

Title	Regulation for the recognition of certification bodies accredited by the other accreditation bodies signatory to the EA/IAF MLA/BLA agreements - General Requirements
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FOREWORD

The objective of ACCREDIA's Department of Certification and Inspection (ACCREDIA-DC) is to contribute to the creation of trust in the conformity assessment system for assessing the conformity of products, processes, management systems and personnel in accordance with the requirements of the applicable national and international standards. It is also to ensure the effectiveness and consistency of the approach on the part of the operators of the system to foster increased national market competitiveness and the well-being of the general public.

In order to achieve this, the ACCREDIA Department of Certification and Inspection, continuing the work previously performed by SINCERT, has maintained the process of recognition with the aims and modalities as described below in such a way as to engender, among all the social and economic parties and, in particular, final users and consumers, a high level of trust in the work of these bodies and in the benefits of the declarations of conformity which are issued.

To accomplish the above aims and to offer assurance of the effectiveness of the recognition process and to guarantee operative consistency of behavior among recognized bodies, the Department of Certification and Inspection has drawn up regulations and criteria for the application of the requirements of the applicable normative references, formalized by the issuance of the present General Regulation, as well as specific regulations for recognition (also by means of the documentation to be applied jointly with the Regulations in question).

0.1. INTRODUCTION

The recognition by ACCREDIA-DC of bodies accredited by other accreditation bodies which are signatory to the EA/IAF MLA/BLA agreements is a complex process, related to the areas in which these bodies operate for the granting of certifications, usually involving mandatory areas.

The recognition activities covered by the present Regulation and the specific regulations for the scope of recognition are not covered by the EA/IAF MLA/BLA agreements, but they refer to certification activities required by national legal requirements.

0.2. SCOPE AND FIELD OF APPLICATION

The present Regulation – General Requirements – shall not be applied separately from the specific regulations for the scope of recognition

The present Regulation and the specific regulations carry contractual obligations between ACCREDIA-DC and accredited bodies whereby:

- ACCREDIA-DC shall undertake, with competence, objectivity, diligence and professional integrity, the conformity assessment of the CB, in accordance with the requirements of the applicable standards/laws and of the ACCREDIA-DC reference documents/regulations and, if the outcome is positive, ACCREDIA-DC shall grant recognition to the CB which is then recorded accordingly in the Register of Recognized Bodies, and ACCREDIA-DC shall give the relative lists to the competent authorities (when applicable and requested);
- the recognized CB shall respect the provisions contained in this document throughout the period of validity of recognition.

Also considered as contractual obligations in the relations between ACCREDIA-DC and the recognized bodies, are the technical circular letters which are issued by ACCREDIA-DC, as annexes to the present Regulation.

It is the responsibility of ACCREDIA-DC to verify – within the limitations of its assessments, and usually by sampling – that the CB possesses the necessary competence in terms of organization, procedures and other operative documents, human resources and any other applicable methods, for it to carry out its certification activities, in accordance with the present Regulation and all other applicable rules and regulations.

It is the responsibility of the CB to ensure and maintain full and systematic compliance with the above rules at all times and in all aspects of its activities.

The present general Regulation and the specific regulations are submitted to ACCREDIA's Directive Council for approval under article 14 of the ACCREDIA statute, provided that the Committee for Accreditation Activities has pronounced a favorable opinion and that they are issued with the authority of the ACCREDIA President.

0.3. REFERENCE DOCUMENTS / LEGISLATIVE REQUIREMENTS

The reference standards for the application of the present Regulation are given in the specific regulations for the scope of recognition.

0.4. TERMS AND DEFINITIONS

- Recognition: declaration by ACCREDIA that a CAB which already holds accreditation, meets the requirements contained in the applicable ACCREDIA documents and regulations, to undertake conformity assessment activities.
- Direct agreement: application for recognition coming directly from a body which is accredited by another AB which is signatory to the EA/IAF MLA/BLA mutual recognition agreements.
- MoU - Memorandum of Understanding: procedure whereby an AB, signatory to the EA/IAF MLA/BLA agreements of mutual recognition, intends to sign a MoU with ACCREDIA, requesting the process of recognition of a CB which it has accredited.
- Certification: declaration by a third party regarding the products, processes, systems or personnel (see ISO/IEC 17000:2004).
- Conformity assessment body (CAB): a body which undertakes conformity assessment activities, including calibration, testing, certifications and inspections (Reg. EC 765/2006/chapter 1, article 2, § 13). For the purpose of the present Regulation and the specific regulations or the scope of recognition, a CAB is a certification body.
- Certification body (CB): a body which undertakes conformity certification.
- Assessment: an assessment carried out by ACCREDIA-DC (initial, supplementary, programmed and non-programmed surveillance) for the purpose of granting and maintaining recognition.
- Witness assessment: an assessment carried out by ACCREDIA-DC assessors (and, when necessary, by technical experts) on the CB during an audit conducted by the CB.

- **Market Surveillance Visit:** an assessment generally lasting one day at a certified organization to establish the level of trust in the conformity of the management system with the specific requirements, and the effectiveness of the accredited certification process (ref. document IAF ID4).

Note: In these cases, where applicable, ACCREDIA-DC, after choosing a file, may ask the CB to send in advance all the documentation of the certification process and a copy of the previous audit reports.

For the objectives and modalities of performance of the market surveillance visit activities, see Annex 1 of the present Regulation.

- **Findings:** a finding is a formal evaluation raised by ACCREDIA-DC and graded as a Nonconformity, a Concern or a Comment.

A finding which is formalized by ACCREDIA-DC to the CB may be the result of two situations:

- failure to fulfill an applicable requirement (normative, mandatory, contractual) with subsequent formal raising of a NC or a Concern.
- the identification of an activity by the CB which is "weak or potentially a failure" which might lead to a NC/Concern, or offer opportunities for improvement. This situation results in the raising of a Comment.

- **Nonconformity:** a finding signaling the presence of a deviation/failure which:

- jeopardizes the reliability of results/performances/services carried out by the CB and/or;
- compromises the capacity of the CB's MS to maintain the established level of quality of the conformity assessment performances or indicates a failure in the functioning of the MS proceedings and/or;
- jeopardizes the credibility of the recognition procedure or the integrity/honesty of or with respect to ACCREDIA and/or;
- reveals a failure to respect the applicable mandatory requirements of the scope of recognition and/or;
- is the result of a repeated failure to address the problems raised by a previous Concern formalized with regard to the CB.

Note 1: The NC is formulated by the ACCREDIA-DC assessors by means of a clear identification of it, and the evidence on which the finding was based and the reference to the requirement which has not been fulfilled shall be reported.

A NC may result in the imposition of sanctions as described in § 1.6.

- **Concern:** a finding caused by the partial implementation of a requirement (of a standard or of the regulations for recognition) the result of which does not impact directly or immediately on the quality of performance or results of the CB.

Note 1: a Concern is formulated by the ACCREDIA-DC assessors by means of a clear identification of it, and the evidence on which the finding was based and the reference to the requirement which has not been fulfilled shall be reported.

Note 2: a Concern which is not closed at the next due assessment may become classifiable as a NC.

- Comment: a finding raised by the ACCREDIA-DC assessors with regard to a CB in the presence of a situation which is not one of objective failure to meet a requirement, but is intended to prevent this from occurring (potentially possible) and/or to provide indications for an improvement of the documents and/or operative modalities of the CB.
- Management of findings by the CB: activities conducted by the CB due to findings raised and formalized by ACCREDIA.

All the findings formalized by ACCREDIA-DC as NCs on the basis of the above criteria shall be re-examined by the CB, which shall send to ACCREDIA-DC, within 15 working days from receipt of the communication confirming the findings, a plan (sent by ACCREDIA-DC within two months of the performance of the assessment) for the handling of the findings which shall include:

- For NCs: the correction (where applicable), an analysis of the root causes and CAs regarding the causes found, with an indication of the implementation timeframe. Evidence of closure of this type of finding shall be evaluated positively by ACCREDIA-DC before the decision to grant recognition by the Sector Accreditation Committee of the Dept. of Certification and Inspection (CSA/DCI).

The CSA DCI may issue a positive decision depending on the full implementation of the CA and it may also decide to delay the decision if there is evidence of the full implementation of the CA.

For maintenance, the NC shall be closed within the fixed timeframe.

It may be necessary to conduct an on-site assessment to ensure that the CAs have been effectively implemented.

- For Concerns: the correction (where applicable) an analysis of the root cause and the CAs, with a fixed timeframe for implementation.

The implementation will be verified during the next surveillance. If deemed necessary by ACCREDIA-DC, the evidence regarding the correction and/or CAs, is evaluated in document form by ACCREDIA-DC, before the next surveillance.

- For Comments: this type of finding can be handled with the opening of an improvement action, or it may not be implemented, in which case reasons shall be given and recorded.

If a CB does not send to ACCREDIA-DC the plan for the management of the findings or the document evidence required within the timeframes in question, the DDC may submit the file to the CSA DCI for the possible imposition of sanctions.

The findings raised by ACCREDIA-DC at the end of an assessment may be reclassified by the Technical Office following an examination of the results.

If the CB does not provide the CA plan and the handling of Comments already completed and in a copiable format during the surveillance, ACCREDIA-DC may increase the duration of the assessment.

- Certification scheme: the rules, procedures and activities undertaken by the CB for the declaration of the conformity of the management system, products and personnel.
- Scope of certification: the field of application of the activity and/or process for which the certificate is issued.

- Scope of recognition: the field of application of the activity and/or process for which the certificate is issued.
- Implementation timeframe: period of time between the date of issue or revision of an ACCREDIA-DC regulatory document and the application date of such document.
- Risk: impact on an activity which may derive from certain processes or activities by the CB, including work performed by its internal staff or by collaborators.

The body should identify risk indicators which are proportionate to the expected effect and probability of occurrence of a certain situation.

- Impartiality: the presence of objectivity.
- Suspension of recognition: the imposition of a sanction whereby recognition of a CB for a determined period is suspended.
- Withdrawal of recognition: the imposition of a sanction whereby the recognition of a CB is withdrawn definitively.
- Technical Officer: person tasked by ACCREDIA to manage the assessment phases for the granting and maintenance of recognition and to coordinate the activities of the assessors.
- Assessor: person qualified and tasked, either individually or as an assessment team member, by ACCREDIA-DC for the conformity assessment of the adequacy of the CBs system in accordance with the applicable reference standard and ACCREDIA-DC regulations.

Technical expert: person qualified and tasked by ACCREDIA-DC, operating under the responsibility of an assessor, providing knowledge and competence concerning the field of accreditation to be assessed and who does not perform evaluations independently.

0.5. ACRONYMS

- CB: Certification body;
- DDC: Director of the Dept. of Certification and Inspection;
- CSA DCI: Sector Accreditation Committee Dept. of Certification and Inspection;
- MSV: Market Surveillance Visit;
- FT: Technical officer.

PART 1: PROVISIONS REGARDING THE RECOGNITION PROCESS

1. REQUIREMENTS AND INFORMATION FOR RECOGNITION

1.1. GENERAL INFORMATION

1.1.1 Il Recognition and subsequent registration on the Registers are granted to CBs operating conformity certifications against the applicable standards and against ACCREDIA-DC regulations and documents applicable to the scope of certification.

1.1.2 Conditions whereby a CB may attain recognition:

- that it conforms with the applicable requirements of the present Regulation, with the standards and specific ACCREDIA reference documents for the scope of recognition and that its behavior is always correct and transparent in its collaboration activities with ACCREDIA-DC;
- that it fulfills the minimum specific requirements contained in the specific regulations.

1.1.3 The granting and maintenance of recognition are subject to:

- a positive result of the various phases of the process of recognition as detailed below;
- the payment of all sums contained in ACCREDIA-DC's quotation and in the final invoice, as described in the ACCREDIA pricelist currently in force;

1.1.4 The records of recognized CBs shall be updated regularly and are available to the public on the ACCREDIA website, www.accredia.it.

1.2. PRESENTATION AND EXPLANATION OF THE APPLICATION FOR RECOGNITION

1.2.1 If an accreditation body intends to begin the process of recognition for a CB which it has accredited, within 15 calendar days of the formal receipt, ACCREDIA-DC prepares a MoU signed by the ACCREDIA President defining the process of recognition and the responsibilities of the applicant CB.

If there is an existing MoU between ACCREDIA and the accreditation body the receipt is sufficient of the written communication by the competent accreditation body requesting the start of the process of recognition for a CB which it has already accredited.

After acceptance of the MoU both on the part of the accreditation body and of a representative or delegate of a representative of the CB applying for recognition, the CB may present the application for recognition.

if the CB, accredited by another accreditation body signatory to the EA/IAF MLA/BLA agreements, requests directly to ACCREDIA-DC to start the process of recognition, ACCREDIA-DC prepares a direct agreement, signed by the President, setting out the phases of the process of recognition as well as the responsibilities of the applicant CB.

After acceptance of the direct agreement by a representative or delegate of a representative of the CB presenting the application for recognition, the CB may present the application for recognition.

The application for recognition of a CB shall be presented to ACCREDIA-DC using the relevant modules which are available on ACCREDIA's website, along with the necessary documents. The application must be fully and clearly completed and give reasons for any inapplicability if this is not done, otherwise it will not be accepted. In the application it must specify the references of the juridical person responsible for the issue of certifications and responsible for the operative locations, specifying also those which are operative in Italy.

The application shall be signed by the Managing Officer (duly identifiable) of the applicant CB.

If the CB's operative location in Italy is a trust company, or if there is a trust company amongst its partners, in order for ACCREDIA-DC to be able to accept the application, it shall perform all the necessary controls, requesting declarations from the CB, specifying, in particular, the names of its partners which are trust companies in order to assess any situations of conflicts of interest.

1.2.2 If the documentation attached to the application is complete and complies with the requests, within 30 calendar days of the date of formal receipt, the Technical Officer formalizes acceptance and prepares a quotation for recognition activities which is signed by the Department Director and sent to the CB.

If the documentation sent by the applicant is incomplete or unclear or the conditions are not all fulfilled, the FT does not accept the application and, asks for - within 30 calendar days - in writing, the outstanding documents required which shall be provided within two months, otherwise the application lapses. If the documentation has been fully provided the application is accepted and a quotation is prepared.

If the controls made of the application reveal that the CB has provided false information, ACCREDIA-DC shall refuse the application and inform the accreditation body in question.

1.3. PROCESS OF RECOGNITION

1.3.1. DOCUMENT REVIEW

1.3.1.1. After acceptance of the quotation by the applicant CB, the recognition process begins with a thorough document review. The document review is carried out within a max of **60 calendar days** of acceptance of the quotation.

If this is concluded satisfactorily, the assessment visits can take place (see § 1.3.2 below).

If, however, the outcome of the document review is negative, ACCREDIA-DC notifies the applicant CB of the need to make the necessary corrections to the documents in accordance with the findings reported.

The cost of the first review is met by ACCREDIA-DC. The cost of all further and subsequent document reviews is met by the CB.

If, three months after the request for correct documentation, the applicant CB has not fulfilled this task, the application for recognition lapses and a new application must be presented, together with all the related requirements, including the cost.

If it is necessary to carry out more than two adequacy actions following the performance of the initial document review, the requirements of § 1.3.1.2 below are applicable.

1.3.1.2 If, following the document review or after other direct contacts with the applicant CB, it turns out that the CB does not possess the necessary level of competence and impartiality, ACCREDIA-DC interrupts the process of recognition.

1.3.1.3 if the CB does not meet the cost of document review, ACCREDIA-DC interrupts the process of recognition and the application lapses.

1.3.2. ASSESSMENTS

1.3.2.1 Following a positive outcome of the document review, after consulting the Department Director, the Technical Officer makes the arrangements for the assessments in compliance with the specific regulations for the recognition scheme.

1.3.2.2 The names of the ACCREDIA-DC assessors and experts, qualified according to ACCREDIA-DC procedures, are approved by the Committee for Accreditation Activities following proposal by the DDC.

The references of the assessors and experts appointed for assessment activities (names and organizations they belong to) are communicated in advance to the CB.

ACCREDIA-DC does not disclose the CVs of its assessors and technical experts.

Upon request, ACCREDIA may give information concerning ongoing collaborations of its assessors and experts with bodies which are potential competitors.

If a CB has reservations about the assessors or experts it must present the reasons in writing to ACCREDIA-DC within **three working days** of receipt of the communication, otherwise the members of the assessment team are deemed to have been accepted.

A CB may object to assessors or experts (or ask for them to be replaced) for the following reasons:

- professionally incorrect behavior (to be shown to ACCREDIA with objective proof of their behavior on-site, only after the CB has expressed its reservations which are evaluated by the Director of Department);
- conflicts of interest (to be communicated to ACCREDIA-DC for verification on the basis of the declaration provided in advance by the assessor). if the reasons are deemed valid the matter will be evaluated in the reports of the ACCREDIA-DC assessors and the technical experts.

Assessors who are ACCREDIA-DC's employees may not be objected to by the CB other than for serious reasons of incompatibility which shall be communicated directly to the Department Director.

1.3.2.3 The CB shall permit access to the ACCREDIA-DC assessment team to its locations, to auditing companies or business partners (where necessary) with which it has signed an agreement and its documents, and shall offer maximum cooperation throughout.

The CB shall also ensure that the ACCREDIA assessment team has access to the CB's certified or applicant organizations' locations.

1.3.2.4 If, during an assessment, witness assessment or MSV, a NC (or more than one) is raised, the recognition process is suspended until the necessary treatments and CAs have been implemented and their effectiveness has been verified by ACCREDIA-DC by means of supplementary assessments.

The end-date for the implementation and verification of the effectiveness of the corrective actions is a maximum of six months, after which the process of recognition is interrupted.

Supplementary assessments may be necessary after the granting of recognition if there is a significant number of findings classified as Concerns.

1.4. DECISION-TAKING PROCESS FOR GRANTING RECOGNITION AND REGISTRATION OF RECOGNITION

1.4.1 After the performance of the assessments as above, the Technical Officer prepares and makes available, in accordance with the procedures and using the appropriate modules, the document summarizing the assessments, which, having been reviewed and validated by the DDC, is submitted to the CSA DCI for deliberation.

The above assessments shall be concluded within 15 working days of the date of the CSA meeting in order to enable the full preparation of the relative documents.

The granting of recognition is exclusively the task of the CSA DCI which decides following a thorough examination of the outcome of the investigation by the personnel, conducted independently of the proposal formulated by the DDC. If a non-positive decision has been reached, the CSA DCI records the reasons for its decision, as it does if it orders additional or supplementary assessments or imposes other conditions.

In all cases, the granting of recognition depends on the payments made in compliance with the cost estimates from ACCREDIA-DC and in accordance with the ACCREDIA pricelist.

1.4.2 The granting of recognition is formalized by means of a communication which is sent to the CB and to the competent AB (only in cases of a MoU). This communication specifies the start-date of recognition and registration of the CB on the Register of Recognized Bodies and published on ACCREDIA's website.

With the granting of recognition, all certifications issued by the CB before recognition acquire the status of recognized certifications.

1.4.3 Registration obliges the CB to maintain its organizational structure and its proceedings in conformity with the present Regulation and all other applicable sector-specific regulations. The specific regulations for the scope of recognition, the standards, the general reference standards and applicable technical regulations.

1.5. SURVEILLANCE OF RECOGNITION

1.5.1. General

1.5.1.1 ACCREDIA-DC undertakes, by means of assessments, constant surveillance activity with regard to the recognized CB, by means of programmed assessments (communicated formally in the form of an annual surveillance program) and special assessments (also at short notice), so as to ensure conformity with the present Regulation, the specific regulations for the scope of recognition and the provisions of the ACCREDIA Technical Regulations and documents.

For recognition by means of a MoU, the annual surveillance program shall also be sent to the competent AB.

1.5.1.2 The CB shall communicate to ACCREDIA-DC all updates to its organization and documentation with respect to the data and information already provided, together with the application for recognition which may involve any significant changes in the human resources and procedures used for certification activities.

1.5.1.3 Maintenance of recognition activity is subordinate to the payment sums contained in ACCREDIA-DC's technical / economic quotation and also at the completion of activities and in accordance with the ACCREDIA pricelist.

1.5.2. PROGRAMMED SURVEILLANCE OF RECOGNITION

1.5.2.1 With regard to programmed assessments (agreed with the CB by means of a technical quotation), the provisions of the specific regulations for the scope of recognition are applicable.

1.5.3. NON-PROGRAMMED SURVEILLANCE OF RECOGNITION

Starting with the annual program, surveillance assessment activities (on-site and witness assessments) may be intensified depending upon the behavior of the CB.

Supplementary and/or extraordinary assessments (also carried out as witness assessments) may be deemed necessary by ACCREDIA-DC following the granting of recognition if a situation of criticality is signaled either by ACCREDIA-DC directly or following indications, remarks or written complaints, with objective explanation, which ACCREDIA-DC has received, or situations of inadequacy which have been drawn to the attention of ACCREDIA-DC.

Such assessment necessities are communicated promptly to the CB, announcing, where necessary, the performance of a specific assessment and clarifying the context of the indication in question.

These assessments, which are to all effects non-programmed assessments, require notice of seven working days during which time the CB is allowed to object to the composition of ACCREDIA's assessment team.

ACCREDIA-DC may undertake a MSV of the CB after the granting of accreditation in cases where as critical situation has been identified, either directly by ACCREDIA-DC or in cases of written remarks/complaints, with objective reasons, received by ACCREDIA-DC, or of situations of inadequacy drawn to ACCREDIA-DC's attention.

In such cases, ACCREDIA-DC communicates promptly to the CB in question, the need to perform one or more than one MSV, clarifying the context of the remark/complaint and asking, where necessary, for the list of all the assessments previously undertaken under recognition (or for a sample, depending upon the needs of the case), reporting also the members of each assessment team, the dates when the assessments were performed and the references of the audited organizations (name, addresses of operative sites and scope of certification) as well as any indications regarding the auditing company or business partner.

After selecting the MSV activities to conduct ACCREDIA-DC communicates to the CB the date of the performance of these activities with at least **7 working days'** notice and the names of the ACCREDIA-DC assessment team and ACCREDIA-DC asks the CB to send, within **3 working days**, all the documents of the process of certification (from the informative questionnaire to the 3-year program, excluding the invoices and including the support checklists) for the entire 3-year period (where applicable).

In cases of a MSV requested following a remark or complaint or decisive for the imposition of a standard, the ACCREDIA-DC lead assessor will probably be assisted by an observer, usually a FT or staff operating exclusively for ACCREDIA-DC. Upon receipt of the documentation from the CB, ACCREDIA-DC sends out the assessment plan to the CB within **three working days** before the market surveillance visit takes place (in exceptional cases this may be within **one working day**), specifying to the CB that it is necessary to send a copy of the plan to the organization in question.

The costs of extraordinary assessments (on-site, witness, MSV) required by ACCREDIA-DC for reasons as stated above, are met by the CB if one or more NCs are raised or if numerous Concerns are reported sufficient to result in a negative result of these activities.

In other cases the costs are met by ACCREDIA-DC.

The aims and modalities for performing a MSV are set out in Annex 1 to the present Regulation.

On-site assessments, witness assessments and MSVs are considered non-programmed surveillances, required also by ACCREDIA's corporate bodies, at CBs operating in sectors or areas which have highlighted serious and numerous criticalities related to the effectiveness of certifications which have been issued. Such assessments are payable by the CB.

Other methods of control may be adopted by ACCREDIA-DC to verify the CB's activities (e.g. direct audits of auditing companies or other outsourcing companies operating for a CB, request for information by ACCREDIA-DC made to consultancy organizations, or other methods of control in accordance with the regulations).

1.5.4. DECISION-TAKING PROCESS AND GRANTING OF THE MAINTENANCE OF RECOGNITION

The results of the above surveillance activities are analyzed by the FT and by the DDC.

After the results of the surveillance assessments and of the subsequent analysis undertaken by the DDC, the following actions are performed:

- if there are no NCs, maintenance of recognition is confirmed by an ACCREDIA-DC FT by means of a simple recording of the confirmation of the results obtained within two months, along with the request for corrective actions for any Concerns which the CB shall send within 15 working days;
- if one, or more than one, NC is raised, the finding is examined and confirmed to the CB by the DDC within two months of the performance of the assessment;

In such cases treatment and CAs are required. These shall be sent by the CB within 15 working days of receipt of the communication of confirmation of the findings by the DDC, implemented by the CB, usually within two months and in agreement with the DDC.

In cases of CAs which are not satisfactory or not effectively implemented the case is submitted to the CSA DC;

- if a situation of critical nonconformity is raised owing to the number and seriousness of the failures and/or the CB is found to have professionally incorrect conduct, the file is submitted directly to the CSA DC as a "critical case" without any need to require that the CB performs treatment activities and CAs.

1.5.5. MODIFICATIONS TO THE STATUS OF RECOGNITION AND THE TRANSFER OF OWNERSHIP OF RECOGNITION

The CB shall communicate promptly to ACCREDIA-DC any modifications to the status of recognition or request for the transfer of ownership of recognition to another body.

In particular the CB shall:

- in cases of a request for the transfer of ownership of recognition to another body, send to ACCREDIA-DC the updated certification of accreditation together with the outcomes of any assessments carried out by the accreditation body in question and ACCREDIA-DC, before presentation of the request to the CSA DCI, verifies the case, reserving the right to ask for further clarifications from the accreditation body in question;
- communicate to ACCREDIA-DC all organizational changes (e.g. new operative locations, new partners etc.) and changes to the status of accreditation (e.g. suspensions, reductions, withdrawals).

1.6. SUSPENSION AND WITHDRAWAL OF RECOGNITION

1.6.1. SANCTIONS

1.6.1.1 If the results of surveillance, supplementary, extraordinary assessments or other controls reveal situations of major criticality, either from a technical or a professional point of view, ACCREDIA-DC may suspend or withdraw recognition depending on the gravity of the case.

Below are some examples of conditions of particular gravity:

- failure to resolve a NC in accordance with the ACCREDIA-DC procedures;
- failure to manage complaints;
- non-fulfillment of requirements of accreditation standards or requirements of the present Regulation or of the specific regulations for the scope of recognition;
- failed implementation of corrections/CAs in cases of certifications unduly issued (a CA could, for example, also lead to a decision with respect to the CB, to suspend or withdraw an unduly issued certification because it is outside ACCREDIA's accreditation of recognition or because it does not conform with the standards applicable to the certification scheme);
- failure to fulfill the requirements of the specific regulations for the scope of accreditation with regard to the transmission of data of certified entities in accordance with the procedures of ACCREDIA-DC;

- if the CB does not allow ACCREDIA-DC to perform assessments in accordance with the present Regulation or refuses access to its locations or to those of a third organization which undertakes part of the conformity assessment process on behalf of the recognized CB.

Any decisions concerning sanctions or the withdrawal of recognition are decided by the CSA DC.

Where necessary, the ACCREDIA President or General Director, in agreement with the DDC, may convene special meetings of the CSA DCI, also by email.

The decisions of the CSA DCI concerning suspension/withdrawal of accreditation, with justification and signed by the ACCREDIA President are communicated to the CB by means of recorded delivery mail or by email or certified email and published on the website.

The DDC deals with the immediate imposition of the sanction as well as all related decisions of the CSA DCI.

The accreditation body in question is also informed of the imposition of the sanction (both with regard to cases of recognition through direct agreement and through a MoU) and the competent authority is also informed (where applicable).

1.6.1.2. The duration of a suspension is established by the CSA DCI.

A sanction of suspension is removed when the CB has demonstrated that the causes of its imposition no longer exist.

A sanction of suspension has a maximum duration of 6 months, but this can be greater to allow the case to be discussed during the first due meeting of the CSA DCI which imposed the sanction.

at the end of the period as described above, if the CB has not restored conformity, suspension becomes withdrawal, following a decision by the CSA.

1.6.1.3 During the period of suspension the CB shall not issue certifications under ACCREDIA recognition. It can, however, proceed to surveillance and renewal of certifications previously issued but only in the terms in which they were issued; the extension of the scope of certification is not permitted. Renewal and maintenance activities for certifications which occur in the period of suspension is submitted to ACCREDIA-DC which defines the related witnessing activities, the costs of which are met by the CB.

1.6.1.4 The suspension of recognition may be imposed automatically by the ACCREDIA General Director in cases where payments are contractually more than 60 days overdue (the date of payment in the invoice), despite the receipt of a reminder after 45 days. Exceptions are made if there is an agreement to defer payment which has been authorized by ACCREDIA's General Director.

1.6.1.5 I Sanctions of suspension are published on ACCREDIA's website and also signaled on the Register of Recognized Bodies and wherever else necessary.

1.6.1.6 Recognition is withdrawn in cases where there is:

- failure to remove the causes of the suspension within the given timeframe;
- illicit or harmful or improper behavior in terms of professional ethics;
- failure to make due payments, if not fulfilled by the CB after six months from the communication of the automatic suspension sanction;

- improper use of the recognition such as to cause damage and/or discredit to ACCREDIA and/or the system of recognition and certification.

Recognition also lapses in cases of cessation of activity of the CB or if the competent AB withdraws recognition or if the CB voluntarily decides to renounce it.

If any fraudulent behavior is evidenced or if the CB deliberately provides false information or if it conceals information, ACCREDIA-DC shall initiate the process for the withdrawal of recognition, informing also the AB in question.

In cases as above, the CB cannot present another application for recognition.

1.6.1.7 Following withdrawal of recognition the CB shall immediately stop issuing certificates which contain references to ACCREDIA recognition.

In cases of withdrawal of recognition the CB cannot make a new application for recognition before 6 months have passed since the decision of the CSA DCI which imposed the sanction unless otherwise decided by the CSA and with the exception of cases of withdrawal of recognition for fraudulent behavior or if the CB deliberately provides or false information or conceals information.

Withdrawal of recognition is published on ACCREDIA's website. The name of the CB is removed from the Register of Recognized Bodies and wherever else necessary.

1.6.1.8 Withdrawal of recognition does not mean that contractual obligations with ACCREDIA-DC are annulled. ACCREDIA has the right to begin forced recovery of sums owed, of expenses with interest, in accordance with the law.

1.6.2. SUSPENSION REQUESTED BY THE CB

1.6.2.1 If a CB autonomously is in a situation of nonconformity with regard to recognition against the applicable standards and reference requirements for recognition, it may make a request for self-suspension to the ACCREDIA Direction for a period which allows it the necessary amount of time to return to conformity. This period shall not exceed 12 months, at the end of which the self-suspension automatically becomes withdrawal. The reasons and duration for such self-suspension are examined by the DDC who may modify and/or add to the conditions and the timeframe for a return to conformity by performing the necessary actions to verify full conformity at the end of the period of self-suspension.

Self-suspension of recognition is communicated to the competent CSA DCI and to the AB in question (both in the case of a direct agreement and also of a MoU) as well as any pertinent competent authorities, and the fact is published on the ACCREDIA website and on the Register of Recognized Bodies.

1.6.3. RENUNCIATION OF RECOGNITION

1.6.3.1 A recognized CB may voluntarily renounce recognition at any time and for any reason (e.g. non-acceptance of changes to the pricelist or the regulations covering recognition activities etc.).

If the CB renounces recognition stating a date in the future, the following conditions are applicable:

- until the moment of withdrawal, the CB may operate according to the normal conditions of recognition;

- ACCREDIA-DC may decide to perform further assessments to those already programmed for the period in question;
- ACCREDIA-DC may request further guarantees to ascertain that the activities, until the effective withdrawal of recognition, were properly conducted (e.g. to request the list of assessments performed, the closure of any findings still open, the conduct of unannounced assessments etc.).

Withdrawal of recognition following renunciation is submitted to the CSA DCI for deliberation.

In cases of renunciation of recognition for QMS certifications, IAF sector 28, the certificates issued shall be considered covered by recognition for a period of 6 months starting from the date of renunciation by the CB of its signatory status of the MLA agreements.

1.6.3.2 Renunciation of recognition does not mean that contractual obligations with ACCREDIA are annulled. ACCREDIA has the right to begin forced collection of sums owed, of expenses with interest, as prescribed by the law.

1.7. RESTORATION OF RECOGNITION

Depending upon the reason for suspension or self-suspension, ACCREDIA carries out the assessment for the restoration/resumption of conformity by means of one or more of the following actions:

- document review;
- on-site assessment;
- witness assessment.

After the assessment for the restoration to conformity the FT prepares a report of the assessment activities undertaken for evaluation by the DDC which decides if it is possible for the suspended CB to return to activities as before.

In cases of self-suspension or if assessment activities are not necessary, restoration of recognition is adopted by the DDC who informs the next due CSA DCI of such.

The list of recognized bodies published on ACCREDIA's website is then updated accordingly.

1.8. COMPLAINTS, RESERVATIONS AND APPEALS

1.8.1. COMPLAINTS

ACCREDIA-DC may receive complaints/remarks concerning:

- ACCREDIA-DC's operative activities;
- the operative activities of recognized bodies;
- poor or inadequate services on the part of certified bodies under recognition.

Within **30 calendar days** of receipt of the complaint/remark, after viewing and evaluating the causes of the complaint/remark, ACCREDIA-DC handles the case according to the procedures in force which guarantee that the examination and handling of the complaint/remark are carried out by persons who are independent of the case.

Anonymous complaints/remarks shall not be accepted so as to avoid speculative cases which may create unfair, or influence, competition.

Regarding the behavior of ACCREDIA-DC assessors (both internal and external), complaints/remarks can be presented within **10 working days** of the performance of the assessment.

1.8.2. RESERVATIONS

With reference to the findings raised by ACCREDIA-DC's assessors, any reservations may be presented within 3 working days of the audit.

ACCREDIA-DC shall give its response to the body after an evaluation, giving reasons for its decision concerning acceptance or non-acceptance of the reservation.

Such decision is the responsibility of the Director of Department.

1.8.3. APPEALS

If the recognized or applicant CB intends to ask ACCREDIA-DC to reconsider an action taken against it, it can present an appeal, using the modalities described in the ACCREDIA document RG-06.

The handling of an appeal is the competence of the Appeals Commission and it does not involve the CSA DCI although it is informed of the presentation of the appeal and of the outcome.

1.9. OBLIGATIONS OF THE CB

1.9.1 CBs shall maintain conformity with the requirements of recognition and shall also maintain behavior which is correct, transparent and in collaboration with ACCREDIA. the CB shall inform ACCREDIA if it is no longer able to maintain the conditions necessary to fulfill its obligations for recognition.

1.9.2 CBs shall send promptly, following acceptance of the cost quotation, to the email address programmazione@accredia.it, the list of audits which are the object of witness assessments. CBs shall also send, upon request by ACCREDIA-DC, the full list of audits performed during the period indicated by ACCREDIA-DC in order to enable the performance of MSV activities.

1.9.3 CBs shall allow the assessments by the ACCREDIA-DC assessment team to be carried out at their location and at those where audit activities take place at third party companies which perform activities as a part of the certification process.

1.9.4 CBs shall communicate to ACCREDIA any important variations in the organizational structure, the transfer of ownership to a new legal entity, changes to the name or legal status, the ceding of activities to another CB and the status of validity of the accreditation.

1.9.5 CBs shall state on certificates issued under ACCREDIA recognition the reference to the Technical Regulation (RT) of the applicable scheme or sector, where such exists.

1.9.6 CBs shall send to ACCREDIA-DC (through the web service – SIAC – made available by ACCREDIA-DC with the collaboration of a company providing such services, directly through access to ACCREDIA’s website and of third parties indicated by ACCREDIA-DC), timely and correct information concerning certificates issued under their responsibility, and CBs shall also communicate promptly all information with regard to the withdrawal of certifications in the QMS scheme, IAF sector 28, also for legal purposes.

If such data is not forthcoming within the established timeframe ACCREDIA-DC may impose sanctions on the CB.

1.9.7 CBs shall retain exclusive responsibility with respect to bodies benefitting from the service offered (e.g. ANAC, SOA, contract tender companies, the market in general.....) and also with respect to ACCREDIA-DC for any damage deriving from inaccuracies and/or delayed or untimely publication of data, removing thereby any responsibility, potential dispute or request for the payment of damages from ACCREDIA-DC concerning such inadequacies or failures.

1.9.8 Information obtained by ACCREDIA-DC may be published on its website and, as it is publicly available information already available on its website, it may be provided by ACCREDIA-DC to third parties which use certification, such as the Chamber of Commerce, research institutes, CRIF, CERVED, ANAC, ENEA, IAF etc. Full information may be provided so that bodies receiving it may in turn pass it on to the public if it has already been disclosed by ACCREDIA-DC.

1.9.9 CBs are obliged to respect all the rules of public safety as well as those contained in the normative requirements, and to provide to ACCREDIA-DC, on the basis of the programmed on-site assessment activities, detailed information concerning accident prevention, protection and emergency measures adopted by sending the module MD-19 within 10 calendar days from the date of the assessment, except in cases of non-programmed surveillances, in which case the information shall be sent within 7 working days.

1.9.10 CBs shall inform ACCREDIA-DC without undue delay regarding the activities covered by recognition. CBs shall also promptly inform ACCREDIA-DC of the administrative and juridical provisions regarding internal staff of the CB concerning activities covered by recognition. CBs shall not send to ACCREDIA-DC juridical data, in accordance with the privacy laws.

1.9.11 CBs shall perform a formal and documented examination if they obtain knowledge through official acts or press entities of occurrences related to organizations which they have certified concerning possible or actual violations of the law which are relevant to the scope of certification. The CB shall inform ACCREDIA-DC and shall record adequate reasons for any actions it undertakes. ACCREDIA-DC may ask for further information without, however, requesting juridical data, in accordance with the privacy laws.

1.9.12 CBs shall collaborate with regard to resolving any complaint communicated by ACCREDIA-DC and which concerns its recognition.

1.9.13 In publicizing and in communicating its recognition to the market, the CB shall commit to publish on its website, in its brochures and all technical and commercial documentation, correct references to the recognition.

1.10. OBLIGATIONS OF ACCREDIA

1.10.1 In cases of variations of the conditions of recognition, e.g. modifications to the regulations and reference standards for recognition, or standards concerning certified bodies, ACCREDIA-DC shall communicate as such to the CB. The CB may retain recognition and make the necessary organizational adjustments within the timeframe set out by ACCREDIA-DC, or it can renounce recognition.

1.10.2 If there is a modification to the pricelist, even if the quotation is still under acceptance, the services will be invoiced according to the costs in place at the time of the activity undertaken. If the costs change, immediately after approval by the Inter-ministerial Surveillance Commission, the CB will be promptly informed (by normal or certified email) and the updated pricelist will be published on ACCREDIA's website.

The CB has the right to renounce recognition within six months of the date of receipt of the communication.

During this period the CB which avails itself of the right to renounce recognition shall respect the pricelist as it was prior to the changes, for activities undertaken until the moment when it renounces recognition.

1.10.3 ACCREDIA-DC shall update regularly the Register of Recognized Bodies and make it publicly available on ACCREDIA's website.

1.10.4 ACCREDIA-DC shall perform an internal audit on the application of internal procedures regarding the definition and implementation of the duration and of the extension of the on-site and witness assessments related to recognition.

2. ACCEPTANCE CLAUSE

By signing the present document the CB declares that it accepts all the conditions and clauses set down in the present General Regulation, in the specific Regulations for the scope of recognition, as well as the standards, guides and reference documents referred to in the present Regulation and in the specific Regulations..

Date.....

Stamp of the Certification Body and signature of the
legal representative or attorney thereof

Pursuant to Articles 1341,1342 of the Italian Civil Code, the conditions of the present General Regulation and of the specific Regulations for the scope of recognition are approved.

Stamp of the CB and signature of the legal representative or authorized attorney..

ANNEX 1: OBJECTIVES AND MODALITIES FOR THE PERFORMANCE OF MARKET SURVEILLANCE VISITS

The aims of the Market Surveillance Visit are as follows:

- to fully ascertain that an audit has been thoroughly performed, and, therefore, whether the report reflects the organization's real situation by interviewing its top management – the Director/s or a representative, and examining the records contained in the last audit report;
- to fully ascertain that the audit report is complete and in line with the processes and requirements to be audited. On the basis of the report the CB makes its decision regarding certification;
- to fully ascertain whether the management system has been consistently applied and is effective or if it is randomly applied;
- to understand whether the 3-year program has been correctly managed: that all the organization's processes have been audited in the 3-year period and that there is evidence of this in the reports.

It is the CB's responsibility to establish contacts with the company for the organization of the market surveillance visit.

An assessment at the construction site or temporary site does not take place for the direct observation of the company's activities unless otherwise specified.

Any findings raise shall be classified as as Nonconformities, Concerns or Comments, whilst in the confidential part the audit team shall give an indication of rating as set out in the document IAF ID 04.

It is not acceptable for the organization to fail to provide the requested documents, i.e. the reference documents that the CB used when it performed the audit.

The ACCREDIA-DC assessor shall communicate, during the initial meeting, who s/he intends to interface with in the performance of his/her activities and s/he shall explain in detail to the organization the aims of the market surveillance visit, requesting transparency and participation during the phase of questions, and s/he shall respect the work times of the organization.

Regarding the questions, the ACCREDIA-DC assessor shall abide by the indications of the IAF document / checklist given in the confidential report of ACCREDIA-DC.

The audit report shall be delivered and explained by the ACCREDIA-DC assessor to the CB's representatives without providing any details regarding the audited organization.