



# *RAC Recertification*

Voluntary certification in regulatory affairs was launched by RAPS in 1990. The certification program is designed to elevate professional standards, distinguish individuals demonstrating knowledge essential to regulatory affairs and enhance individual performance. Since its inception, the RAC Program has steadily gained recognition as an important building block for a career in the regulatory affairs profession.

Continual knowledge acquisition and professional development activities are essential for adapting to rapidly changing conditions in healthcare regulatory affairs and are important elements of recognition as a profession. As is the case with many other professional certifications, recertification reinforces an ongoing commitment to learning and professional development.

To retain the RAC certification, one must accumulate a minimum of 60 recertification credits every three years and submit an RAC Recertification Report to the RAC Program Office. An RAC who has earned both the US and the EU or CAN designations need not accumulate additional credits or recertify more often. Submitting a total of 60 credits every three years is sufficient to retain both certifications. Professional credits can be accumulated through a wide range of professional activities, including attendance at educational meetings and conferences, speaking, writing and participation in professional organizations. RAC recertification is flexible to accommodate the diverse learning styles and approaches to professional involvement. At least 40 credits must be accumulated in activities directly related to regulatory affairs.

## *Recertification Cycle:*

RACs must recertify at three-year intervals to maintain active certification status. Recertification materials must be received by the RAC Program staff by 15 December of the RAC's recertification deadline year. If an RAC has earned more than one designation, he or she is only required to recertify one time over a three-year period. The initial recertification due date will be upheld and the second designation will be applied using the same dates. While RAPS will make every attempt to remind RACs of their recertification deadline, RACs are responsible for meeting their recertification deadlines and should take appropriate steps to do so.

## *Fees*

The fee for each three-year recertification renewal is \$75 (RAPS member) or \$260 (nonmember). Payment must accompany the RAC Recertification Report. Late fees and additional credits apply if not submitted by the due date. Please see "Inability to Meet Recertification Requirements" below for more details.

## *Procedures*

All RACs will receive periodic email notices from the RAC Program Office reminding them of recertification requirements and procedures, provided a current email address is on file. It is important to update your contact information with RAPS if it changes. The RAC Program Office will not be held responsible if these notices are not received. The current RAC Recertification Guide and RAC Recertification Report Form are available on the RAPS website at [www.raps.org/rac](http://www.raps.org/rac). The Report Form is used to record professional activities throughout the three-year cycle. RACs may also submit a separate typed document in place of the Report Form as long as it adheres to the Report Form's numbering system. Electronic and fax copies will be accepted if credit card payment is included.

The Recertification Report may be submitted any time after a total of 60 credits is accumulated. The recertification renewal schedule will remain on the original three-year cycle. Credits earned from the current recertification cycle cannot be forwarded to the next recertification cycle.

Recertification will be processed within four weeks of receipt and RACs will be notified in writing of their recertification status.

## *Temporary Waivers*

Provisions for temporary waivers of recertification credits will be extended under the following conditions:

- An RAC does not currently hold a paid position related to regulatory affairs.

- An RAC is elected or appointed to full-time public office at the local, state or national level.
- Serious illness and/or disability limiting an RAC'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**. For example, if recertification materials are due by 15 December 2009, a waiver request must be received by 15 June 2009. Waiver requests will be reviewed and considered by the Regulatory Affairs Certification Board (RACB). Waivers of professional credits will not be granted for more than three years and are subject to review by the RACB. Individuals granted a temporary waiver from recertification will not be included in listings of RACs during the time the waiver is in effect.

### *Emeritus Status*

RACs who are more than 60 years of age and retired from active practice of the regulatory affairs profession, but who wish to remain affiliated with this professional program, may apply for emeritus status. Requests for this designation must be submitted in writing to the RACB, together with a \$75 (RAPS members) or \$260 (nonmember) one-time fee. If approved by the RACB, individuals may use RAC Emeritus and will be included in a separate section in any RAC listing.

### *Inability to Meet Recertification Requirements*

RACs who do not acquire sufficient professional credits to meet the recertification requirements by their recertification date will be notified in writing of their suspension from using the RAC designation. These individuals will not be listed as RACs in any publication until they meet the conditions for reinstating their RAC status. RAC certification may be reinstated in one of the two following ways:

- Accumulation of five additional credits per year for each year beyond the recertification deadline. Recertification credits still must be submitted for the current three-year time period, with the total number of credits adjusted based on the delinquency period. (For example, an RAC who resubmits for certification within one year after his or her recertification deadline will now be required to accumulate 65 total credits over the three-year period; submission after a two-year delay will require 70 total credits; a three year delay will require 75 total credits over the three most recent years.) The recertification fee will increase for each delinquent year by \$25; this applies to both RAPS members and nonmembers. **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.**
- The individual may retake and pass the RAC Examination following the procedures for application for the examination and must pay the full examination fee.

### *Acceptable Professional Credits for Maintaining Regulatory Affairs Certification*

The RACB has identified several educational, professional and leadership endeavors through which Regulatory Affairs Certification may be maintained. These activities are listed on the RAC Recertification Report Form on the following pages. The RACB will regularly review other activities and programs to identify those meriting inclusion in RAC recertification.

# RAC Recertification Report Form

Name:		Birth year :	
Preferred Mailing Address: <input type="checkbox"/> Home <input type="checkbox"/> Business		If Business, Use this space for company name/title	
Street:		Apt #/Suite/Mail Code:	
City:	State:	Zip:	Country
Phone: Home ( ) Business ( )		Fax: ( )	
Year of initial certification:		E-mail:	
I am a current RAPS Member <input type="checkbox"/> \$75 RAPS Member ID: _____ I am not a current RAPS Member <input type="checkbox"/> \$260		If not a current RAPS member, you are entitled to receive one year of RAPS membership when paying the nonmember fee. To receive this membership you must check the acceptance box here. <i>Membership accepted</i> <input type="checkbox"/>	

This form must be submitted by 15 December of the year due to recertify. The recertification then will continue on a three-year cycle.

- 60 total credits are required to earn recertification, with at least 40 credits in activities directly relevant to regulatory affairs and the regulatory affairs profession.
- Activities included on the recertification report must occur within the three-year recertification time frame.
- Please do not submit supporting documentation with your recertification report but keep it on file. The Certification Program Office reserves the right to audit up to 10% of submissions each year. Candidates will be contacted if they are among those who are randomly selected to follow up with supporting material.
- If requested to follow up with supporting material, you may submit the required information in a separate document. However, please include the appropriate section number with your response. Please number pages and include your full name at the top of every page.

Please enclose \$75 (RAPS members) or \$260 (nonmember) payable to RAPS for RAC recertification. If submitting late, please add applicable late fees pursuant to instructions above for late submission.

**Forward materials by mail to:**

RAC Program  
 c/o RAPS  
 5635 Fishers Lane, Ste. 550  
 Rockville, MD 20852

**By Fax:** (must pay by credit card)

Fax Number: + 1 301 770 2924

**By Email:** (must pay by credit card)

certification@raps.org

METHOD OF PAYMENT <input type="checkbox"/> Check # _____ <input type="checkbox"/> Money Order <input type="checkbox"/> MasterCard <input type="checkbox"/> Visa <input type="checkbox"/> American Express	
Credit Card No. _____ Expiration Date _____	
Amount of Charge: \$75 Raps Member Fee <input type="checkbox"/> \$260 Nonmember Fee <input type="checkbox"/> Other/ Late fee if applicable \$ _____ <input type="checkbox"/>	
Name on Card: _____	Signature: _____

## Recertification by Professional Activities/Credits

### I. Attendance at Education Programs and Courses

### Credits

- |   |   |  |
|---|---|--|
| <ol style="list-style-type: none"> <li>1. Attendance at educational programs directly related to regulatory affairs offered by professional societies, trade associations, higher education institutions, educational service companies or government agencies. (This may include sessions dealing with QA/QC, clinical trials and other issues relevant to regulatory issues.)</li> <li>2. Attendance at educational meetings offered by professional societies, trade associations, higher education institutions, educational service companies or government agencies related to the health industries; related scientific, clinical or engineering disciplines; business; law or other fields. (These meetings may represent the individual's primary technical/scientific field, general business/management enhancement, or other disciplines or topics not specifically focused on regulatory related issues.</li> <li>3. Attendance at internal training courses relevant to regulatory affairs.</li> <li>4. Attendance at internal training/professional development courses on non-regulatory topics (e.g., human resource issues, management methods).</li> <li>5. Completion of self-study courses applicable to regulatory affairs sponsored by a national association or qualified institution. Must include assessment instrument that is scored.</li> <li>6. Attendance at university course for full quarter/semester.<br/><i>(Please keep on file all descriptions, brochures, program/course outlines or agendas, if other than RAPS-sponsored programs. Identify non-regulatory related activities with "*". Attach continuation page if RAC activities do not fit in the space provide below.)</i></li> </ol> | <div style="border-left: 1px solid black; border-right: 1px solid black; border-bottom: 1px solid black; height: 200px; margin: 0 auto;"></div> | <p>1 credit per hour<br/>3 credits per 1/2 day<br/>6 credits per day<br/><b>12 credit maximum per meeting</b></p> <p>Credits determined on review by RACB.</p> <p>10 credits per course.</p> |
|---|---|--|

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Location: \_\_\_\_\_

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Location: \_\_\_\_\_

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Location: \_\_\_\_\_

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Location: \_\_\_\_\_

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Location: \_\_\_\_\_

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Location: \_\_\_\_\_

**TOTAL SECTION I. (RA/non-RA) \_\_\_\_\_/\_\_\_\_\_**

<b>II. Speeches, Instruction and Other Education Program Participation in Regulatory Affairs</b>	<b>Credits</b>
1. Appearance as an instructor or speaker at any regulatory affairs-related educational program, course or RAC study group requiring preparation of course materials or handouts in addition to presentation. Subject matter must be related to regulatory affairs and/or the regulatory affairs profession.	4 credits for each hour of instruction
2. Instruction in credit courses related to regulatory affairs sponsored by an accredited university or college requiring lecture and preparation of course materials.	4 credits for each hour of instruction <b>16 credit maximum per each course</b>
3. Participation as a panel member or respondent on regulatory affairs topics and issues not requiring preparation of course materials or handouts.	2 credits for each hour of presentation
4. Serving as an organizer and/or chair of an educational program, course or annual conference track or session related to regulatory affairs. (Additional credits can be accumulated when also serving as instructor or panel member at these meetings. Presentations should be noted separately from role as organizer.)	2 credits for each program, course
5. Appearance as an 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).	4 credits for each hour of instruction

*(Please keep on file all descriptions, brochures, program/course outlines or agendas if other than RAPS-sponsored programs. Identify nonregulatory related activities with "\*". Attach continuation page for activities that do not fit in the space provide below.)*

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Presentation Length: \_\_\_\_\_

Type involvement (Speaker, instructor, moderator, panel member, organizer/chair, etc.):

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Presentation Length: \_\_\_\_\_

Type involvement (Speaker, instructor, moderator, panel member, organizer/chair, etc.):

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Presentation Length: \_\_\_\_\_

Type involvement (Speaker, instructor, moderator, panel member, organizer/chair, etc.):

**Program/course title:** \_\_\_\_\_

Sponsor: \_\_\_\_\_

Date: \_\_\_\_\_ Presentation Length: \_\_\_\_\_

Type involvement (Speaker, instructor, moderator, panel member, organizer/chair, etc.):

**TOTAL SECTION II.** \_\_\_\_\_

<b>III. Published Articles and Other Literary Contributions to Regulatory Affairs</b>	<b>Credits</b>
1. Each published, peer-reviewed article and/or chapter on topics/issues/advances related to regulatory affairs, including those appearing in newsletters, magazines, journals, books and/or published as monographs or booklets.	5 credits per article
2. Author of book addressing issues/topics relevant to regulatory affairs.	Based on length and topic; maximum of 15 credits.
3. Editor, member of editorial or peer-review board of journal, magazine or book related to regulatory affairs that requires publication planning, author management and review	5 credits per publication
4. Brief editorials or columns (less than 1 printed page) and/or Letters to the Editor related to regulatory affairs published in professional publications.	1 credit each
5. Internet website developer, manager or editor for sites related to regulatory affairs.	Credits determined on review by RACB.

*(Please keep on file a copy of article if published by an organization other than RAPS. Attach continuation page for activities that do not fit in the space provide below.)*

**Title of published work:** \_\_\_\_\_

Publication in which it appeared: \_\_\_\_\_

Date: \_\_\_\_\_

Type (article, editorial, column, book chapter, etc.): \_\_\_\_\_

**Title of published work:** \_\_\_\_\_

Publication in which it appeared: \_\_\_\_\_

Date: \_\_\_\_\_

Type (article, editorial, column, book chapter, etc.): \_\_\_\_\_

**Title of published work:** \_\_\_\_\_

Publication in which it appeared: \_\_\_\_\_

Date: \_\_\_\_\_

Type (article, editorial, column, book chapter, etc.): \_\_\_\_\_

**Title of published work:** \_\_\_\_\_

Publication in which it appeared: \_\_\_\_\_

Date: \_\_\_\_\_

Type (article, editorial, column, book chapter, etc.): \_\_\_\_\_

**Title of published work:** \_\_\_\_\_

Publication in which it appeared: \_\_\_\_\_

Date: \_\_\_\_\_

Type (article, editorial, column, book chapter, etc.): \_\_\_\_\_

**TOTAL SECTION III.** \_\_\_\_\_

**IV. Development of Educational Products Directly Related to Regulatory Affairs and Other Educational Activities**

**Credits**

- |    |  |   |
|----|--|---|
| 1. | Developer, content author of educational products (e.g., self-study guides, DVDs or videotapes, computer-based training modules, etc.) on issues, topics and/or skills relevant to regulatory affairs. | Based on length and topic and review by RACB.   |
| 2. | Content contributor to sections of educational products relevant to regulatory affairs.  | 2 credits per contribution  |
| 3. | Writing RAC Examination items accepted by RAC Examination Committee. <sup>1</sup>  | 3 credits for each question with correct response and distracters;*<br>2 credits for each question with correct response and no distracters;<br>1 credit for each question without response/distracters |

*(Please keep on file a copy of any product summary materials, which include description of content.)*

**Product:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Date: \_\_\_\_\_

**Product:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Date: \_\_\_\_\_

**Product:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Date: \_\_\_\_\_

**Product:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Date: \_\_\_\_\_

**Product:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Date: \_\_\_\_\_

**Product:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Date: \_\_\_\_\_

**TOTAL SECTION IV.** \_\_\_\_\_

<sup>1</sup> The Exam Committee accepts and reviews questions between December and March.

\*distractor: alternatives included with correct response for multiple choice questions.

**V. Service as an Officer, Director, Chairman or Committee Member, Chapter Leader of Professional Association Relevant to Regulatory Affairs** **Credits**

- |  |           |
|--|-----------|
| 1. For each year as an officer or governing board member:                                | 2 credits |
| 2. For each year as a committee or section chairman:                                     | 2 credits |
| 3. For each year as a member of a committee, task force, council, or board. <sup>2</sup> | 1 credit  |

**Position held:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Dates of service: \_\_\_\_\_

**Position held:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Dates of service: \_\_\_\_\_

**Position held:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Dates of service: \_\_\_\_\_

**Position held:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Dates of service: \_\_\_\_\_

**Position held:** \_\_\_\_\_

Sponsoring organization: \_\_\_\_\_

Dates of service: \_\_\_\_\_

**TOTAL SECTION V.** \_\_\_\_\_

**VI. Other Activities Related to Regulatory Affairs or Professional Development.** **Credits**

Relevant activities not included in previous sections must be described in a written attachment. Credits determined on  
 Include appropriate descriptions, dates and supporting documentation.<sup>3</sup> review by RACB.

**Total Credits Regulatory Related Activities** \_\_\_\_\_

**Total Credits Non-Regulatory Activities** \_\_\_\_\_

**Total Recertification Credits** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

<sup>2</sup> Additional credits may be given by the RACB for significant contributions and/or exceptional service as a member of a committee, task force, council or board. Written requests with supporting documentation must be submitted to the RAC Program Office.

<sup>3</sup> You are encouraged to submit other activities and/or requests for additional credits prior to the recertification submission deadline.