



RABQSA International Training Course Certification Criteria

Testing and Calibration Laboratory Lead Assessor Training Course

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1. GENERAL CRITERIA

- 1.1 The achievement of certification and its continuance require that the training provider adhere to the criteria on which the certification is based, and conduct its training operation ethically.
- 1.2 This document is intended for use with the following IATCA documents, the requirements of which are included herein by reference:
 - Criteria for the Assessment of Training Providers and Training Courses (IATCA-PL-01-011)
 - Criteria for Training Providers (IATCA-PL-01-012).
- 1.3 While ISO 19011 was not specifically designed for assessments of testing and calibration laboratories, the International Laboratory Accreditation Cooperation (ILAC) has accepted ISO 19011 criteria as a suitable basis for the conduct of laboratory assessments. These criteria have incorporated ISO 19011.
- 1.4 No other course may be included within this course (e.g., internal auditor).
- 1.5 RABQSA assures confidentiality of all materials provided and any other information or knowledge obtained during the course certification process, with the exception of non-proprietary contact information.
- 1.6 RABQSA will safeguard against conflict of interest between training providers and evaluators.
- 1.7 Program fees and expenses related to certification and maintenance of certification are the responsibility of the training provider.

2. STUDENT PREREQUISITES

- 2.1 Each student shall be required to have studied the current published version of ISO/IEC 17025 prior to attending the course.

Note: A series of questions to be answered by the student and turned in prior to or at the beginning of the course is recommended to demonstrate that the student is sufficiently familiar with ISO/IEC 17025 so as to not impede the successful achievement of the learning objectives.

3. LEARNING OBJECTIVES

- 3.1 This course shall provide for the training of assessors in the principles and practices of Laboratory Competence assessments as it relates to ISO/IEC 17025, based on ISO 19011 criteria. Assessor training shall be based upon the most current version of the standards.

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- 3.2 The course shall include an overview of the following documents, including their criteria, varieties of application, use, controls, and results:
- a) ANSI/NCSL Z540-2: US Guide to the expression of uncertainty in measurement.
 - b) ISO/IEC Guide 43: Proficiency testing by inter-laboratory comparisons
 - c) ISO 5725: Accuracy (trueness and precision) of measurement methods
 - d) ISO 10012: Measurement management systems – Requirements for measurement processes and measuring equipment
 - e) Guide to the Expression of Uncertainty in Measurement (issued by BIPM, IEC, IFCC, ISO, IUPAC and OIML)
 - f) ISO VIM: International vocabulary of basic and general terms in metrology.

3.3 General and Standards

A student who successfully completes this course shall be able to:

- 3.3.1 Explain the need for laboratory accreditation in relation to regulatory, safety, and environmental requirements.
- 3.3.2 Describe the difference between laboratory accreditation and quality management system registration/certification.
- 3.3.3 Understand the role of laboratory-accreditation-related bodies (e.g., International Laboratory Accreditation Cooperation (ILAC), Asia Pacific Laboratory Accreditation Cooperation (APLAC), European co-operation for Accreditation (EA)).
- 3.3.4 Understand how individual accreditation bodies employ unique accreditation criteria.
- 3.3.5 Understand the historical perspective of the development of ISO/IEC 17025 and how it is related to other international standards.
- 3.3.6 Understand relevant terminology used in the current versions of ISO/IEC 17025, ISO/IEC 17000, the VIM and ISO 9000. (e.g., subcontractor, organization, customer, client, calibration, measurement traceability, sampling, uncertainty).
- 3.3.7 Explain the intent and requirement of each clause of ISO/IEC 17025 and understand the principles underlying the requirements of the standard.
- 3.3.8 Identify the evidence needed to demonstrate conformity to the requirements of ISO/IEC 17025.
- 3.3.9 Understand specific requirements relating to human factors, accommodation and environmental conditions, test and calibration methods and method validation, equipment, measurement traceability, uncertainty, sampling and handling of test/calibration items.
- 3.3.10 Describe the use of quality control checks and the role of inter-laboratory comparison and proficiency testing schemes.
- 3.3.11 Describe the function of test and calibration reports.
- 3.3.12 Describe the function of first, and second party audits, and third party assessments, the similarities and differences, and the varying roles and responsibilities of the auditors and assessors, the auditee and the client of the audit/assessment in each of these activities as described in ISO 19011.

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- 3.3.13 Explain the need for assessors to be sensitive to local customs and to obey any rules and regulations of auditees, especially where issues of health and safety are involved.
- 3.3.14 Understand the need for specific assessments of calibration/test methods.
- 3.3.15 Describe the accreditation process for a laboratory.
- 3.3.16 Describe the requirements of ISO 19011 as applicable to the assessment process.
- 3.3.17 Understand the requirements for qualification as a management systems auditor as described in ISO 19011.
- 3.3.18 Understand the requirements for qualification as a laboratory assessor.

3.4 Planning the Assessment

A student who successfully completes the course shall be able to:

- 3.4.1 Plan and organize all aspects of a laboratory assessment, including document reviews, in accordance with ISO 19011.
- 3.4.2 Describe the selection of assessors and competencies required to lead, manage and perform assessment of technical aspects.
- 3.4.3 Explain the purpose of pre-assessment visits and how to evaluate the need for such visits.
- 3.4.4 Determine the pre-assessment information required to effectively plan the duration and the resources required to conduct an assessment.
- 3.4.5 Produce checklists for use during an assessment, and describe the benefits and risks of the use of checklists during assessments.

3.5 Performing the Assessment

A student who successfully completes the course shall be able to:

- 3.5.1 Perform all aspects of an assessment in accordance with ISO 19011.
- 3.5.2 Manage assessment opening and closing meetings and understand the purpose of holding interim meetings with the auditee during the assessment in accordance with ISO 19011.
- 3.5.3 Demonstrate effective interpersonal skills and interview techniques including an ability to listen and question.
- 3.5.4 Understand the need for assessors to talk to laboratory staff, to observe them performing tests/calibrations and to look at all aspects of these processes:
 - a. sample preparation, reception and care,
 - b. equipment and environment used,
 - c. methods,
 - d. method validation,

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- e. traceability of measurement and uncertainty,
 - f. standards and reference materials,
 - g. calibration arrangements, procedures and intervals,
 - h. proficiency testing and inter-laboratory comparisons,
 - i. laboratory data recording and analysis,
 - j. quality control and reporting procedures.
- 3.5.5 Take sufficient notes during the process to provide assessment evidence of system conformity and laboratory competences as well as nonconformity with the assessment criteria.
- 3.5.6 Explain the risks and benefits of sampling during assessments.
- 3.5.7 Collect and analyze evidence during the assessment, relate specific assessment evidence to the appropriate requirements of the standard, and objectively review the evidence collected, including:
- a. the assessment of technical competence
 - b. the assessment of documented test procedures and their validation.

3.6 Reporting and Following Up the Assessment

A student who successfully completes the course shall be able to:

- 3.6.1 Summarize, record and present the results of an assessment and demonstrate the ability to produce clear and concise reports based on the assessment evidence obtained.
- 3.6.2 Evaluate evidence collected during the assessment and prepare reports of conformity and nonconformity to the assessment criteria.
- 3.6.3 Evaluate the significance of nonconformities recorded during the assessment and grade them in accordance with the definitions in the accreditation program (for example: major, minor, observation, etc.). For the purposes of evaluating student competency, the definitions taught during the course shall be used.
- 3.6.4 Evaluate proposals for corrective and preventive actions prepared by the auditee in response to nonconformities recorded during an assessment; evaluate the implementation and effectiveness of corrective actions taken, and evaluate the implementation and effectiveness of preventive actions taken; differentiate between corrective and preventive action.
- 3.6.5 Make recommendations on the competence of the laboratory for accreditation based on assessment evidence obtained during the assessment.
- 3.6.6 Describe the roles and responsibilities of the assessor and the auditee at all stages of the corrective action process.
- 3.6.7 Explain the purpose of ongoing surveillance and reassessment visits.

4. COURSE CONTENT

- 4.1 Early in the course presentation, the training provider shall provide to the students a description of the course format, student responsibilities, how the student will be evaluated, and the basis for each type of evaluation.
- 4.2 The course shall cover:
 - a) all aspects defined under Learning Objectives; and
 - b) local requirements, culture, practices or approaches to assessments and the application of ISO/IEC 17025, as appropriate.

5. COURSE STRUCTURE, TRAINING METHODS AND FACILITIES

5.1 Duration

- 5.1.1 The total course time devoted to direct instruction and to assigned team and individual activities shall be at least 36 hours plus an additional two hours for examination.
- 5.1.2 If the course is given through interpreters, this time shall be increased as required to meet the learning objectives.
- 5.1.3 Time devoted to the examination and to meals, breaks or other free time shall not be included in the calculation of the course duration.
- 5.1.4 The course shall be presented during five consecutive days, unless otherwise authorized by RABQSA (see Section 7).

5.2 Training Methods

- 5.2.1 Training courses shall be designed to have a high degree of interaction between students and instructors. Training methods shall be designed to involve and engage students throughout the duration of the course.
- 5.2.2 The training course shall include both knowledge-based sessions (to facilitate understanding of concepts) and skill-based sessions (application of knowledge and skills in practical activities) and each student shall be subjected to realistic laboratory assessment practices and conditions.
- 5.2.3 Methods for validating student achievement of the learning objectives and for providing timely feedback shall be included in the course.
- 5.2.4 Each student shall actively participate in practical skills-based activities (workshops, case studies, role playing and/or actual assessment situations) as part of the structured class activities. At least 60% of the total course time shall be used for such activities. In actual assessment situations, transit time to and from the assessment site and any delay time is not to be counted in the course duration.

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- 5.2.5 Any case studies shall be designed to cover the important aspects of the standard. If a course is advertised as being industry/sector-specific, the case studies shall relate to that sector (see Section 11).
- 5.2.6 Training aids, such as commercial training videos, videos produced during the course to record and review the performance of student, CDs or interactive training tools that are directly relevant may be used to supplement the training by the instructors. No more than 10% of the total course time may be devoted to commercial training aids.
- 5.2.7 Instructors shall demonstrate effective management of the course, including attention to time schedule, course content, requirements of the standard, instructor conduct, and other course requirements.

5.3 Class Size; Attendance

- 5.3.1 The number of students in a class shall be no greater than 20, nor fewer than four.
- 5.3.2 Under rare and exceptional circumstances, a course offering for fewer than four students or greater than 20 students may be considered for approval in accordance with Section 7.
- 5.3.3 Students shall be required to be in attendance for the full duration of the course. Failure to do so shall be reflected in the student's continual and final evaluations.

5.4 Number of Instructors

- 5.4.1 Each course offering for 11 or more students shall be presented by two instructors, who shall be actively involved in either instruction or evaluation for the full duration of the course. Additional resource people or trainee instructors may be used for specific subjects or activities; however, the two instructors remain responsible for the entire course offering.
- 5.4.2 When the number of students is four to 10, the course may be presented by one instructor.
- 5.4.3 When specific activities (for example; written quizzes or preparation of checklists) involve neither direct instruction nor evaluation, and do not require the availability of the instructors for explanation, clarification, or counsel, only one instructor needs to be present. At least one instructor shall be available to all students during team and individual activities, even if these activities are outside normal class hours.
- 5.4.4 At least one instructor shall be present during the exam to assure good examination practice.

5.5 Course Materials

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- 5.5.1 Each student shall be provided with a complete set of course notes to supplement the training program.
- 5.5.2 The documents included in the course notes shall themselves illustrate good organization, layout and document management practices, including document revision level and appropriate page numbering.
- 5.5.3 The set of course notes shall prominently identify the approved training provider (for example, on the cover page).
- 5.5.4 The notes shall cover each session and shall include all important points of the aspect being covered.
- 5.5.5 Examples of typical documents, reports and forms shall be included.
- 5.5.6 Course notes may include typical examination questions, provided they are not used in any of the examinations, either during the course or following the course.
- 5.5.7 Each student shall have a copy of the current published version of ISO/IEC 17025. If the ISO/IEC 17025 standard is not supplied as part of the course notes, each student shall be required to take a copy to the course. A copy shall be made available for loan to any student who does not have one.
- 5.5.8 Instructor materials shall contain sufficient information to ensure consistency of meeting the learning objectives among varying instructors.

5.6 Facilities

- 5.6.1 The training provider shall see that suitable facilities for training are provided, including classroom, audio-visual and other training equipment, and facilities for team activities.
- 5.6.2 Suitable meal and break arrangements must be planned in advance and communicated to students in literature related to the course presentation.
- 5.6.3 The training provider shall encourage students to be resident at or near the location of the course offering, since this enhances participation in team activities and student contact with the instructors outside the structured class setting.

6. EVALUATION OF STUDENTS

- 6.0.1 Each student shall be evaluated using the following two independent elements, both of which shall be satisfied if the student is to successfully complete the course:
 - ◆ The continual evaluation by the instructors of each student's achievement of the Learning Objectives detailed in Section 3 above; and
 - ◆ A written examination, that tests students' ability to apply principles from ISO 19011 and assessment practices against the requirements of ISO/IEC 17025.

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6.0.2 Each student shall be informed of the exam format, grading procedure, continual evaluation, and the pass/fail criteria at or prior to the beginning of the course.

6.1 Continual Evaluation

6.1.1 The continual evaluation shall be documented and shall evaluate each student's:

- a) achievement of the learning objectives, including, but need not be limited to: 3.3.8, 3.4.1, 3.5.1, 3.5.3, 3.6.1;
- b) attendance and punctuality during the course.

6.1.2 Every student's performance shall be reviewed at the end of each day by the instructor(s). A daily grade shall be assigned for each student.

6.1.3 Course instructors shall identify students who appear to be having difficulty in achieving the learning objectives or who are not performing adequately in course activities. Such students shall be informed privately and in a timely manner of the instructor's observations and shall be given the opportunity to improve.

6.1.4 A student who does not pass the continual evaluation must satisfactorily complete another full training course before being eligible to receive a certificate of successful completion.

6.2 Written Examination

6.2.1 The written examination shall evaluate the students' comprehension of the assessment process defined by ISO 19011 and the application of ISO/IEC 17025, and their ability to provide written justification of their evaluations.

6.2.2 The examination shall be designed so that a competent student (i.e., one who has demonstrated achievement of the learning objectives) could achieve a minimum mark of 70% in two hours.

6.2.3 The time allotted for taking the examination shall be two hours. Strict adherence to the time limit shall be maintained.

6.2.4 The instructor(s) may allow a student whose primary language is not the language in which the course is conducted up to 30 minutes additional time for taking the written examination. The student may use an appropriate two-language dictionary. Any such allowance shall be indicated in the records of the course or of the examination, with supporting reasons.

6.2.5 The instructor(s) may allow a student with a particular disability that adversely affects the student's capability to complete the examination in the allotted time up to 30 minutes additional time for taking the written examination. Any such allowance shall be indicated in the records of the course or of the examination, with supporting reasons.

6.2.6 At least 75% of the examination grade shall be based on questions that require essay responses that test the students' comprehension of the assessment process and the

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application of ISO/IEC 17025, and their ability to provide written justifications of their evaluations.

- 6.2.7 The remainder of the examination grade shall be based on multiple choice, true/false and/or short answer questions.
- 6.2.8 The minimum passing grade shall be 70%.
- 6.2.9 The only reference materials allowed during the examination are a copy of the ISO/IEC 17025 standard, the course notes provided by the training provider and any personal notes made by the student during the course.
- 6.2.10 Copies of examination questions (other than those in an example examination paper), examination papers, solutions or completed examination papers shall not be supplied to any student or any other party (except to the approval body) for any reason.

6.3 Grading; Pass/Fail Decisions

- 6.3.1 Each examination paper shall be graded by one of the instructors. Another instructor shall check the addition of the score allocated in each section and re-grade all examination papers with scores between 60 and 75 percent.
- 6.3.2 Results of the continual evaluation along with the examination grade shall be considered and a final pass/fail mark shall be issued for the class records.
- 6.3.3 The training provider shall have procedures to resolve any differences in grading and to issue final grades.
- 6.3.4 If the course is given through interpreters, the translators who translate the students' written examinations shall be selected by the training provider in such a way that the training provider is confident that they provide impartial, knowledgeable, and accurate translations.

6.4 Re-examination

- 6.4.1 A student who does not pass the written examination but has passed the continual evaluation shall be allowed one re-examination.
- 6.4.2 The re-examination shall be administered within 12 months after the date of the initial examination.
- 6.4.3 The same training provider with whom the student took the course and the (unsuccessful) examination shall conduct the re-examination.
- 6.4.4 A different examination paper shall be used for the re-examination.
- 6.4.5 The re-examination shall be taken in the presence of an approved instructor or other agent of the training provider, as described in the training provider's procedures.

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- 6.4.6 If the student does not pass the re-examination, he or she must again take the complete training course before being eligible to take another examination.
- 6.4.7 A student who has not satisfactorily completed the continual evaluation is not eligible for re-examination. He or she must again take the complete training course before being eligible to take another examination.

7. VARIATIONS

- 7.1 Variations to any of these criteria shall be considered for approval upon written submission by the training provider to RABQSA. Any such request shall be made immediately upon the reason for the variation request becoming known. RABQSA shall respond in writing.
- 7.2 When evaluating a request for variance, RABQSA shall take into account the training provider's:
- a) reasons for the requested variance;
 - b) rationale for the requested variance;
 - c) modified training plan and/or revised course outline; and
 - d) assessment of impact on the learning process.

8. PUBLICITY AND ADVERTISING

- 8.1 The following wording (or other very similar wording that has been approved by RABQSA) shall be used: "This course is certified by RABQSA."
- NOTE: The word "certified" shall be used. Any words that may imply RABQSA sponsorship of the course shall not be used.
- 8.2 The training provider's name shall appear in all promotional materials as it appears on the certification certificate when the RABQSA name and/or logo appear.
- 8.3 No RABQSA-certified course shall be subcontracted and/or licensed to a second organization or training provider. A training provider may, however, contract with another organization to make arrangements such as marketing and/or hotel accommodations for an offering.
- 8.4 If any promotional materials are being contracted through another organization, that organization may be referenced provided the identity of the certified training provider is readily evident. Such materials shall use the wording "this course is being presented in conjunction with (the RABQSA-certified training provider)" or other similar wording that has been approved by RABQSA.
- 8.5 It shall remain the responsibility of the certified training provider to ensure that all contracted materials and/or activities continually conform to all requirements of the training provider and of RABQSA.

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9. USE AND MISUSE OF CERTIFICATES AND LOGOS

- 9.1 The training provider shall exercise proper control over use and display of the RABQSA certification logo.
- 9.2 The training provider shall take suitable action to deal with incorrect references to its certification or certification status or misleading use of the RABQSA certification logo in advertisements, catalogs, etc.
- 9.3 The training provider shall not make statements in advertisements, catalogs, certificates, etc., that could serve to undermine the reputation of the RABQSA programs. Any and all violations shall be subject to suitable actions. Suitable actions may include, but are not limited to, corrective action, suspension, or withdrawal of RABQSA course certification or application for certification and, if necessary, legal action.
- 9.4 In addition to the above, misuse of the RABQSA name and/or logo by a training provider that has not submitted a course for certification or has not yet received certification will jeopardize its current submission or any future attempt to seek RABQSA certification.

End of Criteria