on Authorized Representatives Regulation

5. Review audit reports of the devices' realization and release processor perform these audits to ensure corrective and preventive actions are applied.
   a. Article 10
   b. Article 16
   c. ANNEX I
   d. ANNEX IX
   e. ANNEX XI
   f. ISO 13485 awareness, specific requirements for IVDs

6. Ensure the design team is trained and understands the requirements that are outlined in the IVDR.
   a. Articles 47 through 50
   b. Chapter VI
   c. ANNEX I
   d. ANNEX II
   e. ANNEX XIII
   f. ANNEX XIV

Domain II: Technical Documentation– Exam Weighting Approximately 24%

1. Ensure that the technical documentation is in place and is in accordance with IVDR.
   a. ANNEX I
   b. ANNEX II
   c. ANNEX III

Domain III: Post-marketing Surveillance– Exam Weighting Approximately 19%

1. Establish, implement, and maintain a post-marketing surveillance system.
   a. Article 78 through 85

2. Communicate with Competent Authorities, notified bodies, other economic operators, customers and/or other stake holders.
   a. Article 78
   b. Article 82 through 84
   c. Article 87

3. Ensure processes exist for reporting of serious incidents and field safety corrective actions in the context of vigilance.
   a. Article 78
   b. Article 82 through 87

4. Know and understand the documentation requirements regarding post marketing surveillance.
   a. Article 79 through 81
   b. Annex III

Domain IV: Vigilance– Exam Weighting Approximately 17%

1. Ensure there is a process and procedures in place to manage field safety corrective actions and responsibilities for the process.
   a. Article 82

2. Ensure there is a process for Trend Reporting.
   a. Article 83

3. Ensure required communications with Competent Authority are fulfilled i.e., providing documents, and answering questions related to event/FSCA as applicable.
   a) Article 84

4. Ensure there is a process to manage investigations into adverse events and CAPAs related to safety issues.
   a) Generic

5. Ensure there are processes in place to facilitate feedback from field (HCP, patients, and users) to Manufacturer.
   a) ANNEX I § 20.4.1 (A through F)

6. Report any serious adverse events or concerns related to the vigilance process to the Competent Authority.
   a) Article 82

Domain V: Clinical Investigation/ Performance Study– Exam Weighting Approximately 19%

1. Ensure that a signed statement by the natural or legal person responsible for the manufacture of the performance study device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study.
   a) Chapter VI
   b) ANNEX I
   c) ANNEX XIV

2. Ensure that the performance study is planned in order to protect the health and safety of the subject(s).
   a) ANNEX I
   b) ANNEX XIV

Appendix B

Special Accommodations Request Form

To the Applicant: The Regulatory Affairs Certification Board (RACB) may provide accommodations to candidates with a disability as defined by the *Americans with Disabilities Act (ADA)*. Please review the RCC Candidate Guide before submitting this form to be sure a candidate qualifies for special accommodation.

Please Type or Print Name

Address

First	Last	MI

Street	Mail Stop/Suite/Apt

City	State/Province	Zip/Postal Code	Country

Phone Country & Area Code

Email

For which exam is accommodation requested?

○ RCC-MDR ○ RCC-IVDR

Type of accommodation requested

Have you previously received accommodation in any educational or testing situation ○ Yes ○ No

If yes, please describe the accommodations received

I certify that the above information is true and accurate.

Signature	Date

Appendix B

Documentation of Disability-Related Needs

To the Professional: The individual identified below is requesting accommodation for the Regulatory Compliance Certification (RCC) exam. The Regulatory Affairs Professionals Society (RAPS) requires that candidates requesting testing accommodations provide documentation of the disability from a person qualified to assess the disability.

By completing and signing this form, you are verifying that the individual named below has been diagnosed with the stated disability, and the recommended accommodation is required to fairly demonstrate the candidate's ability on the exam.

Candidate Name	First	Last	MI
Phone	Country & Area Code	**Email**	

Please include the following:

1. **Diagnosis (note: mental and emotional disabilities must include a diagnosis from the DSM-IV)**

2. **Description of the candidate's disability and how the disability affects the candidate's major life activities (e.g. hearing, seeing, walking, talking, performing manual tasks)**

3. **Recommended Accommodations:**

Signature	Date

Appendix C

Code of Ethics

As regulatory professionals, we have the responsibility to maintain particularly high standards of professional conduct while exercising professional requirements and duties in upholding and clarifying the applicable laws and regulations. We strive to make a positive contribution to public health by using this code of ethics in our workplace(s). This is the RAPS Code of Ethics; regulatory professionals understand that their employers and others may have other codes of ethics that they may need to acknowledge, understand, and follow.

Our Code of Ethics was first initiated in 2003 and has been updated twice since then. We vow to regularly assess its applicability and refresh its content as the regulatory profession grows and evolves.

Fundamental Principles

As a regulatory professional I aspire to:

- Provide my employer with the complete regulatory requirements to ensure their activities are conducted in compliance with the laws and regulations of the respective authorities.
- Be competent in performing my duties as a regulatory professional.
- Base decisions on factual, up-to-date information and clearly communicate competing or conflicting concerns, as necessary. Have integrity. Be consistent in making decisions and be trustworthy.
- Be honest with employers and team members to ensure all information and communications are accurate and complete.
- Have the courage to make difficult decisions. Present all relevant information to my organization to promote decisions. Be able to withstand challenges to my views and be accountable for my errors.
- Be fair in my dealings with all stakeholders. Apply regulatory standards equitably. Consider all interests of all parties in the decision processes.
- Be respectful of others. Treat all individuals with dignity and courtesy.

RAPS members perceive eight core values that regulatory professionals use in conducting their professional responsibilities.

Duty

Our role is defined by our responsibility to advise individuals, team members, and organizations regarding the appropriate regulatory context for actions they may want to take. We also must heed our obligations as employees, consultants, and contractors for making products for patients; as members of teams conducting clinical & nonclinical studies; as regulators; and as members of our profession.
Regulatory professionals have a duty to:

- Disseminate and interpret applicable government laws and regulations, industry standards and *good practice* guidelines without bias.
- Provide healthcare professionals (HCPs) with accurate and relevant information regarding the safety and effectiveness of products.
- Maintain the integrity of our profession and strive to preserve the public's trust.

Competence

Competence means the regulatory professional has the knowledge, experience, ability and skill sets to effectively identify, analyze, solve, or recommend solutions for regulatory challenges. We must be dedicated, yet flexible to adapt to the constantly changing requirements.

The diversity of individuals and organizations within the profession necessitates a commitment to evolve by a variety of options: continuing education, work experience, professional training, and certifications. Maintaining regulatory competence is a continual learning process.
Regulatory professionals develop competence by:

- Being knowledgeable about current and future trends.
- Encouraging and supporting professional growth and development among peers and colleagues so all can gain and demonstrate competence in the profession.
- Participating in continuing education opportunities related to regulatory laws, guidance, standards, and other updates.

Objectivity

Regulatory professionals display objectivity by:

- Responding carefully to issues and recognizing other points of views and striving to offer an unbiased expression of facts.
- Presenting regulatory opinions, options and associated risks when developing regulatory strategies.
- Clearly delineating regulatory requirements, internal requirements and personal preferences.
- Appropriately disclosing new information.

Integrity

Regulatory professionals should not compromise their values or trustworthiness for personal gain or professional enhancement. Regulatory professionals shall develop and maintain integrity by:

- Keeping their commitments
- Giving credit for the work of others
- Maintaining confidentiality
- Seeking advice when uncertain
- Maintaining integrity without compromise
- Avoiding situations that put integrity at risk
- Accepting that best option may not be in their employer's short-term interest
- Avoiding conflicts of interest
- Adhering to their employer's Ethics and Compliance Standards

Honesty

Regulatory professionals shall exhibit honesty in all activities. Honesty requires acting free from deceit or deception, including dishonesty by omission or failing to provide comment when ethically required. Regulatory professionals shall build honesty and trust by:

- Ensuring information is accurate and complete.
- Protecting against omission of information or creation of false impressions.
- Resisting pressures to relax standards of honesty to achieve expediency.
- Providing a complete profile of a product under review in all regulatory submissions.

Courage

Regulatory professionals must have courage to evaluate, conclude, and provide consistent and accurate advice. Regulatory professionals develop courage by:

- Encouraging an open exchange of all views, even if they challenge regulatory advice.
- Admitting mistakes, accepting accountability and promptly correcting any errors, miscommunications, or misperceptions.
- Delivering bad news quickly to management when necessary.
- Providing information to all stakeholders regarding risks and consequences if regulatory advice is overruled or ignored.

Fairness

Regulatory professionals strive to treat all persons fairly, equitably, and equally to create and maintain a healthy workplace, so that all people can thrive both personally and professionally. Regulatory professionals demonstrate fairness by:

- Respecting the letter and spirit of laws and regulations.
- Applying the appropriate regulatory standards to all cases.
- Considering cultural and regional differences and local requirements.
- Presenting the facts and objective analysis of scientific information using sound statistical interpretation to minimize bias while clarifying uncertainty.
- Ensuring all interests, public and private, are appropriately considered in the regulatory decision processes.

Respect

Regulatory professionals must respect the roles of their colleagues, and both recognize and acknowledge all. Regulatory professionals develop respect by:

- Listening.
- Treating all parties with dignity and courtesy.
- Accepting personal differences.
- Creating a positive environment where diversity, equity and inclusion thrive.
- Creating an environment where there is zero tolerance for harassment of any kind towards others.
- Finding creative ways to resolve conflict.
- Being patient and forgiving when others make mistakes and not assign blame.

Appendix D

Appeals Request Form

Candidates have the right to request reconsideration of any adverse examination decisions made by the RAPS Program Office. An appeal must be submitted in writing not more than 30 days following the date of notification of the adverse decision using the form provided. Appeals should be sent to the RAPS Program Office at certification@raps.org. All appeals will be acknowledged by RAPS within 10 days in writing. The Regulatory Affairs Certification Board (RACB) will address appeals. Appeals notifications will be provided within 90 days of receipt. All decisions made by the RACB are final.

Candidate Name First | Last | MI

Phone Country & Area Code **Email**

Mark the Pertinent Exam Window and Exam Type:

☐ Spring ☐ Summer ☐ Autumn

○ RCC-MDR ○ RCC-IVDR

1. Mark the reason for the appeal

○ Eligibility
○ Testing Conditions
○ Exam Scoring
○ Other (please specify):

2. Provide a concise description of the situation or issue and your desired outcome.

Signature Date

Appendix E 2023-2024 Application Deadlines and Testing Windows

Application Deadlines and Testing Windows

Windows	Application Deadline	Window Open	Window Close
Autumn 2023	Thursday, 5 October 2023	Monday, 30 October 2023	Friday, 8 December 2023
Spring 2024	Thursday, 22 February 2024	Monday, 25 March 2024	Friday, 26 April 2024
Summer 2024	Thursday, 20 June 2024	Monday, 15 July 2024	Friday, 16 August 2024
Autumn 2024	Thursday, 3 October 2024	Monday, 4 November 2024	Friday, 6 December 2024

Applications and payment must be received by 11:59 pm (US Eastern Time) on the application deadline dates listed above. Applications received after the deadline will not be processed.

Appendix F 2023-2024 Application, Transfer, and Other Fees

Application Fees

	2023 Pricing	2024 Pricing
RAPS Member	$150	See raps.org/rcc
Non-Member	$150	See raps.org/rcc

Candidates must be a RAPS member at the time of application submission to receive the members' rate. If applying for RAPS membership prior to applying, ensure RAPS membership confirmation receipt before submitting the application. RAPS membership information at raps.org.

Other Fees

Category	Amount
Administrative Fee	$100
Transfer Fee	$250
Rescheduling Fee	$50
Form Change Fee	$50

Appendix G Important Contact Information

Meazure Learning
+1 919 572 6880
candidatesupport@MeazureLearning.com

RAPS Program Office/Customer Support

+1 301 770 2920, ext. 200
certification@raps.org