ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

TITLE **GENERAL PROCEDURE FOR THE ASSESSMENT OF TESTING LABORATORIES, MEDICAL LABORATORIES AND PROFICIENCY TESTING PROVIDERS (PTPs)**

REFERENCE **PG-09-DL**

REVISION **08**

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NOTE *The present 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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CONTENTS

1. SCOPE AND FIELD OF APPLICATION

This procedure describes the modalities to be respected by Assessors, Technical Experts and the ACCREDIA personnel for arranging and performing assessments for accreditation, reaccreditation, surveillance, extension, supplementary and non-programmed assessments.

In undertaking and recording their activities the Assessors/Technical Experts shall also respect the operative indications contained in ACCREDIA's modules which are necessary for assessments.

This procedure is applicable to Testing Laboratories, Medical Laboratories and Interlaboratory Proficiency Testing Providers - PTPs.

2. REFERENCE DOCUMENTS AND ABBREVIATIONS

2.1. REFERENCE STANDARDS

2.1.1. INTERNAL DOCUMENTS

- RG-02: Regulation for the accreditation of Testing Labs and Medical Labs;
- RG-02-01: Regulation for the accreditation of Testing Laboratories, Medical Laboratories and interlaboratory multisite Proficiency Testing Providers;
- RG-14: Regulation for the accreditation of interlaboratory PTPs;
- CO-03-DL: Contractual agreement for assessors/Technical Experts – Dept. of Testing Labs;
- RT-08: Provisions for the accreditation of Testing Labs;
- RT-23: Regulation for the definition of the scope of accreditation;
- RT-24: Proficiency Tests;
- RT 26: Provisions for accreditation with flexible scope of accreditation;
- RT-27: Provisions for the accreditation of interlaboratory PTPs;
- RT-35: Provisions for the accreditation of Medical Labs;
- Information and Technical Circulars (for the list of Circulars currently in force see the list LS-19 available on ACCREDIA's website);
- Operative instructions for the online applications for the Testing Laboratories for presenting the application (DA-online) and for managing the visit and post-visit activities (application 3A);
- IO-09-02-DL: Operative instruction for the conduct of unannounced assessments;
- IO-09-05-DL: Operative instruction for the conduct of preliminary assessment activities;
- IO-09-06-DL: Operative instruction for the conduct of remote assessments;
- PG-07-DL: Procedure for the qualification and monitoring of ACCREDIA-DL assessors and technical experts;
- Modules currently in use by the DL.

For each document the latest revision is applicable[1].

[1] Some documents are for internal use only and are not published on ACCREDIA's website.

2.1.2. NORMATIVE DOCUMENTS

- UNI CEI EN ISO/IEC 17011 General requirements for accreditation bodies accrediting conformity assessment bodies;
- UNI EN ISO 19011 Guidelines for management system audits;
- UNI CEI EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;
- UNI EN ISO 15189 Medical laboratories - Requirements for quality and competence;
- UNI CEI EN ISO/IEC 17043 Conformity assessment - General requirements for proficiency testing;
- UNI EN ISO 22870 Point of Care Testing (POCT) - Requirements for quality and competence;
- UNI CEI EN ISO/IEC 17000 Conformity assessment – Vocabulary and general principles;
- EA, ILAC, WADA applicable documents (see LS-04);
- Mandatory standards, where applicable.

2.2. DEFINITIONS

For the purposes of this document the terms and definitions adopted are those of standards UNI/CEI EN ISO/IEC 17011 and UNI EN ISO 17000.

When the terms and definitions are not contained in the above standards, those contained in UNI EN ISO 9000, UNI CEI EN ISO/IEC 17025, UNI EN ISO 15189, UNI CEI EN ISO/IEC 17043 and in the ACCREDIA Regulations are applicable.

The term ‘assessor’ is used, in this procedure with the meaning of assessor and technical expert.

The term 'subcontractor' means organization or person appointed by the proficiency testing organizer to carry out activities specified in this international standard and which have an influence on the quality of a proficiency testing scheme (ref. UNI CEI EN ISO/IEC 17043 §3.14).

2.3. ABBREVIATIONS

The following abbreviations are used in this document:

- Conformity Assessment Body. For the purposes of this procedure a CAB is a Testing Lab (LAB scheme – ISO/IEC 17025); a Medical Lab (MED scheme – ISO 15189); or a PTP (PTP scheme – ISO/IEC 17043);
- CSA-DL: Sector Accreditation Committee Dept. of Testing Labs;
- DDL: Director of the Dept. of Testing Labs;
- ESP: Technical Expert;
- EVA Officer for the monitoring of assessors;
- FT: Technical Officer;
- GVI: Assessment team;
- LAB: Testing Labs;
- MED: Medical Labs;

- PTP: Proficiency Testing Provider;
- RGVI: Lead Assessor.

For anything not expressly indicated, reference should be made to the accreditation regulations and to the EA and ILAC documents, for the schemes covered by this procedure.

3. PRELIMINARY ACTIVITIES

3.1. APPOINTMENT OF ASSESSORS

For all accreditation and reaccreditation procedures the DDL appoints the assessors, and technical experts if necessary for the assessment of the CAB. Unless otherwise decided by the DDL, they shall retain the appointment also for subsequent surveillances (or other) visits at the same CAB for the remaining period of the 4-year agreement of accreditation.

The assessment team usually includes one systems assessor (also tasked to coordinate the team – the lead assessor) and one or more technical assessors. The choice of the technical assessors is made so that their competences cover all the CAB's scope of accreditation, including verification of the requirements for opinions and interpretations (O&I), for testing laboratories according to the standard UNI CEI EN ISO/IEC 17025:2018 and statistical processing of data for PTPs and blood sampling activities and POCTs foe medical labs.

In the case of small CABs and when the competences permit this, the group can also be reduced to a single assessor who, in this case, performs both the function of System assessor and that of Technical assessor, provided that s/he possesses the necessary skills to carry out of the dual role.

The assignment is made according to the methods and criteria set out in Reg. RG-02 and in the PG-08-DL internal procedure.

The assessors receive the communications of appointment and also the documents of the CAB which they will have to examine.

According PG-07-DL criteria and modalities, the DDL also appoints observers, trainee assessors and EVAs.

3.2. ACCEPTANCE OF THE APPOINTMENT BY ASSESSORS

By signing the ACCREDIA DL assessors agreement (CO-03-DL), the assessors assume all the commitments envisaged therein, in particular the conditions of impartiality, independence and confidentiality regarding the acceptance of the tasks proposed by ACCREDIA-DL.

For ACCREDIA employee assessors, the same commitments of impartiality, independence and confidentiality are undertaken by signing the internal personnel regulation.

4. DOCUMENT REVIEW AND FOLLOW-UP ACTIVITIES

4.1. DOCUMENT REVIEW

Before the performance of each on-site assessment, the members of the team shall be given all the information available with regard to the CAB by means of a thorough examination of its application, when necessary, and of all the attached technical/scientific documentation. ACCREDIA ensures that the team has all the necessary documents, carrying information covering previous assessments and the CAB's records and documents needed for the assessment.

ACCREDIA sends the documentation received from the CAB to the team by email, except in cases where the attachments need different types of transmission (i.e. hard copy).

The team shall take into consideration any communications already sent by ACCREDIA to the CAB in the preliminary phase of acceptance of the application for accreditation, and check that the CAB has responded adequately. These communications are sent in copy to the assessors together with the remaining documentation of the CAB.

When strictly necessary, the team can ask ACCREDIA for additional documents to complete their examination, or for the subsequent availability of testing samples or for the preparation of an assessment (e.g. testing standards, other documents from the CAB etc.).

In the phase of examination of the CAB's documents, the assessment team shall verify the conformity of the system as documented, with the requirements of the reference documents as well as those of ACCREDIA, and set out in ACCREDIA's technical regulations RT-08, RT-23, RT-24, RT-26, RT-27 and RT-35 and in any applicable Circulars (e.g. CPR)[2]. The team shall evaluate the aspects related to the structure, organization, main personnel tasks and technical competences of the CAB referring to tests/activities which are necessary for the granting of accreditation.

In particular, for Testing Labs and Medical Labs, the assessment team shall evaluate all the methods concerning the tests/sampling/examinations which are in the scope of accreditation, verifying the consistency between such tests and the relative methods with regard to the title, the field of application, the validation and the normative references, the equipment, the statistical methods.

For Testing Labs requiring assessment according to UNI CEI EN ISO/IEC 17025:2018, and which require O&I under accreditation, the team shall verify the compliance with the requirements of the RT-08 Regulation for staff competence and modalities for expression of O&I.

During the document review phase, the GVI must also evaluate any additional requirements for particular sectors (e.g. WADA, FCC, EPA, CPR, EPPO), as applicable.

The assessment team of a PTP shall evaluate, for all the schemes applied for, the organizational modalities, statistical analysis and preparation of reports.

For CABs accredited with flexible scope, the team shall perform the documental review of all detailed list describing flexible scope, managed by the CAB from de previous on-site assessment, with particular regard to: changes/inclusions/deletions in the detailed list and compliance with the scope of flexibility.

[2] For the list of Circulars currently in force see the list LS-19 available on ACCREDIA's website.

4.1.1. Document review for accreditation and renewal

The documental review for accreditation and renewal includes the application form and all the relative docs.

For renewal, documents also include records and technical information relating to previous assessments, including any document examination of complaints received by ACCREDIA and related to the CAB's work.

4.1.2. Document review for programmed and non-programmed surveillance and supplementary assessments

For programmed surveillance, non-programmed surveillance and supplementary assessments, documents include records and technical information relating to previous assessments, including any documentary examination of complaints received by ACCREDIA and related to the CAB work, new versions of the accreditation application form and its attachments (i.e. All.1 DA-02/06/08, MS Manual) if available, detailed list describing flexible scope, managed by the CAB from the previous on-site assessment.

For PTPs, if the report is not available on the CAB website, the assessors may ask CAB for PT reports issued from the previous on-site assessment, to evaluate contents and calculations.

4.1.3. Document review for extension assessments

The application for extension can be presented by the CAB for a joint assessment with a surveillance, ad hoc or office visit. The CAB documentation to be evaluated for the extension procedure consists of the extension application and the applicable annexes, as required by the General Regulations RG-02 and RG-14.

For automatic extension, the competent assessors shall perform only the document review, specifying if the tests for which extension is sought are similar to those already accredited and if the extension can be granted. The approval of the office extension is however decided by ACCREDIA (see RG-02 e RG-14).

4.1.4. Document review for complaints or other docs

At any time during the accreditation cycle, a document review may be required by one or more of the assessors, without necessarily requiring an on-site assessment. For example, a document review may be required for: general corporate variations, change of location or name, complaints or feedbacks concerning the CAB's work..

The documentation to be evaluated depends on the type of verification requested (see RG-02 and RG-14).

4.2. PREPARATION OF THE REPORT OF THE DOCUMENT REVIEW (RED)

Each assessor, before each assessment, prepares his/her own RED using the MD-09-03-DL module and following the indications it contains.

Each assessor sends, within 15 days of receipt of the appointment, his/her RED to the lead assessor who examines them with a view to a general appraisal concerning the possibility of carrying out the assessment, to be reported in the MD-09-03-DL.

In his/her own MD-09-03-DL, the lead assessor shall indicate all the findings of the team, on the assessed documentation, taking care to integrate in an appropriate way and with uniform language the findings found by the other members of the team; s/he shall avoid any repetitions and highlight, in a note addressed to the Technical Officer, any closure of one or more findings of the other members of the team, or the substantial change, giving explicit motivations.

If the CAB's documentation presents significant failures regarding its management system or technical factors, the lead assessor may request a revision of the documents to be conducted by the CAB in response to the findings. If, however, the documentation conforms with all the applicable requirements and regulations, the lead assessor proposes the performance of the assessment, requesting the CAB, if necessary, to prepare a draft revision for the assessment.

On his/her own RED, after consulting the assessment team, the lead assessor shall indicate the duration foreseen for the activities of each assessor.

For the assessments of the system, the assessment duration is determined on the basis of the results of the examination of the quality manual (or self assessment, if adopted by Testing Labs the MS manual for verification against UNI CEI EN ISO/IEC 17025:2018 for the relevant checks by the Technical Assessors, on the basis of the time necessary to undertake the verification of the tests foreseen by the sampling of tests/exams/schemes (see par. 4.5).

The duration of the assessment in days, however, is decided by ACCREDIA-DL for the performance of a complete risk-based assessment and it is formalized in the assessment plan.

The lead assessor sends to ACCREDIA, **within 20 days** of receipt of the appointment, his/her RED (MD-09-03-DL plus any other data sheets subsequent to MD-09-04-DL) and also those of the other assessors of the team.

4.3. REQUEST FOR ADDITIONAL INFORMATION, CLARIFICATION AND/OR EXTRA DATA

If necessary, on the basis of the overall report received from the lead assessor, ACCREDIA sends to the CAB a request for additional information containing the findings raised and any request for revised documents.

The documental review can be repeated several times before the on-site assessment, provided that the deadlines set by the General Regulations RG-02 and RG-14 are respected.

4.4. PRELIMINARY TECHNICAL MEETING

If numerous significant findings are raised by the assessors with respect to the CAB’s documentation and if deemed necessary to benefit the accreditation procedure, ACCREDIA can offer the CAB the possibility to meet with the system and/or technical assessor, in the presence of the FT.

This meeting takes place at ACCREDIA’s offices or remotely and does not last more than half a day. Its aim is to analyze and clarify the findings and it shall not take the form of a consultancy (also unintentional).

4.5. SAMPLING OF TESTS, EXAMS AND SCHEMES

4.5.1. General indications for the sampling of tests/exams/schemes

FOR ACCREDITATIONS AND REACCREDITATIONS a 4-year sampling plan shall be prepared to ensure coverage of all the matrices and testing techniques during the accreditation cycle:

- covering all the matrices and testing techniques, including sampling where applicable, for testing/medical labs;
- covering all the scheme typologies, for interlaboratory PTPs;
- covering all types of O&I for testing labs.

For reaccreditations, the sampling shall take into account the sampling of the previous accreditation cycle (sent to the technical inspectors with the appointment or available on the 3A app.).

For **multisite CABs**, the provisions of Regulation RG-02-01 apply; therefore, sampling must be arranged for each location where activities within the scope of accreditation are carried out (tests / examinations / schemes / sampling), ensuring the above indications. In locations where partial activities and/or support activities are undertaken under accreditation (e.g. warehouse, sample storage, preparation of the samples), it is not necessary to prepare a sampling form, but it is necessary to define, with the FT, the timeframe for the activities to be performed at this location (for example on the RED form). Considering the site sampling methods regulated by RG-02-01 and unless otherwise indicated by the FT, for multisites with more than one secondary site, the sampling module must be completed only for two visits. This sampling must ensure the representativeness of the overall accreditation scope of the laboratory.

The 4-year sampling plan (2-year plan for secondary multisite locations as per the previous paragraph) may be modified/integrated following a request for **EXTENSION OR REDUCTION** of the scope of accreditation, following complaints or feedbacks, the negative results of PTs or the need to verify the effectiveness of CAs implemented by the CAB or based on the risk analysis following each assessment. In such cases the sampling module shall also contain tests/exams/schemes sampled during the previous cycle so that sampling is always representative of the entire cycle of accreditation. In the case of the elimination of any activities previously sampled tests, it is sufficient to give an indication in the notes section of the module. In all cases, unless it is an ad hoc extension, at least one of the tests during a surveillance shall be sampled.

FOR SURVEILLANCES, the assessor shall send the sampling module of tests/exams/schemes, describing, in the section for notes, any communications to be sent to the lab before the assessment visit (e.g. the single matrices which the assessor intends to assess); any indications for the assessment of the sampling, (e.g. surfaces, carcasses, emissions; communications to be transferred to the lab before the assessment).

If an automatic extension has been granted before the surveillance, the relevant tests shall be sampled in the next surveillance, except for any reasons specified by the assessor.

It is not required to send the test/exam/scheme sampling module in surveillance, in case no variations in the test sampling are necessary, compared to what has already been communicated for previous visits. If necessary to send specific communications to the CAB about the preparation of the sampled activities, the assessor can transmit indications to the FT by email.

If the ACCREDIA decides to modify or make additions to the sampling of tests/schemes prepared by the assessors, these shall be communicated by the FT to the team. If there are three or four technical assessors in the assessment team they shall coordinate the sampling in such a way as to avoid duplication of the assessment of equipment/techniques of tests/examinations/schemes on the basis of the instructions for sharing sent by the technical officer.

The sampling of tests may be modified during the assessment in accordance with § 6.5.

4.5.2. Testing Laboratories and Medical Laboratories

Following receipt of the engagement, and at least one month before the proposal for the assessment, the technical assessors propose to ACCREDIA the sampling of tests/exams to assess during the assessment, on the basis of criteria as defined below:

1. the tests for which the laboratory seeks accreditation will be split into homogeneous groups; the criteria for homogeneity of a group may be, for example, the testing methods, equipment used, the typology of scope of assessment (flexible or fixed) the matrix or product tested, the site of performance of the tests (if the lab has applied for accreditation for tests in categories I, II or III, POC), the frequency of controls and the health importance, where necessary.

2. the sampled tests/examinations may be assessed using the checklists in accordance with three modalities:

    - **LEVEL 1 – VERTICAL**: assessment of the complete performance of the test/exam by a qualified operator in the presence of a technical assessor during the assessment.
    - **LEVEL 2 – DOCUMENTAL**: documental assessment of records, starting with sampled test reports from the archive.
    - **LEVEL 3 – REPEATABILITY AND ACCURACY**: complete performance of a test in duplicate by a qualified operator and assessment by a technical assessor of the results of the uncertainty measurements and repeatability. For some types of activities, verification at level 3 may not be applicable (e.g. qualitative tests, sampling, blood tests).

It is also possible to adopt a combination of **LEVELS 2+3**. In this case, both the above indications for level 2 and level 3 must be applied.

3. for each group of homogeneous tests/examinations, a number deemed enough to determine the technical competence of the laboratory will be sampled, so to guarantee, with a good level of reliability, that operators, equipment and instruments are capable of performing the other tests/examinations, covered by the same homogeneous group satisfactorily and using suitable equipment.
4. consider the criticalities raised during previous visits (e.g. NCs, outcomes of PT participations, staff turnover, suspensions, transfers of location etc.
5. it is also possible to sample internal calibrations of equipment used for accredited tests, in order to integrate the verification of the sampled activities (test/ sampling/examinations).
6. in certain areas a conformity assessment is necessary against specific requirements (e.g. WADA, FCC, EPA, CPR).

For every sampled test or exam the technical assessor shall indicate in the appropriate field of the test/examinations sampling module:

- the homogeneity criteria used;

- the typology of assessment chosen;
- the matrices/parameters/methods chosen which shall be kept and made available by the lab (if, for a single test there are different accredited matrices/parameters/methods);
- the request for duplicate preparation/performance of tests (see §6.5 below);
- the possible need to communicate in advance the test to the lab;
- the specific sampled test (matrix/parameter/method), in the case of flexible scope accreditation, selecting it from the list of the details of the flexible scope tests/exams managed by Testing Labs on ACCREDIA's website and by Medical Labs on their own website;
- notes (if any): if the performance of the test/exam includes successive phases with long intervals (e.g. for conditioning the specimen, for reasons of chemical reactions or growth of cell cultures), the technical assessor may, in order to reduce wasted time in the assessment, request the performance of a series of repetitions of the same test/exam on different samples at different intervals, in order to verify the important phases in a limited period of time. Such request, together with any other necessary ones to ensure that the lab is ready to perform the required tests, shall be indicated by the technical assessor in the notes of the test sampling module.

For the level 2 tests, the assessor shall always verify as follows:

- results of the PTs and/or other quality assurance activities regarding validity of the results;
- the conformity of sampled test reports (if available);
- the records concerning the validation of the testing methods and of the assessment of performances by the lab for the application of the standardized methods;

The assessor shall also specify, on the sampling module, which of the following requirements s/he intends to assess:

- the qualification of personnel, including results of the PTs, with the aim of assessing the competence of a significant number of technicians;
- the calibration of equipment, including measurement traceability;
- measurement uncertainty and repeatability;
- the assessment of the records for evidence of traceability from the sampling to the approval of the results and control modalities of calculations and data;
- other requirements: limit of determination (LOD); limit of qualification (LOQ), recovery etc. and the compliance with any mandatory requirements.

Regarding the **advance communication of tests/examinations** to the laboratory:

- sampled tests/examinations (level 1 and/or level 3) must be communicated in advance to the lab only in cases where failure to communicate could compromise the possibility of carrying out assessments due to the following factors:
  - the need to prepare before the assessment visit;
  - the need for there to be particular ambient conditions (e.g. off-station tests, samplings or long conditioning of the specimen);
  - the tests are to be conducted on samples which are not usually available in the lab;
- the tests/exams sampled at level 2 shall not be communicated beforehand, owing to the fact that performance by the lab is not required.

The number of tests/exams sampled (in terms of technique and/or method, matrices, parameters) shall be representative with respect to the tests assigned to the technical assessor, irrespective of the level of assessment chosen.

In all cases and for every assessment, the technical assessor shall sample at least one level 1 test/exam and others at level 2 and/or 3. It is not acceptable to sample only one test for each level given that the level 2 and 3 tests are assessed only for certain requirements.

In the case of considerably reduced scopes of accreditation, where the sampling of level 1 tests/examinations is already representative, it is not necessary to require as obligatory also level 2 and 3 tests.

Tests/exams may be sampled also more than once during the accreditation cycle and also according to different levels.

4.5.2.1. Criteria and indications for formulation of the sampling

The Technical assessors shall prepare the sampling for the accreditation cycle, considering the risk related to the activities present in the scope of accreditation.

The following are the risk factors to consider in the planning of the four-year sampling:

- **Impact on mandatory activities:** if the CAB carries out activities in a cogent sector or for the purposes of product certification or recognition, it is important that these aspects are considered in the choice of sampled activities (e.g. laboratories operating for certification in the organic sector or for the purposes of CE marking).
- **For Testing Labs carrying out official controls on food** the sampling shall be undertaken taking also into consideration the health relevance of the test concerning food safety with reference to communications through the RASFF (Food and Feed Safety Alerts) system, to the results of the monitoring plans of residues in vegetable origin food products and in the production of foods of animal origin and any notifications on a national level. The sampling shall also take into consideration any nonconformities raised by the Regional Health Authorities and the Ministry of Health (e.g. identification of PCB, PCDD, PCDF, pesticides, mycotoxins, residues of banned veterinary medicines for the chemical sector; research of Vibrio cholerae, salmonella, E. Coli O.157, Campylobacter, Lysteria, TSE, Brucella for the biological sector; identification of emitters of gamma radionuclide for the physical sector, GMO research and other tests), and in correspondence with the introduction of mandatory legal requirements regarding certain categories of food products, the sampling shall include at least one test regarding the matrix which is the object of updated legislation.
- **For Testing Labs carrying out tests on samples obtained during agricultural organic production controls**, in the sampling plan there shall be the tests for recognition of laboratories (see the document ACCREDIA DT-03-DC).
- **For testing labs carrying out tests in certain sectors**, where specific requirements are applicable (e.g. EPA/FCC/WADA/EPPO/CPR): make sure to include in the sampling the activities required for the purpose of any recognition/authorization.

  For laboratories performing tests to determine formaldehyde in wood-based panels for the purpose of EPA recognition, the tests required by EPA must be sampled in every assessment.
- **For Testing Labs performing sampling activities**, sampling activities shall also be assessed, if possible on-site and not simulated.

Emission tests, during the phase of the granting of extension or accreditation, shall be sampled as level 1 (using the relevant checklist). For surveillance or renewal, when applicable, they can be sampled also as level 2 and/or 3.

- **With regard to the analysis of contaminants, chemicals or microbiological substances**, it is necessary to request the availability of a positive sample, either natural or artificially contaminated, in order to assess the capability of the lab also by means of a duplicate test/examination.
- **For microbiological tests**, where applicable, it is necessary to sample both a numerical test (e.g. positive Coagulase Staphylococci) as well as a research of pathogens (e.g. salmonella or lysteria) in order to verify the competence of the lab for both testing categories and all the tests of confirmation shall be assessed.
- **Sensory tests:** they shall always be sampled in the first accreditation assessment.
- **Tests on asbestos:** they shall always be sampled in the first accreditation assessment.
- **CPR**: during all initial accreditation, surveillance and/or extension and renewal assessments, a significant sampling of the tests relating to the CPR sector must be done in accordance with the ACCREDIA regulations, taking into account the risk associated with the activities, sites and personnel who come within the scope of the accreditation. This activity must also take into consideration any tests carried out at the manufacturers' testing facilities, through the use of equipment not owned by the laboratory, or subcontracted tests.
- **Opinions and interpretations (O&I)** – applicable only for Testing Labs performing verification according to UNI CEI EN ISO/IEC 17025:2018 – they shall always be sampled in the initial accreditation assessment or extension phases, regardless of the sampling of the associated test. This shall be a level 2 (document) assessment by means of interviews with staff qualified to issue opinions and interpretations.
- **Frequency of performance:** it is a risk factor related to the ability of the CAB to constantly maintain compliance with the requirements for accreditation. On the basis of the information provided by the DA-online system, where applicable, it is necessary to consider the critical issue of rarely performed activities.
- **Internal/standardized methods:** the use of internal methods is a higher risk factor than standardized methods, as the planning and validation phase of the method is also required. In addition to the document verification required for all internal methods, it is important that these methods are sampled on-site, to verify the design, validation and operativity.
- **Availability of PT, RM, assurance activity of the validity of the results:** the availability of control activities, validity of internal and/or external results, is an indirect tool for the evaluation accredited activity. Sectors in which the availability of activities to ensure the validity of the results is small or absent shall be more closely monitored by means of on-site sampling activities.
- **Accreditation of tests/exams with flexible scope:** this accreditation includes a trust placed in the CAB, which is authorized to manage independently its list of accredited activities, and the verification by ACCREDIA takes place during the visit. Sampling must therefore be based on revisions of the list of accredited activities managed by the lab between two consecutive on-site visits, to assess the records and validation of the methods for which changes were introduced with respect to the previous assessment (see RT-26).

  The technical assessor shall indicate in the sampling module, the specific tests/exams chosen from the list managed by the lab. If several revisions of the detail list have been issued between two consecutive on site visits, the assessor shall take this into consideration, in order to plan

both the choice of the tests and the time commitment required for the verification on site. It is also possible to select tests/exams which the lab has kept in the list of details for a temporary period, because, during the cycle of accreditation it is necessary to guarantee all the relevant records. The tests/exams retained in the detailed list for a limited period of time, which are not accredited at the time of the assessment, can be sampled at level 2-documental.

If, however, the detailed list has not been revised by the previous visit, the assessor considers the detailed list as integrative of the list with fixed accreditation and carries out the sampling according to the criteria of representativeness indicated in the previous paragraph.

- **For Medical Labs requiring POCT and sampling collections site accreditation:** the technical assessor shall prepare a representative sampling of all the types of blood tests and activities carried out at each site and the type of diagnostic systems used at the POCTs.

In the particular case of Medical Laboratories, it may not always be possible to verify the real execution of a sample or examination on a patient; therefore also simulated activities are also acceptable, provided they are representative of the actual conditions and operating procedures.

For POCT the additional requirements of UNI EN ISO 22870 are applicable.

4.5.3. Interlaboratory Proficiency Testing Providers

Following receipt of the assignment and at least one month before the proposed date of the assessment, the FTs propose to ACCREDIA the sampling of the schemes to be assessed. The schemes to be assessed during each assessment shall be sampled in accordance with the PTP's annual plan (also consulting the PTP's website, on the basis of the following criteria:

- assess the PTP's ability to evaluate outsourced critical activities subcontracted to other organizations (which have a significant influence on the quality of the scheme), where necessary;
- ensure the assessment of every type of scheme under accreditation (UNI CEI EN ISO IEC 17043 – Appendix A), during the accreditation cycle;
- ensure the assessment of the techniques and equipment which impact the quality of the scheme in use for the preparation and testing of the objects to be tested during the accreditation cycle;
- ensure the verification of the competence of the staff;
- ensure that the assessment of all the PTP's sites at which activities concerning the accredited schemes take place;
- ensure the assessment of the adequacy of the statistical model used and of the proper implementation of the declared statistical techniques in use;
- assess the performances of the PTP with regard to measurement uncertainties;
- take into consideration the criticalities raised in previous visits (e.g. NCs, turnover of personnel, suspensions, transfer of locations etc.).

The number of sampled schemes shall be sufficient to assess, during the visit, the compliance of the organization with all the requirements of the reference standards and to determine the technical competence (minimum of 2 per assessment).

For every sampled scheme the technical assessor shall indicate in the appropriate fields of the module for the sampling of schemes as follows:

- the criterion of representativeness taken into consideration;

- the specific requirements s/he intends to assess during the visit in question (the absence of indications means the verification of all the requirements);
- any actual or simulated activities s/he intends to assess (e.g. packaging, freeze-drying, preparation of the objects to be tested);
- possible request for the assessment of conformity against ISO/IEC 17025 of one or more tests/calibrations carried out by the lab (or against ISO IEC 15189 if it is a medical lab) if the lab is not accredited against ISO/IEC 17025 – ISO 15189 for the specific test/calibration/exam);
- possible request for the on-site assessment of the audit activities of the technical competence and conformity to requirements of the standard on the part of the PTP regarding subcontractors (e.g. witnessing during the second phase audit performed by the PTP on the subcontractor).

With regard to the **advance communication of the schemes to the PTP**: usually the sampled schemes are not communicated in advance to the PTP except when:

- the scheduled assessments are not in line with the PTP's planning and it is therefore to ACCREDIA's discretion to request the preparation of simulated activities;
- the assessment foresees/requires access to sites and organizations which are not under the accredited PTP's authority; the PTP has the task of managing the logistics with regard to access.

Sampled schemes are assessed using the relative checklists, in accordance with the following modalities:

- document assessment of the records, starting from PT reports sampled from the archive;
- assessment of actual or simulated activities;
- assessment of testing/calibration/examination activities in cases where the PTP has, within its structure, a testing/calibration/medical lab, which performs PT activities organized by the PTP itself (e.g. tests for the preparation of materials, tests for the assessment of homogeneity and/or stability, determining the assigned value);
- assessments at subcontractors.

4.5.3.1. Criteria and indications for the formulation of sampling

The Technical Assessors shall prepare the sampling for the accreditation cycle, considering the risk related to the activities present in the scope of accreditation.

The following are the risk factors to be considered in the planning of the four-year sampling:

- **Mandatory impact:** if the PTP carries out activities in a binding sector or for the purposes of product certification or recognition, it is important that these aspects are considered in the choice of sampled activities.
- **Number of participants:** In choosing the schemes to be assessed, the assessor shall also consider the number of participants, paying particular attention to the schemes with a low number of participants, and to those with very numerous participations, for the appropriate verification of the statistical approach.
- **Accreditation of schemes with flexible scope:** this accreditation includes a trust placed in the CAB, which is authorized to manage independently its list of activities accredited, and the verification by ACCREDIA takes place during the visit. Sampling must therefore be based on revisions of the list of accredited activities managed by the lab between two consecutive on

site visits, to verify the records and activities – planned and undertaken – for which modifications occurred with respect to the previous assessment (see RT-26).

The technical assessor shall indicate in the sampling module the specific schemes chosen from the list managed by the PTP.

It is also possible to choose schemes which the PTP has retained on the list temporarily, because for the accreditation period all the pertinent records shall be guaranteed (the tests kept on the list for a limited period of time, which, at the time of the visit, are not accredited, may be subjected to a document assessment by means of the records).

- **Modality of definition of attributed value:** the assessor shall pay particular attention first to the PTs who attribute the consensus value rather than those using certified reference materials.
- **Test items and metrological traceability:** the assessor shall also consider the critical issues related to the preparation of the object of the evaluation test, the possible purchase and availability of suppliers (e.g. for PT in the calibration field availability of instruments in the case of accreditation with flexible field).
- **Subcontracted activities:** the assessor shall consider the impact on the performance of the PT; s/he can request a verification of the subcontractor, possibly during a verification of the provider at the supplier's premises.

5. PREPARATION OF THE ASSESSMENT VISIT

5.1. PREPARATION AND AVAILABILITY OF CHECKLISTS

An instrument for the assessment of documents is the checklist which every assessor shall fill in during the preparatory phase to the assessment.

On the basis of the information obtained, the assessors may add questions to the checklist for use during the visit. Such questions shall be highlighted and shall not replace the standard ones.

5.2. LOGISTICS OF THE ASSESSMENT VISIT

Outside the assessment the assessors are authorized to communicate with the CAB exclusively for the purposes of the organization of the logistical aspects of the assessment. All other communication regarding the assessment shall be done through the FT tasked with the management of the process. As a general rule it is the duty of the lead assessor to provide for the management and coordination of the logistical aspects of the assessment for all the team.

The date of the visit is agreed with the CAB:

- by the team for the surveillances and supplementary assessments;
- by the FT tasked to manage the process, for all other typologies of assessment.

For the performance of surveillances there is a permitted allowance period of

- one month in either direction with respect to the date set by ACCREDIA for LABs and MEDs,
- two months for PTPs in either direction with regard to the expiry of the surveillance, considering the frequency with which the PTP plans PT plans.

Any changes to this beyond the set schedule shall be authorized by the Director of Department.

The first surveillance takes place 6 months from the date of granting of first accreditation. In cases of transfer of accreditation to another AB, as set out in RG-02/RG-14 it is possible to perform the first surveillance 12 months after granting accreditation.

The subsequent surveillances are conducted every 12 months unless the CSA decides otherwise owing to the results of a surveillance or renewal visit. Following an advance assessment visit the schedule for the next surveillance is recalculated to 12 months, unless otherwise decided by the CSA due to the results of the visit in question.

In the planning phase, taking into account the team's indications, ACCREDIA DL defines the methods for undertaking the visit (in presence, remotely or mixed), on the basis of a preliminary feasibility analysis, in consideration of the risk level of the CAB, the type of activity to be verified and the provisions set out in the accreditation regulations.

6. PERFORMANCE OF THE ASSESSMENT VISIT

A representative of the ACCREDIA management usually participates in the accreditation and reaccreditation assessment. If the Department Director considers it necessary the representative of the management is also present for the surveillance and/or supplementary visits.

Any observers present shall not interfere with the performance of the assessment, but if this occurs the lead assessor ensures their exclusion from the assessment.

The lead assessor shall ask the CAB shall make available a reserved room or area with an internet connection if possible for preliminary, interim and closing meetings of the assessors team.

With regard to the assessment of test reports/reports issued by the CAB, each assessor shall attach reports of sampled test reports/reports sampled from the CAB’s archive following the indications given on the respective checklists.

Where there are no test reports for specific activities available, the technical assessor shall record the information on his/her own checklist, and s/he shall nonetheless verify the applicable requirements concerning the maintenance of technical competence on the part of the CAB (see §6.5.1.1).

Given the commitment to confidentiality of the ACCREDIA team and staff, it is advisable, in general, to make anonymous the heading of the test reports (customer references). In particular technological sectors (e.g. protection of industrial know-out), or in cases where reference is made to personal information (e.g. medical laboratories), anonymity is necessary.

If it is a first assessment the CAB shall have an active MS in place, able to produce reports in conformity with the requirements of the reference standard and with the technical regulations RT-08, RT-27 and RT-35. If it is possible, it is advisable to sample test reports from the archive during the period close to the assessment visit. For PTPs, for each accredited scheme, attached to the application for accreditation, there shall be the last assessment test report issued, therefore the assessor should verify others, if available.

6.1. PRELIMINARY MEETING AT THE START OF THE VISIT AND PREPARATION OF THE ASSESSMENT PLAN

The assessment team holds an meeting before the opening meeting with the CAB. If an ACCREDIA Department representative is present, s/he will take care to remind the assessors about the general criteria for the performance of the visit, as already described during the training course.

The lead assessor, with the help of the other assessors, prepares the schedule for the visit to present to the CAB during the initial meeting, taking into account:

- the availability of staff and the means to carry out a full check of the CAB's management system;
- the need to verify the implementation of the corrective actions related to findings raised during the document review from any previous visit;
- the number, sequence and location of the activities to be performed during the visit;
- the need to verify the truth of any complaint/feedback coming out from the market and the relative management of it.

During preliminary meeting, the lead assessor shall ensure the numbering of all the sampled tests/examinations/schemes in sequential order for each technical assessor.

The lead assessor shall draw the attention of the team to matters associated with security/safety, in compliance with CO-03-DL or with PG-19 in the case of dependent assessors.

6.2. INITIAL MEETING WITH THE CAB

During the initial meeting between ACCREDIA team and the CAB, the lead assessor introduces the ACCREDIA assessors, observers, EVAs and management representatives if present, describing the role of each, explaining the aims of the visit and performing all the steps provided for in the checklist in relation to the specific phase of the assessment.

The lead assessor shall request information with regard to the risks (if not already communicated during the programming of the visit) or request confirmation of the security/safety conditions already communicated to ACCREDIA by means of MD-19 during the programming of the visit (not applicable for remote assessments).

In particular, if the MD-19 was not sent by the CAB before the verification, team shall acquire it, duly completed and signed, during the initial meeting. In the event that it is learned, in the initial meeting or during the verification, that the necessary security conditions are not met, lead assessor shall proceed with the cancellation or interruption of the verification, immediately communicating this decision to ACCREDIA (see RG-02 , RG-14 and CO-03-DL or PG-19) (not applicable for remote assessments).

If there are any related needs signaled by the CAB during the initial meeting such as equipment failure, absence of staff etc., the team may modify the level of test sampling, recording the modification and the reasons for it both in the module MD-09-08-DL, of which a copy is given to the CAB at the end of the visit, and also in the module of appraisal of tests/schemes of the individual technical assessor.

In cases of impossibility of conduct of the test, this shall always be assessed at documental level (level 2), according to the requirements which, in the opinion of the technical assessor, are of greater importance. In addition, if necessary, the technical assessor may ask for the conduct (level 1 or 3) of

tests which, within the scope of accreditation, better correspond to the criteria used for the sampling of tests which were not carried out.

The tests sampled at level 2 shall always be assessed and shall not be substituted in the visit; for accredited tests the records shall always be guaranteed and retained with regard to the maintenance of competence of the lab (e.g. personnel qualifications, measurement traceability, assurance of the validity of results). If test reports are not available (e.g. because the test was not performed in recent years), the technical assessor shall record the information in the checklist, but the requirements concerning the test shall nonetheless be verified also in the absence of tests performed for clients, as it is a test for accreditation.

The assessor may choose to add tests examinations/schemes to those in the plan during the initial meeting if situations arise as described above.

During the initial meeting, the team defines the operators tasked for the sampled tests.

It is necessary to verify the competence of different operators, both for the performance of one assessment, and over the course of time. Regarding authorized personnel of the CAB, the choice of the team shall consider:

- **Occasional performance:** it is important to verify the operators who are qualified for a test/scheme/examination which they do not usually perform.
- **Number of authorized persons with respect to the accredited activities:** this information (available in the online DA system, where used) is necessary both to plan the activities in terms of logistics (number of interlocutors) and to evaluate, albeit on the whole, the relationship between activities and personnel. Any critical issues regarding the provision of the service shall be considered during the on-site verification.
- **Turnover/seasonality**: in some laboratories it is possible that there is a turnover, linked not only to organizational aspects, but also seasonal (e.g. fruit and vegetable harvesting).

  In the case of CAB with seasonal activities and staff, sampling of activities at level 2 (documental) should be preferred, to evaluate the staff even if not physically present during the visit. The high turn-over due to organizational problems may be a critical issue for the continued maintenance of accreditation requirements, which assessors shall report to ACCREDIA.
- **Experience:** in the selection of personnel, the assessors shall also take into account aspects related to the past records of staff within the CAB, evaluating the different critical issues related to highly experienced staff rather than young staff, in relation to the type and criticality of the sampled activity.

6.3. PERFORMANCE OF THE ASSESSMENTS

6.3.1. General

All the assessment activities are performed with the aid of the ACCREDIA checklist which includes a list of questions designed to assess the competence to perform the tests in the scope of accreditation and conformity of the CAB with the requirements of the reference standard and ACCREDIA requirements.

In performing the assessment, the assessors shall comply with the following rules:

- to refrain from asking the CAB for copies of the documents examined, except when this is necessary to provide objective evidence of nonconformities or in the event of reservations by the CAB. In such cases, the copies shall be attached to the checklist and sent to ACCREDIA;
- none of the CAB's documents shall be kept by the assessors for any reason, except for copies of test reports sampled in the file and the test reports of the test performed during the assessment that are to be attached to the checklist;
- to record on the checklist details of the persons interviewed, the equipment checked, the documents examined etc;
- not to provide the CAB, whether orally or in writing, whether during the visit or at any other time, any suggestions or advice on the aspects subject to assessment;
- to assess the records and documentation produced by the CAB from the first issue of the MS manual, where present;
- to check not only the test procedures (see RT-08, RT-27/RT-35 for the definition of "test procedure") but also procedures for management and control of auxiliary equipment for the test (e.g. washing of glassware, maintenance of extraction hoods etc);
- for testing and medical labs, evaluate (where applicable) the data concerning participation at interlaboratory circuits. To be assessed always in cases of labs with WADA accreditation.

6.4. ASSESSMENTS CONDUCTED BY THE SYSTEM ASSESSOR

The system assessor shall check the conformity of the CAB's MS with the requirements of the reference standard (UNI CEI EN ISO/IEC 17025, ISO 15189, UNI CEI EN ISO/IEC 17043) and of ACCREDIA, by filling in the corresponding sections of the checklist in accordance with the instructions given on the checklist itself.

In conducting its own verification, the lead assessor shall sample, as far as possible, activities/personnel not chosen by the technical assessors.

In all the assessments, apart from first accreditation, it is necessary to assess the implementation and effectiveness of the CAs resulting from the previous visit.

In the case of accreditation with a flexible scope, the system assessor must verify the management procedure implemented by the laboratory and its application, through the appropriate records.

6.5. ASSESSMENTS CONDUCTED BY THE TECHNICAL ASSESSOR

6.5.1. Testing Laboratories and Medical Laboratories

The technical assessor assesses the performance of sample tests and all technically related matters, filling in the checklist for each test. The checklists are differentiated for each accreditation scheme and, where necessary, also for specific sectors (e.g. CPR, FCC, WADA). The checklists are available in the reserved area for the DL inspectors and on the ACCREDIA website.

If findings are raised during the assessment with respect to non-sampled activities, these shall be formalized and communicated to the lab, which shall comply with the requirements for all subject activities for accreditation.

The lab carries out sampled activities in conformity with the methods declared in conditions similar to those of normal operations. It is not necessary for the lab to organize and conduct sample activities for exclusive use by ACCREDIA, but where possible and/or requested by the lab, the technical assessor can verify the performance of activities performed on behalf of the lab's clients as long as it is compatible with the timeframe and necessities of the assessment.

The technical assessor can agree with the lab on the performance of one or more activities, either partially or completely simulated where such is difficult to fit in for reasons of time, of operations, of finance and where such does not jeopardize the possibility of a thorough assessment of the technical competence of the lab.

ACCREDIA reserves the right to use a reduced sample, the utilization of which, though undoubtedly valid, should be treated with great caution.

If the sample undergoes any type of handling/manipulation (such as dilution) by the assessor or assistant, in order to avoid the possibility of any protest, it is better to ask the lab to have available a number of samples of the measurand with known value and to choose one to re-determine the value. The use of samples with known values shall not be made solely to verify the value determined by the lab (these assessments shall be conducted using more appropriate instruments such as interlaboratory circuits), but it is useful in assessing the adequacy of the instruments, materials and operative modalities used by the lab in the presence of particular values of the determiner.

Where planned in the sampling of tests/exams, the lab shall carry out duplicate tests/exams, verifying that the difference between the results is compatible with the limits or repeatability indicated by the method or determined by the lab. At the time of the conduct of duplicate tests during the assessment, the assessors can, if it does not compromise the validity of the assessment, ask the lab for repetition of a test on a sample previously tested (e.g. on behalf of a client). In all cases the assessors shall compare the results obtained in the two different tests.

For the surveillance visits the technical assessor has both the right and the duty to ask, when possible, for the activities to be carried out by operators qualified for such tests but different from those assessed during the previous visit and whose names shall also be recorded in the module MD-09-11-DL.

Moreover, if necessary, the technical assessor can require the performance (in the ambit of the accredited activities) of those activities which s/he believes correspond best to the criteria on the basis of which the sampling was done.

If any NCs are raised regarding a sampled activity, such as to lead to a negative judgment, the assessor shall verify if the nonconformity is systemic for the group of activities in question and shall perform, if possible, any necessary additional tests.

In the case of accreditation with a flexible scope, the technical assessor must verify the management procedure implemented by the laboratory and its application in updating the detailed lists. In particular, through the records and published lists, the technical assessor must pay particular attention to: responsibilities, verifications, validations, timelines and dates of publication of the revisions of the detailed list, as well as correctness of entries and compliance with the flexibility perimeter.

If the laboratory has obtained or is in progress of obtaining **international recognitions** (**e.g. FCC, EPA, WADA recognition)** or the accreditation is intended for subsequent **CPR-System AVCP3 notification**, the team, and in particular the technical assessors, shall also verify the requirements for specific sectors and shall use, where required, the appropriate forms prepared and made available by ACCREDIA DL.

If the laboratory **is accredited by WADA**, the technical assessors shall use the appropriate checklist highlighting:

- a specific declaration regarding the outcomes of participation in the PT EQAS and how these were managed by the Laboratory (giving emphasis to possible corrective actions deriving from unsatisfactory results);
- positive aspects that can provide useful information for WADA.

6.5.1.1. Verification of tests/examinations performed rarely

In the list of accredited tests/examinations can also be kept tests/exams that the laboratory rarely performs (or even never) for external customers, provided that the Laboratory maintains all the elements that constitute the technical and managerial competence necessary for the conduct of the tests/exams itself.

Given that the purpose of the assessment of the laboratories is to ascertain the continued compliance with the requirements for accreditation for each test/ examination present in the scope of accreditation, below are indications for the verification of tests/ examinations rarely performed by the Laboratory for clients.

- Consumables: For tests performed rarely, it is acceptable that the Laboratory does not keep in stock products (e.g. reagents, reference materials) expensive and that risk expiring before they have been used. In this case, however, the assessors shall verify that:
  - for products not in stock, the laboratory has evaluated and selected a supplier that promptly, as needed, is able to provide the product and that the laboratory periodically checks on this availability of the supplier.
  - among the supplier evaluation data, the laboratory has also considered the supplier's ability to deliver the products within the required times and, if these are significant, that the Laboratory considers these times during the review of the contract with the customers.
  - in the contractual conditions (e.g. general conditions of sale) the Laboratory has informed the customer that for some types of tests/exams the timing of execution may deviate from that generally guaranteed.
- Testing equipment: for rarely performed tests/exams it is acceptable that the maintenance and the periodic calibration of these devices can be suspended, if they are not used for other accredited tests, and therefore the technical assessors shall verify:
  - that the Laboratory has identified and qualified a laboratory for calibration and assistance for the repair of particular types of equipment, managing the performance times both in the order of calibration/maintenance phase and in the phase of review of the contract with customers.
  - in the case of internal calibration, the Laboratory has the internal calibration procedure, samples/reference materials, and has qualified personnel to perform the calibration/maintenance.

- Facilities and environmental conditions: the technical assessors shall verify that the Laboratory can maintain the environmental conditions necessary for the performance of the test, as regards temperature, pressure, humidity, noise, vibrations, sterility, cross-contamination, and all other factors relevant to the test/exams.
- Competence of personnel: the technical assessors shall verify that:
  - the laboratory keeps active and updated the competences of the people who review the results of the tests/exams, express opinions of conformity, express O&I, perform the technical supervision of the testing staff and sign the reports, in terms of knowledge of the test techniques and any updates to the voluntary and mandatory legislation concerning the test and/or, where relevant, to the products being tested (e.g. food, environmental regulations, marking of products, etc.)
  - there are people qualified and formally authorized by the laboratory according to the procedures of the Laboratory for the management of personnel skills, including the verification of the competences of the operator through the conduct of ad hoc tests, aimed at verifying the competence of the personnel.
  - that the procedure has been applied and that the qualified test/exam operators have successfully passed all the checks indicated in the procedure (for example, PT participation, duplicate tests, tests with reference materials, tests performed under supervision).

NOTE: unlike the above indicated for materials and equipment, it is not acceptable that personnel can be put in "stand-by", and then be re-qualified only when the test/exam is requested by the customers.

6.5.2. Interlaboratory proficiency testing providers

The technical assessor shall verify the sampled schemes and all related technical aspects, filling in the checklist for each scheme.

If, during the assessment, any findings are raised regarding non-sampled schemes, these shall be formalized and communicated to the PTP, which shall comply with the requirements for all subject tests for accreditation.

The technical assessor may request the assessment of activities regarding an ongoing PT, or the performance/assessment of one or more activities partially and/or completely simulated and where such does not jeopardize the possibility of a thorough assessment of the technical competence of the PTP.

During the audit, the Technical assessors shall pay particular attention to the number of results inserted, compared to the number of participants actually enrolled or otherwise expected on the basis of planning, in order to verify the correctness of the statistical approach used.

If the PTP has within its structure a laboratory, which performs activities for the PT organized by the PTP itself (e.g. tests for the preparation of materials, tests for the assessment of homogeneity and/or stability, determining the attributed value) and the lab is not accredited for the specific activities in question, the technical assessor shall verify the conformity of the lab to the technical requirements of ISO/IEC 17025 (or ISO 15189 for medical labs). For this assessment the technical assessor may request the performance of a test/calibration and/or document review of the records (similar to a level 2 assessment for testing/medical laboratories).

In the case of subcontracting of activities, the technical assessor, in addition to verifying the records relating to the qualification and the tests conducted by the PTP on the subcontractor, may request to

be present at the tests conducted by the PTP for the qualification of its subcontractors (e.g. second party audit). In the latter case, it is important to keep in mind that the ACCREDIA assessment is aimed at the PTP and the relative qualification methods of its supplier, and not at the subcontractor. Therefore, the sampled scheme checklist should be used for the assessment, filling in the questions on the applicable requirements and, if necessary, the notes field. Any findings must be referred to the PTP and the relative management of the subcontract, and not to the subcontractor.

On the occasion of a surveillance visit, the technical assessor has both the right and the duty to request, when possible, the assessment of PTs coordinated by personnel, qualified to perform such tests, but different from the assessor who performed the previous visit and whose names shall also be recorded in the module MD-09-13-DL.

In cases where, for reasons of force majeure, it is impossible to carry out sampled activities (e.g. equipment failure, unavailability of personnel), the assessor shall nonetheless perform the document review for the requirements which, in the opinion of the technical assessor, are of greater importance. In addition, if necessary, the technical assessor may ask for the conduct (as a part of the accredited tests) of activities (or other schemes) which, in her/his opinion, better correspond to the criteria used for the sampling.

If any NCs are raised with respect to a scheme such as to lead to a negative judgment, the technical assessor shall verify if the nonconformity is systemic for the group of tests in question and shall perform, if possible, the assessment of one or more of the additional schemes/activities.

In the case of schemes performed rarely (e.g. less than once a year), the technical assessor should evaluate the activities put in place by the PTP to ensure that the competences and requirements for accreditation are maintained.

6.6. FORMULATION OF THE FINDINGS

During the assessments, any failure to satisfy the requirements for accreditation found by assessors shall be signaled as a finding in the checklist. At the end of each important phase of the assessment the assessor shall describe in summary form the outcome of the assessments to the person who has been interviewed mentioning verbally any findings raised.

The assessor shall specify that the findings will be reviewed by the assessment team under the leadership of the lead assessor for confirmation and grading as NCs, Concerns or Comments as defined in the general regulations RG-02 and RG-14.

In formulating the findings in the module MD-09-06-DL, the ACCREDIA assessors shall observe the following rules:

- the contents of the findings and the grading should be agreed unanimously by all the assessment group. Otherwise the decision regarding grading is taken by the lead assessor and any differing opinions shall be signaled in the document MD-09-09-DL. In particular, the lead assessor shall report on MD-09-09-DL, and possibly contacting ACCREDIA beforehand, also by telephone, any aspect for which the team does not share a conclusion, in order to obtain a clarification from ACCREDIA itself;
- the modules shall be filled in using IT techniques (website or specific software provided by ACCREDIA). If it is not possible to use IT the modules shall be filled in with clearly legible writing, if possible in bold, with a black pen for easy reading and photocopying.

- the NCs and Concerns shall be:
    - formalized only if objective support data are available;
    - worded in a negative way, highlighting the failures, concise and complete with references to objective data;
    - written in accordance with the instructions of § 9 below;
    - a new NC may be raised depending upon its gravity by completing MD-09-06-DL if the CAB has not implemented the CAs regarding previous visits and/or regarding exam reports already sent to the CAB. The modalities for completing MD-09-06-DL for this type of NC are given on the module itself;
- any Comments shall refer to any opportunity for improvement and they shall not recommend specific solutions.

It is the responsibility of the assessors to inform the CAB's staff that any objection or differing opinion regarding the findings raised by the assessors shall be recorded in writing in the module MD-09-07-DL.

In the case of multisite labs the formulation of results of the assessment visit is usually done during the closing meeting of the assessment. However at the end of each assessment at the individual sites, every assessor makes available an MD-09-14-DL module containing the records of the findings signaled by the assessor in the location in question and which is presented to the head of the lab. All the findings raised in the various locations and signaled by the assessors will be re-examined with regard to the classification and any necessary reformulation by the team during the meeting which takes place before the closing meeting.

For POCTs and blood sampling sites (medical labs) it is not necessary to complete an MD-09-14 for each site, but it is possible to fill in an overall one for the blood sampling sites and one for the POCTs.

6.7. INTERRUPTION OF THE ASSESSMENT

If serious failures on the part of the CAB emerge with regard to the requirements of the accreditation standard or of ACCREDIA documents during the assessment, the lead assessor can, after consulting the other assessors and the Director of Department, propose interruption of the visit to the CAB's head, in accordance with RG-02 and RG-14.

If the interruption goes ahead, the assessors shall hold the meetings in accordance with points 6.9 and 6.10 below, formalizing the findings and indicating, in the summary assessment report, that the assessment was interrupted in agreement with the CAB, providing motivations.

If the CAB wishes to continue the assessment the assessors shall record as such in the summary assessment report, and the assessment activities according to the plan.

6.8. INTERIM MEETINGS

The assessors can, if they consider it necessary, hold interim meetings during the assessment, in order to:

a) update the time-plan of the assessment program;
b) exchange information useful for the further progress of the assessment visit;

c) define any changes to the time-plan of the visit due to findings which have been raised (e.g. changes to the testing program);

d) jointly evaluate the closure of findings concerning the previous assessment or raised in the ongoing visit.

Interim meetings are held in the reserved room for assessors or in another area where confidentiality is possible.

If the circumstances as defined in point c) above occur, the lead assessor shall communicate to the CAB's manager the modified schedule of the assessment.

6.9. MEETING PRELIMINARY TO THE CLOSURE OF THE ASSESSMENT AND RESULTS OF THE VISIT

Before the final meeting with the CAB, the assessors shall hold a preliminary internal meeting, during which the following forms shall be made available and completed using ACCREDIA-DL's IT system for each accreditation scheme:

- the checklist (as indicated in the instructions given in the module);
- MD-09-06-DL;
- MD-09-08-DL;
- MD-09-09-DL;
- MD-09-11-DL/MD-09-13-DL.

For multisite CABs the following modules are made available and completed:

- checklist (as indicated in the instruction given in the module itself);
- MD-09-06-DL (containing the findings of all the assessed locations);
- MD-09-08-DL (one single module regarding multisite labs);
- MD-09-09-DL (one single module regarding multisite labs);
- MD-09-11-DL/MD-09-13-DL (specific for individual locations).

The judgments regarding the competence of the CAB and the performance of the tests (MD-09-08-DL, MD-09-09-DL, MD-09-11-DL/MD-09-13-DL) shall be consistent with the findings raised. In particular, in cases of a negative judgment of the sampled activities, it is the assessor's duty to report in MD-09-11-DL/MD-09-13-DL the reference to the findings and any further negative judgment regarding other accredited activities.

Assessors are required to report to ACCREDIA any critical issues that emerged during the assessment, but not detected as non-conform by means of the checklist or MD-09-09-DL (e.g. staff turnover, seasonality, inability to sample personnel different due to absence on the verification days)

The above documentation is sent to ACCREDIA by the lead assessor within 5 working days of the end of the visit.

At the end of the conformity assessment the reports of the tests/exams (level 1) carried out during the assessment are attached to the documents to be sent to ACCREDIA after the visit.

Also, in order to evaluate the maintenance of conformity of the test reports, copies of them which are representative of the sampled activities (for all sampling levels, where applicable) shall be taken from the archive, assessed, and attached to the dossier of the visit by both the technical and the systems assessors.

For the recording of the results of the visit and of the post-visit activities, ACCREDIA DL has implemented an online application (named 3A), accessible to the assessment team, the Laboratory and ACCREDIA, according to specific credentials and qualifications. The application is currently only available for the scheme UNI CEI EN ISO/IEC 17025 for testing laboratories, while it is being developed for other accreditation schemes. The functioning of the application is described in the specific instructions available on the ACCREDIA website.

Regarding this, where in this procedure reference is made to paper records of the visit results, for testing laboratories these are replaced by electronic records in the 3A application. Similarly, the handwritten signature of the documentation itself is replaced by electronic 'acknowledgment/confirmation' systems, through specific credentials. The specific details are given in the management instruction of the 3A application.

6.10. CLOSING MEETING

The ACCREDIA assessors, the management system personnel, the CAB's manager and, if necessary, his/her assistants attend the closing meeting.

The lead assessor, assisted by the technical assessor for the activities of his/her competence, present to the CAB manager as follows:

- a brief summary of the actions performed;
- the content of the document MD-09-08-DL;
- the modules MD-09-06-DL, describing the contents and specifying that the CA management plan shall be proposed by the CAB shall be completed only following receipt by ACCREDIA of the request of the management plan for the findings, following both the assessment and the control of the findings by the DDL.

The CAB's manager shall act as follows:

- report in the module MD-09-07-DL any reservations regarding the findings already raised and give them to the lead assessor;
- sign for confirmation that MD-09-08-DL has been viewed as well as all the modules MD-09-06-DL; if any objections or reservations have already been made, the manager indicates as such in the appropriate box in MD-09-06-DL.

A copy of MD-09-06-DL and MD-09-08-DL is given to the Manager of the CAB.

Any objections or reservations regarding the findings which have been notified to the assessors shall be formulated by the CAB's manager on the modules MD-09-07-DL (given during the final meeting), and they can be:

- given to the lead assessor during the closing meeting,

  or
- sent to ACCREDIA within 3 working days.

NOTE: In case of multisite labs, the three days period starts from the day of the closing meeting at the last assessed site.

Acceptance or rejection of the objections/reservations issued by the CAB is the responsibility of the DDL and the related management process takes place in accordance with the internal procedure PG-08-DL and the applicable accreditation regulations.

6.11. TASKS OF THE REPRESENTATIVE OF THE DEPARTMENT DIRECTION

The representative of the Direction takes part in the assessment with these tasks:

- to collaborate with the assessors to ensure that the assessment of the CAB takes place in conformity with UNI CEI EN ISO/IEC 17011 and with the ACCREDIA documents;
- to provide to the assessors and/or to the CAB any clarifications concerning the requirements of UNI CEI EN ISO/IEC 17025, UNI EN ISO 15189, UNI CEI EN ISO/IEC 17043 and the ACCREDIA documents;
- to issue, where necessary, any NCs raised against the applicable ACCREDIA documents with regard to the assessors' activities;
- to undertake monitoring activities of assessors;
- to evaluate on-site the adequacy of the planning of the assessment carried out, taking into account the risks, and obtain indications to review it, if necessary.

7. VERIFICATION OF THE PLAN FOR THE MANAGEMENT OF FINDINGS

Following the visit, ACCREDIA notifies the CAB concerning the NCs, Concerns and Comments, using the modalities set out in RG-02 and RG-14.

The modules MD-09-06-DL[3] which contain the plan for the management of the findings proposed by the CAB are sent to all assessors/auditors in the team.

With regard to Comments it is not explicitly required for the CAB to reply using the modules MD-09-06-DL, because the actions implemented by the CAB – the motivation for the failure to address the comment – is submitted to the next due on-site assessment. If it has been completed by the CAB it must, in any case, be evaluated by the audit team.

In the verification of the plan for management of finding, for those classified as NC and CN, each assessor shall verify that what is proposed also includes an analysis of the extent and causes of the findings.

Each assessor sends to the lead assessor, in accordance with his/her competences, his/her opinion regarding the acceptability of the management plan for the findings and the need (or absence of need) to obtain further objective evidence, especially regarding the NCs and the more important Concerns.

After receiving the opinions and after consulting (when necessary) the other assessors to clarify any doubts, the lead assessor sends to ACCREDIA the opinion of the assessment team within 7 days of receipt of the plan for the management of findings.

[3] In the case of implementation of the 3A application for the MED and PTP schemes, the xls module MD-09-33-DL can be used in the transitional phase.

If there are differing opinions regarding the acceptability of the plan, the overall opinion of the team will be put forward by the lead assessor nonetheless, and the other opinions are recorded and sent to ACCREDIA for analysis and subsequent decisions.

If ACCREDIA does not consider the plan for the management of findings sent by the CAB to be acceptable in terms of contents and/or timing of implementation or closure, it can ask – within 15 working days of receipt of the assessment – for a new proposal, specifying implementation and closure times.

The subsequent examination by the assessors of objective evidence of the implementation of the plan for the management of the findings follows a process similar to the one described above. The objective evidence or a revision of them may be required at any time during the process (e.g. for the approval of the plan for the management of the findings to be deliberated by the CSA-DL).

In the next due visit the assessors shall verify thoroughly the adequacy and effectiveness of the CAB's actions.

8. OTHER ASSESSMENTS

8.1. PRELIMINARY ASSESSMENTS

If, during the phase of preliminary contacts and preparing the cost estimate, the CAB requests the FT for a preliminary assessment, this can be organized in order to ascertain any failures in the management system or in the competences of the applicant CAB, compared to the accreditation requirements.

Only one preliminary assessment may be performed for the accreditation standard and only at the CAB's premises.

Activities shall be conducted in such a way as to exclude the risk of consultancy.

A special cost estimate shall be prepared for this activity, signed by the DDL and shall not last longer than an initial accreditation visit, invoiced in man-days, in accordance with the ACCREDIA pricelist.

Under no circumstances can a preliminary assessment be transformed into an initial accreditation audit.

The responsibilities, operative modalities and criteria for the performance of a preliminary assessment are given in the operative instruction IO-09-05-DL.

8.2. REMOTE ASSESSMENTS

ACCREDIA may perform remote assessments, also using the CAB's IT systems (see RG-02 for applicable cases). For the performance of these assessments it is possible to use remote assessment techniques by means of inter-active communication between the ACCREDIA team and the CAB's staff – e.g. internet meeting, teleconference, telephone or other electronic method.

The responsibilities, operative procedures and criteria for conducting remote verification activities are reported in Operative Instruction IO-09-06-DL. In its application, the provisions deriving from the ACCREDIA Policy for the conduct of remote assessments and from the accreditation regulations in force must also be taken into account.

The modalities for recording the results of remote assessments and the timeframe for sending reports by the ACCREDIA assessors are the same as those specified in §5 and §6.

An initial and a closing meeting with the CAB take place also in the case of remote assessments.

Remote assessments can be used for multisite CABs, where the management and organizational system allows it:

- during the surveillances the systems assessor may assess parts of the requirements by remote mode, without going to all the sampled sites in question.
- the technical assessors/experts perform a remote assessment of the activities performed also at the other sites, even if not sampled, as well as the programmed on-site assessments.

8.3. MIXED-MODE ASSESSMENTS

In addition to completely in presence and completely remote assessments, ACCREDIA can also conduct assessments in mixed mode, with GVI partly in presence and partly remotely.

This verification method is always subject to a prior assessment of feasibility, as indicated in the current revision of the accreditation regulations.

8.4. NON-PROGRAMMED SURVEILLANCE ASSESSMENTS

Non-programmed surveillances can be carried out in the cases provided for by Regulations RG-02 and RG-14.

ACCREDIA may request supplementary and/or extraordinary assessments or adopt other control methods, following the granting of accreditation/extension, following the identification of critical situations, both directly by ACCREDIA and following reports and/or complaints written and objectively motivated, received by ACCREDIA, or of inadequate situations of which ACCREDIA obtains knowledge.

8.4.1. Supplementary assessments

Supplementary assessments can be carried out in the cases provided for by Regulations RG-02 and RG-14.

The scope of a supplementary visit is to verify the closure of the findings raised during the previous visit, i.e. to verify on-site the full implementation of corrections and/or of CAs as communicated by the CAB.

The team leader shall only verify the object of the supplementary visit.

The supplementary visit is conducted with the same modalities as those set out in point 6 above, using the same modules. The checklist shall be used in the applicable parts; in all cases, as a minimum, the following parts of the system checklist shall be used:

- the first and the subsequent pages regarding the identification of the visit and of the CAB;
- the parts concerning the opening and closing meetings;
- the parts concerning the performance of tests (if carried out).

In order to give evidence about the implementation and effectiveness of corrective actions the checklist may be supplemented, when necessary, with continuation sheets which must be identified and numbered as indicated in the form itself and the MD-09-06-DL may be attached with the CAB's management plans and further notes by the assessor on the closure of each action.

8.4.2. Extraordinary assessments

Extraordinary assessments are usually performed following complaints, market feedback or as a consequence of decisions taken by the CSA or the DDL, after obtaining (when necessary) the opinion of the DG.

For this assessment, which is to all effects the same as a non-programmed assessment, advance notice of 7 working days is required, within which the CAB may, if necessary, present an objection to the composition of the ACCREDIA team.

For on-site extraordinary assessments, the objectives of the assessment are indicated on the assessment plan.

The extraordinary assessment is conducted with the same modalities as those set out in point 6 above and using the same forms for recording the outcomes.

The costs of extraordinary visits are met by the laboratory if the reasons for the assessment are well founded, if there are any NCs or numerous Concerns such as to result in a negative outcome of the assessment. In other cases, the costs are sustained by ACCREDIA DL.

8.4.3. Assessments of transition to a new accreditation standard

In cases of transition to new editions of accreditation standards, the checks are conducted according to the methods established by ACCREDIA DL (e.g. through specific Circulars), in accordance with the indications at international level (ISO, ILAC, EA).

8.5. OTHER METHODS OF CONTROL

Other methods of control may be adopted by ACCREDIA DL to assess the CAB's operations direct assessments of outsourced companies working for the laboratory, unannounced assessments at the laboratory's locations, mystery shopping, requests for information made to consultancy organizations, or other methods in accordance with the regulations).

8.5.1. Unannounced assessments (without prior notice)

ACCREDIA may perform unannounced visits at the CAB's head office or, if applicable, at other sites of the CAB.

The responsibilities, operative modalities and criteria for the conduct of unannounced visits are set out in the Operative Instruction IO-09-02-DL.

8.6. CROSS FRONTIER ASSESSMENTS

In cases of sub-contracting of assessment activities to ACCREDIA by another AB, on the basis of the requirements of PG-12, ACCREDIA-DL plans the assessment on the basis of indications received from

the AB and after (when necessary) asking for additional information if the information received initially is insufficient to correctly plan the activities in question.

The assessment is then confirmed by ACCREDIA to the CAB and to the sub-contracted AB.

The assessment is conducted with the same modalities as those set out in point 6 above and using the same modules for recording the outcomes.

9. GUIDE TO THE FORMALIZATION OF FINDINGS AND EXAMPLES OF CLASSIFICATION

Assessors are reminded that findings raised during the document review or during the assessment visit shall be comprehensible and self-supporting, containing the information on the basis of which the ACCREDIA bodies decide whether to grant, extend, maintain, suspend, reduce or withdraw accreditation.

The above involves, for a correct formalization of the findings, respecting the following procedures:

- indicate clearly the reference to the object of the finding: reference, revision of a document, registration number of a piece of equipment etc;
- indicate the reference to the requirement in the reference document which is not fulfilled by the CAB;
- present the finding in such a way as to highlight the failures;
- avoid generic findings and describe the reason for which the document, piece of equipment etc. is considered inadequate;
- for findings of a general nature, deriving from a repetition of the same failure, to issue one single finding giving the references for each individual failure;
- the findings are generally not to be merged by point of standard except for cases with common aspects, for which the team wants to highlight their systematic nature;
- if a finding is raised against a specific test, it is necessary to indicate, as well as the number of the test, also a brief description of its contents (e.g. "test 1: lead in wines"); do not indicate only the test number (e.g. NOT "test 1") nor the entire indication of the test number/matrix/measurand/method (e.g. NOT "test 1: wines, must, concentrated rectified must, vinegar: Metals: Lead – method OIV-MA-AS323-07 R2010");
- if it is a multisite lab, generalized findings raised in more than one location, may be incorporated in one general finding; contrarily, if a finding is specific to a single site, the site in question shall be indicated;
- in the case of repeated findings from a document review or previous visit, the assessor should indicate in the text of the new finding the reference to the previous one which he considers repeated, for example by repeating the text or summarizing it.

Some examples are presented in the table below:

	NO	**YES**
1	point 4.6 of the QM is not self-explanatory	Rev. 2 of the MS does not contain sufficient information to understand how the procurement activities are managed (e.g. acceptance and storing of reagents, review and approval of purchase orders, evaluation of suppliers) (see. RT-08 and UNI CEI EN ISO/IEC 17025 point 8.1.1)

2	The chloride test method lacks information	The internal test method MI-02 rev.1 does not specify how to prepare the specimen. (see UNI CEI EN ISO/IEC 17025 point 7.2.1)
3	The estimated uncertainty is wrong	The procedure PG-10 rev. 0 "Estimate of measurement uncertainty" does not provide for the evaluation and quantification of the contribution of Category B. (see UNI CEI EN ISO/IEC 17025 point 7.6)
4	The laboratory's documentation is not adequately controlled	The laboratory's documentation is not properly controlled; e.g.in the Quality Manual index the attachments are not detailed; The Procedures PG-03 and PT-02 are distributed as revision 4 whilst in the general list of documents they are in revision 3. The operators in the rooms A and B have available, respectively, the 1996 edition (superseded) and 2004 (updated) to the testing standard ISO 4444. (see UNI CEI EN ISO/IEC 17025 point 8.3)
5	The laboratory should utilize control cards	The data resulting from participation in interlaboratory circuits (e.g. report n. 04/43 of 10/11/2005) are not recorded in such a way as to show trends. (see UNI CEI EN ISO/IEC 17025 point 7.7)
6	The receiver does not have LAT calibration with regard to the input impediment	Traceability of measurements carried out by the lab is not ensured in the following cases: - receiver EM 343 is not calibrated regarding input impediment (see standard CISPR 16-1); - reference standard thermocouple T 233: the validity of calibration expired on 23/12/2021. (see UNI CEI EN ISO/IEC 17025 point 6.5)
7	The thermocouple T 233 has not been calibrated	
8	A standardized method was modified without validation of the modifications	The lab has expanded the measurement field foreseen by the standardized method against UNI EN ISO 12345:2012, without validation of the modification. (see UNI CEI EN ISO/IEC 17025 point 7.2)
9	There are some deviations in the Lab's testing procedure with respect to the standardized method	The testing procedure POP-05 rev. 1 includes the use of a different technique from the one used in the standardized method UNI EN ISO 6789:2012 (emission spectrometry instead of atomic absorption). see UNI CEI EN ISO/IEC 17025 point 7.2)

9.1. EXAMPLES OF FINDINGS CLASSIFIABLE AS NCs

- The lab no longer has a manager or anyone else competent for an essential position. The lab continues to issue testing reports in that field without informing the AB and without self-suspension of accreditation.
- Despite a previous finding the lab continues to issue testing reports with the accreditation mark and with tests which do not come within the scope of accreditation without indicating as such.
- There are no available records of actions performed following an unsatisfactory result of a PT. Also, there is no evidence that other quality assurance results of the data have been monitored and/or assessed.
- There is significant evidence that the MS is not kept under control. the PTP has not carried out an internal audit for over 18 months.
- The lab does not provide evidence that the calibration of its equipment ensures an adequate metrological traceability.

9.2. EXAMPLES OF FINDINGS CLASSIFIABLE AS CONCERNS

- The result of a recent PT gave a Z-score > +/- 3 and a CA has not yet been identified or the problem resolved.
- The lab's premises are not clean and/or tidy enough. Nevertheless the quality control and environment management data indicate that the results should not have been influenced.
- The internal audit program is two months behind schedule. Two or more points of the most recent audit program have not been fulfilled.
- The lab has not provided evidence of the effective assessment of training conducted in the last year and/or the identification of training needs.
- In the calculation of measurement uncertainties (metrological approach) consideration was not given to the contribution tied to the criterion of acceptability of the calibration curve.

9.3. EXAMPLES OF FINDINGS CLASSIFIABLE AS COMMENTS

- The necessity to check the English translation of the test reports should be considered.
- Considering the limited number of NCs recorded, it is recommended to re-assess the modalities of the records.
- Identify the modalities for signaling the most useful complaints from clients.

9.4. BEHAVIOURS WITH REGARD TO POTENTIAL BREACHES OF MANDATORY AND CONTRACTUAL REQUIREMENTS

If, during an assessment, an ACCREDIA assessor or expert finds a breach of a legal or contractual requirement, with regard to the mandate received from ACCREDIA, the team shall respect the following behaviour, against potentially breached mandatory requirements:

1. if the breach of the legal or contractual requirement comes within the scope of the assessment, the assessor raises a NC or other finding against the specific requirement if it has already been adequately raised by the CAB.
2. if the breach of the legal or contractual requirement is only a related matter the assessor shall issue a Comment so that the CAB keeps the problem under control for the subsequent assessments in this scheme.
3. if the presumed breach of the legal or contractual requirement does not come within the scope of the assessment, the assessor does not need to include anything in his report also due to the fact that it is not possible to guarantee competence on every normative matter which is not within the scope of the assessment.

In all cases, where there are doubts concerning the interpretation and assessment of mandatory requirements – especially with regard to possible breaches of criminal law – the assessor shall always inform the Department Director before writing the report to be counter-signed by the CAB.

9.5. CRITERIA ADOPTED BY ACCREDIA FOR REMARKS/FEEDBACKS TO THE PUBLIC AUTHORITIES

Refer to §6 of the ACCREDIA three-year plan for transparency and anti-bribery annex to the organizational model, relating to all ACCREDIA Departments and published in the transparency section of the ACCREDIA website.