June 2019

Regulatory Affairs Certification

RECERTIFICATION GUIDE

RAPS.org/RAC

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

- Reinforce the importance of advancing knowledge and skills of the RAC credentialed regulatory professional
- Enhance the ongoing professional development of RAC credentialed professionals
- Sustain the global recognition, professional status and value of the of the RAC 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. RAC holders are expected to read and follow the Code of Ethics for Regulatory Professionals (See page 7 of the Recertifcation Guide)

Credentialed professionals holding more than one RAC credential are only required to submit a single recertification application containing 36 credits. If a current RAC holder 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.

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

PROFESSIONAL DEVELOPMENT AREA	CREDITS
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
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.	36 credits - see 'General Requirements' above
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

PROFESSIONAL DEVELOPMENT AREA	CREDITS
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
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

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 summer and 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 most recent 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 RAC 5635 Fishers Lane Suite 400 Rockville, MD 20852 USA
	Form and copy of bank wire confirmation to: RAPS Account #1000043228997; ABA #061000104 Swift Code SNTRUS3A; Suntrust Bank, 303 Peachtree St. NE, Atlanta, GA 30308. Must reference name of Registrant. All bank charges are the responsibility of the payer. For all wire payments: 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 400
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.

Code of Ethics

As the international leader for the healthcare regulatory profession, RAPS has initiated and supported the development of this code of ethics for the profession. Following a series of surveys and focus groups held over two years, a task force of volunteers was convened in February 2003. Their work, reviewed and shaped by many regulatory professionals, forms this code.

The task force identified eight core values that regulatory professionals embrace. The principles embodied by these core values are outlined in the section (below) entitled "Fundamental Principles." Following that, each core value is presented with suggested behaviors that should be encouraged or discouraged.

RAPS believes that this is a living document and encourages your feedback. Use this code of conduct in your work and share it with your colleagues and employer.

Statement of Personal Responsibility

Regulatory professionals have the professional and ethical responsibility to maintain the highest standards of professional conduct as they exercise their professional duties of upholding and clarifying the laws and regulations of the authorities under which we operate.

As individual regulatory professionals, we are making a positive contribution to public health and we aspire to embody this code of ethics in our words, actions and deeds.

As regulatory professionals, we play a pivotal role in ensuring compliance with applicable laws and regulations in the development and commercialization of healthcare products. We are a diverse profession: we work in healthcare companies, for government regulatory agencies, for contract research organizations and as independent consultants around the world. Our profession includes attorneys, engineers, managers, nurses, pharmacists, physicians and scientists, among others. We are a growing profession and we are developing and continually exploring our core values in an increasing complex global regulatory environment. We do this in the hope that everyone who practices in this field will aspire to these principles. We do this also in the hope that those whom we serve will hold these principles as inviolable.

The following eight core values defined below are maintained from the original code:

- Regulatory Compliance
- Competency
- Objectivity
- Integrity
- Honesty/Credibility
- Accountability
- Equitability
- Dignity and Respect

Fundamental Principles

As a regulatory professional I aspire to:

- To ensure my employer's activities are conducted in compliance with the laws and regulations of the authorities under which we operate, consistent with advancing, preserving and protecting public health.
- Be competent to perform the services I have been hired or retained to perform. As a regulatory professional, I hereby commit myself to continual learning while being able to acknowledge areas outside my expertise.

- Act in an objective manner. As a regulatory professional, I will base decisions on factual information. I will not be unduly influenced by competing or conflicting interests and I will clearly communicate competing or conflicting interests when appropriate.
- Have integrity. As a regulatory professional, I must be principled and consistent in applying my views. I must live up to my commitments, and be trustworthy and scrupulous at all times.
- Be honest in all dealings with my employers and others with whom I interact. As a regulatory professional, I must ensure all information and communications, whether oral or written, are accurate and complete. I acknowledge and affirm personal and institutional credibility is crucial to my success.
- Have the courage to make difficult decisions. As a regulatory professional, I will present all relevant information to my organization to promote wise decisions. I must be able to withstand challenges to my views, while at the same time being accountable for my mistakes.
- Be fair in my dealings with all parties. As a regulatory professional, I must apply legal and regulatory standards equitably. I must be just in considering the interests of all parties in decision processes.
- Be respectful of others. I must treat all individuals with dignity and courtesy.

Duty

Our role as regulatory professionals is defined by our duty to advise individuals and organizations regarding the appropriate regulatory context for actions they may want to take.

Our role is further defined by our obligations as employees of companies making important medical products for patients, as members of teams conducting nonclinical and clinical studies, as regulators and as members of our profession.

Regulatory professionals have a duty to:

Disseminate and interpret relevant governmental regulations, industry standards and good practice guidelines without bias.
Ensure products are safe and beneficial to patients, while maintaining the long-term interests of our employers.
Ensure, to the extent possible, the benefits justify the risks for those who participate in clinical studies and who use regulated products.
Provide physicians and other healthcare professionals with accurate and complete information about the safety and effectiveness of products.
Maintain the long-term integrity of our profession and strive to deserve the public's confidence and respect.

Competence

Competence means a regulatory professional has the knowledge, experience, ability and skill necessary to effectively identify, analyze and solve or recommend solutions to regulatory challenges. Regulatory professionals must be dedicated and flexible enough to adapt to the ever-changing realm of the regulatory profession.

The diversity of individuals and organizational contexts within the regulatory profession necessitates commitment to continually develop competence by a variety of means: seeking continuing education, work experience, professional training and certification.

Just as the regulatory profession continues to evolve, maintaining competence within the field is a continual learning process.

Regulatory professionals develop competence by:

- Being informed and knowledgeable about cur-rent and future trends.

- Claiming competence only in areas where they have a thorough understanding.
- Encouraging and supporting professional growth and development among peers and subordinates so all who work in the field can gain and demonstrate competence in the profession.

Objectivity

Regulatory professionals must be objective and must display their objectivity by representing facts without distortion by personal feelings or biases. The regulatory professional must understand the facts and must evaluate information from several points of view.

Regulatory professionals must understand their decisions may affect the interests of many parties including companies, regulators, healthcare professionals, patients and shareholders. Regulatory professionals must be aware of these differing interests without letting them influence their final regulatory interpretations and actions.

Regulatory professionals develop objectivity by:

- Responding carefully to opinions and issues and recognizing a single right or wrong answer is rare. Opinions can often take on a partisan perspective. The regulatory professional should always strive to offer an unbiased expression of facts.
- Presenting reasonable regulatory opinions, options and associated risks when developing regulatory strategies.
- Clearly differentiating among regulatory requirements, internal requirements and personal preferences.
- Disclosing new information appropriately within the proper context.

Integrity

Regulatory professionals with integrity will not compromise their values or trustworthiness for personal gain or professional enhancement. Individuals with integrity are principled, scrupulous and trustworthy. Having integrity suggests that one is "whole," and one's beliefs, words and actions are congruent and consistent.

Regulatory professionals develop and maintain integrity by:

- Keeping commitments.
- Giving credit for the work of others.
- Maintaining confidentiality of information and never disclosing information concerning the business or technical affairs of others without their consent.
- Seeking advice from others when uncertain.
- Considering their obligations and the long-term consequences of their actions when asked to compromise integrity for the sake of one party over another.
- Avoiding situations that put their integrity at risk.
- Recognizing the best course of action may not be in the short-term interest of their employer.
- Accepting compensation only when earned.
- Avoiding conflicts of interest or making conflicts known when they are unavoidable.

Honesty

Regulatory professionals must exhibit honesty in all of their activities. Honesty is truthfulness, candor and sincerity. Honesty requires a regulatory professional to act in ways free from deceit or deception, including dishonesty by omission or failing to say something when comment is ethically required. Honesty requires candid and forthcoming actions, not simply refraining from false statements.

Regulatory professionals build honesty and trust, which is absolutely essential to fostering effective working relationships, by:

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

Courage

Regulatory professionals demonstrate courage by choosing the right thing even when doing so is difficult. Regulatory professionals must have the courage to evaluate, conclude and provide consistent and accurate regulatory advice while accepting the consequences of their actions. They must gain access to information required to do their jobs as completely as possible.

Regulatory professionals develop courage by:

- Reviewing and reiterating their advice and strategy when necessary or when challenged and changing their advice when appropriate.
- Asking for help when needed.
- Encouraging an open exchange of views even if those views challenge their regulatory advice.
- Admitting mistakes, accepting accountability and taking appropriate measures to promptly correct any errors, miscommunications or misperceptions.
- Delivering bad news quickly to management when necessary.
- Providing information to stakeholders about regulatory risks and describing consequences if regulatory advice is overruled or ignored.

Fairness

Regulatory professionals strive to treat all persons fairly, equitably and equally in accordance with the law by holding all those with common responsibilities to a common standard. Regulatory professionals should consider the rights and needs of all parties in the context of all applicable laws, regulations and scientific and societal norms.

Regulatory professionals demonstrate fairness by:

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

Respect

Regulatory professionals demonstrate respect by appreciating the worth or value of people and things. Regulatory professionals must respect the roles of their colleagues and should recognize and acknowledge the worth of all parties.

Regulatory professionals develop respect by:

- Listening to what others have to say.
- Treating all parties, regardless of level or position, with dignity, civility and courtesy.

- Accepting personal differences but working diligently toward accommodating those differences where ever possible.
- Creating a positive environment encouraging participation of all parties without embarrassment, ridicule or hurtful actions or inactions.
- Sharing what they know in a nonintimidating way.
- Tolerating and encouraging those who do not initially understand.
- Avoiding conflict where possible and finding creative ways to resolve conflict quickly.
- Being patient and forgiving when others make mistakes and working to prevent mistakes from recurring rather than assigning blame