Re-Registration Requirements

1. Significant Change(s) from Previous Version

Revised to clarify acceptable sources of re-registration activities and to add instruction on submitting activities for review online.

2. Purpose

This SOP defines the requirements for re-registration of Registered Quality Assurance Professionals (Registrants).

3. Scope

This SOP applies to:
- Council on Professional Registration (Council)
- Registered Quality Assurance Professionals (RQAP)
- SQA Headquarters

4. Responsibilities

4.1 The Registry of Quality Assurance Professionals was established by the Society of Quality Assurance (SQA) as a professional enhancement opportunity for individuals working in quality assurance in the disciplines of GLP or GCP. It is essential that Registrants refresh their skills and remain current in the latest regulatory requirements and interpretations. Registrants provide quality assurance expertise within industry, government, academia, and other organizations.

4.2 The objective of the RQAP re-registration program is two-fold: first, to encourage and recognize continued participation in the field of regulatory quality assurance, and second, to ensure that quality assurance professionals remain informed and knowledgeable in their profession.
5. Procedures

5.1 The re-registration program requires that Registrants complete a total of twelve (12) units within the re-registration period. A minimum of six (6) units shall be based on discipline specific activities and the remaining six (6) units may be based on relevant professional activities (e.g., a seminar in a related discipline; a workshop on organizational effectiveness, process improvement or facilitator training; formal education courses; participating in professional committee work; etc.). Candidates who pass the examination shall receive a list of re-registration criteria along with a letter informing them of their status.

5.2 Documentation of units earned must be submitted with the re-registration application.

5.2.1 It is the responsibility of the Registrant to provide unequivocal documentation of the units earned. The supporting documentation must be clear, concise, traceable/verifiable and complete. Units without the supporting documentation will not be credited towards re-registration.

5.2.2 Examples of acceptable documentation include agendas, content outline and learning objectives, each supported by enrollment verification or a certificate of participation. This documentation should clearly indicate the date of training, length of time, and the name of the Registrant.

5.3 Units in support of re-registration may be earned as follows:

5.3.1 Attendance at professional meetings, training workshops/courses, seminars or conferences: 1 hour of classroom time (not including meals or breaks) = 0.25 unit.

5.3.1.1 SQA Meetings (the units earned are based on the length of the meeting); SQA Chapter Meetings; and other relevant professional association/society meetings (e.g., JSQA, BARQA, RAPS, DIA, ACS, ACRP, NAICC, AALAS, etc.).

5.3.1.2 If any not-for-profit organization wishes to obtain pre-approval of re-registration credit for a scheduled conference, training or event, they must use the standardized form available on the SQA website and pay all applicable fees to make this request. CPR shall review any such applications and approve re-registration units for the activity as appropriate. Re-registration units shall not be awarded to activities that are perceived to be primarily marketing events for commercial entities.
5.3.1.3 In-house Continuing Education: documentation must include a session description or agenda, duration of the training, and proof of attendance.

5.3.1.4 Web-based seminars: documentation must include a session description or agenda, duration of the seminar, and proof of attendance (i.e., attendance roster, sign-in sheet, e-mail attendance verification, or seminar notes).

5.3.2 Instructing, lecturing or training: each unique, non-repetitive session presented: 30 minutes of presentation time = 0.25 unit.

5.3.3 Participating author for published, peer-reviewed articles, books or book chapters: each published work = 1 unit.

5.3.4 Primary or first author on technical articles for a relevant professional membership association/society newsletter (SQA, SQA Chapters and other relevant professional associations/societies) = 0.5 unit.

5.3.5 Primary or first author for a poster presentation: each unique, non-repetitive poster = 1 unit.

5.3.6 Attendance at relevant university course(s): 1 semester/quarter credit = 1 unit (e.g., one 3-credit university course = 3 units).

5.3.7 Membership in a relevant professional membership association/society (SQA, SQA Chapters and other relevant professional associations/societies) = 0.25 unit per year (each), not to exceed 1 unit per year from association memberships.

5.3.8 Any member of an elected or appointed Committee OR Board-approved Chair or Vice Chair of a volunteer Committee or special interest group (i.e., Specialty Section) in a relevant professional membership association/society (SQA, SQA Chapters and other relevant professional associations/societies) = 1 unit per year (each). A maximum of 3 GLP or GCP discipline specific units may be used from this category. The remainder must be used as non-discipline specific units.

5.3.9 Submission of solicited questions for the RQAP-GLP or RQAP-GCP examination: every 10 questions submitted = 1 unit. (Attendance at item writing workshops will be granted units under section 5.3.1 above for training workshops.)
Note: Unsolicited questions will NOT be accepted for credit. Contact the respective Chair of the Examination Committee prior to writing exam questions.

5.3.10 SQA, SQA Chapter and other relevant professional associations’/societies’ Mentoring Programs (Mentors, Mentees and Peer Partners): per mentoring partnership = 2 units; maximum per year = 4 units.

5.3.11 Abstract reviewer for a professional conference = 0.25 unit per conference, with a limit of 0.25 unit per year. A letter or email from the conference chairperson identifying the Registrant as an abstract reviewer is required for documentation.

5.3.12 Volunteering to explain/conduct QA activities with young people (at a STEM expo or career fair, for example) = 1 unit per day of volunteering, with a 4-hour minimum volunteer time per day

5.4 Re-registration procedure for Dual Registrants (a person holding both the RQAP-GLP and RQAP-GCP credential) shall be as follows:

5.4.1 Two separate applications and fees are required.

5.4.2 Of the required 6 GLP + 6 GCP discipline specific units, GCP units may be used as non-GLP and GLP units may be used as non-GCP units for a total of 12 units. During a re-registration cycle, 6 units of each will provide sufficient credit for both registrations.

5.4.3 The same units cannot be used for discipline specific credit for both disciplines (e.g., one meeting cannot be used for both GLP and GCP units).

5.4.4 Non-discipline specific units can be used for both re-registrations.

**Example of 12 units that meet both applications’ requirements:**

<table>
<thead>
<tr>
<th><strong>GCP Re-registration Application</strong></th>
<th><strong>ACTIVITY</strong></th>
<th><strong>DATE</strong></th>
<th><strong>DURATION</strong></th>
<th><strong>GCP UNITS</strong></th>
<th><strong>NON-GCP UNITS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>ICH E6 r2 training</td>
<td>2/5/2018</td>
<td>16 hours</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mentoring partnership</td>
<td>5/31/2018</td>
<td>6 months</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSV training</td>
<td>1/10/2019</td>
<td>12 hours</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA seminar</td>
<td>4/3/2018</td>
<td>12 hours</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>GLP Re-registration Application</strong></th>
<th><strong>ACTIVITY</strong></th>
<th><strong>DATE</strong></th>
<th><strong>DURATION</strong></th>
<th><strong>GLP UNITS</strong></th>
<th><strong>NON-GLP UNITS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>CSV training</td>
<td>1/10/2019</td>
<td>12 hours</td>
<td>3</td>
<td></td>
<td></td>
</tr>
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<td>2/5/2018</td>
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<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Mentoring partnership              | 5/31/2018   | 6 months | 2            |               | ```
5.4.5 If desired, a Dual Registrant may synchronize his/her re-registration due dates so that both credentials are due for re-registration in the same year. In order to synchronize due dates, the Registrant shall follow these procedures:

5.4.5.1 The Registrant shall notify SQA Headquarters in writing of his/her desire to synchronize re-registration due dates.

5.4.5.2 The Registrant shall submit an application with supporting documentation of the usual number of re-registration units (12) and fee for the next re-registration due date s/he has for the credential that is due at that time. The Registrant shall also submit an application for the second credential (which may be due for re-registration the following year or two years later) with documentation of a pro-rated number of re-registration units (e.g., 8 if the re-registration is due the following year and 4 if it is due in two years, with half of the pro-rated units required to be specific to the discipline of the credential) and a fee.

Example: If a Registrant’s RQAP-GCP re-registration is due in October 2014 and his RQAP-GLP re-registration is due in October 2015, and he wants to synchronize his re-registration due dates, then in October 2014 he shall submit an application, documentation and fee for his RQAP-GCP credential including 12 re-registration units (at least 6 of which must be GCP-specific), and he shall also submit an application, documentation and fee for his RQAP-GLP credential including 8 re-registration units (at least 4 of which must be GLP-specific). As noted in 5.4.2 above, some of the units can overlap so that the 6 GCP units can also count as non-GLP units, and the 4 GLP units can also count as non-GCP units.

5.4.5.3 Provided that the Council approves both applications, the Registrant shall then be required to re-register both credentials simultaneously with the full 12 units (6 of which as specific to the discipline of the credential) after the usual three-year re-registration period has elapsed.

5.5 The Council reserves the right to determine applicability of re-registration items submitted for credit that are outside of the items described in the SOP. The Council’s decision regarding re-registration credit will be final.

5.6 The re-registration process shall operate on the honor system. Fraudulent submission of information will be pursued with a penalty of revocation of registration privileges.
5.7 All professional activities applied to re-registration must take place within the re-registration period between successfully taking the examination and applying for re-registration or between re-registration periods.

5.7.1 The first re-registration period begins on 1 April of the exam year and ends on 30 September three years later, e.g., 1 April 2006 – 30 September 2009.

5.7.2 All subsequent re-registration periods begin on October 1 of the re-registration year and end on 30 September three years later, e.g., 1 October 2009 – 30 September 2012.

5.8 Re-registration activities may be submitted to the Council as they are completed by using the Non-SQA RQAP Unit pre-approval form on the SQA Online Learning Center.

5.8.1 This submission form is unnecessary for any SQA or SQA Chapter activities which have designated RQAP units for which the Registrant has earned a certificate. Any SQA or SQA Chapter activity for which a Registrant has been granted a certificate can be verified by SQA Headquarters.

5.8.2 For non-SQA activities or for SQA or SQA Chapter activities for which no certificate with RQAP units indicated was issued, Registrants may access the SQA Online Learning Center to submit information about and documentation for the activities in question.

5.8.3 Registrants shall submit the following information for each activity for which they are requesting Council approval:

5.8.3.1 Activity Title (e.g., “2016 ACRP Conference”)

5.8.3.2 Activity Type (selected from a drop-down list organized by the possible activities described in section 5.3)

5.8.3.3 Date Completed (the date the activity was completed)

5.8.3.4 Credit Type (GLP/non-GCP units, or GCP/non-GLP or GCP/GLP or non-GCP/non-GLP; a value must be entered into each credit type field: three fields should have zeroes and one field a unit value up to two decimal places calculated according to section 5.3)

5.8.3.5 Attachment (must include both proof of attendance/participation by you as an individual and a schedule/agenda documenting the subject matter and length of time spent in the activity minus any meals or breaks)
5.8.3.6 Description (provide additional details about the activity or enter a schedule/agenda here if you do not have one available for your attachment)

5.8.3.7 Number of Hours (excluding meals/breaks; this should not be the same as your Credit Type numbers since receiving one hour of training equates to 0.25 unit – you would write 0.25 for your Credit Type and 1 for the Number of Hours; write “N/A” here if this is an activity for which units are awarded independent of time factors, such as membership in an association/society)

5.8.4 A separate submission shall be required for each activity. For example, if a Registrant attends four separate RAPS training courses and wishes to request RQAP units for them, the Registrant must submit each course independently in four separate submissions (rather than a single submission entitled “Four RAPS training courses”). The reason for this is that each activity may qualify for different types of RQAP units; some may be approved for GLP units, some for GCP, and some for non-GCP/non-GLP. Organizational memberships, however, may be submitted in a single activity (i.e., “RAPS membership 2014-2016” with attached documentation for all three years).

5.8.5 Council members shall review submitted activities as they are able, with a goal of completing the initial activity review within eight weeks of the submission date. After a Council member has reviewed an activity, the Registrant shall receive an automatically generated email indicating the activity has been Approved, Declined, or is marked More Information Required. If the activity is marked More Information Required, the Registrant shall access the SQA Online Learning Center to view his/her current activity requests, read any Notes provided by the Council about what is needed, and Edit the submission to address the Council member’s Notes.

5.9 The completed application for re-registration must be submitted (by e-mail, mail, etc.) to SQA Headquarters on or before 31 October of the re-registration year; if the application is submitted by mail, the application must be postmarked on or before the due date. Late applications shall be accepted within a 31-day window following the due date. No applications submitted more than 90 days past the 31 October deadline shall be accepted; Registrants may appeal to the Council if there are extenuating circumstances. An example application is attached to this procedure (Attachment 1); an application form may be obtained from the SQA website.

5.9 The current re-registration fee ($US) must be submitted with the application (Attachment 1). The current re-registration fee is noted on the SQA website.

5.10 If a Registrant submits documentation of a professional development activity that is not accepted by the Council for re-registration, leaving the Registrant short of the
re-registration requirements, an opportunity shall be provided for the Registrant to supplement his or her application with additional activities to meet the minimum requirements for re-registration by the deadline stated in the notification.

6. Other Documents to Consider

None

SOP Reviewed by:

<table>
<thead>
<tr>
<th>Signature on file</th>
<th>30 October 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alison Cockrell</td>
<td>Date</td>
</tr>
<tr>
<td>SQA Executive Director</td>
<td></td>
</tr>
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</table>

SOP Approved by:

<table>
<thead>
<tr>
<th>Signature on file</th>
<th>30 October 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jacqueline M. Bushong, RQAP-GCP</td>
<td>Date</td>
</tr>
<tr>
<td>SQA Board Liaison</td>
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</tbody>
</table>
Attachment 1

SQA RQAP RE-REGISTRATION APPLICATION

Application Type: □ RQAP-GCP   □ RQAP-GLP

Name ____________________________________________________________

Company/Organization/Affiliation __________________________________________

Address ____________________________________________________________

City __________________________ State/Province/Region ____________ Zip Code/Postal Code ________

Telephone __________________________ E-mail ____________________________

Application Instructions:

Please list continuing professional activities on page two and attach additional sheets if necessary. The re-registration program requires that Registrants complete a total of twelve (12) units with at least six (6) of them based on your discipline-specific activities (GCP or GLP) within the three-year re-registration period.

Supporting documentation must be provided for all described activities. For activities not organized or overseen by SQA and/or not pre-approved for re-registration units (with RQAP units indicated on the event certificate), proof of attendance AND documentation of the length of time spent in the activity must be provided. If you are providing presentation slides as documentation, you do not need to submit the entire slide deck unless asked by the Council. Do not include documentation for more than 20 units.

Attendance at professional meetings, training workshops/conferences, seminars or conferences: 1 hour of classroom time (not including meals or breaks) = 0.25 unit. For more information on how to calculate RQAP units, please visit the RQAP Re-registration webpage via www.sqa.org.

Signature __________________________________________ Date ____________

(Signature certifies all information and supporting documentation is correct and that the applicant ascribes to the Council on Professional Registration Ethics Policy, SOP CP-14.xx)
<table>
<thead>
<tr>
<th>Description of Professional Activities (attach supporting documentation)</th>
<th>Date of Activity</th>
<th>Total Duration (Non-SQA Activities only)</th>
<th>Please indicate if you were the trainer/presenter</th>
<th>GCP/GLP Units</th>
<th>Non-GCP/GLP Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: GLP Training Course Title</td>
<td>20 Aug 2014</td>
<td>4 hours</td>
<td>Y</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

TOTAL NUMBER OF UNITS