



Regulatory Affairs Certification

RECERTIFICATION GUIDE



RAC Recertification

Introduction

This guide describes the requirements and processes for maintaining the Regulatory Affairs Certification (RAC) credential. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.

Recognizing the diversity in the scope of practice and range of approaches to professional development for regulatory professionals, the RACB developed a recertification framework that allows flexibility in the content and approaches to meet individual knowledge and professional development needs. This recertification guide outlines the types of professional activities that earn recertification credits. The RACB also recognizes that there may be other relevant professional activities not covered in this guide and invites RAC-credentialed professionals to contact the RAC Program Office for guidance on any activities not specifically outlined in the guide.

Purpose of Recertification

The regulatory profession is knowledge-driven and it is essential for competent professionals to be familiar with changing regulations and other new and updated information related to the healthcare product lifecycle. Recertification reinforces the importance of advancing your regulatory knowledge and skills and enhances ongoing professional development. The professional development required to maintain the RAC credential also helps sustain the global recognition, status and value of the credential.

General Requirements

To maintain the RAC credential, each RAC-credentialed professional must earn 36 professional development credits related to the regulatory profession every three years. These credits are obtained through participation in a wide range of professional activities including completion of educational programs, speaking, writing and holding leadership roles in professional organizations.

Credentialed professionals holding more than one RAC credential are only required to submit a single recertification application containing 36 credits. The certification cycle for multiple credential holders is based on the date of the initial certification earned.

Categories for Earning Recertification Credits

The primary categories for earning recertification credits and the number of credits awarded for each activity are summarized in the table below:

| PROFESSIONAL DEVELOPMENT AREA | 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, postmarket 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 |

| PROFESSIONAL DEVELOPMENT AREA | CREDITS |
|---|---|
| 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. | 20 credits per credential |
| 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 |
| 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 a 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 | |
| Officer or board member. | 2 credits per year of service |
| Committee or section chairman. | 2 credits per year of service |
| Member of a committee, task force, council or other appointed group ¹ . | 1 credit per year of service |

| PROFESSIONAL DEVELOPMENT AREA | CREDITS |
|--|------------------------------------|
| Other | |
| <p>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.</p> <p>RAC professionals may also contact the RAC Program Office and request consideration of professional development activities not covered in the above categories.</p> | Determined on a case-by-case basis |

Tracking Professional Development Activities

Most professionals will find it effective to maintain an ongoing record of their professional development activities. RAPS provides a [Professional Development Tracker form](#) which can be used to record professional development activities. This form must be submitted with the recertification application.

Audit

The RAC Program Office audits a percentage of recertification applications. Supporting documentation for listed credits is not required with submission of the recertification application, but must be submitted upon request. The RAC Program Office will randomly select applications for audit from all submitted applications.

Recertification Cycle

Professionals who hold an RAC credential must recertify every three years. The recertification cycle begins on 15 June for those passing the examination during the spring testing cycle and on 15 December for those passing the examination during the autumn testing cycle. This cycle will remain the basis for recertification of all credentials if additional RAC credentials are earned.

Credentialed professionals receive information about certification expiration dates in the initial certification confirmation letter. All communication about recertification will be via email. It is the credentialed professional's responsibility to ensure that the RAC Program Office has up-to-date contact information. Credentialed professionals who fail to recertify by the due date will be removed from the list of RAC holders on the RAPS website until they reinstate their RAC status. See "Reinstatement of RAC Credential" below.

A Recertification Application may be submitted at any time once 36 credits are accumulated within the three-year certification period. Credits must be earned within the three-year certification period. Credits earned in one recertification cycle cannot be transferred to another recertification cycle.

Credentialed professionals holding more than one RAC credential are only required to submit a single recertification application containing 36 credits. The recertification cycle for multiple credentials is based on the date of the initial certification earned.

Recertification Application

RAC credentialed professionals must complete and submit the RAC Recertification Application and Professional Development Tracker listing the date, title and credits awarded for each professional activity completed within the current three-year cycle. The Recertification Application and Professional Development Tracker are available at the end of this Guide or on at RAPS.org/rac/maintain.

Recertification Fees

For applications submitted by the certification expiration date, the recertification fee is \$175 (US) for RAPS members and \$285 for nonmembers. Payment must accompany the RAC Recertification Application submission. Applications will not be accepted without payment. For applications submitted after the certification expiration date but within one year, late fees apply and must be

submitted in addition to the recertification fee. For RAPS members, the late fee is \$150. For non-members, the late fee is \$250. Applications submitted more than one year after the certification expiration date will not be accepted.

How to Submit Payment

Payment must accompany a completed application. You may submit your completed application and payment in the following ways:

| Payment Type | Application Submission Method |
|------------------------------------|---|
| Credit Card | For credit card applications, please complete the recertification form and email to: certification@raps.org |
| Check Or Money Order | Postal mail only to: Regulatory Affairs Professionals Society c/o Suntrust Lockbox Dept. P.O. Box 79546 Baltimore, MD 21279-0546 USA |
| International Wire Transfer | Fax a completed form and copy of bank wire confirmation to: RAPS Account #1000043228997; ABA #061000104 Swift Code SNTRUS3A; Suntrust Bank, Richmond, VA. Must reference name of Registrant. All bank charges are the responsibility of the payer. For all wire payments: fax (+1 301 770 2924) or email (certification@raps.org) a completed form and copy of bank wire confirmation to confirm your registration. |

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 be notified via email.

Failure to Recertify or Meet Recertification Requirements

Credentialed professionals who do not acquire at least 36 applicable professional development credits by the within the three-year certification period or who fail to submit a completed Recertification Application with Professional Development Tracker will have the RAC status revoked. The individual will not be listed as an RAC credentialed professional until meeting the conditions for reinstatement of the RAC credential.

Reinstatement of RAC Credential

The RAC credential can be reinstated if recertification credits and fees are submitted within one year of the certification expiration date.

Recertification credits must be obtained during the three-year certification period. The recertification fee plus the late fee must be submitted with the completed RAC Recertification Application and Professional Development Tracker. RAC-credentialed professionals who recertify after, but within one year of, the certification expiration date, will maintain the original certification expiration date. The certification expiration date will not be adjusted based on the date of the late submission.

After the one-year delinquency period, individuals will be required to retake the RAC examination in order to reinstate RAC status.

Failure to recertify within one year of the certification expiration date will inactivate all RAC credentials held by a credentialed professional. However, retaking the examination for one of the previously held RAC credentials will reinstate all previously held RAC credentials.

Temporary Waiver

A temporary waiver of recertification credits will be extended if:

- An RAC professional does not currently hold a paid position related to the regulatory profession.
- An RAC professional is elected or appointed to full-time public office at the local, state or national level.
- An RAC professional has a serious illness and/or disability limiting the professional's ability to meet the recertification requirements.

A request for waiver must be submitted in writing 60 days prior to the certification expiration date. Individuals granted a temporary waiver will be listed as an RAC for up to 12 months. If the individual fails to recertify during the 12 month period, they will no longer be listed as an RAC and must re-take the certification examination to reinstate RAC status.

Appeals Process

RAC-credentialed professionals may appeal any adverse decision regarding recertification made by the RAC Program Office. An appeal must be initiated, in writing, by the affected individual within 30 days of the adverse decision. The appeal should be sent to the RACB In care of the RAC Program Office. The RACB will address all appeals and may contact the individual to request additional information as needed. Decisions made by the RACB regarding the appeal will be final.

Emeritus Status

RAC-credentialed professionals who 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, may apply for emeritus status. Requests for this designation must be submitted in writing to the RACB through the RAC Program Office, with a one-time \$150 fee for RAPS members or a \$250 for nonmembers. Requests for emeritus status must be received prior to the certification expiration date. If approved by the RACB, individuals 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, will be contacted and may lose emeritus status.

Release of Information

A list of RAC-credentialed professionals will be posted on RAPS.org. RAC-credentialed professionals may opt out of being included in this list by contacting the RAC Program office. The RAC Program Office will not release the date that a credentialed professional received the credential. 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.

Contact Information

Regulatory Affairs Professionals Society®
 Attention: RAC Program Office
 5635 Fishers Lane, Suite 550
 Rockville, MD 20852
 USA

Tel: +1 301 770 2920, ext. 200

Fax: +1 301 770 2924

Email: certification@raps.org

RAPS.org/rac

Footnotes

- 1 Additional credits may be accumulated for special work produced by a committee such as a white paper, standards or other materials of significance to the profession. Individuals may request additional credits by submitting a written request to the RACB through the RAC Program Office. This request must include a description of the outcome or product and its importance to the profession and/or regulatory community.