

TITLE **REGULATION FOR THE PROCEEDINGS OF THE
SECTOR ACCREDITATION COMMITTEE OF THE
DEPARTMENT OF TESTING LABORATORIES (CSA DL)**

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

PREPARATION

THE DIRECTOR OF DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE GENERAL DIRECTOR

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1. SCOPE AND FIELD OF APPLICATION

This document defines the tasks, criteria and operative procedures for the activities of the Sector Accreditation Committee (CSA DL) of the Department of Testing Laboratories.

This Sector Accreditation Committee deliberates with regard to the accreditation of:

- Testing Laboratories: standard UNI CEI EN ISO/IEC 17025;
- Medical Laboratories: standards UNI EN ISO 15189 and UNI EN ISO 22870 for POCT;
- Proficiency Testing Providers: standard UNI CEI EN ISO/IEC 17043.

2. REFERENCES

2.1. NORMATIVE REFERENCES

- UNI CEI EN ISO/IEC 17011 General requirements for accreditation bodies accrediting conformity assessment bodies;

2.2. INTERNAL DOCUMENTS

- ST-00 ACCREDIA Statute;
- ST-01 Regulation for the application of the Statute;
- MQ Quality Manual;
- RG-04 Regulation for the proceedings of the Accreditation Committee;
- RG-04-01 Regulation for the proceedings of the Accreditation Sub-committees;
- General and Technical Regulations for the accreditation of CABs reporting to the Department of Testing Laboratories, specific to the different schemes.

The above documents are applicable in the version currently in force.

2.3. ABBREVIATIONS

The abbreviations used in this document are as follows:

CSA DL: Sector Accreditation Committee of the Department of Testing Laboratories;

DDL: Director of the Department of Testing Laboratories;

ST CSA: Secretariat of the Sector Accreditation Committee;

dRSG: Management System Reference Officer of the department;

CAB: Conformity Assessment Body: for the purposes of this Regulation, this term refers to Testing laboratories, Medical laboratories and inter-laboratory Proficiency Testing Providers.

3. DECLARATION OF INDEPENDENCE, IMPARTIALITY AND CONFIDENTIALITY

The members of the Sector Accreditation Committee and the technical experts shall fulfill the requirements contained in the ACCREDIA Quality Manual and shall sign the declaration of independence, impartiality and confidentiality upon acceptance of their engagement.

The members and experts of the Committees shall declare that they have not been the subject of any judiciary proceedings with regard to the Anti-mafia Code, the Anti-bribery Code, the Consumer Code, the Code of Public Tenders, the Environmental Code or of any sanctions following inquiries made by independent authorities (such as AGCM, AGCOM, ANAC or other similar authorities).

All members and experts of the CSA DL Committees shall sign and comply with the ACCREDIA Code of Ethics and Conduct.

Membership of the CSA is incompatible with these positions:

- Membership of the ACCREDIA Steering and Guarantee Committee;
- ACCREDIA Assessor;
- owners or stakeholders of the accredited or applicant CABs, persons who have an operational, managerial or representative role in them, persons who belong, in any capacity, to the representative associations of the accredited or applicant CABs (e.g. director, employee or collaborator of accredited or applicant CABs, or their associations);
- member of the deliberating body and of the committee or mechanism for the Safeguarding of Impartiality (CSI) of a CAB accredited by ACCREDIA or in any case operating in the sectors covered by ACCREDIA accreditation (e.g. laboratories, certification of management systems, products, persons, inspections or verifications).
- ACCREDIA employees.

The Members of the CSAs cannot take part in any decision relating to CABs with whom they have had relations, as directors, employees, consultants or assessors, in the last three years, or when they have carried out, in relation to the CAB in question, assessment activities for accreditation purposes.

4. COMPETENCES, KNOWLEDGE AND TRAINING OF THE MEMBERS OF THE SECTOR ACCREDITATION COMMITTEE

For the application of the General Regulation for the application of the ACCREDIA Statute, the composition of the Committees shall ensure, for each member, knowledge regarding as follows:

- a) the normative requirements which are applicable to the activities of Accreditation Bodies (Reg. 765/2008, Decision n. 768/2008, UNI CEI EN ISO/IEC 17011 and any other mandatory document issued by the government or by EA/IAF/ILAC/ISO concerning Accreditation Bodies);
- b) the rules and processes of accreditation (e.g. accreditation regulations, procedures, technical documents etc.);

- c) the individual normative documents (e.g. the standards UNI CEI EN ISO/IEC 17025, 17043, UNI EN ISO 15189, etc.) and the requirements of the conformity assessments schemes;
- d) the techniques of assessment and the main general methodologies regarding management systems, as well as the principles of risk based assessment;
- e) the techniques of assessment and the main general methodologies regarding management systems, as well as the principles of risk based assessment;

In relation to the above knowledge, ACCREDIA DL, through the DDL, dRSG and ST-CSA, both during the establishment of the CSA DL, and during the insertion phase of new members appointed by the Directive Council, provides for specific training on the above topics.

All members of the CSA DL shall possess competence in the ability to understand and assess the outcomes of assessments performed, including the findings and recommendations of the assessment team. With regard to the evaluation of these competences, ACCREDIA DL shall present and explain the documentation supporting the decisions of the CSA DL (see § 7) with applied practical examples, and, following this activity, shall verify the effectiveness of the training by means of tests or discussions of specific cases.

Further details concerning training of the CSA DL members are contained in the internal operative instructions.

5. TASKS OF THE SECTOR ACCREDITATION COMMITTEE

The committee has the following tasks:

- decide regarding the conformity of CABs with the requirements for granting, maintenance, extension, renewal and extension of expiry of accreditation;
- decide regarding the granting and renewal of recognition of CABs accredited by other Accreditation Bodies signatory to the EA MLA agreements;
- decide with regard to the suspension, reduction, withdrawal of accreditation and resumption of accreditation following suspension⁽¹⁾ or self-suspension⁽²⁾.

Each CSA DL member and, if necessary, also the president, has the task to act as rapporteur and in the competence sector in question, operating in support of the DDL, in managing the procedure for accreditation, renewal of accreditation, surveillance and extension.

In order to ensure the flexibility and the necessary competences, the CSA DL may be supported by technical experts, for explanatory activities regarding specific files. The technical experts also attend the meetings giving their technical opinion for reaching decisions.

¹ In cases of particular urgency and criticality, suspension of one or more tests/examinations/proficiency testings may be decided by the DDL after consultation with the competent rapporteur. Such measure shall be communicated to the CSA DL at the first due meeting. The suspension of accreditation owing to contractual insolvency is provided for by the ACCREDIA General Director and is not submitted to the CSA.

² In cases of self-suspension and if audit activities are not necessary, the resumption of accreditation is approved by the DDC who informs the first due Sector Committee.

The DDL assigns the accreditation files to the competent member of the CSA DL, appointed as rapporteur, taking into consideration the typologies of tests/PTs/exams and the number of files for which s/he is tasked. In certain cases where a number of competences is required, the DDL may assign the same file to two or more members of the CSA DL, one of whom acts as rapporteur and the others as co-rapporteurs.

If certain competences are required the DDL may appoint a technical expert instead of a rapporteur.

The distribution of the files amongst the CSA DL members may vary in cases of replacements or the inclusion of new members or to improve the operative activities of the CSA DL.

If the rapporteur/co-rapporteur/technical expert cannot take up the appointment either due to lack of competence in the sector of tests/PTs/exams as required by the accredited CAB, or because s/he had previous professional relations with the CAB which could compromise impartiality and independence, in accordance with article 18 of the ACCREDIA Statute, s/he informs the DDL who proceeds with the appointment of another member.

6. CONVENING OF MEETINGS

The committee meetings are usually held on a monthly basis, and the schedule for the year is agreed with the CSA DL members at the final meetings of the year before.

The notice of call for a meeting and the agenda are prepared by the DDL in agreement with the president of the committee and sent by the ST CSA to the members of the CSA DL and the experts called. The notice of call must specify: the date, time, place of the meeting, or the connection platform if it is by videoconference.

CSA DL meetings are chaired by the committee president. In the event of absence or unavailability of the president, the meeting is chaired by a committee member who is appointed for the purpose by the committee.

In the preparation of the meeting agenda, the DDL shall, together with the technical officers, specify:

- the members of the CSA DL who perform the role of rapporteur or co-rapporteur, tasked to present to their colleagues the most important elements of each accreditation file for which they are responsible;
- any technical experts, called in the case of files requiring specialist competences in the professional sectors or technical and regulatory areas in question, who take part in the CSA DL to give their technical opinions for decisions.

The agenda lists the accreditation files to be discussed and decided and the other topics requiring decisions or evaluations as well as other issues upon which the CSA DL is required to decide or express evaluations according to the applicable requirements of the Statute and regulations. The agenda may also include communications to the committee members and experts by the president and/or the General Director and/or DDL.

A typical agenda is as follows:

1. Quorum/validity of the meeting.
2. Approval of the agenda.
3. Approval of the minutes of the previous meeting.
4. Communications.
5. Start of procedure regarding the accreditation of laboratories and the appointment of rapporteurs/co-rapporteurs and technical experts.
6. Deliberation regarding accreditations.
7. Deliberation regarding accreditation renewals.
8. Deliberation regarding accreditation maintenance and extensions.
9. Deliberation regarding the closure of files, withdrawals, reductions, renunciations and suspensions of accreditation.
10. Deliberation regarding the annulment of suspension.
11. Deliberation regarding the transfer of ownership of accreditation.
12. Approval of the sampling plans of multisite CABs.
13. Certificates with extended validity.
14. Other business.
15. Confirmation of the date of the next meeting.

The Committee meetings can be attended, without voting rights, by:

- the ACCREDIA General Director;
- the DDL, who performs the task of Secretary of the Committee, with the possibility of delegation to technical officers;
- the technical officers appointed to organize CSA DL meetings and to take care of the minutes;
- the technical officers of the department, to provide further evaluation regarding the activities undertaken by the CAB;
- the management system head officer.

The presidents of the Sector Accreditation Sub-committees are invited to the meetings but without voting rights, if established.

Meetings can be held in presence, by videoconference or in mixed mode. In the latter two cases, attendance checks are carried out by video camera, or in other the ways permitted by law. If held in presence, the meetings are generally held in the department's head office in Rome.

In special cases where consultation has the aim of reaching an urgent decision (e.g. the restoration of accreditation after a period of suspension/self-suspension, extension of expiry of an accreditation certificate, transition to a new standard etc.), the DDL, following consultation with the President of the CSA DL, may consult the members and experts of the CSA DL by email.

In such cases the DDL shall:

1. fully describe the case;
2. fix a deadline for responses from the members;
3. make available, in the reserved area, with advance notice of not less than 3 calendar days with respect to the deadline as defined in the above point, all the necessary documentation for informing the members;
4. specify any necessity for intervention by technical experts;
5. with the agreement of the CSA DL president, formulate a proposal for deliberation regarding which the members shall clearly express their opinions (any abstentions or failure to respond will not be taken into consideration in terms of the required majority);
6. provide for drawing up the report of the meeting to be signed by the president of the CSA, attaching all the incoming and outgoing emails concerning the decision, the date of which must coincide with the expiry date for responses by the members (point 2).

In cases of discussion of critical cases for the imposition of sanctions of suspension, reduction or withdrawal of accreditation, following discussion of the case with the president of the CSA DL, the DDL may convene an extraordinary meeting of the CSA DL.

7. RULES FOR TAKING DECISIONS

For meetings of the CSA DL to be valid the presence of at least half the members is necessary and delegation is not permitted. The presence of technical experts does not count with regard to a quorum.

Collective competence is guaranteed by the members taking the decisions, by the experts and by absent members who may send written statements for reading during the meetings.

Decisions taken by the CSA DL are valid if approved by a two-thirds majority of those present.

Decisions shall be reported including general and precise motivations.

The committee's decisions are reported by the secretary. The individual decisions adopted take immediate effect.

The decisions are communicated by the ST CSA **within 5 (five) working days** to the technical officers for updating in the corporate IT system of the accreditation files relating to CABs, to the Communication Office for publication and to the ACCREDIA administration office, for compliance formalities, for the issuance of invoices and financial documents.

8. SUPPORT DOCUMENTATION TO THE DECISIONS OF THE SECTOR COMMITTEES

The department makes available to the CSA DL the documentation containing information regarding the assessed CABs and the results of the assessment activities in order to permit an adequate assessment of the accreditation procedure in terms of demonstrating the competence of CABs and the conformity of their system with the applicable standards and requirements of accreditation.

As provided for by the applicable procedures of the department, the support documents to accreditation decisions, renewals and extensions, presented to the committee, consist of the assessment report file which is made available by the technical officer, checked by the ST CSA and approved by the DDL and also of the checklists filled in by the assessment team during the assessment.

The assessment report contains the summary of the development of the file with the proposal of the DDL, the presentation of the plan for the management of findings or proposed by the CAB under assessment and the assessment reports prepared by the lead assessors.

The supporting documentation (as a corollary) to any critical cases and/or proposals for the imposition of sanctions (reductions, suspensions, withdrawals of accreditation) as well as those relating to other specific obligations (e.g. restoration of accreditation, transfer of ownership of the accreditation, etc.), can be contained within the individual files and be the subject of a specific note communicated directly during the meeting by the DDL.

The DDC/dRSG/ST CSA shall also communicate the start of new accreditation schemes/conformity assessment schemes and updates made to the general and technical regulations of accreditation.

Usually at least **7 calendar days** before the meeting, the support documentation regarding the decisions is published by the ST CSA in the reserved area of ACCREDIA's intranet for examination on the part of the CSA members and experts and also by the appointed rapporteurs. In the same area, the final draft of the minutes of the previous meeting is also published.

9. CONDUCT OF THE MEETINGS

In cases where the DDL or the members of the CSA intend to propose additions or modifications to the agenda, they shall present the motivation and communicate their request at the start of the meeting, corresponding to the point "approval of the agenda". The committee decides immediately whether to approve the modification, i.e. whether to postpone discussion of newly introduced topics to the subsequent committee meeting.

During the meeting, the rapporteurs and/or co-rapporteurs or technical experts present to the other members the most important elements of each accreditation file as well as a summary of the type and criticality of the findings issued by the assessors during the visit, highlighting the opinion formulated and expressed by the DDL.

The co-rapporteur (if there is one) intervenes with her/his own judgment autonomously, only for the areas of her/his competence.

The rapporteurs and/or co-rapporteurs or technical experts who are not able to attend a committee meeting shall present in advance his/her remarks and opinions in writing to the ST CSA. The DDL then presents the relevant file as indicated by the absent rapporteur/co-rapporteur or expert.

The members of the CSA DL, on the basis of the evidence that emerged and the number and criticality of the non-conformities, the corrective actions proposed by the CAB, the comments of the assessment team and the opinions of the DDL and the rapporteurs/co-rapporteurs/technical expert, after discussion and any further information provided by the DDL and, where necessary, by the representative of the department management who participated in the visit or by the reference technical officer, they express their opinion on the compliance of the CAB with the accreditation requirements.

If the CAB is found to be in conformity, the CSA DL decides in favor of accreditation.

If the CSA DL decides that the CAB is not accreditable, the CSA DL authorizes the DDL to take further action such as a supplementary visit, or the imposition of sanctions or further document assessment, the outcome of which could be assessed by the assessment team and also, if required, by the CSA DL. If a supplementary visit is required, the results shall be submitted to the CSA DL for evaluation.

In urgent cases the CSA DL may delegate the rapporteur to examine the results of subsequent actions and, if the evaluation is positive, the president of the CSA DL, to decide in favor of accreditation.

Should one of the committee members have been involved in past work relationships with the accredited CAB, that could affect his/her independence and impartiality, on the basis of article 18 of the ACCREDIA Statute, s/he informs the CSA DL, which decides if the member can retain voting rights.

9.1. FIRST ACCREDITATION AND RENEWAL

After the assessment regarding the accreditation or re-accreditation, the ST CSA makes available to the rapporteur/co-rapporteur/technical expert the followings documents relating to the results of the visit:

- the file regarding the CAB;
- the list of tests/PTs/exams required for accreditation;
- the opinion of the DDL regarding the accreditability of the CAB, possibly subordinate to precise requirements;
- a brief judgment of the assessment team regarding the CAB and with regard to the assessment visit;
- proposals of the assessment team regarding the continuation of the accreditation procedure;
- brief judgment of the tests/PTs/exams sampled;
- findings raised by the assessors during the visit together with the management plan proposed by the CAB;
- any reservations formulated by the CAB and relative responses given by ACCREDIA;
- any evaluations of the evidence of implementation of corrections/CAs approved by the assessors;
- checklist completed by the assessors;
- copy of the test/PTs/reports and assessment tests issued by the CAB containing the results of the sampled tests/PTs/exams.

The rapporteur/co-rapporteur/technical expert, having viewed the documentation received as well as the opinion of the DDL, expresses her/his own judgment.

The rapporteur/co-rapporteur/technical expert may contact the competent technical officer in order to obtain clarifications, and if necessary, ask for additional information.

9.2. SURVEILLANCE

After the surveillance assessment, the ST CSA makes available to the rapporteur/co-rapporteur/technical expert, in the reserved website area, the documentation containing the results of the assessment and enters the CABs in the agenda of the first due meeting of the CSA DL.

If, after the evaluation of the results of the surveillance, the DDL expresses a positive judgment about the maintenance of accreditation, and the rapporteur/co-rapporteur agrees with the positive opinion expressed by DDL, and the subsequent actions proposed are also agreed to, the CAB will not be discussed by the CSA DL except if there is a request from the rapporteur/co-rapporteur to consider certain aspects or findings. The committee may decide nonetheless to confirm the decision or to examine the file.

If the file evaluation or the actions proposed by the DDL and the rapporteur/co-rapporteur do not concur, the results of the assessment of the CAB will be discussed by the CSA DL.

If the file is entrusted to a technical expert the results of the assessment of the CAB will be discussed by the CSA DL and the opinion of the technical expert will be counter-signed by the president of the CSA DL.

9.3. EXSTENSION

If the extension covers a new technical sector outside the competence of the appointed rapporteur, the DDL selects the committee member as co-rapporteur to assist the rapporteur in carrying out all the necessary actions.

With regard to approval of the extension by the rapporteur/co-rapporteur and the CSA DL, activities continue for the surveillance. If the extension concerns tests/PTs/exams of the competence only of the co-rapporteur, the rapporteur is informed but the extension file is presented directly to the CSA DL by the co-rapporteur.

Automatic extension of accreditation of one or more tests/PTs/exams may be granted upon request by the CAB under the following conditions: tests/PTs/exams conducted with the same technique have already been accredited on a similar matrix for different measurands; there is a favourable opinion of the technical assessor tasked for the assessment, of the DDL/rapporteur and co-rapporteur (if one is appointed); if the extension does not regard tests/PTs/exams within the competence of the rapporteur. The automatic extension shall be attached to the first assessment report of the CAB submitted to the CSA DL (e.g. surveillance/renewal) which has been informed accordingly.

If the file has been assigned to a technical expert, the results of the assessment of the CAB shall be discussed during the first due meeting of the CSA DL for deliberation.

9.4. MULTISITE CABs

The CSA DL deliberates the sampling plan of the sites proposed by the DDL, drawn up according to the criteria contained in the document RG-02-01.

The CSA DL may, concurrently with the approval of the surveillance assessment, review the sampling plan for the sites as provided for in document RG-02-01.

10. SURVEILLANCE OF THE PERFORMANCE OF THE ASSESSORS AND THE DIRECTOR

During the examination of the files, the members of the CSA DL verify and evaluate the assessment process with regard to: the extension of verifications already performed; the clarity and completeness of records reported on the checklist by the assessors; the clarity and relevance of the findings raised by the assessors and of any modifications made by the DDL/VDDL regarding the classification of the findings and possible requests for review of the plan for the management of the findings proposed by the CAB.

Following these assessments, during the discussion of the files, the members can formulate any recommendations to be sent to ACCREDIA, to the assessors and/or to the CAB.