

Calibration Laboratories Department

Regulation for the proceedings of the Sector Accreditation Committees of the Department of Calibration (CSA DT)

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1. Scope and field of application

This document defines the tasks, criteria and operating procedures for the activities of the Sector Accreditation Committee of the Department of Calibration Laboratories (CSA DT).

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

- Calibration Laboratories: standard UNI CEI EN ISO/IEC 17025;
- Reference material producers: standard UNI CEI EN ISO 17034;
- Reference medical laboratories: standards UNI CEI EN ISO/IEC 17025 and UNI EN ISO 15195;
- Biobanks: standard UNI EN ISO 20387.

2. References

2.1. Normative/legislative references

- UNI CEI EN ISO/IEC 17011 General requirements for Accreditation Bodies accrediting conformity assessment bodies;
- Law 273/91 Establishment of the National Calibration System

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 Sector Committee of Accreditation;
- RG-04-01 Regulation for the proceedings of the Sector Sub-committees of Accreditation;
- General and Technical Regulations for the accreditation of CABs reporting to the Certification and Inspection Department, specific to the different schemes;
- INRIM-ACCREDIA agreement;
- ENEA-ACCREDIA agreement;
- ISS-ACCREDIA agreement.

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

2.3. Abbreviations

The abbreviations used in this document are as follows:

CSA DT: Sector Accreditation Committee of the Department of Calibration Laboratories;

DDT: Director of the Department of Calibration Laboratories;

ST CSA: Sector Accreditation Committee secretariat;

RSG: Management System Head Officer;

dRSG: Management System Reference Officer of the department;

STS: Technical and Support Service;

CAB: Conformity Assessment Body: for the purposes of this Regulation, this term refers to Calibration laboratories, Reference Medical Laboratories, Producers of Reference Materials, Biobanks;

EA: European Accreditation for Cooperation;

EA MLA: EA Multilateral Agreements;

IAF: International Accreditation Forum;

ILAC: International Laboratory Accreditation Cooperation.

Where the term “Laboratory” is used, this refers both to a laboratory or a calibration centre, and where the term “Producer” is used, this refers to a Producer of Reference Materials.

Where the term “Committee” is used, this refers to the CSA DT.

3. Declaration of independence, impartiality and confidentiality

The Members of the Sector Accreditation Committee and the 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 Committee 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 operative, 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 CSA DT cannot take part in any decision relating to CABs with whom they have had relations, as directors, employees, consultants or evaluators, 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 Committee 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, 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. regulations of accreditation, procedures, technical documents etc.);
- c. the individual normative accreditation document (e.g. the standards UNI CEI EN ISO/IEC 17025, 17034, UNI/ISO 20387, 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 applicable regulatory requirements for conformity assessment activities.

With regard to the competences as described above, ACCREDIA DT, through the DDT, dRSG and ST CSA, both during the phase of setting up the CSA DT and when the new members are nominated by the Directive Council, performs specific training in the matters stated above.

All members of the CSA DT shall be able to show competence in the ability to understand and assess the outcomes of assessments, including the findings and suggestions of the assessment team. With regard to the evaluation of these competences, ACCREDIA DT shall present and explain the documentation supporting the proposals for decisions with applied practical examples, and, at the end of this activity, shall verify the effectiveness of the training by means of tests or discussions of specific cases.

Further details relating to the training of CSA members are reported 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 on the suspension, reduction, withdrawal of the accreditation, or restoration of the accreditation following suspension¹ or self-suspension²;
- decide regarding the transfer of ownership of accreditation;
- decide regarding the closure of the procedure of accreditation and extension;
- decide regarding the definition of the metrological sectors of accreditation.

The decisions are taken on the basis of an evaluation of operations undertaken by the department regarding the capacity of a laboratory to operate in conformity with UNI CEI EN ISO/IEC 17025 or of a Producer to operate in conformity with UNI CEI EN ISO 17034 or of a biobank to operate in conformity with UNI ISO 20387 and with other specific technical standards for the sector in question, also in compliance with the EA and ILAC regulations and the operative procedures of the department and, where applicable, with respect to the technical and organizational suitability, to take part in the National System of Calibration (Law 273/1991) as set out in the ACCREDIA General Regulation for Calibration Laboratories and RMPs and in the specific department procedures.

In addition, the Committee makes a technical evaluation of the documents prepared by the department and used by the accredited CABs and by the assessors as technical guides for assessment of conformity to the applicable requirements.

The activities of maintaining accreditation (surveillance) are managed by the personnel and are not submitted for assessment by the CSA DT. However, if from the results of the assessments, criticalities emerge that could compromise the maintenance of the accreditation issued, the department management shall make available to the CSA DT all the documentation concerning the file, for the relative discussion and, if necessary, extraordinary assessments and/or the imposition of sanctions.

Similarly, the information relating to complaints against CABs is provided during the renewal of accreditation, with the exception of critical cases that may lead to the imposition of sanctions.

The amendments to the annex to DA-05 "Correspondence of metrological areas - sectors" for the introduction of new metrological sectors following the presentation of accreditation applications or following technical sector assessments are also subject to decision taken by the CSA DT. In this case, the decisions are taken on the basis of technical reports presented by the DDT who describes in detail the need for variation.

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¹ The suspension of accreditation due to contractual insolvency is automatically ordered by the general management of ACCREDIA and is not submitted to the CSA DT.

² In the case of self-suspension and if no assessment activities on changes of previous accreditation are necessary, the provision for the restoration of accreditation is adopted by the DDT, which communicates it at the first CSA DT.

6. Convening of meetings

Committee meetings are usually held every two months. The annual calendar is agreed with the members of the CSA during the final meeting of the year.

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

The meetings of the CSA DT are chaired by the president of the committee. If the president is absent or unavailable it is chaired by a member who is appointed by the committee for the meeting in question.

In the preparation of the agenda, the DDT, together with the president of the CSA DT and the technical officers, must specify the participation at the CSA DT meeting of any technical experts, in order to ensure specialist knowledge and competence and providing technical opinions for reaching decisions.

The agenda lists the accreditation files to be deliberated as well as the other matters requiring decisions or evaluations to be performed by the CSA DT, in accordance with its the tasks as set out in the applicable requirements of the statute and the regulations. The agenda may also include communications to the CSA DT members and experts by the president of the committee and/or the vice president and/or the General Director and/or the DDT. A typical agenda is as follows:

1. Approval of the agenda.
2. Approval of the minutes of the previous meeting.
3. State of implementation of the actions reported in the previous minutes.
4. Communications.
5. Deliberation regarding the the maintenance.
6. Deliberation regarding the accreditations.
7. Deliberation regarding the accreditation renewals.
8. Deliberation regarding the accreditation extensions.
9. Deliberation regarding the accreditation withdrawals.
10. Deliberation regarding the suspensions.
11. Acknowledging self-suspension.
12. Acknowledging the imposition of sanctions.
13. Deliberation regarding the scope reductions.
14. Deliberation regarding the transfer of ownership of accreditation.
15. Deliberation regarding the transitions.
16. Deliberation regarding the extension of expiry of the validity of accreditation certificates.
17. Deliberation of the closure of accreditation files.
18. Deliberation of accreditation tables.
19. Resolution of Annex 1 to the application for accreditation.
20. Any other business.

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

- the vice president delegated by the Council to supervise the department;
- the ACCREDIA General Director;
- the management system Head Officer.

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

- the DDT, who performs the tasks of committee secretary with the possibility of delegation to a technical officer;
- the department's technical officers who present the files to be deliberated and resolved.

The presidents of the sector accreditation sub-committees, if established, are invited to the committee meetings, without the voting rights.

Meetings can be held in presence, by videoconference or in mixed mode. In the latter two cases, attendance checks are carried out by means of a video camera, or in any way permitted by law. If in presence, the meetings are generally held in Turin, at the head office of the department.

In particular cases where, for reasons of urgency, a decision must be taken quickly, the DDT, after consulting the president of the CSA, may consult the members and experts of the CSA by email.

Below are some examples of this type of case:

- confirmation of previously deliberated sanctions;
- restoration of accreditation following suspension;
- restoration of accreditation following self-suspension already extended;
- restoration of the reduction of accreditation;
- extension of the expiry date of accreditation certificates;
- transition to new normative standards.

In these cases the DDT 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 established as above, all the necessary documentation for informing the members;
4. highlight any possible need for intervention by technical experts;
5. with the agreement of the president of the CSA, formulate a proposal for deliberation regarding which the members shall clearly express their opinions (any abstentions, regarding the proposal, are considered as votes against);

6. provide for the writing of the report to be signed by the president of the CSA, attaching all the incoming and outgoing emails concerning the decision. The date of the decision must coincide with the expiry date for responses by the members (point 2).

In case of discussion of critical cases for the imposition of sanctions of suspension, reduction or withdrawal of accreditation, the DDT, after consulting the president of the CSA, may convene an extraordinary meeting of the CSA DT.

7. Rules for taking decisions

The meetings of the CSA DT are valid with the presence of at least half of the members, and delegation is not possible. The presence of technical experts does not count with regard to a quorum.

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

The decisions taken by the CSA DT are valid when they are approved by at least two thirds of those present.

Decisions relating to the imposition of sanctions of all kinds must be recorded together with the general and detailed motivations.

The secretary records the Committee's decisions and communicates them immediately to the ST CSA for the predisposition of the decision and for the possible signing of the agreement with the CAB, for updating the lists of accredited CABs and for other formal compliance obligations.

The individual decisions adopted take immediate effect.

The decisions are communicated by the ST CSA **within 5 (five) working days** to the ACCREDIA administration office, for formal compliance, for the sending of invoices and economic documents to the STS coordinator for the updating of the IT system and the publication on the website. The decision, prepared by the ST CSA in collaboration with the DDT, is sent to the Communication Office for publication on the website.

8. Support documentation to the decisions of the Sector Committee

The department makes available to the CSA DT the documentation with information relevant to the assessment visit results, in order to allow an adequate evaluation of the accreditation procedure.

As provided for by the applicable procedures of the department, the documentation supporting the decisions regarding accreditations, renewals, extensions, reductions, suspensions, restoration of accreditation and withdrawal of accreditation presented to the committee, consists of the final assessment report, the reports on the measurement comparisons, the summary reports of the assessments containing also details of the resulting corrective actions and the annex to the accreditation certificate (accreditation table). The documentation relating to other specific obligations (e.g. transfer of ownership of the accreditation, etc.), may

be contained within the individual files and form the subject of a specific note that is directly presented and described in a meeting organized by the DDT.

The start of new metrological sectors and the updating of the list (for information) of assessors are also the subject of a specific note prepared by the DDT.

Normally at least **7 calendar days** before the meeting, the documentation supporting the decisions is published by the ST CSA in a reserved area of ACCREDIA's intranet site of, for examination by the CSA DT members and experts. The final draft of the minutes of the previous meetings is also recorded in this area.

9. Conduct of the meeting

In cases where the DDT or the members of the committee 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 meeting.

During the meeting, the technical officers present to the members and experts of the CSA DT the most important elements of each CAB's accreditation file, within their specific area of competence,

The activities of maintenance of accreditation (surveillance) are managed as described in paragraph 4 above. However, if the results of the assessments reveal unclosed non-conformities or criticalities that could compromise the maintenance of the accreditation issued, the DDT submits the case to the CSA DT providing all the documentation concerning the file, for the relative discussion and deliberation.

Any appointed experts who are not able to be present at the meeting of the CSA DT, shall transmit in writing their comments and an opinion, in advance, to the ST CSA, which will distribute them to all participants at the beginning of the meeting and to the DDT.

10. Surveillance of the activities of Assessors and of the Director

During the examination of the files, the members of the CSA verify and evaluate the assessment process regarding: extension of the assessments carried out; clarity and completeness of the records reported on the checklist by the assessors; clarity and relevance of the findings formulated by the assessors and any changes made by the DDT to the classification of the findings and any requests for revision of the plan for the management of the findings proposed by the CAB.

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

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