

TITLE REGULATION FOR THE PROCEEDINGS OF THE

SECTOR ACCREDITATION COMMITTEES OF THE DEPARTMENT OF CERTIFICATION AND INSPECTION

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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.

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APPROVAL

THE DIRECTIVE COUNCIL

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1. SCOPE AND FIELD OF APPLICATION

This document defines the responsibilities, criteria and operative modalities for the activities of the Sector Accreditation Committees of the Department of Certification and Inspection.

2. REFERENCES

2.1. NORMATIVE REFERENCES

• UNI CEI EN ISO/IEC 17011 Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies.

2.2. INTERNAL DOCUMENTS

- ST-00 The ACCREDIA Statute;
- ST-01 General Regulation for the application of the ACCREDIA 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 Certification and Inspection Department, specific to the different schemes;
- RG-16 Regulation for the recognition of Certification Bodies accredited by other Accreditation Bodies signatory to the EA/IAF MLA/BLA agreements General Part;
- RG-16-01 Regulation for the recognition of Certification Bodies accredited by other Accreditation Bodies signatory to the EA/IAF MLA/BLA agreements, for the issuance of certifications of conformity to the standard UNI EN ISO 9001 (ACCREDIA document RT-05);
- RG-16-02 Regulation for the recognition of Certification Bodies accredited by other Accreditation Bodies signatory to the EA/IAF MLA/BLA agreements, for the issuance of certifications of conformity to the standards UNI 10891, UNI 11068/EN 50518 and UNI 10459.

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

2.3. ABBREVIATIONS

The abbreviations used in this document are as follows:

CSA: Sector Accreditation Committee;

DDC: Director of the Dept. of Certification and Inspection;

VDDC Vice-director of the Dept. of Certification and Inspection;

ST CSA: Sector Accreditation Committee secretariat;

RSG: Management System Head Officer;



dRSG: Management System Reference Officer of the department;

CAB: Conformity Assessment Body: for the purposes of this Regulation, this term refers to Certification, Inspection, Validation and Verification Bodies;

EA: European Accreditation for Cooperation;

EA MLA: EA Multilateral Agreement/s;

IAF: International Accreditation Forum;

ILAC: International Laboratory Accreditation Cooperation.

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 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 Sector Accreditation Committees shall guarantee, 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. regulations of accreditation, procedures, technical documents etc.);
- c) the individual normative document (e.g. the standards UNI CEI EN ISO/IEC 17020, 17021, 17024, 17065, 14065, 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.

In relation to the above knowledge, ACCREDIA-DC, through the DDC/VDDC and dRSG, both during the establishment of the CSAs, and during the insertion of new members appointed by the Directive Council, provides for specific training on the above topics.

All members of the CSA 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-DC shall present and explain the documentation supporting the decisions of the Sector Committees (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 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/recognition and of resumption of accreditation following suspension⁽¹⁾, self-suspension⁽²⁾.

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.



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 $^{^{1}}$ The suspension of accreditation owing to contractual insolvency is provided for by the ACCREDIA General Director and is not submitted to the CSA.

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 DDC/VDDC in agreement with the president of the Committee and sent by ST CSA to the members of the CSA and to the experts convened. The notice of call must specify: the date, time, place of the meeting, or the connection platform in the case of videoconferencing.

The meetings of the CSA are chaired by the president of the committee. In the event of absence or unavailability of the president, the meeting is chaired by a member designated for the occasion by the committee.

In preparing the agenda, the DDC/VDDC, in agreement with the technical officers, shall specify as follows:

- the members of the CSA who, if necessary, shall perform the tasks of rapporteurs in the specific sector of competence, tasked to present to the other members the most important aspects of each accreditation file which they have been assigned;
- any technical experts, guaranteeing their specialist competences in professional sectors or technological and regulatory sectors of particular importance. The technical experts will attend the CSA meeting in order to provide technical opinions in decision-taking concerning accreditation.

The meeting agenda lists all the accreditation files for deliberation as well as other topics that it must deliberate or express an opinion in accordance with the applicable requirements of the Statute and regulations. The meeting agenda may also provide for communications to the members and technical experts of the CSA from the committee president or from the General Director or the DDC/VDDC/dRSG. A typical agenda is as follows:

- · quorum / validity of meeting;
- approval of the agenda;
- approval of the minutes of the previous meeting;
- communications;
- critical cases and cases for discussion (complaints and/or outcomes of surveillance activities);
- confirmation of decisions of the Sector Accreditation Sub-committees;
- decisions regarding accreditation: new accreditations, extensions, renewals, reductions, suspensions, withdrawals, renunciations, resumption after suspension, self-suspension or other provisions, transitions;
- decisions regarding recognition: new recognitions, renewals, reductions, suspensions, withdrawals, renunciations, resumptions of recognition after suspension, selfsuspension or other provisions;
- · certificates with extended validity;
- other business:



confirmation of the date of the next meeting.

The following may participate in Committee meetings, without voting rights:

- the ACCREDIA General Director, the DDC/VDDC who performs the tasks of committee secretary with the possibility of delegation to technical officers regarding the CSA in question, dRSG/RSG;
- the technical officers of the department, to provide further considerations concerning the activities undertaken by the CABs.

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

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 Milan.

If an urgent or quick consultation decision has to be taken, such as the confirmation of sanctions which have been discussed and agreed by the SCSA, or the restoration of accreditation following a period of suspension or self-suspension, or the postponement of an expiry date for an accreditation certificate, for transition to a new accreditation/certification standard etc., after consulting the president of the CSA, the DDC/VDDC may consult the CSA members and experts by email.

The DDC/VDDC shall:

- 1. fully describe and explain the case;
- 2. fix a final date for answers obtained 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 point 2 above, all the necessary documentation for the members;
- 4. specify the members of the CSA who, if necessary, will perform the tasks of rapporteurs, and technical experts;
- formulate, in agreement with the president of the CSA, a proposed decision with respect
 to which the members shall give a clear response (any abstentions or failure to respond
 within the timeframe will not be counted for the purposes of reaching the required
 majority);
- 6. prepare a report, to be signed by the president of the CSA, attaching all incoming and outgoing emails regarding the decision. The date of the decision shall coincide with the expiry date fixed for the responses on the part of 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, the DDC may convene an extraordinary meeting of the CSA.



7. RULES FOR TAKING DECISIONS

The meetings of the CSAs are valid with the presence of at least half of the members and delegation is not allowed. The presence of Technical Experts is not counted for the purpose of verifying the quorum.

Collective competence is guaranteed by the members who take decisions, by the experts, and by the absent members who can forward written briefs, which are read in the meeting.

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

Decisions must be recorded complete with general and detailed motivations.

The decisions of the committee are recorded by the secretary. The individual decisions are adopted directly during the meeting.

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 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, consists of the accreditation file which is made available by the technical officer and approved by the DDC/VDDC.

The form contains the summary of the development of the file with the proposal of the relevant area of the department, the presentation of the corrective actions implemented or proposed by the assessed CAB and the assessment reports drawn up by the lead assessors (RGVI). The form contains, in the case of renewal, the list of assessments carried out in the accreditation cycle and the financial data.

The supporting documentation (as a corollary) to any critical cases and/or proposals for the imposition of sanctions (reductions, suspensions, resumption of accreditation, withdrawal of accreditation), as well as those relating to other specific obligations (e.g. 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 DDC/VDDC. In more complex cases, the above file is prepared and made available.



The DDC/VDDC/dRSG 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 department director 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 meeting.

During the meeting, the rapporteurs, with the support of technical experts if necessary, within their specific area of competence, describe to the other members the most important elements of each accreditation file.

If a rapporteur or technical experts is not able to attend a committee meeting s/he shall present his/her remarks and opinions in writing to the CSA secretariat which then forwards them to all the participants at the start of the meeting and also to the DDC/VDDC/dRSG who present the relevant file as indicated by the absent rapporteur.

The files are submitted to the CSA for examination in accordance with the four levels given below in rising order of complexity:

- AA)files concerning extensions with clear and satisfactory results of audits at which only Comments were raised; these files are presented by the DDC/VDDC/dRSG or by a technical officer;
- A) files with clear and satisfactory audit results with elements which are certain in terms of the positive results of examination, despite the raising of findings classified as Concerns;
- B) files for which the outcome of the examination was positive, but which nevertheless had a complicated development, for which it was necessary to repeat assessments, in order to check the effective closure of non-conformities raised previously, or for which further verifications are required, such as surveillance activities or confirmation by means of supplementary assessments;
- C) in the case of files signaled as critical both due to decisions which must take into consideration particularly complex factors, and due to grave technical failures, there is the possibility of imposing sanctions on the CAB.

Files which have been submitted to previous CSA meetings without a positive outcome shall be presented a second time and classified as files of the "B" category.

A rapporteur is appointed for the presentation of files classified as A and B; the rapporteur is chosen from among the members of the CSA and is assisted, where necessary, by a technical expert.



Maintenance of accreditation activities (surveillance) are managed by the ACCREDIA personnel and are not submitted to the CSA for evaluation. Nevertheless if any unresolved nonconformities emerge from the assessments or any criticalities which may compromise maintenance of accreditation, the DDC/VDDC/dRSG submits to the CSA all the documentation concerning the file, for discussion and decision.

In cases where files regarding various schemes/sectors must be submitted to the relevant sector committees, the following rules apply:

- for renewals: in cases where files whose scope of accreditation includes regulated sectors, these files shall be submitted to the first competent CSA meeting for regulated areas which deliberates regarding the entire scope of accreditation. Subsequently the files are presented to other CSAs for confirmation of the specific part of the scope. If a committee does not agree with the decision in favor of renewal, the accreditation is reduced for the specific sector. In exceptional cases (e.g. a certificate of accreditation which is due to expire), the file is submitted to the first due CSA meeting;
- for files whose scope of accreditation only regards voluntary activities, they shall be presented to the relevant CSA and, if applicable, to the Sub-committees;
- for transition to new accreditation standards the files shall be submitted to the first due CSA following the chronological order of the calling of meetings and, if necessary, to the Sub-committees;
- for transition to new certification standards or the granting/withdrawal of the flexible scope the files shall be submitted to the competent CSA and, if necessary, to the Subcommittees;
- for renunciation and self-suspension of the entire accreditation scheme the files shall be submitted to the first due CSA meeting following the chronological order of the calling of meetings and, if necessary, to the Sub-committees;
- for renunciation and reduction regarding a certification scheme the files shall be submitted to the competent CSA and, if necessary, to the Sub-committees;
- for transfer of ownership of accreditations (e.g. change to the CAB's name, merger, ceding or renting of a company branch to another CAB etc.): the files shall be submitted to the to the first due CSA and, if necessary, to the Sub-committees;
- for critical cases the files shall be submitted to the competent CSA and, if necessary, to the Sub-committees;
- in cases of horizontal criticality the CAB shall submit the criticalities to all the interested CSAs and, if necessary, to the Sub-committees;
- in cases of extension of expiry of certificates beyond the first one, which can be issued automatically by the DDC, the certificates shall be submitted, with motivations, to the relevant CSA.

Note: in the cases set out above, regarding files which can be submitted to the first due CSA meeting following the chronological order in which they are convened, for CABs accredited only for one scope in a specific area (e.g. notified bodies), these files shall be submitted to the relevant CSA.



10. SURVEILLANCE OF THE ACTIVITIES OF ASSESSORS AND OF THE DIRECTORS

On the occasion of 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 in the assessment report by the assessors; clarity and relevance of the findings formulated by the assessors and any modifications made by DDC/VDDC 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 assessments, during the discussion of the files, the members can formulate recommendations to be sent to ACCREDIA, to the assessors and/or to the CAB.

