



Regulatory Affairs Certification (RAC) Recertification Guide



REGULATORY
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RAC Recertification

Introduction

This guide describes the requirements and processes for maintaining the Regulatory Affairs Certification (RAC) credentials for RAC-Devices and RAC-Drugs.

The requirements and standards for recertification were developed by the Regulatory Affairs Certification Board (RACB).

This recertification framework allows for flexibility in the content and approaches to meet individual professional development needs. RAC-credentialed professionals may contact the RAC Program Office for guidance on activities not specifically outlined in the guide.

Purpose of Recertification

Recertification reinforces the importance of ongoing professional development. The professional development required to maintain the RAC credential also helps sustain the global recognition, status and value of the credential.

Earning Recertification Credits

Every three years, you must earn 36 professional development credits on topics related to the exam content outline. These credits are obtained by completing professional development activities such as educational programs, speaking, writing and volunteering.

A list of professional activities and the number of credits awarded for each activity are found in Appendix A.

Credits must be earned within your three-year certification cycle. Credits earned in one recertification cycle cannot be transferred to another.

Recertification Cycle

It is your responsibility to recertify every three years. Recertification deadlines can be found in Appendix B.

Recertification Communication

RAPS will send you email reminders about your certification expiration date. Regardless of whether reminders are sent or received, recertification deadlines are your responsibility. It is also your responsibility to ensure that the RAC Program Office has your current contact information. Please contact certification@raps.org if you need to change your email address.

Multiple RAC Credentials

If you hold more than one RAC credential you are only required to submit a single recertification application with a total of 36 credits. The recertification cycle is based on your most recent RAC credential.

Track Credits

Login to your account at raps.org to record your professional development activities as you complete them to track your progress.

Application & Fee

You may submit your recertification application at any time within your three-year recertification cycle once you have accumulated 36 credits.

Login to your account at raps.org to submit your activities and recertification fee. All fees can be found on the [RAPS website](#).

Payment must accompany a completed application. You may submit your completed application online or by email.

For emailed submissions, please complete the recertification form and email to: certification@raps.org. Please call the RAPS customer care office to provide your credit card information. Do not send credit card information by email.

Submitting your application early does not change your next recertification cycle.

Notification

RAC-credentialed professionals will be notified via email of the acceptance of their recertification application.

Individuals who submit a recertification application but do not meet the recertification requirements will also be notified via email. You can also login to your account at raps.org to view your certification status.

Audit

The RAC Program Office audits a percentage of recertification applications. Supporting documentation for listed credits is only required if you are audited. The RAC Program Office will randomly select applications for audit from all submitted applications. Selected applicants will be notified by email. It is therefore recommended that you keep copies of event documentation in your records in the event you are asked to produce it during an audit.

Late Submissions

You may submit a late application for up to one year following your expiration date. A non-refundable late fee applies to all applications submitted after the deadline.

During this one-year late period, you are only permitted to submit your application for review. You are not permitted to earn or accumulate credits beyond your original recertification cycle. Meaning, if your recertification cycle ends on 31 December 2027 you must earn all your credits by that date.

Your next certification cycle and expiration date will remain the same. It will not be adjusted based on the date of the late submission.

Credentials will be inactive during this late period and will be reinstated after the late submission has been approved.

Failure to Recertify

If you do not acquire at least 36 applicable professional development credits within the three-year certification cycle or fail to submit a completed application by the credential expiration date your RAC status will be revoked.

You will no longer be listed as an RAC credentialed professional until meeting the conditions for reinstatement.

Reinstatement

Your RAC credential can be reinstated if:

- You have obtained 36 qualifying recertification credits during the three-year certification cycle, and you submit your application and fees within one year of your certification expiration date.

Or,

- You retake and pass the RAC examination.

Temporary Waiver

A temporary waiver allows you to remain in good standing while providing extra time to earn recertification credits beyond the expiration date due to extenuating circumstances. It is the only exception that allows you to earn credits beyond the end date of your recertification cycle.

A temporary waiver of recertification credits will be granted if:

- You do not currently hold a paid position related to the regulatory profession.
- You are elected or appointed to full-time public office at the local, state or national level.
- You have a serious illness and/or disability limiting your ability to meet the recertification requirements within three years.

A request for waiver must be submitted in writing 60 days prior to your RAC expiration date. If you are granted a waiver you will continue to be listed as an RAC holder for up to 12 months past your cycle expiration date.

If you are granted a temporary waiver, it does not change the dates of your next recertification cycle. For example, your original expiration date is 31 December 2027 and your waiver gives you until 31 December 2028 to earn credits and recertify. Your next recertification cycle dates will be 1 January 2028 to 31 December 2030.

The RAPS Program Office reserves the right to extend the waiver period in extenuating circumstances and on a case-by-case basis if approved by the RACB.

Appeals Process

You may appeal any adverse decision regarding recertification made by the RAC Program Office. An appeal must be initiated, in writing, within 90 days of the adverse decision. The RACB will address all appeals and may contact you to request additional information as needed.

Decisions made by the RACB regarding the appeal may take up to 90 days, and their decision will be final. If you wish to appeal, see the appeals form in the Candidate Guide.

Emeritus Program

If you are more than 60 years of age, have been actively involved in the regulatory profession and retired from practice, but wish to remain affiliated with the RAC program, you may apply for emeritus status. Requests for this designation must be submitted in writing to the RACB through the RAC Program Office.

If you have retired from practice but do not meet the age requirement you may also submit a request for consideration. These requests will be reviewed and approved at the discretion of the RACB.

Requests for emeritus status must be received prior to your certification expiration date. To apply for emeritus status, you will need to complete the emeritus application and pay a one-time fee. The RAPS Program Office will review and approve the application on behalf of the RACB in most instances.

If you are requesting any exceptions, you may submit an appeal. Appeals typically require 90 days or more to process as they must be escalated to the RACB for review.

If approved, you may use the “RAC Emeritus” title. Those holding emeritus status found to be using the RAC credential outside of its intended purpose, i.e., as part of employment advertising, may lose emeritus status.

The RAPS Program Office reserves the right to extend the emeritus late period in extenuating circumstances on a case-by-case basis in consultation with the RACB.

Release of Information

A list of RAC-credentialed professionals can be found on raps.org. You may opt out of being included in this list by contacting the RAC Program Office. If you are an RAC professional in good standing and do not see your name listed as such on raps.org, please contact the RAC Program Office. The RAC Program Office will not release the date that you received the credential.

Contact RAPS

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

Appendix A

Professional Development Activities and Credits

PROFESSIONAL DEVELOPMENT ACTIVITY	CREDITS
Continuing Education and Training Activities	
Training and/or educational programs directly related to the scope of practice of a regulatory professional offered by professional societies, trade associations, higher education institutions, educational service companies or government agencies. This includes sessions pertaining to preclinical activities, clinical activities, manufacturing, quality assurance or quality control, compliance, post-market surveillance, and other relevant regulatory topics.	1 credit per hour 3 credits per half day 6 credits per day 12 credits maximum per multiday event
Online or other self-study courses related to the scope of practice of regulatory professionals offered by a qualified, recognized organization. The course must include some type of assessment or evaluation process.	1 credit per course hour 12 credits maximum per course or as designated by the provider
Web-based conferences about topics relevant to the scope of practice of regulatory professionals, including relevant business and management topics.	1 credit per hour 1.5 credits per 90 min
Continuing Education and Training Activities	
Training and/or education related to the biomedical/healthcare sector; scientific, clinical or engineering disciplines; business; law or other fields. This includes sessions pertaining to the individual's primary technical/scientific field, general business/management, or other disciplines or topics not specifically focused on regulatory or regulatory-related issues.	1 credit per hour 3 credits per half day 6 credits per day 12 credits maximum per multiday event
University courses related to the scope of practice of regulatory professionals. This may include coursework related to business management. Courses must be full quarter or semester courses.	15 credits per semester; 10 credits per quarter with maximum of 30 credits per year
Additional Professional Credentials Earned	
Additional RAC credentials earned. Successful attainment of an additional RAC credential must occur during the three-year certification period.	If a candidate passes an additional RAC, the cycle is updated, and candidates will have three years to recertify from the date of the most recently passed RAC exam.
Other relevant professional credentials earned (e.g., quality, clinical research, project management). Successful attainment of an additional credential must occur during the three-year certification period.	5 credits per credential
Course Organizer, Faculty, Speaker	
Faculty, instructor or speaker at a training or educational program, course or RAC study group directly related to the scope of practice of a regulatory professional requiring preparation of course, materials or handouts in addition to presentation. Subject matter may include business and management functions.	4 credits per hour of instruction
Faculty or instructor at a regulatory-related course offered by an accredited university or college, requiring lecture and preparation of course materials. Presentations that are repeated may not be included unless content has been revised.	4 credits per hour of instruction 16 credits maximum per course
Panel member or respondent on regulatory topics and issues panel not requiring preparation of course materials or handouts.	2 credits per hour of presentation

PROFESSIONAL DEVELOPMENT AREA	CREDITS
Member of organizing or planning committee for a regulatory or regulatory-related training and/or educational program, course or conference track or session. Additional credits can be earned for speaking at this event (see above for speaker credits). Presentations should be noted separately from role as organizer.	2 credits per program, course
Instructor or speaker on regulatory-related presentations or training programs within your organization. If presentations are offered on a single topic throughout the year, list topic and total presentations for the year. This does not include presentations completed about company-specific information which is part of one's paid position.	4 credits per hour of instruction
Articles, Books and Other Published Content (May include materials published in print and/or electronic format.)	
An article and/or chapter about regulatory-related topics, issues or advances published in a newsletter, magazine, journal, book, or as a monograph or booklet.	5 credits per article
Author of a book addressing issues/topics relevant to the regulatory profession.	Based on length and topic; maximum of 15 credits
Editor, member of editorial or peer-review board of journal, magazine or book related to the regulatory profession requiring publication planning, author management and review.	5 credits per publication
Brief editorial or column (less than one printed page) and/or Letter to the Editor related to regulatory issues and published in a professional publication.	1 credit each
Internet website developer, manager or editor for sites related to regulatory profession.	Credits determined on review by RACB
Leadership in Relevant Professional and Trade Organizations	
Non-RAPS Organization	
Officer or board member	2 credits per year of service
Committee or section chairperson	2 credits per year of service
Member of a committee, task force, council or other appointed group	1 credit per year of service
RAPS	
RACB officer or board member	12 credits per year
RAC exam committee officer or member	12 credits per year
RAC Prep volunteer	Based on length and assignment
Other	
The RACB and the RAC Program Office may identify other special initiatives, including participating in research studies about the profession that are eligible for recertification credits. These special initiatives and other eligible professional development opportunities will be announced to RAC professionals via email and on the RAPS website. RAC professionals may also contact the RAC Program Office and request consideration of professional development activities not covered in the above categories.	Determined on a case-by-case basis

Appendix B

Recertification Deadlines

Exam Window	RAC Expiration Date	Recertification Application Deadline
Spring 2022	30 June 2025	Jun 30, 2025
Summer 2022	Sep 30, 2025	Sep 30, 2025
Autumn 2022	Dec 31, 2025	Dec 31, 2025
Spring 2023	Jun 30, 2026	Jun 30, 2026
Summer 2023	Sep 30, 2026	Sep 30, 2026
Autumn 2023	Dec 31, 2026	Dec 31, 2026
Spring 2024	30 June 2027	30 June 2027
Summer 2024	30 September 2027	30 September 2027
Autumn 2024	31 December 2027	31 December 2027
Spring 2025	30 June 2028	30 June 2028
Summer 2025	30 September 2028	30 September 2028
Autumn 2025	31 December 2028	31 December 2028
Spring 2026	30 June 2029	30 June 2029
Summer 2026	30 September 2029	30 September 2029
Autumn 2026	31 December 2029	31 December 2029