ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Certification and Inspection Department

Regulation for the accreditation of Verification and Validation Bodies

RG-01-05

REVISION
03

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TITLE **Regulation for the accreditation of Verification and Validation Bodies**

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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.*

PREPARATION
The Director of Certification and Inspection Department

APPROVAL
The Directive Council

AUTHORIZATION
The President

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Contents

0. Foreword

0.1 Scope and field of application

The present Regulation is applicable to the accreditation of verification and validation bodies (hereafter referred to as VBs). It defines the conditions and procedures for granting, surveillance, extension, renewal, reduction/self-reduction, suspension/self-suspension, restoration, renunciation and withdrawal of accreditation of VBs, in compliance with applicable rules and guides, with the introduction of appropriate clarifications where the reference regulations/standards for the scheme contain rather general requirements and where the conditions and procedures are not covered by the General Regulation RG-01.

The present regulation shall not be applied separately from the application of the General Regulation RG-01.

0.2 Normative references

The normative references to be considered for the application of the present Regulation are detailed/referred to in the version in force of the ACCREDIA document LS-12: *"Reference standards and documents for the accreditation of Verification and Validation Bodies."*

It follows that, within the scope of a given validation or verification accreditation scheme, this Regulation is supplemented by specific Regulations/Technical Documents (RT and DT) and technical circulars, where applicable.

0.3 Terms and definitions

The terms and definitions set out in General Regulation RG-01 and in the applicable standards shall apply.

0.4 Acronyms

- ACCREDIA–DC: ACCREDIA Department of Certification and Inspection Bodies;
- CSA: Sectoral Accreditation Committee;
- DDC: Director of the Department of Certification and Inspection;
- VDDC: Vice Director of the Department of Certification and Inspection;
- FT: Technical Officer;
- VB: Verification/Validation body.

Part 1 - General requirements regarding the accreditation process

1. Criteria and information for accreditation

1.1. General information

Accreditation and the subsequent recording in the ACCREDIA database are issued to bodies which operate against reference standards and documents applicable to them and reported in the ACCREDIA document LS-12.

Consequently, within the scope of a specific accreditation, validation/verification scheme, programme, this Regulation is supplemented by specific Regulations/Technical Documents (RT and DT) and technical circulars, where applicable.

1.2. Submission and processing of the application for accreditation

The provisions of General Regulation RG-01 shall apply, with the clarification that an application for accreditation of a VB must be submitted to ACCREDIA-DC using the relevant forms DA-00 and DA-11, available on the ACCREDIA website, together with the documentation required therein.

1.3. Process of accreditation

1.3.1. Document review

The provisions of General Regulation RG-01 shall apply.

1.3.2. Assessments

The provisions of General Regulation RG-01 shall apply, with the clarification that the duration of the office assessment shall be determined taking into account the specific features of the scheme (e.g. number and criticality of the groups of activities required, number of sites to be assessed) and other factors such as the number of document review findings to be closed, language, and travel time.

In specific cases (e.g. notifications, EU ETS, etc.) witness assessments can be carried out after the granting of accreditation and the corresponding Ministerial Authorization. In such cases, the VB shall inform ACCREDIA-DC about the conduct of the first assessment, during which the witness assessment will be organized.

For accreditation areas intended for notification purposes, this activity must be carried out within 18 months from the issuance of the specific accreditation. If this is not possible, the provisions of the current revision of document DT-01-DC will apply (see § 1.9.2 below). The 18-month timeframe also applies to other possible

accreditation scopes where it has not been possible to conduct the Witness Assessment prior to the accreditation decision, without prejudice to cases where different timeframes have been agreed with the relevant Authority and/or through the issuance of specific circulars, and/or established by applicable EA/Global documents.

1.4. Decision-making process and granting of accreditation

The requirements of General Regulation RG-01 shall apply, with the following clarification:

- the accreditation certificate, limited to the attachment CSA CI, will have a duration of 5 years and no prolongations are allowed.

The provisions of Technical Document DT-01-DC, in its current revision, shall also apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.5. Surveillance and renewal of accreditation

1.5.1. Surveillance of accreditation

1.5.1.1. General

The requirements of General Regulation RG-01 shall apply.

1.5.1.2. Scheduled surveillance of accreditation

The requirements of General Regulation RG-01 shall apply, with the following clarification:

- office and witness assessments shall be planned so as to allow a representative sampling of the accreditation scope over the accreditation cycle.

1.5.1.3. Unscheduled surveillance of accreditation

The requirements of General Regulation RG-01 shall apply.

1.5.1.4. Unscheduled and scheduled remote surveillance

The requirements of General Regulation RG-01 shall apply.

1.5.1.5. Decision-making process and granting of maintenance of accreditation

The provisions of General Regulation RG-01, as well as those of Technical Document DT-01-DC, in its current revision, shall apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.5.1.6. Variation of the accreditation scope and accreditation standards

The requirements of General Regulation RG-01 shall apply.

1.5.1.7. Transfer of accreditation between accreditation bodies

The requirements of General Regulation RG-01 shall apply.

1.5.1.8. Transfer of ownership of accreditation

The requirements of General Regulation RG-01 shall apply.

1.5.2. Renewal of accreditation

1.5.2.1. Process of the renewal of accreditation

The requirements of General Regulation RG-01 shall apply.

1.5.2.2. Decision-making process and granting of renewal of accreditation

The provisions of General Regulation RG-01, as well as those of Technical Document DT-01-DC, in its current revision, shall apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.6. Extension of accreditation

1.6.1. General information

The requirements of General Regulation RG-01 shall apply.

1.6.2. Submission and processing of the application for extension

The provisions of General Regulation RG-01 shall apply, with the clarification that an application for extension of a VB's accreditation must be submitted to ACCREDIA-DC using the relevant forms DA-00 and DA-11, available on the ACCREDIA website, together with the documentation required therein. Where the VB requests an extension with a flexible scope pursuant to Regulation RT-37, the application shall be submitted to ACCREDIA-DC using form DA-10, which is also available on the ACCREDIA website.

1.6.2.1. Flexible scope

For the extension of accreditation to flexible scope, the requirements set out in the General Regulation RG-01 and in the Technical Regulation RT-37 in current revision apply.

Bodies operating for validation and verification activities shall maintain a fixed accreditation scope, without prejudice to the possibility of applying a flexible accreditation scope, upon specific request by the competent Authorities. The requirements set out in the current revisions of Regulation RT-37 shall apply.

1.6.3. Document review

The requirements of General Regulation RG-01 shall apply.

1.6.4. Assessments

The requirements of General Regulation RG-01 shall apply.

In specific cases (e.g. notifications, EU ETS, etc.), the witness assessments can be conducted after the granting of the extension and the corresponding Ministerial authorization. In such cases, the VB shall inform ACCREDIA-DC about the performance of the first assessment, during which the witness assessment will be organized.

For accreditation areas intended for notification purposes, this activity must be carried out within 18 months from the issuance of the specific accreditation. If this is not possible, the provisions of the current revision of document DT-01-DC will apply (see § 1.9.2 below).

The 18-month timeframe also applies to other possible accreditation scopes where it has not been possible to conduct the Witness Assessment prior to the accreditation decision, without prejudice to cases where different timeframes have been agreed with the relevant Authority and/or through the issuance of specific circulars, and/or established by applicable EA/Global documents.

1.7. Decision-making process and granting of extension of accreditation

The requirements of General Regulation RG-01 shall apply.

The provisions of Technical Document DT-01-DC, in its current revision, shall also apply to the maintenance of accreditations for notification purposes relating to CE marking.

1.8. Additional provisions

The requirements of General Regulation RG-01 shall apply.

1.9. Suspension, withdrawal and reduction of accreditation

1.9.1. Minor sanctioning measures

The requirements of General Regulation RG-01 shall apply.

1.9.2. Major sanctioning measures (suspension, reduction, withdrawal)

The requirements of General Regulation RG-01 shall apply.

In cases where the Validation and Verification Body requests accreditation for the purpose of subsequent initial authorization for Notification or another form of public authorization in regulated areas, ACCREDIA shall carry out at least one Witness Assessment among those provided for during the first assessment activity performed by the Body.

This witness assessment must be carried out within a maximum period of 18 months from the granting of the accreditation/extension. If the assessment is not conducted within this period, the accreditation for that conformity assessment activity shall be revoked. The 18-month timeframe also applies to other possible accreditation scopes where it has not been possible to conduct the Witness Assessment prior to the accreditation decision, without prejudice to cases where different timeframes have been agreed with the relevant Authority and/or through the issuance of specific circulars, and/or established by applicable EA/Global documents.

Once the accreditation has been withdrawn, the CAB may submit a new application. With regard to the scopes for notification purposes, the option to be accredited with the deferral of the witness assessment activity (i.e., after receiving the first client requests) will no longer be applicable. In such cases, the normal accreditation procedure shall be followed, including the execution of the witness activity (obviously simulated) prior to the accreditation/extension decision.

1.9.3. Suspension requested by the VB

The requirements of General Regulation RG-01 shall apply.

1.9.4. Procedural reduction of scope and renunciation of accreditation

The requirements of General Regulation RG-01 shall apply.

1.9.5. Restoration of accreditation

The requirements of General Regulation RG-01 shall apply.

1.10. Complaints/reports, reservations and appeals

1.10.1. Complaints/reports

The requirements of General Regulation RG-01 shall apply.

1.10.2. Reservations

The requirements of General Regulation RG-01 shall apply.

1.10.3. Appeals

The requirements of General Regulation RG-01 shall apply.

1.11. Obligations of the VB

The requirements of General Regulation RG-01 shall apply.

1.12. Obligations of ACCREDIA-DC

The requirements of General Regulation RG-01 shall apply.

2. Part 2 - Requirements for Validation and Verification Bodies

For the various programmes, the reference documents and circulars listed in LS-14 and LS-12 shall apply.

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