ISO 13485

Auditor Certification

Program

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The information detailed within this document was correct at the time of publication.

TRA Certification International - Personnel Certification Program

For ISO 13485 Auditors

This Auditor Certification Program offers assurance to organizations that the certified ISO 13485 Auditor conducting audits in their facilities is qualified and competent to perform auditing activities that are in compliance with the applicable standard(s), regulations and recognized practices. In the description of this program the term medical devices is understood to include in-vitro diagnostics.

This program for the certification of third-party lead auditors and auditors is based on the evaluation of the applicant's skills, knowledge and experience. The criteria are based on the principles of the International Personnel Certification Association (IPC) auditor scheme and the precepts of ISO 19011:2011 (*Guidelines for Auditing Management Systems*).

This program is intended for:

- Quality auditors employed by third party certification bodies / registrars;
- Quality consultants, quality managers and/or other quality personnel; and
- Employees conducting internal compliance system audits within their own organization or supplier audits.

The granting of certification by TRA Certification International means the applicant has been recognized and is competent to:

- Uphold the principles of proper ethical conduct, fair presentation and due professional care
- Communicate clearly orally and in writing
- Plan and organize a ISO 13485 Audit
- Accurately report findings and conclusions
- Lead the audit team and manage the audit process
- Audit a management process

The scope of certification covers medical devices generally and does not imply expertise in a specific specialty. Certification is available, without restriction to all individuals who satisfy the certification requirements.

Once an applicant is certified as a ISO 13485 Auditor thru TRA Certification International, certain information about that auditor will be included in the public registry which will be available on line. Applicants may decline to be listed in the registry.

Auditor Certification Status Levels

There are three levels of certification offered thru the TRACI ISO 13485 Auditor Certification Program.

ISO 13485 Provisional Auditor

This is the entry level for individuals seeking qualification as auditors of medical device facilities. This level recognizes that the individual has the proper personal attributes, education, experience and professional / technical competencies but have not yet had the opportunity to meet the auditing experience required for auditor certification.

Minimum Requirements:

- At least secondary education
- Work Experience of 5 years, or 4 years with a four-year degree
- Two years of work experience in the field of Medical Devices
- Successful completion of an accepted ISO 13485 Auditor / Lead Auditor course
- Documented personal behavior and attitude evaluation
- No auditing experience is required

ISO 13485 Auditor

A candidate for ISO 13485 Auditor must meet the education, work experience, and training requirements for Provisional Auditor, and demonstrate sufficient auditing experience. The some of the auditing experience may be in fields other medical devices.

Minimum Requirements:

- At least secondary education
- Work Experience of 5 years, or 4 years with a four-year degree
- Two years of work experience in the field of Medical Devices
- Successful completion of an accepted ISO 13485 Auditor / Lead Auditor course
- Documented personal behavior and attitude evaluation

- Four (4) audits as an auditor-in-training totaling 20 days with a minimum of 16 of those days on site. At least 10 days (8 days on site) must have been at a Medical Device facility.

ISO 13485 Lead Auditor

The candidate for Lead Auditor must demonstrate audit experience, knowledge and skills of the ISO 13485 Auditor, as well as the ability to plan, conduct, report and complete an audit. The candidate must submit evidence of audits conducted under his/her direction as lead auditor, lead-auditor-in-training, or solo auditor.

Minimum Requirements:

- At least secondary education
- Work Experience of 5 years, or 4 years with a four year-degree
- Two years of work experience in the field of medical devices
- Successful completion of an accepted ISO 13485 Auditor / Lead Auditor course
- Documented personal behavior and attitude evaluation
- Three (3) audits as lead auditor-in-training totaling 15 days with a minimum of 12 days on site in addition to the auditing requirements of an ISO 13485 Auditor.

Classification of Auditor Technical Experience

The level of an applicant's certification is determined by documented audit experience. Additionally an applicant's certification will be classified according to his/her work and audit experience. The classifications, Class 1, Class 2, and Class 3, will correspond to experience with medical devices listed in Annex A of IAF Mandatory Document MD9:2015 *Application of ISO/IEC 17021 in the Field of Medical Device Quality Systems (ISO 13485).* Class 1, Class 2, and Class 3 will reflect experience with medical devices as listed in Table A-1-1, A-1-2, and A-1-3, respectively. *In vitro* diagnostics are included in Class 2.

Two years of relevant work experience are required for classification. Audit experience may be substituted for work experience as the rate of twelve audit days for one year of work experience.

Initial Certification

Candidates must file an application to TRA Certification International and each application will be evaluated based on the individual's demonstration of the experience and competencies needed for effective ISO 13485 auditing. These competencies should be demonstrated through a combination of education, work experience, training and audit experience.

Education

For all levels of certification an applicant is required to have completed a minimum of secondary education.

Work Experience

5 years of general, relevant work experience is required for all levels unless the applicant holds a four year degree. In this case, the work experience requirement is reduced to 4 years. Relevant work experience is considered to be technical, managerial or professional positions that require use of judgment, problem solving, and communication with management, employees, customers and/or stakeholders.

Medical Device Work Experience

Work experience in the field is also required, where quality and/or regulatory issues form the major part of the position. (All levels = 2 yrs experience). Such experience must have provided the applicant with the practical knowledge necessary to audit quality management systems effectively and may be included as part of the general work experience requirement.

Auditor Training

For **all levels**, an applicant must successfully complete an accepted ISO 13485 Auditor/Lead Auditor Course. An acceptable ISO 13485 course is one that has been approved by a nationally recognized training approval body or otherwise recognized by TRA Certification. As an alternative the candidate may offer evidence of completions of a recognized ISO 9001 Lead Auditor training course and a course on ISO 13485 of no less than twenty hours. Certification as a Biomedical Auditor by the American Society for Quality will also satisfy this requirement

Auditing Experience

- For the **Provisional Auditor level**, there is no requirement for documented auditing experience.
- For the **Auditor level**, the applicant must have completed at least 4 complete audits. Auditing activity must include document review, preparation and performance of on-site audit activities and audit reporting. The duration of these audits must not be less than 20 days with 16 days being on site.
- For the **Lead Auditor level**, the applicant must have completed the 4 complete audits that are required for the Auditor level plus 3 acceptable audits as the leader of an audit team which included at least one other auditor. The duration of the 3 lead audits must not be less than 15 days with 12 days being on site.

It is recommended that the audits required for Auditor and Lead Auditor levels be completed under the direction and guidance of an auditor that has been certified as a team leader however it is acknowledged that this may be difficult and costly to arrange. TRACI will accept a minimum of 1 audit under these conditions and may require the team leader from that audit to attest to the competence of the applicant to audit as a team member or team leader.

Guidelines for Acceptable Audits for Fulfilling the Auditing Experience Requirement:

- Accepted:
  - For all certification levels that require auditing experience all audits used for fulfilling the auditing experience requirement for certification must be completed during the five year period prior to application for certification. These audits must be performed in accordance with the auditing guidance standard ISO 19011 and for compliance with ISO 13485 or an alternative standard that TRACI accepts as equivalent.
- Not Accepted:
  - Surveillance (partial system) Audits are not accepted for initial Auditor Certification but will be accepted for Certification Renewal.
  - Audits of the same ISO 13485 that are repeated more frequently than once every 12 months

- Audits of less than one day duration)
- GAP Analysis, close out or follow up visits
- Audits conducted as a consultant
- Audits performed before successful completion of formal training requirement

How to Apply

1) Go online at www.personnelcertification-tra.com or tracert.memberclicks.net, download printable version, and prepare your responses for an online submission.
2) TRACI will provide an application package free of charge upon request.

   Mail: TRA Certification Int'l, Inc.
   P.O. Box 1081
   700 E. Beardsley Ave
   Elkhart, IN 46515
   Telephone: (574) 333-3302
   E-Mail: astewart@tracertification.com

3) Complete and submit "On line" the application form and upload the supporting documents. Complete the forms as outlined in the instructions which will be enclosed in the application package.
4) Online Application will require Fee Payment before submission is Complete. If mailing in be sure to Complete all sections required on Application Form, send along with the application fee, to TRACI for review.
5) All applications are to be submitted in the English language or be accompanied by certified translations of the originals.

All qualifications must be supported by documented evidence. Examples of acceptable evidence would be:

- A good quality photocopy of the original certificate indicating the awarding body, the title and date of the award and the name of the person to whom the award was made. If any of this information is not available or is not clear, additional documentation may be requested.

- An official letter from the awarding body confirming the award which includes the title and date of the award, the name of the person the certificate was awarded to and the date of the award.
- A transcript of an award would also be acceptable evidence if it clearly states the date and title of the award
- Work history in a resume with references and contact information
- Audit log with contact information

Application Review

TRACI will verify that all required documentation has been submitted for the review process. If any documentation or the application fee is not included in the submission package, the applicant will be advised and the package will be put aside pending further information.

Once all required documentation is received, the application and supporting documents will be evaluated against the requirements and some or all of the information will be verified. Verification is considered to be a very important aspect of the certification approval process which could cause some delays in the final recommendation if verifiable information is difficult to obtain. At the conclusion of this evaluation, a recommendation for certification will be forwarded to the TRACI Director of Certification.

The final decision for certification is made by the TRACI Director of Certification. The certification decision is performed independently of the Evaluation activity detailed above.

If the Director of Certification makes the decision to award certification, a formal offer of certification will be sent to the applicant. Included in this letter will be the request for the first annual fee. Once that fee is received, the certification will be awarded, information is added to the certified auditor database and a certificate and wallet card will be forwarded to the newly certified auditor.

Certification Period

Certification is for 3 years beginning the month that the favorable certification decision was made. At the end of each 3 year period, it is required that certifications be renewed prior to the indicated expiration date on the issued certificate and wallet card.

Certificates and Wallet Cards

A certificate of and 'certification' wallet card will be issued to auditors upon initial certification and renewal. The wallet card is evidence of certification and should be available, upon request, for presentation at any and all audits conducted. This card is issued to the auditor, but it remains the property of TRACI and must be returned to TRACI upon request.

ISO 13485 Auditor Directory

Each Certified Auditor will be listed in the TRACI on line directory unless an auditor specifically requests that they not be listed.

Each entry will include:

- Auditor Name
- Address
- Telephone &/or Fax Numbers
- E-Mail Address
- Certification Grade
- Date of Certification
- Date of Expiration
- Availability for Hire

A printed directory is also available on request.

How to Upgrade Certification

At any time, an individual can upgrade from one status level to the next. To apply for an upgrade, a certified individual may complete and submit supporting documentation to TRACI for review. If the upgrade is requested at any time other than renewal, an upgrade fee applies. If the upgrade is requested at the same time as a 3-year renewal, there is no additional fee.

The documents will be reviewed by the Director of Certification and he/she will either allow or disallow the upgrade. Upon this decision a communication will be prepared and forwarded to the applicant.

- If the upgrade is approved, the current 3-year renewal date in effect at the same time will not change.
- If the upgrade is not approved, the applicant will be provided with the reasons for denial.

Annual Maintenance

Certifications are to be annually maintained thru the following:

1. Compliance with and restatement of agreement to the TRACI Code of Conduct
2. Payment of Annual Fees
3. Submission of Audit Logs
4. Submission of Continued Professional Development (CPD).

Renewal

Certifications must be renewed every 3 years. A letter or email will be forwarded to each certified individual approximately 60 days prior to the expiration date of their certification.

The following requirements will be assessed during the review process for decision to renew:

1. Continuing Professional Development,
   Each auditor seeking renewal of certification to ISO 13485 Auditor or ISO 13485 Lead Auditor must have successfully completed a minimum of 45 hours of appropriate continued professional development training and provide evidence of completion. Renewal an ISO 13485 Provisional Auditor will require evidence of 20 hours of appropriate continued professional development training.
2. Declaration of Complaints
   The auditor seeking renewal to all levels must report any complaints that have been made against them. All complaints will be investigated during the review process. Failure to report such complaints could result in suspension or withdrawal of certification if discovered from another source.
3. Compliance with the TRACI Code of Conduct
4. Payment of Annual Fees.
   Payment records will be reviewed to ensure that all annual fees have been paid in a timely manner. Recertification will not be granted if there are outstanding fees due.

Fees

Fees are reviewed and set annually and apply for the calendar year (Jan 1 thru Dec 31). (See Appendix A for a current list of fees)

- Application Fee – This fee is paid at the time of application to become certified and should be forwarded along with the original application.
- Annual Certification Fee – This fee covers the annual cost of administering an individual's certification. The fee will be invoiced upon approval of certification and again each year one month prior to the due date.
- Application for Upgrade Certification – This fee covers the cost of evaluating the upgrade application and should be forwarded with the original application form.
- 3-Year Renewal Fee – The 3-Year renewal fee is to be forwarded with the supporting evidence that is required for a certification renewal.

Suspension and Withdrawal of Certification

A certification may be suspended or withdrawn if:

- An auditor fails to meet the certification criteria for the status level to which he/she is certified.
- Breach of Code of Conduct.

COMPLAINTS AND APPEALS

- Complaints Against Auditors:

  Complaints received regarding the actions or conduct of a certified auditor will be reviewed and investigated according to TRACI documented procedures. A valid substantiated complaint may result in the suspension and/or withdrawal of certification.

- Complaints Against TRACI:

  Complaints received against TRACI may be submitted in writing to the TRACI Auditor Certification Department. Each complaint will be reviewed, investigated and resolved in a timely manner through a formal documented process.

- Appeals:

  An appeal against adverse certification or recertification decisions or cancellation of certification must be submitted in writing. The written appeal will be reviewed, investigated and resolved in a timely manner through a formal documented process. Appeals may be made on the following decisions:

  - Refusal to grant initial certification
  - Refusal to grant the continuation of certification
  - Refusal to grant an upgrade of certification
  - Reduction in certification grade
  - Suspension or Withdrawal

  All appeals shall be submitted in writing to the TRACI Auditor Certification Department. The applicant shall submit his or her appeal to TRACI no later than 30 days after notification of the decision. The appeal shall include appropriate substantiation for the appellant's position and it must contain additional or updated information.

APPLICATION SUPPORTING DOCUMENTATION

Accompanying the application, the applicant must provide objective evidence that each of the requirements has been met. Completion of the training and knowledge examination may be certified by a nationality certified training provider. Education and experience requirements can be documented in a resume or *curriculum vitae* with sufficient references to enable verification.