

Prot. DC2020OC298

Milan, 16/10/2020

To all certification bodies

To the associations of conformity assessment bodies

**Object: Informative circular DC N° 18/2020  
Accreditation in accordance with article 43, paragraph 1, of Reg. (UE) n. 2016/679 and article 2 - septiesdecies of Legislative Decree n. 196/2003**

Following the publication of the provision of the Guarantor for the protection of personal data n. 148 of 29 July 2020 - Additional accreditation requirements of Certification Bodies (published in the Official Gazette n. 201 of 12-8-2020), it is confirmed that ACCREDIA is available to accept applications for accreditation in accordance with art. 43 paragraph 1, of Regulation (EU) n. 2016/679 (hereafter referred to as "Regulation") and art. 2 - Septiesdecies of the legislative decree n. 196/2003 (hereafter referred to as the "Code").

ACCREDIA can accept applications for accreditation only referring to certification schemes approved by the Guarantor for the protection of personal data or by the European Data Protection Board (EU Seal).

These certification schemes will be available on the "European Register of Certification Mechanisms, Seals and Marks" accessible at the following URL [https://edpb.europa.eu/our-work-tools/accountability-tools/certification-mechanisms-seals-and-marks\\_en](https://edpb.europa.eu/our-work-tools/accountability-tools/certification-mechanisms-seals-and-marks_en).

Accreditation can be granted to CBs which have demonstrated conformity with:

- ISO/IEC 17065 and
- "additional" accreditation requirements approved by the Guarantor, with the above provision (as required by article 43, paragraphs 1, letter b, and 3 of the Regulation).

Persons/bodies interested in accreditation should contact Angelo del Giudice at [a.delgiudice@accredia.it](mailto:a.delgiudice@accredia.it).

Below there is some information relating to the accreditation process.

### **Process of accreditation**

The requirements of ACCREDIA regulations RG-01 and RG-01-01 remain applicable for obtaining accreditation and extension to accreditation.

Based on any accreditations already held by the CB that submits the application for accreditation, different cases may be presented: new ISO/IEC 17065 accreditation or extension of accreditation to ISO/IEC 17065.

Furthermore, in the event that the CB already holds ISO/IEC 17065 accreditations issued by another Accreditation Body, a case-by-case assessment must be carried out, based on the applicable EA / IAF MLA agreements.

A CB does not need to have already issued certificates relating to the scheme for which accreditation or extension is requested.

The accreditation certificate shall contain the list of accredited certification schemes.

The flexible scope cannot be applied.

A	CB already accredited to ISO/IEC 17065	<p>Document review of 1 day (to be done if possible, together with the CB – on-site or remote).</p> <p>1 witness assessment of a duration appropriate to the structural/organizational size of the client. ACCREDIA reserves the right to evaluate case by case the suitability of the organization and of the audit team proposed by the CB for accreditation and subsequent surveillance activities.</p>
B	CB already accredited to ISO/IEC 17065 for other schemes compliant to the Regulation	<p>Document review of 0.5 day (to be done if possible, together with the CB – on-site or remote).</p> <p>1 witness assessment of a duration appropriate to the structural/organizational size of the client. ACCREDIA reserves the right to evaluate case by case the suitability of the organization and of the audit team proposed by the CB for accreditation and subsequent surveillance activities.</p>
C	CB not accredited to ISO/IEC 17065, but accredited to other accreditation standards (e.g. ISO/IEC 17021-1, ISO/IEC 17024)	<p>Document review of 1 day at the CB's location (to be done if possible, together with the CB – on-site or remote). Assessment of 2 days to be conducted at the CB's location.</p> <p>1 witness assessment of a duration appropriate to the structural/organizational size of the client. ACCREDIA reserves the right to evaluate case by case the suitability of the organization and of the audit team proposed by the CB for accreditation and subsequent surveillance activities.</p>
D	CB not yet accredited in any scheme	<p>Document review of 1 day at the CB's location (to be done if possible, together with the CB – on-site or remote). Assessment of 4 days to be conducted at the CB's location.</p> <p>1 witness assessment of a duration appropriate to the structural/organizational size of the client. ACCREDIA reserves the right to evaluate case by case the suitability of the organization and of the audit team proposed by the CB for accreditation and subsequent surveillance activities.</p>

Documentation to be presented to ACCREDIA for the document review:

- a) Qualification criteria and CVs of auditors (personnel responsible for audits), of those who carry out the review phase and, if different, of those who approve the certification (personnel responsible for decisions relating to certification) with evidence of adequate knowledge, skills and experience, and constantly updated regarding the application of the data protection regulations and the related technical and organizational data measures, including any certifications in this area;
- b) integrity requirements of personnel responsible for decisions relating to certification (personnel responsible for decisions relating to certification);
- c) procedure for setting up and managing an audit team;
- d) attestation/certificate issued by the CB;
- e) list of certificates already issued, if available, and of upcoming audit activities (necessary data for planning the witness assessment);

- f) procedures and contractual regulations applicable to the audit, as well as the internal procedures for managing the certification file (from the offer to the certification) with particular reference to the certification agreement and the detailed description of the object of certification (object of the audit);
- g) support documentation to the additional accreditation requirements, as follows:
1. formal commitment to comply with all regulations applicable to the performance of the CB's functions and, in particular, the relevant provisions of the Regulation and the Code, including the obligation to inform ACCREDIA and the Guarantor of any significant change in the de facto or legal situation of the CB, with particular reference to the requirements relating to: responsibility, impartiality, financial capacity, confidentiality, transparency, competence, rapid and effective response to complaints;
  2. any act of appointment of a Data Protection Officer (DPO) in line with Article 37 of the Regulation or of the adoption of policies and procedures for the protection of personal data, within the framework of the certification process, in line with Article 24, paragraph 2 of the Regulation;
  3. declaration that there are no ongoing proceedings facing the Guarantor such as to imply a failure to meet the accreditation requirements;
  4. separate proof of the independence of the CB in line with Article 43, paragraph 2, letter a) of the Regulation, in particular as regards the financing, and of the absence of any conflicts of interest (e.g. statute and articles of association of the CB; rules and procedures for the composition, appointment, remuneration methods and duration of the mandate of the members of the CB responsible for making decisions relating to certification activities; documentation showing the commercial, financial, contractual or other relationships between the CB and the client);
  5. declaration not to be subject to insolvency or bankruptcy proceedings, to be up to date with the payment of pension and welfare contributions, not to be subject to compulsory tax collection proceedings and that the legal representatives of the CB have not had any legal convictions for culpable crimes related to the activities of the CB;
  6. evaluation of the risks deriving from the specific certification activities and adoption of suitable measures to mitigate the identified risks (e.g. insurance);
  7. obligations of the confidentiality commitment made by personnel;
  8. evaluation of the object of certification, with particular regard to the requirements concerning the examination of the application and the assessment methods, as well as the necessary coexistence of technical and legal competences for the purposes of this evaluation;
  9. client information modalities in the event of any non-conformities issued (at least the type and timeframe of this information);
  10. procedures for periodic review and withdrawal of certification in accordance with the GDPR and for the verification at the client's location of the absence of legal proceedings facing the Guarantor which could affect the certification;
  11. management of changes affecting certification under the Regulation (changes to data protection normative obligations, delegated acts of the European Commission, changes relating to the state of the art, etc.);

12. procedures to inform the Guarantor and ACCREDIA, where relevant, about the measures implemented and the maintenance, reduction, suspension and withdrawal of certifications also following complaints or appeals (it is confirmed that the information relating to all the accredited certifications must be uploaded by each CAB on the ACCREDIA database, with the same methods already adopted for product and MS certifications);
  13. procedures for the management of complaints presented to the CB specifically regarding the certification scheme;
  14. the CB's management system and the respective implementation modalities.
- h) for CBs which are NOT accredited to ISO/IEC 17065, as well as the documents reported above, it is necessary to send the documentation required as specified in the application for accreditation.

### **Maintenance of accreditation**

During the first 4 years of accreditation, annual on-site and witness assessments will be performed.

Subsequently, during the entire accreditation cycle (3 surveillances and the renewal assessment), except in particular situations (e.g.: management of complaints and reports, changes in the certification scheme, changes in the structure of the CB, situations of non-conformity...), will be conducted.

- a) annual on-site assessments,
- b) witness assessments
  - o if the CB has issued fewer than 20 certificates in the certification scheme, one witness assessment shall be carried out during the entire accreditation cycle;
  - o if the CB has issued between 21 and 200 certificates in the certification scheme, 2 witness assessments shall be carried out during the entire accreditation cycle;
  - o if the CB has issued 201 or more certificates in the certification scheme, 4 witness assessments shall be carried during the entire accreditation cycle;

We are available for any clarifications.

**Emanuele Riva**  
**Director of the Department of**  
**Certification and Inspection**