



**REGULATORY AFFAIRS CERTIFICATION
POLICIES & PROCEDURES**

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Key Terms used in this Guide

- RAC—Regulatory Affairs Certification
- RACB—Regulatory Affairs Certification Board
- RAPS—Regulatory Affairs Professionals Society
- Candidate(s)—an individual who is interested in taking, or who has applied to take, an RAC examination or who has taken an examination but has not yet been notified of the result
- Certificant—an individual who passes one or more RAC examinations and actively maintains their status
- RAC-related individuals—members of the RACB, examination committees, staff supporting the RAC Program, vendors and consultants
- RAC testing vendor—contracted organization providing psychometric and testing support services for the RAC program

1. INTRODUCTION

The mission of the Regulatory Affairs Certification (RAC) program is to advance the regulatory profession and the profession's role in the development, review, registration and monitoring of healthcare products. The RAC program's goals include:

- Identify a body of knowledge and skills necessary to regulatory professional practice at early career stages (targeted to individuals with three to five years of experience in healthcare product regulatory practice).
- Recognize individuals who demonstrate a proficiency in regulatory professional practice at the targeted career level.
- Improve the practice of the regulatory professional by establishing professional development and continued learning goals.

The RAC program was initiated in 1991. It is a voluntary professional credential (certification) recognizing individuals who have the knowledge and skills to guide healthcare products through the correct regulatory pathways throughout the product lifecycle. The RAC designation is granted to individuals with documented education and regulatory-related work experience who pass a comprehensive examination. Maintaining the RAC credential requires continuing education and professional development. The regulatory professional who achieves this certification agrees to abide by the provisions of the *Code of Ethics for Regulatory Professionals*, developed and maintained by the Regulatory Affairs Professionals Society (RAPS).

The RAC credential can be earned by individuals engaged in the regulation of healthcare products working in all settings including: regulatory agencies, government and inter-governmental bodies, industry, consultancies, professional organizations, healthcare facilities, research institutions and educational institutions around the world.

The Regulatory Affairs Certification Board (RACB) is the formal governing body for the RAC program, responsible for developing, implementing and administering RAC policies and procedures. The RACB is responsible for ensuring the fairness, relevance and quality of the RAC program. The RACB is responsible for any changes in the scope of the RAC program, eligibility requirements, recertification policies and processes, and appeals processes. Each certification examination is developed by an examination committee of experts in regulatory affairs. The examination committees report to the RACB.

The *RAC Program Policies and Procedures Guide* is prepared to ensure that the RAC program is administered in a uniform and equitable manner. The guide describes the specific policies for the RAC program developed and managed by the RACB, procedures for general program administration, and management of committees, vendors and staff. This guide is reviewed regularly by the RACB and updated as needed.

Non-Discrimination

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

2. CANDIDATE REQUIREMENTS/APPLICATION FOR INITIAL CERTIFICATION

2.1 Eligibility

To be eligible to take any of the RAC examinations, professionals must meet the following requirements:

1. Education and experience:
 - A minimum of baccalaureate or equivalent first university degree *and* at least three years of regulatory or regulatory-related experience*; or
 - A master's degree *and* at least two years of regulatory or regulatory-related experience*; or
 - A doctorate degree (e.g., medical, dental degree, PharmD, PhD, ScD, JD) *and* at least one year of regulatory or regulatory-related experience*
2. Submission of complete application materials
3. Agreement to abide by the RAPS Code of Ethics

*Regulatory-related experience may include quality assurance, quality control, clinical research, healthcare product project management or other related areas.

Membership in RAPS is not required to apply for or take an RAC examination or to maintain the RAC credential. However, members of RAPS will be entitled to reduced fees.

2.2 Application Process

- The RACB will determine and publish the application content, submission and review processes and submission deadlines for all RAC examinations.
- The RAC examination application will be available online in electronic and printable versions.
- Applications and accompanying payment are accepted online, via email, through postal service or by fax.
- No application is accepted after the published application deadline.
- All deadlines are *postmark* dates, which include system date/time stamps for postal service, online, email and fax delivery. Applications are not accepted after 11:59 pm (US Eastern Time) on the deadline date.
- Applications must be completed in entirety by the candidate and include the candidate's signature or electronic signature/acceptance in the case of online submission.
- Candidates must acknowledge reading and accepting the RAPS Code of Ethics as part of the application process.
- Incomplete and/or unsigned applications will not be accepted. If an incomplete application is received, the RAC Program Office will contact the candidate and the candidate will have until the application deadline to complete the application. Applications remaining incomplete at the time of the application deadline will be rejected.
- Full payment must accompany the application.

2.3 Multiple Examination Applications

- Candidates may apply for and take one or more of the available RAC examinations during a testing cycle.
- Scheduling of multiple examinations is based on testing site availability. The RAC program does not guarantee that requests to schedule multiple exams in a single day will be accommodated.
- Candidates cannot retake the same examination during the same testing cycle.

2.4 Application Review

The RAC Program Office makes every effort to conduct timely review of all applications. The guidelines for application review, based on the method of submission are:

- Online (using the RAC online forms): Receipt acknowledgement is immediate. Candidates are encouraged to register online.
- Paper submission (post, fax): 10 business days, with additional time when paid by check.
- Email attachment (PDF format): 10 business days.

There may be occasions in which a review will take longer than the amount of days set forth above.

2.5 Candidate Notification

The primary mode of notification will be through email, at the address selected by the candidate on the schedule noted above (section 2.4). Candidates are responsible for notifying the RAC Program Office with any changes in email address.

Notice to schedule the exam date, location and time will be sent via email directly from the contracted testing vendor approximately 15 days prior to the start of the testing cycle.

2.6 Reasons for Rejecting an Application

An application for the RAC Examinations may be rejected due to one or more of the following:

- Failure to meet eligibility requirements
- Failure to meet deadlines
- Failure to submit a complete application
- Falsification of application form
- Using fraud or deception to obtain certification
- Knowingly assisting another person(s) in obtaining or attempting to obtain certification by fraud or deception
- Illegal use of the credential certificate or falsification of credentials
- Unauthorized possession or distribution of any official RAC examination materials, including copying or reproduction of any part of the RAC examination
- Exhibition of unethical or inappropriate behavior during prior examinations
- Conviction of a felony or a crime of moral turpitude in a court of law
- Revocation of a professional license
- Debarment under state, federal or territorial laws

2.6.1 Status of Returned Applications

- Candidates found ineligible because they do not meet the minimum eligibility requirements will be refunded exam fees, less a processing fee (see Section 14).
- Applications postmarked after the late deadline will not be processed.

2.7 Application Withdrawal

- A candidate may withdraw his or her application prior to the application deadline for the selected testing cycle. The withdrawal must be submitted in writing (through postal delivery, fax or email). It is the responsibility of the candidate to confirm receipt of the request. Withdrawal by telephone will not be accepted.
- Withdrawn applications will be refunded fees, less the processing fee (see Section 14). Candidates also will have the option to transfer to the next available testing cycle (see Section 4.5 for more information). Applications may not be withdrawn after the application deadline for the selected testing cycle. The only exception will be documented medical emergencies or death in the immediate family. In these cases, the application will be transferred to the next testing cycle (see Section 4 for more information) and a transfer fee will be applied (see Section 14 for fees).

3. APPLICATION FEES

RAC application fees are determined by the RACB. The RACB will review the fee structure at least every three years. The fee structure will reflect fair and reasonable costs for developing and administering the examinations and maintaining the highest quality of professional certification activities. Reduced application fees will only be offered to active members of RAPS.

All application fees are presented in Section 14: RAC Fees.

4. EXAMINATION SCHEDULING

4.1. Testing Cycles

The RAC examinations are offered during two testing cycles: spring, 1 April–31 May; and autumn, 1 October–30 November.

4.2 Site and Date Scheduling

RAC testing site management and scheduling is administered by a testing vendor pursuant to the terms of the contract between the RACB and the vendor. Examination site selection and appointment scheduling will be available on a secured website managed by the testing vendor. Telephone support and assistance will be available, if needed.

Approved candidates will receive an email from the testing vendor at least 10 days prior to the opening of the selected testing cycle. The email will include specific instructions for scheduling an examination appointment.

Candidates may schedule the examination appointment as soon as they receive notice from the testing vendor but no later than four days prior to the close of the testing cycle. Candidates may schedule an examination appointment online on the testing vendor's designated website or by telephone.

4.3 Special Accommodations

Requests for special accommodations must be made in writing at the time of application to the RAC Program Office and at least 45 days prior to the preferred examination date. Candidates may be required to submit supporting medical or other documentation describing the basis for the request. The RAC Program Office and testing vendor will contact candidates to discuss the requested accommodations.

4.4 Examination Appointment Changes

A candidate requesting changes in the examination appointment (i.e., date, time or location) must contact the testing vendor directly.

Changes must be made more than four business days before the candidate is scheduled to take the examination. Candidates may only reschedule to another date within the current testing cycle.

There are additional fees for changes to location, time or date, payable directly to the testing vendor (see Section 14).

4.4.1 Change in Examination Type

A candidate requesting to change the type of examination they wish to take (e.g., scheduled for RAC (US) and wish to change to RAC (Global), etc.) must submit the request to the RAC Program Office no later than seven business days prior to the scheduled testing appointment. RAC program staff will notify the testing vendor no later than four business days prior to the candidate's scheduled examination appointment. An additional fee will apply (see Section 14).

4.5 Transfer to Another Testing Cycle

Candidates may submit a written request (through postal delivery, fax or email) to transfer their applications to the next testing cycle. It is the candidate's responsibility to confirm receipt of request. There will be no additional fees when a transfer request is received by the application deadline. Transfer requests will not be honored if received after the application deadline, except in the event of an emergency (as determined by the sole discretion of the RACB or its staff representatives). Only one transfer per application will be allowed. Candidates are not eligible for a refund after transferring to another testing cycle.

4.5.1 Emergency Transfer Requests

In an emergency (i.e., personal medical emergency or death in the immediate family) the candidate or a representative must contact the RAC Program Office as soon as possible and no more than five days after the scheduled examination date. The candidate or representative is required to submit written documentation regarding the emergency. Documentation must be received within 30 days after the missed examination date. Candidates may only request one examination testing cycle transfer per application.

Work-related "emergency meetings" or similar reasons do *not* qualify for this exception.

4.6 Examination No-Shows

A no-show occurs when a candidate:

- Fails to schedule an exam appointment within the testing cycle for which he or she applied
- Does not appear for the scheduled exam appointment
- Arrives more than 15 minutes late for the exam appointment
- Does not have proper identification (Section 5.2)
- Cancels an appointment later than 12:00 noon (US Eastern Time) four business days before the scheduled exam (without a documented personal or medical emergency)

Candidates considered no-shows will forfeit all fees. No-show candidates may submit a new application for a future testing cycle and pay the full application fee.

4.7 Reexamination/Reapplication

- Candidates who do not pass the examination or who fail to appear for a scheduled examination may retake the exam during a later testing cycle. Candidates must submit a new application and payment by the relevant deadline for the testing cycle.
- There is no limitation to the number of times a candidate may take an examination. However, a candidate may not retake the same examination during a testing cycle.

5. GENERAL RULES OF EXAMINATION CENTERS AND TEST TAKING

The RAC examinations are computer-based and administered only at testing centers selected and confirmed by the testing vendor. RAC examinations will not be stored or accessible through the internet and will not be offered at facilities that are not pre-selected and qualified for security measures.

5.1 Testing Site Requirements and Management

The RAC testing vendor has contractual responsibility for selecting and managing an international network of computer-based testing centers. The testing vendor is responsible for assuring that testing centers have up-to-date, functional equipment and software, stringent security measures and appropriately trained personnel.

5.2 Candidate Identification Requirements

- Candidates must provide a valid confirmation notice and current government-issued or other official photo identification with a signature to be admitted into a testing center. If a candidate's government-issued identification does not contain a photograph or signature, a secondary identification may also be used as long as it includes the missing photograph or signature. Candidates who are unable to comply with this requirement must contact the RAC Program Office at least 14 days before the scheduled examination appointment.
- The candidate's name on the identification must match the name appearing on the examination scheduling notification. Candidates with hyphenated last names whose photo IDs show only one of the last names may be admitted if the single name matches part of the hyphenated name and the signature and photograph clearly match. Candidates whose middle names are spelled out on their ID but are listed with a middle initial on the application may be admitted as long as the initial matches the first letter of the middle name and the signature and photograph match. This also applies to candidates who use their middle names instead of their first names on their applications but their IDs display their first, middle and last names.
- The following are acceptable forms of government-issued identification:
 - Valid driver's license
 - Valid passport
 - Valid military ID
 - Valid national identification card
- The following are acceptable forms of secondary identification to supplement a missing photo or signature:
 - Valid employee ID (with photo)
 - Valid credit card (with signature and photo, if available)
 - Valid bank card (with signature or photo)
- The following are **not** acceptable forms of identification:
 - Social security card
 - Library card
 - Insurance cards

5.3 Testing Aids

- Candidates are prohibited from bringing anything into the testing area, except as may be specifically allowed in writing by the RAC Program Office in response to a request for special accommodations.
- Note paper and pencil or erasable noteboards and markers will be provided in the testing room for use during the examination. These materials cannot be removed from the testing site and must be returned to the proctor at the conclusion of the examination.

5.4 Test Site Conduct

- No visitors are permitted in testing rooms, including children.
- No personal belongings are allowed in the testing room, including but not limited to coats or jackets, sweaters, books, notes, cell phones, pagers, computers, PDAs, food or drink. Exceptions may be specifically allowed in writing by the RAC Program Office in response to a request for special accommodations.
- Smoking is not permitted in testing centers.
- Disruptive behavior at the testing site will not be tolerated and may be grounds for removal from the testing room and forfeiture of all applicable fees.

5.5 Termination of Examination Administration/Grounds for Candidate Dismissal

- Candidates must conduct themselves in a professional manner.
- The test center administrator or proctor is authorized to dismiss a candidate from an examination testing site and the RAC Program may cancel a candidate's score(s) or take other action when there is a reasonable basis for concluding any of the following:
 - Using or attempting to use someone else to take the examination
 - Failing to provide acceptable personal identification
 - Having access to or using notes or other prohibited aids related to the test
 - Creating a disturbance or disruptive behavior of any form. The test center administrator has sole discretion for determining whether specific behavior is disruptive.
 - Communicating in any manner with another person other than the test administrator or proctor, including attempting to give or receive assistance from other persons.
 - Attempting to remove note paper from the testing site
 - Eating or drinking in the test room
 - Leaving the test room or facility without permission
 - Removing or attempting to remove or copy examination-related material(s)
 - Tampering or attempting to tamper with computer equipment
 - Engaging in any dishonest or unethical conduct such as cheating
 - Failing to follow any examination related policies and procedures
 - Behaving in general in a manner that in the sole reasonable discretion of the RACB, the testing vendor, or any other agent of the RACB is unethical or inappropriate
- The RAC Program Office and the RACB reserve the right to take other action, including but not limited to:
 - Canceling the examination score(s). If a score is canceled, the candidate will be notified in writing of the action and the basis for the action. Examination fees will *not* be refunded in any part.
 - Barring the candidate from future RAC examinations

5.6 Reporting Test Site Irregularities

Candidates should contact the RAC Program Office as soon as possible to report any test site or other irregularities. These may include:

- Problems with test site access, facilities or equipment
- Lack of adequate security, privacy or conditions for acceptable examination administration
- Cheating or other dishonest behavior by another candidate. All information in these instances will be held in strict confidence.

In the event that a candidate is unable to complete the examination due to a documented testing irregularity that is not resolved within 30 minutes, the candidate will be offered the option to continue waiting for a resolution or to reschedule the testing session to a future available date at no additional charge.

6. RAC EXAMINATIONS

The RAC examination is the determinant in RAC certification. The RAC program offers four examinations: United States (US), European Union (EU), Canada (CAN) and Global.

Each examination covers the regulatory framework and processes in the country or area. Each examination covers all regulated healthcare products (i.e., pharmaceuticals, medical devices, IVDs, biologics/biotechnology products) throughout all stages of the product lifecycle. The rationale for covering multiple product types on each examination includes:

- Recognition of the many links between drugs, devices and biologics and the related regulatory frameworks
- Recognition that professionals are engaged in work across product types
- The cross-product scope may better prepare professionals for scientific advances and the changing nature of products

Each examination consists of 100 multiple choice questions to be answered in a two-hour time period. Additional time may be allowed for candidates who have requested and received special accommodations (e.g., individuals with physical or other disabilities). Requests for special accommodations must be submitted with the application and at least 45 days prior to the candidate's preferred examination date, along with the basis for the request. A determination regarding whether an accommodation is appropriate will be made by the RACB or its designee(s) at its sole reasonable discretion. Documentation (e.g., a doctor's note) may be necessary for the RACB or its designee(s) to make such a determination (see Section 4).

The examination is computer-based and administered only at secure testing sites that are pre-screened and approved by the RAC testing vendor.

The specific content of each examination includes performance domains, tasks and associated knowledge and skills and is based on a job analysis, statistical/psychometric analyses guided by subject matter and testing experts.

Each examination is updated annually during the period of March–June, to reflect regulations and guidance documents in effect as of 31 December of the previous year. The updated examination is first offered in the October–November testing cycle and then in April– May of the following year.

6.1 Job Analysis and Exam Content Outlines

Each year at the RACB annual meeting, the RACB will discuss any significant changes that have occurred in the industry, and whether such changes warrant a new job analysis to be conducted for the RAC exams. Under normal circumstances it is expected that a job analysis will be conducted every 5-8 years. However, the RACB in consultation with RAC staff and the RAC testing vendor, will make a final determination as to the need for a job analysis to be conducted.

Job analysis validation studies are used as the foundation for developing RAC examinations. A job analysis is required for the development of every RAC examination. The job analysis will be repeated at periodic intervals, determined by the examination committee and the RACB, based on changes in the scope of practice or knowledge and skills required of the target level professionals.

The job analysis serves as the basis for developing RAC examination content outlines, including subject areas, allocation of examination questions and the type of examination questions. The content outline is used as a guide in developing examinations. Content outlines for RAC examinations are publicly available in RAC-related materials.

6.2 Examination Development

Each RAC examination is developed and reviewed by a unique, appointed examination committee composed of subject matter experts in the regulatory profession. Examination committees develop each examination based on the content outline. Each examination committee is supported by a test development expert from the testing vendor who assures that developed questions and examinations are consistent with the job analysis and accepted psychometric principles.

Examinations are reviewed and updated annually by the respective examination committee to assure consistency with updates to related regulations and guidance documents. Each updated exam is reviewed relative to the related content outline to assure adherence to exam specifications. Examination questions and each examination in its entirety are reviewed by the respective examination committees prior to administration.

6.3 Test Item Bank Maintenance and Security

The testing vendor is responsible for securely maintaining the bank of test questions for each RAC examination. The bank will only be accessible to examination committee members and appropriate testing vendor staff members. RAC program staff and other volunteers will *not* have access to the test item bank. A secure Internet accessible site may be established to allow RAC examination committee members to remotely submit or review test questions.

6.4 Cut Score Determination

The cut score for each RAC examination is determined by the respective RAC examination committee, with training and support from the testing vendor. Cut scores are determined using a modified Anghoff method and expert judgment of committee members. This methodology involves developing a profile of the minimally competent candidate who has 3–5 years of regulatory experience, and assessing each test question relative to this profile.

A new cut score is determined following each job analysis, when there are changes in the body of knowledge underlying the examination or when equator questions are changed (see Section 6.5). Cut score determinations are presented to the RACB for review.

6.5 Exam Scoring and Scaled Score Determination

- RAC examinations are scored by the testing vendor at the conclusion of the testing cycle.
- Initial scoring results are reviewed by the testing vendor's psychometrician, the RAC examination committee chairman and other committee members as needed to develop a scaled score that takes into consideration the degree of difficulty of test questions and the performance statistics of individual test questions and the exam as a whole.
- Equating methods are used to determine scaled scores. Each RAC examination includes 25 equator questions. A new cut score will be determined if equator questions are changed.
- Final scoring will be completed within four weeks after the close of the exam testing cycle.
- The testing vendor will provide a report of the statistics for each examination including reliability and standard error of measurement, which will be reviewed by each examination committee, the RACB and appropriate RAC program staff.

6.6 Analysis and Reporting of Examination Cycle Results

- The RAC testing vendor and RAC program staff compile aggregate analyses of examination and candidate performance. Under no circumstances will analyses include any individual assessment or identifying information.
- Analyses will be used by the RACB, examination committees and RAC program staff for planning and administration.

- The RACB may release summary reports of performance trends from the RAC examinations.

6.7 Candidate Score Reporting

- Candidates will receive their scaled score, pass/fail status and a score report summarizing performance on each domain.
- Candidates do not receive a copy of the examination, their examination score sheet, information on the performance statistics of specific examination questions or information on the performance of other individual candidates or group of candidates.

6.8 Cancelled Scores

The RACB reserves the right to withhold or cancel test scores if there is reason to question their validity.

Factors that may lead to cancelling a score include:

- Suspected candidate misconduct: The RACB may initially withhold a test score and notify the candidate of the reported misconduct. In such event, the candidate will be given an opportunity to provide additional information, and the RACB may also undertake a confidential review of the circumstances giving rise to the questionable score. If it is determined there is sufficient cause to question score validity, the RACB may cancel the score, inform the involved party, and offer the individual an opportunity to appeal the determination of the RACB, pursuant to the appeals procedures.
- Irregularities: Scores may be withheld or canceled due to circumstances beyond candidates' control, such as faulty test materials or testing site problems. In this unlikely event, candidates will be informed and offered an opportunity to retake the examination at no additional charge.
- Other violations: The RACB may withhold or cancel examination results if a candidate violates RAC policies as outlined in the *Candidate Guide*.

(Also see Section 5.5. Termination of Examination Administration/Grounds for Dismissal)

7. CANDIDATE RECORDS

7.1 Record Content and Maintenance

- RAC candidate and certificant files are maintained in a secure database accessible by authorized RAC program staff.
- RAC files include demographic and examination specific information contained on the application form. Payment-related information is maintained in a linked but separate, secure accounting section of the database.
- RAC files include examination score, pass/fail status by exam, testing year and cycle. Actual examination scores are purged from the files after three years.
- Individual score reports are maintained as separate secure electronic files and are not linked to, or accessible through, the database. Score reports are maintained for three years from the testing date and are then purged.
- Paper applications are maintained in a secure file area for the period of time required by financial auditing standards (seven years). Application materials are shredded after this period.
- Certificant files stored in the secure database include recertification information, including date of recertification, contact and demographic information and original exam files. Recertification submission information is maintained for no more than three years following acceptance of the recertification data. Paper submissions are shredded after this period.

7.2 Confidentiality and Release of Information

- The RAC program maintains strict procedures for ensuring the confidentiality of candidate records. Information about a candidate is *not* released to any individual other than the candidate, except to the extent compelled by law.
- Individual candidate information will be released to the candidate through electronic communication or mailed to postal addresses provided by candidates.
- Candidate pass/fail status or scores are *not* released by telephone or fax, even to the candidate.
- For inquiries from individuals other than the candidate, the RACB and RAC program staff are authorized only to release information to confirm that an individual holds the RAC designation.

8. RECERTIFICATION

RAC recertification supports the continuing professional development of RAC credentialed individuals. The purpose of recertification is to:

- Reinforce the importance of advancing knowledge and skills of the RAC credentialed regulatory professional
- Enhance the ongoing professional development of RAC credentialed professionals
- Sustain the global recognition, professional status and value of the RAC credential

8.1 Recertification Cycle and Requirements

- The cycle for recertification is every three years, based on the dynamic scope of practice of the regulatory profession and consideration of a reasonable time period for participating in professional development activities.
- Recertification requires a minimum of 36 professional development credits. Credits may be gained in a variety of ways (e.g., conferences, distance education, academic courses, serving as a speaker, author and engagement in professional activities, obtaining additional certifications) according to criteria established by the RACB. Criteria reflect professional development in areas related to the scope of practice of the regulatory professional.
- The RACB periodically reviews the recertification parameters, including total credits required, credits awarded for specific activities, fees and processes and makes adjustments as appropriate.
- The RACB determines what materials are required to support the recertification application.
- The recertification application includes acknowledgement of having read and accepted the Code of Ethics for Regulatory Professionals. However, the RACB does not assume any enforcement role related to the Code of Ethics.
- The RAC program publishes a *Recertification Guide* containing recertification policies, procedures and fees.
- The recertification cycle (anniversary) is every three years from the testing cycle (spring or autumn) during which initial certification is earned (i.e., 15 June or 15 December). This cycle remains the basis for recertification for all credentials if additional RAC credentials are earned.
- Recertification materials may be submitted when the certificant achieves 36 professional development credits but must be received no later than the designated deadline. The recertification cycle will not change with early submission of the recertification application.
- Recertification credits must be obtained during the certified period and cannot be transferred from one cycle to another.
- Individuals who hold more than one RAC designation are only required to submit a single recertification application with a total of 36 credits. The recertification cycle is based on the initial RAC certification and the related recertification cycle.

8.2 Recertification Fees

- The RACB will determine the fee for recertification. Members of RAPS are eligible for a reduced recertification fee.
- The fee structure applies to individuals with single or multiple RAC credentials (See Section 14).

8.3 Failure to Meet Recertification Requirements

- The RAC designation is revoked 15 days after the certificant's recertification due date (15 June or 15 December). The individual will not be listed as an RAC and will not be able to use the RAC designation until he or she meets conditions for reinstating the RAC status.
- The conditions for reinstatement of the RAC are:
 - The RAC designation can be reinstated only if recertification credits and fees are submitted within one year of the certificant's recertification expiration date.
 - Recertification credits must be submitted for the delinquent three-year period. The certificant must submit the recertification payment plus the delinquency fee (see Section 14).
 - Certificants will maintain their original recertification expiration date. The recertification expiration date will *not* be adjusted based on the late submission.
 - After the one-year delinquency period, certificants will be required to retake the RAC examination to reinstate RAC status.
 - Failure to recertify within one year of the recertification due date will inactivate all RAC credentials held by the certificant. However, retaking one of the previously held RAC credential exams will reinstate all previously held RAC credentials.
- Adverse decisions on recertification matters will be subject to the appeals procedures set forth in Section 12.

8.4 Temporary Waivers

Temporary waivers of recertification will be extended under the following conditions:

- The certificant does not hold a paid position related to the regulatory profession.
- The certificant is elected or appointed to full-time public office at the local, state or national level.
- Serious illness or disability limits the certificant's ability to meet the recertification requirements.

A request for waiver must be submitted to the RAC Program Office at least 60 days prior to the certification expiration date. Individuals granted a waiver based on medical needs or unemployment will be listed as an RAC for up to 12 consecutive months. If the individual fails to recertify during this period, they will not be listed as an RAC until the requirements are met.

8.5 Emeritus Status

- Emeritus status may be requested by certificants who are 60 or more years of age and retired from active practice of the regulatory profession, but who wish to remain affiliated with this professional program. Requests for emeritus status must be submitted in writing to the RACB, together with the applicable one-time fee. Requests for consideration for emeritus status must be received prior to the individual's recertification cycle deadline.
- If approved by the RACB, individuals may refer to themselves as "RAC Emeritus" and will be included in a separate section in any RAC listing.
- The RACB will determine and periodically review the fee structure for application for emeritus status. See Section 14 for specific fees.

9. LISTING OF RAC CERTIFICANTS

- The RAC program will publish a list of current RAC certificants on the RAC webpages. Any listing of RAC certificants will be limited to the individual's name, country of residence and include which RAC designations the individual has earned. These listings will be available for verification of RAC certificants. Certificants may opt out of being included in this listing.
- The listing of RAC certificants will be updated after completion of each exam administration cycle and after completion of each recertification cycle.
- Certificants who do not maintain recertification will not be listed.

10. USE OF THE RAC CREDENTIAL

- A certificant may begin using the RAC credential upon receiving written confirmation of passing an RAC examination.
- A certificant may use RAC after his or her name in professional communications, business cards, job applications, publications and presentations and other professional contexts. The RAC credential may be used for as long as the individual maintains active certification status.
- A certificant who has passed multiple RAC examinations may identify his or her status through a listing in their resume or curriculum vitae. Alternatively, the individual may use RAC (US) (EU) (CAN) (Global).
- The RAC designation cannot be used if an individual fails to recertify or fails to uphold the requirements of RAC credentialed professionals.

11. LOSS OF RAC CREDENTIAL

An RAC certificant may lose RAC status based on any of the following:

- Illegal use of the credential or falsification of credentials
- Conviction of a felony or a crime of moral turpitude in a court of law
- Revocation of a professional license
- Debarment under state, federal or territorial laws
- Failure to meet the recertification requirements of RAC

Decisions to remove the RAC credential(s) will be made by the RACB. This decision applies to all RAC credentials held by the individual. The individual will be notified in writing of the loss of the credential(s). The individual will not be listed in any publication or directory of RAC certificants. The individual may appeal this determination in accordance with the appeals process set forth in Section 12.

12. RAC APPEALS PROCESS

Individuals have the right to appeal any adverse decision made by the RACB or its designee(s) regarding a candidate or certificant. An appeal must be initiated in writing by the affected individual not more than 30 days following the date of the adverse decision and must be sent to the RACB chairman, through the RAC Program office. The RACB will address the appeal; any RACB member who may be involved in the adverse decision will be removed from the appeals process. The RACB may appoint a special subcommittee of not less than three current or former members of the RACB to handle such appeals.

The RACB shall provide the affected individual an opportunity to provide input and present to the RACB before a final determination is made by the RACB. Decisions by the RACB shall be final.

If additional review is needed (such as when there are not at least three RACB members who can serve impartially as reviewers of the applicable decision), the RACB may ask the RAPS board of directors to appoint a special group to review the matter in question. The RAPS board of directors will have the option to take no additional action if the matter has been handled fairly and appropriately.

13. GOVERNANCE AND MANAGEMENT OF THE RAC PROGRAM

13.1 Regulatory Affairs Certification Board (RACB)

The RACB is the governing body of the RAC program. The RACB responsibilities are to:

- Develop, implement and administer the RAC Program
- Create and maintain RAC policies and procedures to ensure the fairness, relevance and quality of the RAC program
- Ensure that the RAC program is responsive to the regulatory profession and organizations served by these professionals
- Approve all changes to the RAC qualifications, examination structures, and content outlines
- Appoint and oversee examination committees
- Ensure reliability and validity of the examinations and adherence with sound psychometric principles
- Review and approve recertification conditions and credits
- Review and approve RAC related fees
- Review and approve recommendations of RAC program staff for vendors and other consultants involved with and/or supporting the development and administration of the RAC program
- Ensure equability between the various examinations
- Recommend establishing new examinations and elimination of examinations that are no longer viable

13.1.1 RACB Membership, Selection and Tenure

- The RACB consists of a minimum of seven members, including: the RACB chairman, the chairman of each examination committee, at least one member holding an RAC who does not serve on an examination committee, and one public member who does not hold the RAC designation.
- The public representative will be selected from experienced regulatory professionals, senior level officials in organizations involved with healthcare products or the general public. The public representative must have an understanding of the healthcare product sector, the role of the regulatory profession and an understanding of professional credentialing.
- The size of the RACB may be changed based on the addition of new examinations or the need to include additional perspectives from the credentialed or related communities.
- The RACB is responsible for developing and approving recommendations for RACB membership.
- RACB members are appointed to a three-year term of service and are eligible for appointment to a second term. Members may not serve more than two consecutive terms on the RACB. Total consecutive years of service on the RACB or any examination committee should not exceed nine years.
- Exceptions to total consecutive years of service will be considered when there is a compelling case reviewed and approved by the RACB.
- An outgoing RACB member may not serve on an examination committee for one year after completing an RACB term.

13.1.2 RACB Member Responsibilities

- Serve the interests of the RAC program and its role in serving the profession
- Fully engage in the responsibilities and deliberations of the RACB
- Conduct themselves in a professional manner
- Not use their position on the RACB for personal gain
- Attend all meetings of the RACB. If a member cannot be present, he/she must notify the RACB chairman in advance of the meeting. Absence from two consecutive meetings may result in removal from the RACB.

13.1.3 RACB Chairman

The chairman provides leadership to the RACB in carrying out its responsibility for the RAC program, guiding certification planning and policy development, and presides at all RACB meetings. The chairman serves as an official representative of the RACB and the RAC program and an ex-officio member of all RAC-related committees.

Selection and tenure

- The chairman must have previously served on the RACB and must hold an active RAC.
- The outgoing chairman nominates and the RACB appoints the new chairman.
- The chairman is appointed to a three-year term of service and is eligible for appointment to a second term. The chairman may not serve more than two consecutive terms on the RACB. Total consecutive years of service on the RACB or any examination committee should not exceed nine years.
- Exceptions to total consecutive years of service will be considered when there is a compelling case reviewed and approved by the RACB.
- An outgoing chairman may not serve on the RACB or on an examination committee for one year after completing the term of service.

Responsibilities

- Serve as representative for RACB and RAC program
- Serve as ex-officio member of all RACB subcommittees
- Communicate with RAC program staff, executive director, other RACB members and RAPS board of directors as necessary to conduct the business of the RACB in a timely and efficient manner
- Prepare the agenda for board meetings and preside over RACB meetings
- Maintain awareness of all issues that affect RACB and its certified professionals

13.2 Examination Committees

A committee will be established for each examination developed and administered under the RAC program. Examination committees report to the RACB.

Panels of SMEs are required to assist the RAC program in developing the exam. The RAC program requires standing exam committees, outlined in 13.2 above. Panels are also required once every few years for job analysis and standard setting processes. The following guidance gives an outline for these panels and how they are selected. Exceptions to the guidance may occur if availability of specific member types are not available, however, such occurrences will require approval by the RACB Chair.

RAC Exam Committees:

- 8-10 members total
- Minimum requirements: Current RAC holder and at least 3 years' regulatory experience

- Each Exam Committee will, where possible, include at least one member from the following communities: Medical Device, Pharmaceuticals, Biologics and regulatory agency (such as the FDA).
- A maximum of 2 individuals from any one agency, organization or company may be included on a Committee to avoid the possibility of undue influence.
- Committees will also attempt, where possible, to involve members from a variety of geographic locations that reasonably represents the scope of the RAC exam.

Job Analysis Panel:

- 10-12 members total
- Minimum requirements: Current RAC holder and at least 3 years' regulatory experience
- The job analysis panel will, where possible, include at least one member from the following communities: Medical Device, Pharmaceuticals, Biologics and regulatory agency (such as the FDA).
- A maximum of 2 individuals from any one agency, organization or company may be included on a Committee to avoid the possibility of undue influence.
- The panel will also attempt, where possible, to involve members from a variety of geographic locations that reasonably represents the scope of the RAC exam.
- The job analysis panel may include one representative from the exam committee, or RACB but will otherwise be separate from those committees.

Standard Setting Panel:

- 8-10 members total
- Minimum requirements: Current RAC holder and at least 3 years' regulatory experience
- The job analysis panel will, where possible, include at least one member from the following communities: Medical Device, Pharmaceuticals, Biologics and regulatory agency (such as the FDA). A maximum of 2 individuals from any one agency, organization or company may be included on a Committee to avoid the possibility of undue influence.
- The panel will attempt, where possible, to involve members from a variety of geographic locations that reasonably represents the scope of the RAC exam.
- The panel will attempt where possible to include a mixture of both recent RAC passers (within the last two years) and those that have held the RAC for a longer period.
- The standard setting panel may include one representative from the exam committee, or RACB, but will otherwise be separate from those committees.

13.2.1 Examination Committee Responsibilities

- Develop and periodically update the content outline for the exam based on data obtained through a job analysis
- Develop the examination based on the content outline and assure that the exam consists of appropriate and accurate test questions, and that the distribution of the questions meets the requirements specified by the detailed content outline
- Develop, annually update and refine the bank of test questions for the examination
- Review all questions submitted for inclusion into the test questions pool for content and structure, and revise test questions as necessary

- Revise test questions, as needed, to meet the needs and accuracy of the examination and the changing regulatory environment
- Serve as the expert panel for cut score determination
- Members of the examination committees will be required to sign an annual confidentiality agreement related to specific examination content. This agreement will be kept on file by the RAC testing vendor and the RAC Program Office.

13.2.2 Membership and Tenure

- Examination committees typically consist of 8– 10 members, with a balance of expertise among the major product types, product lifecycle and regulatory roles.
- Examination committee members are appointed to a three-year term of service and are eligible for a second term. Examination committee members may not serve more than two consecutive terms on an examination committee.
- Exceptions to total consecutive years of service will be considered when there is a compelling case reviewed and approved by the RACB.
- Individuals may not concurrently serve on more than one examination committee.
- Committee member appointments are reviewed and approved by the RACB.
- Committee members should be RAC credentialed and are expected to maintain the RAC while serving on the examination committee. Exceptions may be made by the RACB chairman in consultation with the examination committee chairman
- An ex-RAC examination committee member will not be permitted to take the RAC examination for three years after completion of service.
- An ex-RAC examination committee member will not receive the RAC credential based on their service on the committee. The only exception to this policy will occur when a new examination is created. In this case the committee responsible for writing the first examination will be grandfathered and receive the appropriate RAC credential. Following grandfathering to receive the credential, the certificant will be required to meet all recertification policies to maintain the credential.
- Examination committees report to the RACB.
- The roster of examination committees will not be publicly released by the committee, the RACB, RAPS or any other source.

13.2.3 Examination Committee Chairman

- Guides the work of the committee, with assistance from the RAC program staff and testing vendor, including managing meetings, reviewing annual schedule of activities and identifying potential new committee members
- Reviews each year's examination in its entirety before signing off the examination to the vendor
- The chairman or other designated committee members review the post-examination report prepared by the RAC testing vendor following the scoring of the RAC examinations prior to determining the scaled scores.
- Serves as a member of the RACB.
- Must have served on the committee immediately prior to being appointed as chairman.
- Appointed to a three-year term of service and eligible for appointment to a second term. The chairman of an examination committee may not serve more than two consecutive terms on the examination committee. Total consecutive years of service on the RACB and/or any examination committee should not exceed nine years.
- Exceptions to total consecutive years of service will be considered when there is a compelling case reviewed and approved by the RACB.
- An outgoing examination committee chairman may not serve on the same examination committee or the RACB for one year after completing service.

13.3 RAC Program Office and Program Staff

The RAC Program Office resides in space within the RAPS headquarters, with access to full operational services available at RAPS. Staff support for the RAC program is provided by qualified RAPS employees. The RAPS executive director serves as executive director of the RAC program and works directly with the RACB, its committees and vendors. RAPS also will provide staff support for finance and general administration, vendor management, customer service, marketing, and technology services and support. Staff supporting the RAC program will be accountable to the executive director and will record actual time allocated to RAC program activities.

The executive director will review staff requirements and issues with the RACB chairman.

13.4 Confidentiality, Conflict of interest and Copyright

These policies apply to RAC-related individuals, defined as all members of the RACB, examination committees, staff supporting the RAC program, and vendors and consultants as appropriate.

RAC-related individuals, defined as all members of the RACB, examination committees, staff supporting the RAC program, and vendors and consultants, may not disclose, divulge, or make accessible confidential information belonging to, or obtained through their affiliation with the RACB program to any entity, including RAPS departments, for developing or producing RAC related preparation material or products.

13.4.1 Confidentiality

- RAC-related individuals may use confidential information solely for the purpose of performing services related to the RAC program.
- RAC-related individuals may not disclose, divulge, or make accessible confidential information belonging to, or obtained through their affiliation with the RACB program to any person, other than those who have a legitimate need for such information and to whom the RACB has authorized disclosure. This policy is not intended to prevent disclosure where disclosure is required by law.
- RAC-related individuals must always exercise good judgment and care to avoid unauthorized or improper disclosures of confidential information. Conversations in public places should be limited to matters that do not pertain to information of a sensitive or confidential nature. RAC-related individuals should be sensitive to the risk of inadvertent disclosure and should, for example, refrain from leaving confidential information on desks or otherwise in plain view and refrain from the use of speakerphones to discuss confidential information if the conversation could be heard by unauthorized persons.
- At the end of a term of service or upon the termination of an agreement with the RAC program, RAC-related individuals shall return all documents, papers and other materials, regardless of medium, that may contain or be derived from confidential information or confirm that these materials have been properly destroyed.
- RAC-related individuals will be required to sign a non-disclosure/confidentiality statement.

13.4.2 Conflict of Interest

RAC-related individuals are obligated to conduct business within guidelines that prohibit actual or potential conflicts of interest. An actual or potential conflict of interest occurs when an RAC-related individual is in a position to influence a decision that may result in a personal gain for the individual, his or her organization or for a relative or action by the RAC program and the RACB. For the purpose of this policy, a relative is any person who is related by blood or marriage, or whose relationship with the employee is similar to that of persons who are related by blood or marriage. Personal gain may result not only in cases where an RAC-related individual or relative has a significant ownership in a firm with which the RAC program does business, but also when an RAC-related individual or relative receives any

special consideration, substantial gift, or other financial payment as a result of any transaction of business dealings involving the RAC program. No presumption of inappropriate behavior or guilt is created by the mere existence of a relationship with outside firms.

RAC-related individuals with any involvement or any influence on transactions involving purchases, contracts, or leases must disclose any relationships to the RACB and executive director for the RAC program in advance of being involved in decision making.

RACB and examination committee members are required to complete and sign a conflict of interest statement annually. Vendors, consultants and staff may also be asked to sign statements.

In the event of actual or potential conflict of interest, the RACB (absent the affected member) shall determine what action, if any, is appropriate to address the conflict, including, for example recusal of the affected member from related discussions and votes. The RACB may consult legal counsel in this endeavor.

13.4.3 Non-Compete, Assignment of Copyright

The materials, products, designs, plans, ideas, and data of the RAC program are the property of the RAC program and cannot be given to an outside firm or individual except with appropriate authorization from the RACB chairman and executive director. Any improper transfer of material or disclosure of information by an RAC-related individual even without personal gain by such action constitutes unacceptable conduct.

RACB and examination committee members and other key RAC related individuals will be required to complete and sign a non-compete/assignment of copyright agreement at the beginning of their tenure.

13.5 RACB and Examination Committee Expense Reimbursement

RACB and examination committee members and other vendors or volunteers will be reimbursed for travel and related expenses when involved with RAC business when expenses cannot be covered by the member or member's organization.

The RAPS Expense Statement is used for requesting reimbursement and must be submitted within 30 days of completion of the trip. Receipts are required for all expenditures including credit card charges, airfare purchased, and applicable hotel charges. Receipts are required for all expenditures paid by the traveler that exceed \$25 (US). Any unusual items must be fully explained regarding their relevance to RAC business. Receipts and other appropriate documentation must be attached. There is no reimbursement for expenses related to spouse or family travel, or for telephone, business center, laundry service, movies or other personal expenses

- Expense statements are reviewed by the staff liaison and reviewed and approved by the executive director or business operations staff.
- Expenses incurred in prior years will not be reimbursed.
- RAPS, on behalf of the RAC program will make every attempt to process expense reimbursement requests within 21 days.

13.5.1 Reimbursable Expenses

Airfare—the least expensive direct commercial airfare in coach class will be reimbursable from the airport nearest the traveler's home or office to the airport nearest the destination. Unless the travel is unexpected or unplanned, transportation reservations should be made at least 21 days in advance of travel. The traveler will not be reimbursed for any special fees associated with booking through a travel agent or fees for special delivery of tickets. Any additional expense related to companion travel

is the responsibility of the traveler. Preferred carriers may be utilized if the airfare is equivalent to the lowest fare available. Mileage earned while on RAC business is the property of the traveler and may be used at the traveler's discretion. If the traveler prefers upgraded travel arrangements, he or she will be reimbursed only for the equivalent of a 21-day advance purchase, coach ticket. The traveler is responsible for the difference in airfare.

- **Automobile, train, or bus**—Total reimbursable expenses, including expenses incurred en-route, shall not exceed the cost of airfare. Automobile expenses shall be reimbursed at the current mileage reimbursement rate utilized by RAPS.
- **Shuttle, taxi, personal automobile**, or other similar cost means to and from the airport at the credits of origin and destination, and taxi fare if essential for business purposes. The traveler will not be reimbursed for individual limousine service if it exceeds normal taxi or shuttle service. Receipts must be provided.
- **Parking** at the airport of origin if personal automobile is used. Long-term or satellite parking should be used. Parking at the meeting site if travel by automobile is required.
- There is no reimbursement for car rental and related expenses unless this is the most economic means of transportation.

Lodging

- Lodging costs will be covered if the traveler is more than 50 miles from home or other circumstances necessitate accommodations. Lodging will be reimbursed at the single-room rate for the days of meeting, including the night before and after if flight schedules make necessary such stays. Any requested upgrades in room, amounts resulting from spouse or family attendance or extended stays beyond the RAC related event will be the responsibility of the individual.
- The traveler will not be reimbursed for telephone calls, business services, in-room movies, mini bar, laundry service or other miscellaneous expenses.

Meals

- The traveler will be reimbursed the reasonable cost of meals while attending meetings, if meal service is not offered at the event. If meals are provided as part of the event, appropriate reimbursement will be offered for meals not covered.
- There is no coverage of meal expenses for spouse, family or guests, unless related to RAC business or approved in advance.
- The following are guidelines for meal reimbursement *not* provided at the event:
 - Breakfast \$15
 - Lunch \$25
 - Dinner \$50

Meals should not exceed \$90 day and must include receipts. (This guideline will be reviewed annually and updated based on cost perspectives.)

13.5.2 Non-Reimbursable Expenses

Expenses not previously listed will not be reimbursed. Other examples of items that cannot be claimed include:

- Travel insurance. Insurance coverage for volunteers and staff traveling on RAC business is provided by RAPS.
- When lodging accommodations have been arranged by the RAC program or RAPS and the traveler elects to stay elsewhere, reimbursement is made at an amount no greater than the rate negotiated by RAPS, and reimbursement is not made for transportation between the alternate lodging and meeting site.
- If an individual accompanies the traveler, it is the responsibility of the traveler to determine the added cost for double occupancy and related expenses and to make the appropriate adjustment in the reimbursement request.

- Entertainment costs including movies, liquor, or bar costs
- Telephone, fax, computer and other business expenses

13.6. RAC Operational Plans, Budget and Financial Management

- The RAC fiscal year will be 1 January to 31 December.
- Operational plans for the RAC program will be developed by the RAC program staff, working in consultation with the RACB chairman, examination committee chairman and vendors.
- Operational plans will present the annual activities for the RAC program and associated budgets.
- Budgets will include income and direct expenses. Estimates of indirect costs (including staff costs) will be provided as an estimate.
- The RAC budget will be reviewed by the RACB.
- The RAC budget will be included as a distinct component of the overall RAPS budget.
- Any questions or suggested modifications to the RAC budget offered by the RAPS board of directors during their overall budget review will be referred to the RAC program staff and RACB.
- RAC finances will be managed by the RAPS finance staff, reviewed by the RAPS accountants. Monthly financial statements will be prepared and reviewed by the RAC program staff.
- RAC finances will be annually reviewed as part of the RAPS audit.

14. RAC FEES

Fees related to RAC functions are as follows:

RAC Exam Application Fees:	MEMBER	LIST
Registration Fees:	\$435	\$535
Change in Test Site Location and/or Date (after scheduling)	\$50 payable to testing vendor	
Processing fee for withdrawn, cancelled or incomplete applications:	\$100	
Rescheduling fee prior to application deadline	No Charge (allowed one time)	
Rescheduling fee after application deadline	\$250 (This fee may be waived for emergency situations only – preapproval required)	
Change in examination (e.g., US to Global, etc.)	\$50	
Recertification Application Fees	MEMBER	LIST
Recertification Fees:	\$150	\$250
Recertification Late Fees:	\$150 + \$150 late fee (within one-year grace period)	\$250 + \$250 (within one-year grace period)
RAC Emeritus Status Application	\$150	\$250

15. CHANGES TO THE RAC POLICIES AND PROCEDURES DOCUMENT

- Changes to the Regulatory Affairs Certification Policies and Procedures may include clarifications to existing policies and procedures, content revision that changes the intent of the policy or procedure, addition of new policies or procedures.
- Minor changes, such as editorial clarifications to content, may be approved by the RACB chairman.
- Content revisions (e.g., changes in intent) to existing policies and procedures require review and approval by the RACB. The proposed additions, deletions or amendments will be handled as formal motions submitted to the RACB.
- The Regulatory Affairs Certification Policies and Procedures will be updated by the RAC program staff following appropriate approval of editorial corrections, content revisions or additions within 30 days following approval.
- RAC program staff will incorporate all changes into relevant candidate guides, recertification guides and in all RAC electronic and print materials.