



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)—individuals who are interested in and/or who have submitted an application to take an RAC examination and those who have taken an examination but have not been notified of their pass/fail status
- 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 health care products. The RAC Program's goals include:

- To 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 health care product regulatory practice).
- To recognize individuals who demonstrate a proficiency and comprehension of regulatory professional practice at the targeted career level.
- To improve the professional practice of the professional by establishing professional development and continued learning goals.

The RAC was initiated in 1991. It is a voluntary certification to recognize individuals with the knowledge and skills to guide healthcare products through the correct regulatory pathways throughout the product life cycle. The RAC designation is granted to individuals with documented education and/or work experience who pass a comprehensive examination. The RAC designation is maintained through recertification based on continuing education and professional development. The professional who participates in this certification also 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 designation can be earned by individuals practicing regulatory affairs in every sector of healthcare including manufacturing industry, consulting and professional organizations, healthcare facilities, research and educational institutions, public bodies, government and inter-governmental and international organizations.

The RAC Program is overseen by the Regulatory Affairs Certification Board (RACB), a formal governing entity. The RACB has full responsibility for development, implementation and administration of the RAC Program, including all 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 process and policies, and appeals process. 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 the administration of the RAC Program in a uniform and equitable manner. It describes the specific policies for the RAC Program developed and managed by the RACB and procedures for general program administration, and management of committees, vendors and staff. This Guide is regularly reviewed by the RACB and updated, as needed.

Non Discrimination

The RAC Program does not discriminate among candidates on the basis of 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 apply for any of the RAC examinations, professionals must meet the following requirements:

1. Education and experience requirements
 - A Bachelors/Baccalaureate or university awarded first degree; or
 - A minimum of three years of health care product regulatory experience
2. Submission of complete application materials
3. Agreement to abide by the RAPS Code of Ethics

Membership in RAPS is not a requirement 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.
- RAC examination applications will be made available in electronic (online) and printable versions.
- Applications and accompanying payment will be accepted online, via email, through postal service or by facsimile.
- No applications will be accepted after the final deadline.
- An early application deadline at a reduced fee may be offered.
- All deadlines are *postmark* dates, which includes system date/time stamps for postal service, online, email and fax delivery. Applications will not be accepted after 11:59 pm (US Eastern Time) on the late-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.
- Payment must accompany applications.
- An application to take a different RAC examination is treated as a new application (not a reapplication) and new application fees and processes will apply, even if the candidate holds an RAC.

2.3 Multiple Examination Applications

- Candidates may apply for and take one or more of the four available RAC examinations during a testing window.
- Scheduling of multiple examinations will be based on testing site availability. The RAC Program does not offer any assurances that multiple exam requests can be scheduled in a single day.
- Candidates are not permitted to retake the same examination during the same testing window.
- Multiple examination requests may be designated on a single application.
- There is no differential in examination fees for multiple examination requests.

2.4 Application Review

The RAC Program strives for timely review of all applications. The following guidelines apply to different methods of submission. The timelines are response targets for responding to submitted applications; there may be occasions in which a review will take longer than the amount of days set forth below.

- Online (using the RAC online forms): Five business days
- Paper submission (post, facsimile): Ten business days
- Email attachment (PDF format): Ten business days

2.5 Candidate Notification

The primary mode of notification will be through email, at the address selected by the candidate. Email notification of acceptance (or rejection) of an application will be sent immediately after completion of the application review. Hard copy notification will not be sent unless specifically requested by the candidate. The candidate notification will include information about scheduling examination date(s) and location.

2.6 Reasons for Rejecting an Application

Applications for the RAC Examinations may be rejected due to 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 in an attempt 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 be returned unprocessed.
- Candidates submitting incomplete applications may have an opportunity to correct deficiencies if the application is received prior to the final deadline. Candidates will be charged an additional resubmission fee (see Section 14).

2.7 Application Withdrawal

- A candidate may withdraw his/her application prior to the final application deadline for the testing window. The withdrawal must be submitted in writing (through postal delivery, facsimile or email). Withdrawal by telephone will not be accepted.
- Withdrawn applications will be refunded fees, less the processing fee (see Section 14). Candidates will also have the option to transfer to the next available testing window (see Section 4.5).
- Applications may not be withdrawn after the final application deadline of the testing window. In these cases, the application will be handled as a transfer. The only exception will be documented medical emergencies.

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 Windows

The RAC examinations are offered during two testing windows: 1 April-30 May and 1 October-30 November.

4.2 Site and Date Scheduling

Examination site management and scheduling will be administered by the RAC testing vendor pursuant to the terms of a 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 be sent an email from the RAC testing vendor at least 15 days prior to the opening of the testing window. The email will include specific instructions for scheduling an examination appointment.

Candidates may schedule the examination appointment as soon as they received notice from the testing vendor but no later than 15 days prior to the close of the testing window. Candidates may schedule an examination appointment online on the RAC testing vendor's designated website or by telephone.

4.3 Special Needs

Requests for special accommodations must be made at the time of application. Accommodation of reasonable special needs requests will be made. Candidates are required to submit to the RAC Program Office a written request for special accommodation and may be required to submit documentation (e.g., a note from a doctor) describing the basis for the request. The RAC Program Office and RAC testing vendor will contact special needs candidates to discuss testing site locations or time considerations.

4.4 Examination Appointment Changes

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

Restrictions: Changes must be made more than four (4) business days before the candidate is scheduled to take the examination. Candidates may only reschedule to another date within the current testing window.

Fee: There is an additional fee for changes to location, time, and or date, payable to the RAC testing vendor (see Section 14).

4.5 Transfer to Another Testing Window

Candidates may submit a written request (through postal delivery, facsimile or email) that their application be transferred to the next testing window. There will be no additional fees when a transfer request is received by the deadline. Transfer requests will not be honored if received after the late

deadline, except in the event of an emergency (as determined by the sole discretion of the RACB or its staff representatives).

4.5.1 Emergency Transfer Requests

For emergency requests, the candidate (or a representative) must contact the RAC Program Office and RAC testing vendor immediately and in no event more than four (4) days after the scheduled examination date and time. The candidate (or a representative) may be required to submit written documentation regarding the emergency. Candidates may only request one examination testing window transfer per application.

Work-related "emergency meetings" or similar reasons will not be considered to 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 window for which they applied.
- Does not appear for their scheduled exam appointment.
- Arrives more than 15 minutes late for their appointment and/or do not have proper identification (Section 5.2).
- Cancels their 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 window and pay the full reapplication 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 window. These candidates are eligible for reexamination status for a period of three years after the initial testing date. Candidates must submit a new application for reexamination by the relevant deadline for their chosen testing window.
- There is a reduced fee for reapplications received during this three year period (see Section 14. RAC Fees). After the three-year period, the candidate must submit a new application and pay the full fee.
- There is no limitation to the number of times a candidate may take an examination.

5. GENERAL RULES OF EXAMINATION CENTERS AND TEST TAKING

The RAC examinations are offered as computer-based examinations administered only at testing centers selected and confirmed by the RAC 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 for the RAC Program will be assigned contractual responsibility for selecting and managing an international network of computer-based testing centers. The RAC testing vendor will be 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 current government-issued or other official photo identification with a signature in order 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 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 an 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 applies to candidates who use their middle name instead of their first name on their application but their ID displays their first, middle and last name.
- 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 for 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 special needs request.
- Note paper and pencil 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.
- Dictionaries are allowed for English as a Second Language (ESL) sites.

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 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 special needs request.
- Smoking is not permitted in testing centers.
- Disruptive behavior at the testing site will not be accepted and may be grounds for removal from the 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 site administrator/supervisor has sole discretion for determining whether specific behavior is disruptive.
 - Communicating in any manner with another person other than the test administrator, supervisor 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 other examination related policies and procedures.
 - Behaving in general in a manner that in the sole reasonable discretion of the RACB, the RAC testing vendor, or any other agent of the RACB is unethical or inappropriate.
- The RAC Program Office and the RACB reserves the right to take other action, including but not limited to:
 - Canceling the examination scores. 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 are required to contact the RAC Program Office as soon as possible to report any test site or other irregularities. This may include:

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

6. RAC EXAMINATIONS

The RAC Examination is the determinant in RAC Certification. The RAC Program offers four examinations: US, European Union, Canada and General Scope.

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

- Recognition of the many links between drug, device 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 is comprised of a core of 100 multiple choice questions to be answered in a 2 hour time limit. Additional time may be allowed for candidates with special needs (e.g. individuals with physical, visual or other disabilities). Requests for additional time period needs must be submitted with the application 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.

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 guidances in effect as of 31 December of the previous year. The updated examination is first offered in the October through November testing window and then in April to May of the following year.

6.1 Job Analysis and Exam Content Outlines

Job analysis validation studies are used as the foundation of 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 and/or knowledge and skills 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 will be made publicly available in RAC related materials.

6.2 Examination Development

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

Examinations are reviewed and updated annually to assure consistency with updates to related regulations. The updated exam is reviewed relative to the job analysis and related content outline to assure adherence to exam specifications. Examination questions and the examination in entirety are reviewed by the respective examination committee prior to administration.

6.3 Item Bank Maintenance and Security

The bank of items relevant to each RAC examination will be securely maintained by the RAC testing vendor. The bank will only be accessible to Exam Committee members and appropriate staff of the RAC testing vendor. RAC Program staff and other volunteers will not have access to the item bank. A secure internet accessible site may be established to allow RAC Exam Committee members to remotely submit and/or review banked items.

6.4 Cut Score Determination

- The cut score for each RAC examination will be developed by the respective RAC Examination Committee, with training and support from the RAC testing vendor. Cut scores will be based on a modified Anghoff method, using expert judgment of the committee members who will develop a profile of the minimally competent candidate with 3-5 years of regulatory experience and assess each item relative to this profile.
- Cut scores will be updated with each job analysis update, when there are changes in the body of knowledge underlying the examination or when equater questions are changed (see 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 RAC testing vendor at the conclusion of the testing window.
- Initial scoring results are reviewed by the RAC testing vendor 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 questions and the performance statistics on individual questions and the exam as a whole.
- Equating methods will be used for determining scaled scores, to the extent possible. Each RAC examination should include up to 25 equater questions. If equater questions are changed a new cut score will be determined.
- Final scoring will be completed within four weeks after the close of the exam testing window.
- The RAC 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 Exam Cycle Results

- The RAC testing vendor and RAC Program staff will compile aggregate analyses of exam and candidate performance. Analyses will be based on candidate demographic and related factors. Under no circumstances will analyses include any individual assessment or individual identifying information.
- Analyses will be used by the RACB, Exam Committees and 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 Rescoring Requests

- Candidates may request a rescoring/hand scoring of their examination within 30 days of receiving their score and score report. Candidates must contact the RAC Program Office to request a rescoring. The fee for rescoring (see Section 14) is the responsibility of the candidate and must be received by the RAC program office prior to rescoring.

6.9 Cancelled scores

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

The RACB reserves the right to withhold or cancel test scores if there is reason to question their validity. Scores may be considered for cancellation based on:

- 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 and/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 commits violations of RAC policies as outlined in the Candidate Guide.

7. CANDIDATE RECORDS

7.1 Record Content and Maintenance

- RAC candidate and certificant files will be maintained in a secure database accessible by authorized RAC Program staff.
- RAC files will include demographic and exam specific information contained on the application form. Payment related information will be maintained in linked but separate, secure accounting sections of the database.
- RAC files will include a section with exam score and pass/fail status, by exam type and testing year and cycle. Exam scores will be purged from the files after three years.
- Individual score reports will be maintained as separate secure electronic files and will not be linked to or accessible through the database. Score reports will be maintained for three (3) years from the testing date and will then be purged.
- A copy of paper applications will be maintained in a secure file area for the period of time required by financial auditing standards (seven years). Application materials will be shredded after this period.
- Certificant files stored in the secure database will include recertification information, including date of recertification, in addition to contact information, demographic information and original exam files. Recertification submission information will be maintained for no more than three years following acceptance of the recertification data. Paper submissions of the reports will be 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 on 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 only to the candidate and only to electronic or postal addresses provided by the candidate.
- Candidate pass/fail status and/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. Under no circumstances will information be released on: whether an individual is or has been a candidate, if they have not passed an examination (and therefore not listed as an RAC), scores on examinations, even if the candidate passed the examination).

8. RECERTIFICATION

RAC recertification supports the continuing professional development of individuals who have attained the RAC credential(s). The purpose of recertification is to:

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

8.1 Recertification Cycle and Requirements

- The cycle for recertification is every three (3) years, based on the dynamic nature of scope of practice of the regulatory professional and consideration of a reasonable time period for participating in professional development activities.
- Recertification requires a minimum of 60 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) according to criteria established by the RACB. Criteria will 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, credits awarded for specific activities, fees and processes and makes adjustments, as appropriate.
- The RACB will determine what materials are required to support the recertification application.
- The recertification application will include acknowledgement of having read and accepted the Code of Ethics for Regulatory Professionals. However, the RACB will not assume any enforcement role related to the Code of Ethics.
- The RAC Program will publish a Recertification Guide containing the recertification policies, procedures and fees.
- The recertification cycle begins on 1 January of each year. For new certificants, the recertification cycle begins on 1 January in the year immediately following earning the RAC (i.e. for individuals who pass the exam in the April-May cycle or in the October-November cycle, the cycle begins on the following 1 January).
- Recertification submissions are due no later than 15 December of the third year of the recertification cycle. Recertification materials may be submitted when the certificant achieves 60 professional development credits. The recertification cycle will not change with early submission.
- Recertification credits 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 60 credits required. The recertification cycle will be 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 will be eligible for a reduced recertification fee.
- The fee structure applies to individuals with single or multiple RAC credentials.
- See Section 14. RAC Fees for recertification fees.

8.3 Late submission of recertification materials

- Recertification materials submitted after 15 December but before 30 December of the recertification will be considered as a late submission.
- Recertification materials submitted after 30 December will require 5 additional credits.
- A late fee will be assessed for late submissions (see Section 14).

8.4 Failure to Meet Recertification Requirements

- Failure to meet recertification requirements will result in suspension of the RAC credential.
- Certificants who do not acquire sufficient professional credits to meet the recertification requirements by the recertification date will be notified in writing of the suspension.

- The RAC designation will be dropped after 30 December and the individual will not be listed as an RAC until they meet conditions for reinstating their RAC status.
- The conditions for reinstatement of the RAC are:
 - Accumulation of five additional credits per year for each year beyond the recertification deadline. Recertification credits must be submitted for the current three-year time period, with the total number of credits adjusted based on the delinquency period. A late fee for each year of delinquency will be assessed in addition to the standard applicable recertification fee (see Section 14). The individual may retake and pass the RAC Examination. The individual must follow the procedures for application for the examination and must pay the full examination fee.
 - When five or more years have passed from the recertification deadline, the individual will be required to retake the RAC Examination, following all procedures and requirements.
- Adverse decisions on recertification matters will be subject to the appeals procedures set forth in Section 12.

8.5 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 and/or disability limiting the certificant's ability to meet the recertification requirements.

A request for waiver must be submitted in writing by 15 June of the year when recertification is due. Waiver requests will be reviewed and approved by the RAC Program Office. Waivers will not be granted for more than three years. Certificants granted a temporary waiver from recertification will not be included in listings of RAC certificants during the time the waiver is in effect.

8.6 Emeritus Status

- Emeritus status may be requested by certificants who are 60 or more years of age, are 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 RACB will publish a list of current RAC certificants on the RAC web pages, in the RAPS member directory and other electronic and print publications of RAPS. 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 their name in professional communications, business cards, job applications, publications and presentations and other professional contexts. The RAC credential may be used as long as the individual maintains active certification status.
- A certificant who has passed multiple RAC examinations may identify their status through a listing in their resume or curriculum vitae. Alternatively, the individual may use RAC (US) (EU) (CAN) (GS).
- 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. 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

Any adverse decision by the RACB or its designee(s) with regard to a candidate or certificant may be appealed. An appeal must be initiated in writing by the affected individual not more than thirty (30) days following the date of the adverse decision and must be sent to the RACB Chairman, through the RAC Program office. An appeal will be addressed by the RACB; 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 a minimum of 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 is responsible 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 approaches.
- 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 is comprised 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 health care products, or the general public. The public representative must have an understanding of the health care 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 and/or the need to include additional perspectives from the credentialed or related communities.
- The RACB will be 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 and/or any Examination Committee should not exceed nine (9) 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, the Chairman must be notified in advance. Absence from two consecutive meetings may result in removal from the Board).

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 as 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 Chairman is nominated by the outgoing Chairman and appointed by the RACB.
- 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 and/or any Examination Committee should not exceed nine (9) 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 sub-committees
- Communicate with RAC Program staff, Executive Director, other RACB members and RAPS Board of Directors as necessary in order 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 distinct committee will be established for each examination developed and administered under the RAC Program. Examination Committees report to the RACB.

13.2.1 Examination Committee responsibilities

- Develop and periodically update the content outline for the exam
- Develop the examination based on the content outline and assure that the exam consists of appropriate and accurate questions, and that the distribution of the questions meets the requirements specified by the detailed content outline
- Develop and annually update and refine the bank of questions for the examination
- Review all questions submitted for inclusion into the question pool for content and structure and will revise them as necessary
- Revise questions as needed to meet the needs of, 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 to 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 appointment to 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 certified, and expected to maintain the RAC credential while serving on the Examination Committee. Exceptions may be made by the RACB Chairman in consultation with the Examination Committee Chairman
- A non-RAC Examination Committee member will not be permitted to take the RAC Examination for three years after completion of service
- A non-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 which case the committee responsible for writing the first examination will be grandfathered and receive the appropriate RAC 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

- The Chairman guides the work of the Committee, with assistance from the RAC Program staff and RAC testing vendor, including managing meetings, reviewing annual schedule of activities and identifying potential new committee members. The Chairman reviews each year's Examination in its entirety before signing off the examination to the vendor. The Examination Committee Chairman and/or other designated committee members Review the post-examination report prepared by the RAC testing vendor service following the scoring of the RAC Examination prior to developing scaled scores
- Serves as a member of the RACB
- Must have served on the committee immediately prior to being appointed as Chairman.
- The Chairman of an Examination Committee is appointed to a three year term of service and is 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 (9) 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 and/or the RACB for one year after completing service.

13.3 RAC Program Office and Program Staff

The RAC Program Office will reside in space within the RAPS headquarters, with access to full operational services available at RAPS. Staff support for the RAC Program will be provided by qualified RAPS employees. The RAPS Executive Director will serve as Executive Director of the RAC Program and will work directly with the RACB, its Committees and vendors. RAPS will also 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/consultants, as appropriate.

13.4.1 Confidentiality

- *RAC related individuals* shall 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 exercise good judgment and care at all times 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 have an obligation 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 chief staff executive for the RAC Program in advance of being involved in decision-making.

RACB and Examination Committee members will be 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 will be reviewed by the staff liaison and reviewed/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, s/he will be reimbursed only for the equivalent of a 21 day advanced 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, and/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, **provided** that 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:

		RAPS Member	Non Member
RAC Exam Application Fees	Initial Application		
	Early Registration	\$325	\$510
	Registration	\$375	\$560
RAC Exam Application Fees	Reapplication		
	Early Registration	\$225	\$410
	Registration	\$275	\$460
	Processing fee for withdrawn/cancelled applications*	\$100	\$100
	*Applies to applications cancelled or withdrawn before the registration deadline		

	Fee for resubmission of an incomplete application	\$20	\$20
Test Site Fees	Optional testing site fees: An additional fee may be charged to candidates who select a testing site that is not listed on the RAC testing vendor's website. Candidates will be notified in advance of any additional charge for these sites when they register.		
	Change in test site location &/or date	\$75 payable to RAC testing vendor	\$75 payable to RAC testing vendor
Recertification Fees	Recertification Fees	\$75	\$260
	Recertification Late Fees	\$25 for each delinquent year (+\$75 recertification fee)	\$25 for each delinquent year (+\$260 recertification fee)
	RAC Emeritus Status Application	\$75	\$260
Rescoring Fees	Rescoring Fees	\$35	\$35

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.
- Editorial clarifications, including correction of spelling, conformance to style/format and/or other non-substantive editorial corrections 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 the approval.
- RAC Program staff will incorporate all changes into relevant Candidate Guides, Recertification Guides and in all RAC electronic and print materials.