

TITLE **REQUIREMENTS FOR THE ACCREDITATION OF
MEDICAL LABORATORIES - UNI EN ISO 15189:2023**

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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.*

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THE DIRECTOR OF TESTING LABORATORIES DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE PRESIDENT

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NOTE: modified parts are not highlighted in this document, as this is a general revision.

INTRODUCTION

This document defines the general criteria for the accreditation of medical laboratories by the ACCREDIA (the Italian accreditation body) Department of Testing Laboratories.

The objective of the application of these criteria is to promote 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.

Accreditation attests the technical competence of the laboratory to perform the activities contained in the field of application of accreditation.

SCOPE AND FIELD OF APPLICATION

1.1. This regulation refers to the requirements of the standard UNI EN ISO 15189:2023 "*Medical laboratories - Requirements for quality and competence*" and is intended to provide, for certain aspects, indications and clarifications necessary for the application of this standard. The numbering of the paragraphs coincides with those of the UNI EN ISO 15189 standard.

Additional sector-specific requirements may be defined by mandatory regulations or at international or national level (EA, ILAC, ISO, EN, UNI, etc.).

1.2. This document is applicable to all medical laboratories, both those that are organisationally and commercially independent and those that are dependent on a larger organisation (such as hospitals, public or private organisations, research centres, etc.).

1.3. 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.

1.4. The Laboratory is obliged to comply with this document, the ACCREDIA document RG-09 and other documents, where applicable (e.g., RG-02, RT-24, RT-26).

REFERENCE STANDARDS AND DOCUMENTS

The reference standard for this scheme is UNI EN ISO 15189:2023. The list of reference documents (LS-04) can be found at www.accredia.it.

For some technical sectors there are specific documents for the application of the UNI EN ISO 15189 standard. These documents, if not explicitly indicated as mandatory, are guidelines and do not constitute additional requirements but help in the consistent application of what is already required; however, if the laboratory decides not to apply what is stated in them, it must demonstrate the validity and suitability for the scope of its work.

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

3. TERMS AND DEFINITIONS

The definitions of UNI EN ISO 15189¹, of the reference standards (UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI CEI EN 45020), of Regulation (EC) No. 765/2008 and of the applicable ACCREDIA Regulations (e.g., RG-02, RT-26) apply.

Internal examination procedure²: method designed or developed by the laboratory, or method specified in the instructions for use of *in vitro* diagnostic medical devices placed on the market in accordance with EU Reg. 2017/746 but used outside the intended purpose specified by the manufacturer or modified.

Internal examination procedures therefore include:

- a) methods entirely (*de novo*) developed by the laboratory;
- b) methods developed or modified by the laboratory from a published source (scientific literature), or from design specifications produced by another laboratory or any other source;
- c) methods involving the use of parts of existing *in vitro* diagnostic medical devices
- d) methods combining an *in vitro* diagnostic medical device with another *in vitro* diagnostic medical device (IVD assembly) or with another type of product or parts of product, where the combination creates a new *in vitro* diagnostic medical device;
- e) methods that modify an existing *in vitro* diagnostic medical device on the market to create a new *in vitro* diagnostic medical device;
- f) methods used for a purpose other than that intended by the manufacturer, e.g., when a method declared '*for research use only*' (RUO) or '*for laboratory use only*' is used for diagnostic purposes.
- g) methods not used in accordance with the manufacturer's instructions for use, including significant changes in the intended use, e.g., applying it to other types of samples.

Other terms commonly used to define an internal method are: *in-house method*, *laboratory-developed tests* (LDT).

IVDR examination procedure³: method specified in the instructions for use of *in vitro* diagnostic medical devices placed on the market in accordance with EU Reg. 2017/746, used by the laboratory without modification and within the intended purpose specified by the manufacturer.

Also included, until the end of the transitional period of Regulation (EU) 2017/746, are those specified in the instructions for use of devices placed in accordance with Directive 98/79/EC.

¹ Pending the availability of the Italian translation of UNI EN ISO 15189:2023, the terms in this document are a translation by ACCREDIA.

² In this document, the word 'method' can sometimes also be understood as 'measurement procedure' or 'examination procedure'.

³ The term 'IVDR examination procedure' replaces the previously used term 'recognised examination procedure'.

4. GENERAL REQUIREMENTS

The requirement of the standard is applicable.

4.1 IMPARTIALITY

The requirement of the standard is applicable.

Please remember, when applying the requirements, to take into account what is stated in Note 2 to §8.5.2 of the standard.

4.2 CONFIDENTIALITY

The requirement of the standard is applicable.

4.3 PATIENT-RELATED REQUIREMENTS

The requirement of the standard is applicable.

5. STRUCTURAL AND GOVERNANCE REQUIREMENTS

5.1 LEGAL ENTITY

The requirement of the standard is applicable.

5.2 LABORATORY DIRECTOR

The requirement of the standard is applicable.

5.3 LABORATORY ACTIVITIES

The requirement of the standard is applicable.

5.3.1 The requirement of the standard is applicable.

Accreditation is granted to a laboratory only for those activities it carries out on its own and for which ACCREDIA verifies its competence. The outsourcing of activities on an ongoing basis is therefore excluded from the scope of accreditation.

It should be noted that the outsourcing of accredited activities on a non-continuous basis is only the case where the laboratory has the resources and expertise to perform the activities, but for unforeseen reasons finds itself unable to perform them in whole or in part.

The sampling/collection activity performed at a sample collection facility, including its transport to the examination site, is only accreditable if it is associated with a subsequent accredited

examination and if it is conducted within the management system of the legal entity seeking accreditation.

Point-of-Care Testing (POCT) may be included in the accreditation if the laboratory also ensures for these examinations the applicable requirements of EN ISO 15189, including those indicated in Annex A.

5.3.2 The requirement of the standard is applicable.

Among the requirements that the Laboratory must fulfil for compliance with ISO 15189 are also included the legislative requirements for the exercise of the laboratory activity subject to accreditation. For these requirements, compliance must be demonstrated by providing evidence of the authorisation to operate issued by the competent authority.

5.3.3 The requirement of the standard is applicable.

5.4 STRUCTURE AND AUTHORITY

5.4.1 The requirement of the standard is applicable.

The laboratory must have an organisational chart that clearly illustrates its organisation and its relationships with any other functions that have an influence on the laboratory's operations (e.g., purchasing, personnel records, consumables warehouse, departments/units where POCTs are located, internal departments that deal with equipment maintenance/calibration). These functions, even if not dependent on the laboratory, must operate in accordance with the applicable points of UNI EN ISO 15189 and the laboratory must co-ordinate with them to comply with the applicable requirements.

5.4.2 The requirement of the standard is applicable.

5.5 OBJECTIVES AND POLICIES

The requirement of the standard is applicable.

5.6 RISK MANAGEMENT

The requirement of the standard is applicable.

6. RESOURCE REQUIREMENTS

6.1 GENERAL

The requirement of the standard is applicable.

6.2 PERSONNEL

6.2.1 The requirement of the standard is applicable.

6.2.2 The requirement of the standard is applicable

When defining personnel competence requirements, the Laboratory must take into account any mandatory requirements applicable to the activities subject to accreditation (e.g., registration, possession of specialisations)

6.2.3 The requirement of the standard is applicable.

6.2.4 The requirement of the standard is applicable.

6.2.5 The requirement of the standard is applicable.

6.3 STRUCTURES AND ENVIRONMENTAL CONDITIONS

The requirement of the standard is applicable.

6.4 EQUIPMENT

The requirement of the standard is applicable.

Please remember to also manage the equipment in the emergency trolley.

6.5 CALIBRATIONS AND METROLOGICAL TRACEABILITY OF EQUIPMENT

6.5.1 The requirement of the standard is applicable.

6.5.2 The requirement of the standard is applicable.

6.5.3 The requirement of the standard is applicable.

In addition, clarifications on the policy of metrological traceability of measurement results are given below:

a) Traceability obtained by means of 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-MRA⁴ agreement within the limits of the internationally accepted metrological capabilities (CMC) and published in the KCDB by the BIPM⁵.

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.

⁴CIPM-MRA: CIPM Mutual Recognition Arrangement

⁵ KCDB: BIPM Key Comparison DataBase: contains information on internationally accepted metrological capabilities (CMC)

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 possibilities 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:

3a - 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

3b - 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).

Calibrations carried out by the manufacturer of the equipment or by other laboratories not accredited for the specific calibrations are not accepted, except for case 3b above.

b) 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 producer,

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 VEQ⁶ (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).

INTERNAL CALIBRATIONS

It should be noted that if the laboratory carries out the calibration of its own measuring instrumentation itself (hereinafter referred to as internal calibration), the reference standards used for calibration (e.g., the reference thermometer used for calibrating temperature gauges, or the weigher used for calibrating scales) must in turn be calibrated in accordance with the above cases and be the property of the laboratory or the legal entity to which the laboratory belongs.

Such internal calibration must also be carried out using appropriate calibration procedures and competent personnel.

Internal calibration is also considered to be that performed by personnel from outside the laboratory, provided that the laboratory possesses the reference standards and has incorporated

⁶ The term VEQ (*Valutazione Esterna della Qualità*) corresponds to the acronym EQA (External Quality Assessment), also known as Proficiency Testing (PT).

the calibration procedure used by external personnel into its management system. The documented instructions concerning calibration operations (calibration procedures) must, where applicable, give indications (or contain references to other documents) for:

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

Please note that calibration procedures that do not refer to recognised calibration methods (e.g., ISO 8655-6 for calibration of piston micropipettes) are only accepted if validated by the laboratory.

It is also considered to be an internal calibration when it is carried out by a metrology service belonging to the same organisation as the laboratory, but which is not integrated into the laboratory (e.g., 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, in this regard, the guidance in Annex A of ILAC document P10] This system may be autonomous or integrated into that of the medical laboratory. The metrology service will be subject to ACCREDIA evaluation and on-site assessments will, where possible, be combined with those of the laboratory. The internal metrology service carrying out an internal calibration will not be able to issue a calibration report with the ACCREDIA logo or offer its services under accreditation to third parties, implying that the metrology service is accredited to ISO/IEC 17025.

6.6 REAGENTS AND CONSUMABLES

The requirement of the standard is applicable.

6.7 AGREEMENTS REGARDING THE PERFORMED SERVICE

The requirement of the standard is applicable.

6.8 PRODUCTS AND SERVICES PROVIDED EXTERNALLY

The requirement of the standard is applicable.

7. RESOURCE REQUIREMENTS

The requirement of the standard is applicable.

7.1 GENERAL

The requirement of the standard is applicable.

7.2 PRE-EXAMINATION PROCESSES

The requirement of the standard is applicable.

7.3 EXAMINATION PROCESSES

7.3.1 General

The requirement of the standard is applicable.

In the case of missing information on performance characteristics in the instructions for use, or in the absence of documented information from the method manufacturer/developer, the performance characteristics relevant to the intended use are to be determined by the laboratory.

7.3.2 Verification of examination methods

The requirement of the standard is applicable.

It should be noted that in order to be able to compare laboratory performance with that specified by the producer or procedure, it is important that the statistics and terminology are the same.

7.3.3 Validation of examination methods

The requirement of the standard is applicable.

Methods subject to validation include in-house methods (see definition para. 3), thus including those declared by the manufacturer for research use (RUO), when used by the laboratory for diagnostic purposes.

Appropriate validation procedures are those based on recognised protocols, i.e., where they exist, defined by scientific reference organisations (e.g., CLSI, IFCC, EFLM), and/or standardised (e.g., ISO 21474-2 for multiplex molecular tests for nucleic acids).

The Laboratory that applies for accreditation, with fixed scope, of examinations performed according to in-house methods, must send ACCREDIA a copy of these methods, accompanied by the validation and suitability statement (summary of the records foreseen in §7.3.3. e) of the standard). Each revision must be sent to ACCREDIA; if the Laboratory does not send ACCREDIA such documentation, the relative examinations will be excluded from accreditation.

In the case of flexible accreditation, for examinations performed according to in-house methods, ACCREDIA reserves the right to request copies of these procedures and the relevant validation and suitability statements (summary of the records provided for in §7.3.3 e) of the standard).

7.3.4 Evaluation of measurement uncertainty

The requirement of the standard is applicable.

The communication of the measurement uncertainty to the applicant must also contain the associated confidence level and the coverage factor used. It is generally accepted to use a coverage factor $k = 2$, corresponding to a confidence level of 95%. Example of a statement of

the confidence level and coverage factor used: "*The uncertainty reported in this document is the expanded uncertainty and is obtained by multiplying the compound standard uncertainty by a coverage factor $k = 2$, which for a normal distribution leads to a confidence level of approximately 95%*".

7.3.5 Biological reference intervals and clinical decision limits

The requirement of the standard is applicable.

7.3.6 Documentation of examination procedures

The requirement of the standard is applicable.

7.3.7 Ensuring the validity of examination results

The requirement of the standard is applicable.

7.3.7.1. General

The requirement of the standard is applicable.

7.3.7.2 Internal Quality Control (IQC)

The requirement of the standard is applicable.

7.3.7.3 External Quality Assessment (EQA⁶)

The requirement of the standard is applicable.

The laboratory must plan its participation in external quality assessments (EQAs) using a risk-based approach. Participation in EQAs may be requested by ACCREDIA from laboratories under accreditation or already accredited, as an element of assessment for granting or maintaining accreditation.

Whenever possible, the laboratory must use EQA providers accredited in accordance with UNI CEI EN ISO/IEC 17043. The use of non-accredited EQA providers must be justified.

7.3.7.4 Comparability of examination results

The requirement of the standard is applicable.

7.4 POST-EXAMINATION PROCESSES

7.4.1 Reporting of results

The requirement of the standard is applicable.

If an examination report (report) contains references to accreditation (e.g., because it bears the ACCREDIA mark), what is covered by accreditation must be clearly distinguished from any non-accredited activities performed by the laboratory. Please note that the use of the ACCREDIA mark

(and/or reference to accreditation) on reports is only allowed if the report contains at least one accredited examination performed by the laboratory itself.

See also ACCREDIA Regulation RG-09.

Regarding point c) of 7.4.1.7, if the external laboratory that performed the examinations is accredited ISO 15189 for those specific activities, it is not necessary to indicate that those examinations are not accredited, provided that the accreditation number of the external laboratory is indicated and, in the case of a non-Italian accreditation body, the name of the accrediting body.

Concerning report corrections, it is specified that reports must be corrected and reissued in case of

- incorrect or misleading use of the ACCREDIA Mark or reference to accreditation
- errors in examination results
- any other deficiency or error that may lead to the misuse of the report or compromise the correct understanding of the results.

When a report containing this type of deficiency is identified, the laboratory must provide, as part of the management of the non-compliant activity, to review all the reports issued, trace, correct and re-issue all those affected by the same deficiencies.

In the case of corrections, the new document issued by the laboratory must clearly indicate whether the original report is cancelled and replaced.

In exceptional cases where it is necessary to correct purely formal (editorial) aspects of reports already issued without changing their validity, it may be acceptable to issue a general correction document, provided that the information required by the standard in §7.4.1.8 is guaranteed (e.g., clear identification of reports affected by the same deficiency, corrected information, reasons for correction).

7.4.2 Post-examination handling of samples

The requirement of the standard is applicable.

7.5 NON CONFORMING ACTIVITY

The requirement of the standard is applicable.

Please note that for non-conforming activities that impact on the possibility of maintaining the requirements for accreditation, the laboratory must communicate ACCREDIA the accreditation self-suspension for the non-conforming activities.

7.6 DATA CONTROL AND INFORMATION MANAGEMENT

The requirement of the standard is applicable.

7.7 COMPLAINTS

The requirement of the standard is applicable.

7.8 CONTINUITY PLANNING AND EMERGENCY PREPAREDNESS

The requirement of the standard is applicable.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1 GENERAL REQUIREMENTS

8.1.1. The requirement of the standard is applicable.

At the first accreditation and renewal stage, the Laboratory shall provide ACCREDIA with sufficient information to allow an understanding of how the Laboratory operates to achieve and maintain compliance with the requirements of UNI EN ISO 15189 and ACCREDIA.

To this end, the Laboratory must indicate at least the following on the appropriate ACCREDIA forms (*self-assessment*):

- a brief description of how the laboratory applies the requirements of UNI EN ISO 15189, without excessive reference to procedures and/or annexes
- the main responsibilities involved in the implementation of procedures and record keeping
- in the case of laboratories with several locations, including those where samples are collected and taken (sample collection facilities), an indication of where the activities are carried out and records kept
- in the case of laboratories seeking accreditation also for examinations performed at the point of care (POCT) a brief description of how the laboratory applies the requirements of Annex A of UNI EN ISO 15189, without excessive reference to procedures and/or annexes
- any exclusions or inapplicability of certain requirements, together with the corresponding reasons.

As an alternative to *self-assessment*, the laboratory may prepare a Management System Manual including the above information.

In the event of significant changes to the Laboratory's organisation and/or adopted policies and procedures, ACCREDIA may request an update of the *Self-Assessment/Management System Manual*.

Please note that the self-assessment is a form prepared by ACCREDIA and filled in by the Laboratory, for the purpose of submitting the application for accreditation and, as such, does not replace what is required by the UNI EN ISO 15189 standard at § 8.2.1.

8.1.2 The requirement of the standard is applicable.

8.1.3 The requirement of the standard is applicable.

8.2 MANAGEMENT SYSTEM DOCUMENTATION

The requirement of the standard is applicable.

8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS

8.3.1 The requirement of the standard is applicable.

In the case of updates to documents of external origin (e.g., documents that the laboratory must incorporate into its management system, standards, methods, regulations), unless a transitional period is defined otherwise, and without prejudice to any mandatory provisions, the laboratory is obliged to apply the new versions within three months of issue.

8.3.2 The requirement of the standard is applicable.

Handwritten corrections are permitted on documents for internal use only, if there is an urgency. Such amended documents shall be updated promptly.

8.4 CONTROL OF RECORDS

8.4.1 The requirement of the standard is applicable.

8.4.2 The requirement of the standard is applicable.

8.4.3 The requirement of the standard is applicable.

In particular, all records must be kept for a period of time at least equal to that defined by the legislation applicable to the activities subject to accreditation and, if not provided for, must be maintained for at least 48 months.

8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES FOR IMPROVEMENT

The requirement of the standard is applicable.

8.6 IMPROVEMENT

The requirement of the standard is applicable.

8.7 NONCONFORMITIES AND CORRECTIVE ACTIONS

The requirement of the standard is applicable.

8.8 EVALUATIONS

8.8.1. General

The requirement of the standard is applicable.

8.8.2. Quality indicators

The requirement of the standard is applicable.

In order to promote the appropriateness of the improvement objectives that the laboratory defines and monitors, the use of harmonised indicators is recommended (See for example the list of indicators of the *International Federation of Clinical Chemistry and Laboratory Medicine* (IFCC) working group and the CLSI document QMS12-A).

8.8.3 Internal audits

The requirement of the standard is applicable.

Internal audits may be performed either by internal personnel or by external assessors, provided that objectivity and impartiality of the process is ensured and provided that the personnel performing the audit demonstrates the necessary competence with regard to knowledge of the UNI EN ISO 15189 standard and the requirements of accreditation.

Second- and third-party audits cannot replace internal laboratory audits.

8.9 MANAGEMENT REVIEW

8.9.1. The requirement of the standard is applicable.

Extraordinary reviews may become necessary as a result of findings whose corrective actions require special investments (e.g., purchase of new equipment, recruitment of staff) or organisational-structural changes (laboratory layout, staff reorganisation).

8.9.2 The requirement of the standard is applicable.

8.9.3 The requirement of the standard is applicable.

ANNEX A – ADDITIONAL REQUIREMENTS FOR POINT-OF-CARE TESTING (POCT)

The requirement of the standard is applicable.

The laboratory may only apply for accreditation of examinations performed in the proximity of patients (POCT) if it ensures compliance with the applicable requirements of UNI EN ISO 15189, including those set out in Annex A. The laboratory does not necessarily have to have the same examinations requested at the POCT in its scope of accreditation.