TITLE **REQUIREMENTS FOR THE ACCREDITATION OF MEDICAL LABORATORIES**

REFERENCE **RT-35**

REVISION **01**

DATE **05-10-2022**

NOTE *This document is the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to the Italian version only.*

PREPARATION

THE DIRECTOR OF TESTING LABORATORIES DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE PRESIDENT

APPLICATION DATE

01-02-2023

CONTENTS

0. INTRODUCTION

0.1 This document defines the general criteria for the accreditation of medical laboratories by the ACCREDIA Department of Testing Laboratories.

0.2 The objective of the application of these criteria is to promote and enhance the creation and maintenance of the trust of clients in the testing activities of accredited laboratories as well as the impartiality and integrity of the related technical and commercial activities. ACCREDIA grants accreditation to laboratories which conform with the requirements of UNI EN ISO 15189, with this document and with all other applicable ACCREDIA, EA and ILAC documents.

0.3 This document makes reference to the provisions of the standard UNI EN ISO 15189 "Requirements for the quality and competence of medical laboratories", and to the standard UNI EN ISO 22870 (POCT). The numbering of the paragraphs for chapters 4 and 5 coincides with that of the standard UNI EN ISO 15189. In these chapters, the application of the requirements of the standard is referred to and, in some cases, some clarifications necessary for the application of the standard are also given.

0.4 Accreditation attests the technical competence of the medical lab to perform the tests contained in the scope of accreditation and the implementation of a quality management system in line with the principles of UNI EN ISO 9001 for activities within the scope of accreditation.

1. SCOPE AND FIELD OF APPLICATION

1.1. This document sets out the general and management requirements and those regarding the technical competence for medical labs.

1.2. Labs taken into consideration are those which are organizationally and commercially independent as well as those which depend on a larger organization, such as a hospital or public/private organizations, research centers etc.

1.3. The requirements of this document are valid for all areas and types of tests, including POCTs and any pre-analytical phases eventually required for accreditation by the laboratory at the locations indicated by the laboratory in the accreditation application, in both the fixed and flexible scopes. Specific requirements set out in the mandatory and/or international standards (EA, ILAC, ISO, EN, etc.) or by ACCREDIA are listed in the reference documents and/or in ACCREDIA's website, www.accredia.it.

1.4. In order to obtain and maintain accreditation the lab shall demonstrate conformity with all the requirements of the standard except for those declared, with justification, to be inapplicable, for all activities defined in the field of accreditation.

2. TERMS AND DEFINITIONS

The terms and definitions used in this document are those contained in UNI EN ISO 15189 (para. 3), *UNI EN ISO 9000 Quality management systems – fundamentals and vocabulary, and UNI CEI 70099 International vocabulary of metrology – basic and general concepts and associated terms (VIM)*

Recognized organization: public or private entity possessing recognized technical excellence and reliability, operating in the sector of diagnostic preventive human medicine in the treatment of pathologies and all else related to human health (e.g. WHO, IFCC, CLSI, EFI, JRC).

Recognized test procedure: procedure defined by consent, prepared for the purpose of providing a better response in a given context, validated and approved by a recognized organization. This typology of procedure usually includes tests performed using an in vitro diagnostic medical device (IVD) in conformity with the directives and regulations of the European Union.

Internal test procedure: test procedure based on the following method typologies:

- methods not defined by means of consent and not approved by a recognized organization;
- methods defined (but not validated) by means of consent and approved or not approved by a recognized organization;
- methods planned or developed by the lab;
- methods which were validated but subsequently modified;
- recognized test procedures used outside their scope of application or modified substantially so as to alter the method.

This type of procedure includes procedures performed with diagnostic systems declared by the manufacturer for research use only (RUO).

Note that internal testing procedures are subject to validation by the laboratory.

3. REFERENCE STANDARDS AND DOCUMENTS

The list of reference documents (LS-04) can be accessed at www.accredia.it.

It is the responsibility of the laboratory to ensure the validity of the applicable documents.

4. MANAGEMENT REQUIREMENTS

4.1. ORGANIZATION AND MANAGEMENT RESPONSIBILITIES

4.1.1. Organization

4.1.1.1. General. The requirement of the standard is applicable.

4.1.1.2. Legal entity. The requirement of the standard is applicable.

The medical laboratory or the organization to which it belongs shall be a juridical corporate entity. The legal entity shall be stated in the lab's QM.

If the laboratory intends to apply for accreditation also for POCT, the POCT must come within the same legal entity as the laboratory.

Accreditation concerns the legal entity of the laboratory, which also assumes responsibility for the provision of the POCT service, the POCT results and reports issued and the guarantee of compliance with UNI EN ISO 15189 and UNI EN ISO 22870.

4.1.1.3. Ethical conduct. The requirement of the standard is applicable.

***4.1.1.4. Lab director*.** The requirement of the standard is applicable.

4.1.2. Management responsibilities

4.1.2.1. Tasks of the top management. The requirement of the standard is applicable.

4.1.2.2. Needs of the users. The requirement of the standard is applicable.

4.1.2.3 Quality policy. The requirement of the standard is applicable.

4.1.2.4 Quality and planning objectives. The requirement of the standard is applicable.

The lab shall define in a system document the modalities and responsibilities for the management of changes.

4.1.2.5. Authority and inter-relational responsibilities. The requirement of the standard is applicable.

The lab shall have available an organization chart which clearly reflects its organization and the relations with other personnel with influence on the lab's activities.

If a lab belongs to a bigger organization there shall also be an organization chart showing the position of the laboratory.

There shall be a written definition of the authorizations for the issuance of reports with reference to any specific areas of relevance.

4.1.2.6. Communication. The requirement of the standard is applicable.

4.1.2.7. Quality manager. The requirement of the standard is applicable.

If the quality manager is a consultant the contract shall specify the time period covered for the activities in question (e.g. at the lab).

4.2. QUALITY MANAGEMENT SYSTEM

4.2.1. General requirements. The requirement of the standard is applicable.

4.2.2. Documental requirements

4.2.2.1. General. The requirement of the standard is applicable.

4.2.2.2. Quality Manual. The requirement of the standard is applicable.

The manual shall provide enough information to make it clear how the lab operates to achieve and maintain conformity to UNI EN ISO 15189 and to ACCREDIA's applicable documents.

The manual shall describe the scope of application of the QMS and it shall define the lab's processes, distinguishing between those managed by the lab and those entrusted to other offices or departments (e.g. blood samples, purchases etc.). The QM shall also have a brief description of the processes, of their interaction and of the modalities used to ensure effectiveness.

In the case of multisite laboratories, the manual shall specify, where applicable, the location where the activities it describes are carried out.

For the analytical stations of remote medical labs at health care sites (temporary bed-care areas, medical clinics, points-of-care), the requirements of ISO 22870: *Point of care testing - POCT – requirements for quality and competence*, and the QM shall refer to the requirements of that standard.

The manual may describe activities which are not part of the requirements for accreditation (e.g. if the lab is part of a large structure) as long as the parts of the manual which regard the accreditation can be clearly distinguished and, taken on their own, constitute a complete QM, meeting the requirements of UNI ISO 15189 and of this document.

The manual shall also contain a table of correlations between its contents and the contents, by paragraph, of this document.

4.3. MANAGEMENT OF THE DOCUMENTATION

The requirement of the standard is applicable.

If the QM or other documents sent to ACCREDIA contain abbreviations or acronyms these shall be explained to ACCREDIA in written form.

The laboratory shall send to ACCREDIA the revisions of the Management System Manual and of the test procedures designed and developed by the l laboratory, as well the documents required by the application module DA-08. Other documents shall be sent if requested by ACCREDIA.

4.4. AGREEMENTS REGARDING THE PERFORMED SERVICE

4.4.1. Definition of the agreements regarding performed activities. The requirement of the standard is applicable.

The lab shall inform the client with regard to the meaning of accreditation.

4.4.2. Review of the agreements regarding performed activities. The requirement of the standard is applicable.

4.5. TESTS PERFORMED BY EXTERNAL LABORATORIES AND CONSULTANTS

4.5.1. Selection and evaluation of external labs and consultants

The requirement of the standard is applicable.

Accreditation is granted to a lab only for those tests which it carries out itself and for which ACCREDIA assesses the competence. The use of external labs or consultants, on a continuous basis for accredited tests is not permitted; however it is permitted in exceptional cases, for example temporary equipment failure, temporary unavailability of reagents or absence of staff.

If, in exceptional circumstances, a lab uses an external lab or a consultant, it shall:

- inform the client beforehand;
- verify the competence of the external lab (accreditation by an AB signatory to the EA MLA or MRA ILAC agreements of mutual recognition of an external lab is a guarantee of competence) or of a consultant;
- include all relevant information in the report.

4.5.2 Communication of the results of the tests. The requirement of the standard is applicable.

4.6. PROCUREMENT OF SERVICES AND SUPPLIES

The requirement of the standard is applicable.

4.7. CLIENT SERVICES

The requirement of the standard is applicable.

4.8. COMPLAINTS

The requirement of the standard is applicable

4.9. IDENTIFICATION AND CONTROL OF NONCONFORMITIES

The requirement of the standard is applicable.

As well as the actions defined in § 4.10 if any NCs are raised which could cast doubt on the validity of the results of accredited tests (e.g. use of equipment with expired period of calibration or maintenance or for which the calibration or maintenance activities had a negative outcome, use of expired reference materials and so forth), the lab shall suspend the issuance of reports carrying the ACCREDIA mark or any other reference to accreditation related to these tests until a positive verification is made of the corrective actions implemented and this suspension shall be communicated to ACCREDIA.

4.10. CORRECTIVE ACTIONS

The requirement of the standard is applicable.

CAs which were planned and communicated after second or third party audits (e.g. by ACCREDIA) shall be managed within the lab's MS.

4.11. PREVENTIVE ACTIONS

The requirement of the standard is applicable.

4.12. CONTINUOUS IMPROVEMENT

The requirement of the standard is applicable.

4.13. TECHNICAL AND QUALITY RECORDS

The requirement of the standard is applicable.

All records shall be kept for at least as long as required by the legal requirements applicable to accredited activities.

Technical and quality records, e.g. NCs, CAs and PAs, audits, management reviews etc. shall be kept for a mini-mum of 48 months.

4.14. ASSESSMENTS AND AUDITS

4.14.1 General. The requirement of the standard is applicable.

4.14.2 Periodical review of the requirements and suitability of procedures and of the sampling requirements. The requirement of the standard is applicable.

4.14.3 Evaluation of information sent by users. The requirement of the standard is applicable.

4.14.4 Suggestions of personnel. The requirement of the standard is applicable.

4.14.5 Internal audits. The requirement of the standard is applicable.

CVs and attestations of competence of the evaluators shall be provided with regard to the standards UNI EN ISO 15189 (and UNI EN ISO 22870 in the case of POCTs) and the requirements for accreditation.

Internal audits may be performed (if there are not internal resources) by qualified auditors external to the lab.

Second and third party audits cannot substitute internal lab audits. The audit cycle shall be completed in one year.

4.14.6 Risk management. The requirement of the standard is applicable.

4.14.7 Quality indicators. The requirement of the standard is applicable.

Different indicators and terminologies are currently in use. To enable comparison of the performance of processes between laboratories, and therefore the appropriateness of the improvement goals set by the lab, it is recommended to use – when they are available – harmonized indicators. With regard to this, see the list of indicators of the working group of the *International Federation of Clinical Chemistry and Laboratory Medicine* (IFCC) and the document QMS12-A - CLSI (formerly GP35).

4.14.8 Review following the evaluations undertaken by external organizations

The requirement of the standard is applicable.

The lab shall carry out a review also after second and third party audits (e.g. ACCREDIA assessments) if any NCs were raised, and the lab shall plan CAs etc.

4.15. MANAGEMENT REVIEW

4.15.1 General. The requirement of the standard is applicable.

The review shall be carried out at least once a year.

4.15.2 Input elements to the review.

The requirement of the standard is applicable.

Among the inputs it is necessary to control also the results of internal quality controls.

In point n), the changes regarding equipment and software are considered if this has not been done as set out in point a).

4.15.3 Review activities. The requirement of the standard is applicable.

4.15.4 Output elements from the review. The requirement of the standard is applicable.

5. TECHNICAL REQUIREMENTS

5.1 PERSONNEL

5.1.1 General - The requirement of the standard is applicable.

For POCTs: If the POCT equipment is managed by personnel belonging to a legal person, there must be a clear contractual agreement for the use of such personnel and for the competence requirements of the personnel.

5.1.2 Qualification of personnel. The requirement of the standard is applicable.

5.1.3 Description of professional roles. The requirement of the standard is applicable.

5.1.4 Personnel and workplace conditions. The requirement of the standard is applicable.

5.1.5 Training. The requirement of the standard is applicable.

5.1.6 Evaluation of competences. The requirement of the standard is applicable.

The laboratory shall record the names of authorized persons competent to perform individual tests or homogeneous groups of tests and to have available a matrix or other document which provides an overview of tests and competent staff.

The criteria for the evaluation of staff competences may take into consideration the contents of Note 1.

5.1.7 Re-assessment of competences. The requirement of the standard is applicable.

5.1.8 Continuous training and professional development. The requirement of the standard is applicable.

5.1.9 Records. The requirement of the standard is applicable.

5.2 WORKPLACE AREAS AND AMBIENT CONDITIONS

5.2.1 General. The requirement of the standard is applicable.

If the laboratory manages an accredited POCT, it must prepare a list of the sites and departments where they are located, with particular reference to those considered critical for the patient's health (e.g. operating rooms, emergency departments).

5.2.2 Laboratory and nearby areas. The requirement of the standard is applicable.

5.2.3 Storage areas. The requirement of the standard is applicable.

5.2.4 Areas/rooms dedicated to personnel. The requirement of the standard is applicable.

5.2.5 For keeping the samples of patients. The requirement of the standard is applicable.

5.2.6 Maintenance services and workplace ambient conditions. The requirement of the standard is applicable.

5.3 EQUIPMENT, REAGENTS AND CONSUMABLES

5.3.1 Equipment

5.3.1.1 General. The requirement of the standard is applicable.

5.3.1.2 Verification of the acceptability of equipment. The requirement of the standard is applicable.

5.3.1.3 Instructions for the use of equipment. The requirement of the standard is applicable.

5.3.1.4 Calibration of equipment and metrological traceability. The requirement of the standard is applicable.

Traceability by means of calibration carried out by a competent laboratory

In accordance with the provisions of the document ILAC P10, when metrological traceability of the results is required and this traceability is not given by the use of certified reference materials, which are dealt with in the next point, the equipment must be calibrated by:

1. National Metrological Institutes (NMI) and other designated institutes whose services are suitable and covered by the CIPM-MRA[1] agreement within the limits of the internationally accepted metrological capabilities (CMC) and published in the KCDB by the BIPM[2].

   The presence of the CIPM MRA note and/or logo on the Calibration Certificates demonstrates the coverage of the CMCs; where the note and/or logo are not present, their inclusion being discretionary, the laboratory must verify the coverage of the CMCs by consulting the BIPM website at*: www.bipm.org* or *kcdb.bipm.org.*

   or by

2. Accredited calibration laboratories whose services are suitable and whose accreditation is granted by ABs signatory to the EA-MLA or ILAC-MRA agreement for the scope "calibration" in the framework and within the limits provided for by the CMCs published by ABs.

The use of calibration certificates issued within the framework of these two possibilitiès is to be considered of equal validity, notwithstanding the different value of the calibration uncertainties, which must be adapted to the needs of the laboratory.

If it is not possible to obtain metrological traceability from either of the two cases reported above, the following alternatives are acceptable, provided that appropriate evidence is available on the competence of the supplier, with particular reference to traceability and measurement uncertainty of the calibrations provided:

3.a National Metrological Institutes whose services are suitable but not covered by the CIPM-MRA agreement. This case should not be chosen on the basis of purely economic or logistical reasons, but should be considered as a last resort when cases 1 and 2 are not available.

or

3.b Calibration laboratories whose services are suitable, but not covered by ILAC agreements or by regional agreements recognized by ILAC. This option should only be chosen if type 1, 2 and 3a suppliers are not available. The modalities by which the CAB has assessed the supplier are subject to assessment by ACCREDIA.

In cases 3a and 3b the laboratories must ensure evidence of the declared metrological traceability and measurement uncertainty; this evidence is evaluated by ACCREDIA (see the guide reported in ILAC P10 Appendix A).

It should be noted that if the laboratory carries out the calibration of its own measurement instrumentation itself (hereafter referred to as internal calibration), the reference standards

[1] CPM-MRA: CIPM Mutual Recognition Arrangement – Mutual Recognition between National Metrological Institutes

[2] KCDB: BIPM Key Comparison DataBase: contains information on internationally accepted metrological capabilities (CMC)

used for calibration (e.g. the reference thermometer used for the calibration of temperature meters, or the weight set used to calibrate the scales) must:

- be calibrated according to cases 1 or 2 above;
- and be the property of the laboratory or of the legal identity to which the laboratory belongs.

This internal calibration must also be performed against suitable calibration procedures and make use of competent personnel.

Calibration performed by persons external to the laboratory is also considered to be internal calibration, provided that the laboratory has the reference samples and has incorporated the calibration procedure used by external personnel into its management system. The documented instructions relating to the calibration operations (calibration procedures), must, where applicable, give indications (or contain references to other documents) for:

- the issuance of calibration reports;
- the affixing of labels or other identification of the calibration status of the calibrated instruments;
- the evaluation of the calibration results (acceptability criteria of the calibration results).

Calibration procedures that do not refer to recognized calibration methods (e.g. ISO 8655-1 for the calibration of piston micropipettes) are accepted only if validated by the laboratory.

Calibrations performed by a metrological service belonging to the entity of which the laboratory is a part, are also considered to be internal calibration, but not integrated into the laboratory (for example, in the case of hospitals, *clinical engineering*). In this case, the metrology service must have a quality management system that meets the applicable requirements of UNI EN ISO/IEC 17025. [See, regarding this, Annex A of the document ILAC P10: records of the validation of the calibration method (7.2.2.4), procedures for the evaluation of measurement uncertainty (7.6), documentation and records for the metrological traceability of the measurement results (6.5), documentation and records to guarantee the validity of the results (7.7), documentation and records for personnel competence (6.2), records for equipment that can influence calibration activities (6.4), documentation and records for equipment and environmental conditions (6.3), metrology service audits (6.6 and 8.8)]. This system can be autonomous or integrated into that of the medical laboratory. The metrology service will be subject to ACCREDIA assessment and the on-site assessments will, where possible, be combined with those of the laboratory. The internal metrology service that carries out an internal calibration will not be able to issue a report with the ACCREDIA logo or offer its services under accreditation to third parties, giving the impression that the metrology service is ISO/IEC 17025 accredited.

Traceability by means of certified values of certified reference materials

If the metrological traceability is provided by producers of reference materials (RMP) through certified reference materials (CRM), it is considered, in accordance with ILAC P10, that the certified values assigned to a CRM have a valid metrological traceability when produced by:

4 NMIs whose production service is included in the KCDB of the BIPM.

The presence of the CIPM MRA note and/or logo on the reference material certificate is a demonstration of this inclusion; where the note and/or logo are not present, their inclusion being discretionary, the laboratory must verify that the service is included by consulting the BIPM website at: *www.bipm.org* or *kcdb.bipm.org*.

or

5 RMPs accredited to ISO 17034, whose service is included in the field of accreditation,

or

6 Organizations listed in the JCTLM database (www.bipm.org).

Recognizing that the production of CRMs is still under development, if it is impossible to find CRMs coming within the previous three cases (4, 5 and 6), the laboratory may resort to the use of CRMs produced by other manufacturers, demonstrating that they are competent and that the CRMs are suitable for their intended use. The extent of the verifications made by the laboratory regarding the manufacturer depends on the information available as well as on the nature of the material.

If it is not technically possible to document the metrological traceability to the international system of measurement units (SI), the laboratory must, in accordance with ILAC P10:

7a use certified values of certified reference materials supplied by a competent manufacturer,

or

7b provide evidence of adequate comparison to reference measurement procedures with specified methods or consensus references clearly described and accepted as suitable for the intended use.

Note 1: When metrological traceability to SI units alone is not appropriate or applicable for that specific application, a clearly defined measurand should be selected. Establishing metrological traceability includes both proof of the identity of the measured property and the comparison of the results with an appropriate declared reference. The comparison is established by ensuring that measurement procedures are adequately validated and/or verified, that measurement equipment is correctly calibrated, and that measurement conditions (such as ambient conditions) are assured in the form necessary to provide a reliable result.

Note 2: Surplus materials are often available from suppliers of VEQ (PT). The use of these materials to ensure the validity of the results should not be carried out if the supplier of these materials cannot provide further information on the stability of the value of the property and the matrix of the test material.

Note 3: If the value assigned to the material by the VEQ (PT) supplier is determined based on the consensus value of the participants and the VEQ (PT) participants have used different measurement procedures and the result is operationally defined, this assigned value cannot be used to establish the metrological traceability of results (see also ISO Guide 35).

5.3.1.5 Maintenance and repair of equipment. The requirement of the standard is applicable.

5.3.1.6 Communication of adverse events regarding equipment. The requirement of the standard is applicable.

5.3.1.7 Equipment records. The requirement of the standard is applicable.

5.3.2 Reagents and consumables

5.3.2.1 General. The requirement of the standard is applicable.

5.3.2.2 Reagents and consumables – Receipt and storage. The requirement of the standard is applicable.

If the lab is not the location of the final storage location of reagents and consumables, it shall ensure that such products are kept in adequate conditions in compliance with the producer's instructions.

5.3.2.3 Reagents and consumables – Controls upon receipt. The requirement of the standard is applicable.

5.3.2.4 Reagents and consumables – Management of the inventory. The requirement of the standard is applicable.

5.3.2.5 Reagents and consumables – Instructions for use. The requirement of the standard is applicable.

5.3.2.6 Reagents and consumables – Communication of adverse events. The requirement of the standard is applicable.

5.3.2.7 Reagents and consumables – Records. The requirement of the standard is applicable.

5.4 PRE-TEST PROCESSES

5.4.1 General - The requirement of the standard is applicable.

The pre-analysis activity of blood testing and gathering of a sample performed at a POC can be accredited only if associated with a subsequent accredited test and if conducted within the management system of the legal entity applying for accreditation.

5.4.2 Information for patients and users. The requirement of the standard is applicable.

5.4.3 Request for information. The requirement of the standard is applicable.

5.4.4 Gathering and handling of primary samples

5.4.4.1 General. The requirements of the standard and of Note 2 are applicable.

5.4.4.2 Activities preparatory to the gathering of the sample. The requirement of the standard is applicable.

5.4.4.3 Gathering of samples. The requirement of the standard is applicable.

5.4.5 Transport of samples. The requirement of the standard and the Note are applicable

5.4.6 Receipt of samples. The requirement of the standard is applicable.

5.4.7 Handling, preparation and preservation of samples before the performance of tests. The requirement of the standard is applicable.

5.5 TEST PROCESSES

5.5.1 Choice, verification and validation of test procedures. The requirement of the standard is applicable.

5.5.1.1 General. The requirement of the standard is applicable.

5.5.1.2 Verification of test procedures

The appropriate guidelines for performing the independent confirmation of the performance characteristics declared in the test procedure are those issued by the Clinical and Laboratory Standards Institute (CLSI) or by scientific organizations of the recognized sector. In order to compare performance characteristics obtained by the lab with those which were declared, it is important that the statistics and the terminology are the same.

In cases of a lack of information regarding the performance characteristics stated in the instructions for use, or absence of documented information on the part of the producer or developer of the method, the performance characteristics relevant for the use shall be determined by the lab.

5.5.1.3 Validation of the test procedure. The requirement of the standard is applicable.

The validation procedure shall indicate the bibliographical reference/s on which the statistics and method-ology used are based for determining the performance characteristics. Appropriate guidelines for this reference are those issued by international scientific organizations such as the Clinical and Laboratory Standards Institute (CLSI), EURACHEM, IUPAC or other recognized associations.

The test procedures deriving from methods designed or developed by the lab (5.5.1.3-b of UNI EN ISO 15189), if they are the object of accreditation, shall be updated in distribution, also to ACCREDIA, and accompanied by the record containing the result of the test review of the validation, signed by the officer responsible for the review.

The record containing the result of the test review of the validation shall include an outline of the results of the performance characteristics of the test procedure. ACCREDIA may ask the lab to send also the reference documents of the test procedure.

The test procedure that involves the use of a measurement system consisting of an in vitro diagnostic medical device (IVD) in compliance with the Directive of the European Union (EU) 98/79, now replaced by the Regulation (EU) 2017/746, and therefore which has the CE marking, does not require validation by the laboratory.

5.5.1.4 Uncertainty of the values of the measured quantities. The requirement of the standard is applicable.

Regarding the communication of measurement uncertainties to the applicant, the lab shall report it as an expanded uncertainty. It is generally accepted to use a cover factor k = 2, corresponding to a trust level of 95%.

With reference to EA-4-/16, the uncertainty shall be accompanied by a declaration regarding the level of trust and the cover factor used. For example: "The uncertainty stated in the present document is the expanded uncertainty and it is obtained by multiplying the standard uncertainty composed by a cover factor k = 2 which, for a normal distribution, leads to a trust level of approximately 95%."

5.5.2 Reference biological intervals or clinical decision levels. The requirement of the standard is applicable.

The lab shall confirm at least once a year the suitability of the biological reference intervals (or clinical decision levels) in use, re-examining the indications provided by the consensus conferences or health clinics requiring the tests.

5.5.3 Test procedures - The requirement of the standard is applicable.

5.6 DATA QUALITY ASSURANCE

5.6.1 General. The requirement of the standard is applicable.

5.6.2 Quality control. The requirement of the standard is applicable.

5.6.2.1 General. The requirement of the standard is applicable.

5.6.2.2 Quality control materials. The requirement of the standard is applicable.

5.6.2.3 Quality control data. The requirement of the standard is applicable.

5.6.3 ILCs.

5.6.3.1 Participation.

The requirement of the standard is applicable.

ACCREDIA Regulation RT-24 is applicable.

The laboratory shall, where possible, avail itself of ILC organizers, preferably accredited, operating in conformity with UNI CEI EN ISO/IEC 17043.

In case of non-accredited organizer, the laboratory must demonstrate that it operates in compliance with the above standard. The extent of the verifications made by the laboratory regarding the VEQ/PT supplier depends on the information available as well as on the nature of the material.

5.6.3.2 Alternative approaches. The requirement of the standard is applicable.

5.6.3.3 Interlaboratory circuit sampling analysis. The requirement of the standard is applicable.

5.6.3.4 Performance evaluation of the laboratory. The requirement of the standard is applicable.

5.6.4 Comparability of test results. The requirement of the standard is applicable.

5.7 POST-TEST PHASE

5.7.1 Review of results. The requirement of the standard is applicable.

5.7.2 Storage, preservation and disposal of clinical samples. The requirement of the standard is applicable.

5.8 REQUIREMENTS OF "REPORTS"

5.8.1 General. The requirement of the standard is applicable.

5.8.2 Comments regarding the results. The requirement of the standard is applicable.

5.8.3 Contents of the report. The requirement of the standard is applicable.

If the report makes reference to accreditation (e.g. by using the mark) and it contains a number of tests of which some are without accreditation, the lab shall signal unambiguously the unaccredited ones. For reports containing tests with ACCREDIA accreditation, the lab may use the ACCREDIA mark or other reference to accreditation in conformity with ACCREDIA Reg. RG-09.

With regard to measurement uncertainty, if stated in the report, the contents of § 5.5.1.4 are applicable.

5.9 ISSUANCE OF THE RESULTS

5.9.1 General. The requirement of the standard is applicable.

5.9.2 Automatic selection and issuance of results. The requirement of the standard is applicable.

5.9.3 Reviewed reports. The requirement of the standard is applicable.

5.10 INFORMATION MANAGEMENT

5.10.1 General. The requirement of the standard is applicable.

5.10.2 Authority and responsibility. The requirement of the standard is applicable.

5.10.3 IT system management. The requirement of the standard is applicable.