

INFORMATIVE CIRCULAR Ref. DC20220C066

DATE Milan, 30-09-2022

To all foreign CAB's legal entities accredited or in the process for the accreditation

<u>Loro sedi</u>

SUBJECT Certification and Inspection Department Informative circular DC N° 22/2022 – Updates of Regulations for the accreditation of certification, inspection, validation and verification bodies.

Dear Sirs,

we are pleased to send you here attached the new revision of the ACCREDIA's Accreditation Regulations will be in forced on 1^{st} January 2023 for the legal entities already accredited. For the new applications the new rules will be immediately applied.

Below is a summary of the main modifications made to the individual Accreditation Regulations of the Certification and Inspection Department with the clarification that the current structure consists of a General Regulation (RG-01 General Part) and five different specific Regulations by accreditation standards (RG-01-XX) has remained unchanged.

The main objectives of the review include:

- the necessity to include in the General Regulations all the requirements of the specific Regulations by accreditation standard, which were found to be transversal and therefore applicable to all active accreditation areas;
- the need to update the specific regulations for accreditation standards following the revisions of the normative documents and the EA/IAF/ILAC documents and to implement clarifications following the accreditation of new conformity assessment schemes.

The details of the changes introduced for each Regulation are reported below.

REGULATION FOR THE ACCREDITATION OF CERTIFICATION, INSPECTION, VALIDATION AND VERIFICATION BODIES - RG-01 GENERAL PART

The main modifications regard the following aspects/necessities:

- adaptation of normative terminology in the context of validation activities;
- updating of references to the various international documents and ACCREDIA regulations;
- reference to the subsequent amendments of the EC Reg. 765/2008 updated in 2019;



Certification and Inspection Department **REGISTERED HEAD OFFICE** Via Guglielmo Saliceto, 7/9 00161 Roma - Italy T +39 06 8440991 F +39 06 8841199 accredia.it / info@accredia.it VAT 10566361001 OPERATIVE AND ADMINISTRATION OFFICE

- updating of the definitions in order to harmonise them, in particular, with the provisions of the standards UNI CEI EN ISO/IEC 17011:2018 and UNI CEI EN ISO/IEC 17000:2020;
- inclusion of some requirements that could be imposed by scheme owners (e.g. the possibility for scheme owners to participate in ACCREDIA assessment activities etc.);
- specification of the times of sending to the Conformity Assessment Bodies (CAB) the results of the management of the findings (evaluation of the analysis of the causes, treatments, corrective actions proposed by the Body);
- specification of the methods for managing comments that emerge during the document review for renewal;
- specification of the roles of the personnel of the Accreditation Body with specific reference to the role of the Technical Expert in compliance of IAF/ILAC FAQ dated 19.08.2020;
- implementation, with respect to what is already indicated in the DA-00 format, of the operating procedures that ACCREDIA can adopt in cases where the accreditation application is signed by a person delegated by the legal representative of the CAB;
- alignment of the phases of the accreditation process with the current pricelist;
- specification of the procedures for managing accreditation and extension applications in cases where the CAB has not made itself available to carry out the subsequent assessment activities following the successful completion of the document examination;
- additional specifications regarding the procedures for managing cases in which the CAB provides ACCREDIA with false information;
- definition of the timing of publication of accreditation certificates on the ACCREDIA's database;
- updating of the process of issuance of the Accreditation Agreement with the current rules (single agreement for each Body);
- specification of the possibility for ACCREDIA to be able to undertake assessment activities also at the premises of clients/suppliers to which the CAB subcontracts audit activities;
- operative specifications for the aerospace sector;
- details on the performance of unannounced assessments;
- details on the application of remote scheduled and unscheduled surveillance activities, acknowledging, with regard to this, the recommendations approved by the Steering and Guarantee Committee at the meeting of 23 November 2021;
- new methods of managing accreditation transfers that incorporate the clarifications provided by the EA Horizontal Harmonization Committee following a question presented by ACCREDIA-DC in 2020;
- specification of the minimum documentation to be re-evaluated during the document review for renewal;
- inclusion, among the causes underlying the imposition of major sanctions:
 - failure to respond to requests for clarification formulated by ACCREDIA-DC;
 - failure to transmit the treatment plan and corrective actions following reminders;
 - withdrawal at the indisputable discretion of ACCREDIA for geopolitical reasons;
- specification that the validity of the sanctions measures starts from the date of receipt of them by the CAB in question;
- specifications regarding the procedures for restoring accreditation following the self-suspension requested by the CAB itself;





new procedural methods regarding the management of reservations with specification of the relative response timelines.

REGULATION FOR THE ACCREDITATION OF MANAGEMENT SYSTEM CABs RG-01-01

The main modifications regard the following aspects/necessities:

- elimination of the requirements for presenting an application for accreditation (the previous version provided for the need to have already issued certificates for at least 12 months);
- inclusion of references to module DA-04 for the notified area since, based on the revision of document EA 2/17 M: 2020, module H is also considered part of the management system;
- specification that for some management system schemes, accreditation can be granted • according to the provisions contained in the ACCREDIA's circulars and/or other specific applicable legislation (e.g. Ministerial Circulars, IAF mandatory documents, etc.).
- specification of the timelines within which all witness assessments must be carried out and the accreditation scope covered;
- specification of the complete information that must be contained in the quotations that the CAB issues to its customers or potential customers;
- clarifications regarding the use of the IAF sectors on certificates issued in the aerospace sector;
- clarifications regarding the methods of formulating the scopes of accreditation in the case of consortiums:
- elimination of the entire annex 1 which reported the version translated into Italian of the old revision, now no longer in force, of the document IAF MD 17.

REGULATION FOR THE ACCREDITATION OF CERTIFICATION BODIES OF PERSONS RG-01-02

The main modifications regard the following aspects/necessities:

- harmonisation of the terminology with the provisions of ISO/IEC 17024:2012; •
- updating of the various definitions;
- elimination of the requirements for presenting an application for accreditation (the previous • version provided for the need to have already approved or certified at least 5 people for each conformity assessment scheme for which accreditation was requested);
- specification of the accreditation management methods in cases where the certification • schemes are based on European para-normative documents or owner schemes;
- inclusion of references to module DA-04 for the notified area since, based on the revision of document EA 2/17 M: 2020, module H is also considered part of the certification of persons;
- specifications regarding the management of the examination centers; •
- specifications regarding the procedures for managing the exams, including the requirements in the case of written/oral tests and practical tests;

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details on the management of certificate transfers between accredited CABs.



UPDATES OF REGULATIONS FOR THE ACCREDITATION OF

VALIDATION

AND

REGULATION FOR THE ACCREDITATION OF PRODUCT/SERVICE/PROCESS CERTIFICATION BODIES RG-01-03

The main modifications regard the following aspects/necessities:

- inclusion of the "process" as a possible object of certification;
- elimination of the requirements for presenting an application for accreditation (the previous version provided for the need to have already issued certificates for at least 12 months);
- specification of the timelines within which all witness assessments must performed for the purposes of accreditation or extension in specific areas (e.g. notified bodies, protected designations of origin, Biofuels/Bioliquids, etc.);
- reference to the requirements established by regulations/laws for the signing of the insurance policy in certain areas;
- specification of the possibility and relative modalities, on the part of CABs, regarding the use of particular audit techniques.

REGULATION FOR THE ACCREDITATION OF INSPECTION BODIES RG-01-04

The main modifications regard the following aspects/necessities:

- updating of the definitions incorporating the contents of the ILAC document G28: 07/2018;
- elimination of the requirements for presenting an application for accreditation (the previous version provided for the need to have already issued inspection reports for at least 12 months);
- specification that, for some areas defined from time to time by ACCREDIA in Technical Circulars, the application for extension can be evaluated only on a documental basis, without performing the office assessment at the CAB or by witnessing activities;
- reference to the requirements established by regulations/laws for the signing of an insurance policy covering certain areas.

REGULATION FOR ACCREDITATION OF VERIFICATION AND VALIDATION BODIES RG-01-05

The main modifications regard the following aspects/necessities:

- the subdivision of the Regulation into two parts, the main one relating to ISO/IEC 17029:2020 (currently a level 3 standard) and a specific annex for the standard ISO 14065 which will be subsequently withdrawn when the transition period is concluded and ISO 14065 will become a level 4 standard;
- adaptation of regulatory terminology in the context of validation activities;
- unification of the forms/modules in use;
- the possibility, for some areas, to conduct the witness assessment after the granting of accreditation/extension;
- elimination of the requirements for presenting an application accreditation (the previous version provided for the need to have already issued declarations of verification of inventories or declarations of verification and validation of CFPs for at least twelve months). The requirement in the ETS area remains confirmed;
- specification of the documentation that ACCREDIA must evaluate during the witness assessments in the ETS context and of the methods of performance.



In each scheme-specific regulation, the recommendations expressed by the Steering and Guarantee Committee for the evaluation of the independence and impartiality requirements were referred to.

We are at your disposal for any clarification.

Best regards.

Dott. Emanuele Riva

Director Department Certification and Inspection



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