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Description of the revision	- *Update to legislative references to Ministerial Decree no. 188/2020* - *Inclusion of a remote audit among the options for conducting stage 1*

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1. Purpose and effective date of this document

The purpose of this document is to supplement the RGSG on the Certification of Management Systems (RSSG) of TÜV Italia srl (hereinafter TÜV Italia) for the certification of quality management systems.

2. Field of application

These rules apply to activities relating to the certification of quality management systems under the ACCREDIA accreditation system, and also to quality management systems certified without ACCREDIA accreditation; TÜV Italia operates in all 39 of the EA classification sectors.
The regulations and standards applicable to quality management systems are:
- ISO 9001;
- ISO 13485.

Depending on the certification type, and the commodity sector, reference will also be made to the following documents issued by ACCREDIA and available at www.accredia.it:

RG-01 Regulations on the accreditation of Certification, Inspection, Verification and Validation Bodies – General Section
RG-01-01 Regulations on the accreditation of management system certification bodies
RT-05 Requirements for the accreditation of bodies assessing and certifying quality management systems of construction firms and installers of systems and services (sector EA 28)
RT-21 Requirements for the accreditation of bodies certifying quality management systems (QMS) of organisations verifying the design of works, for validation purposes on a mandatory level.

These rules also apply for the certification of Quality Management Systems in sector IAF 24 referred to in Ministerial Decree no. 188/2020 ("Regulations governing the discontinued qualification of paper and cardboard as waste, pursuant to Article 184 - ter, section 2, of Italian Legislative Decree no. 152 of 3 April 2006"), governed by Accredia Circular no. 23/2021.

3. Terms and definitions

The terminology used in these regulations corresponds to the following standards:
- UNI EN ISO 9000:2015 "Quality management systems - Fundamentals and vocabulary"
- UNI CEI EN 45020:2007: "Standardization and related activities - General vocabulary"
- UNI CEI EN ISO/IEC 17000:2005 “Conformity assessment - Vocabulary and general principles”

For the definition of:
- Deficiency (CA)
- Nonconformity (NC)
- Observation (OBS)
- Comment (COM)

see the RGSG.

4. Responsibilities

The contents of section 4 of the RGSG will apply.

5. Control of the rules

These rules are available to interested parties at https://www.tuvsud.com/it
Organisations may request a copy in printed or digital format.
The contents of section 5 of the RGSG will also apply.

6. Certification procedure

6.1 General information

The contents of section 6.1 of the RGSG will apply, with the following additions:
In addition to the contents of the RGSG, in order to obtain certification by TÜV Italia in accordance with the requirements of ISO/IEC 17021-1:2015, a Quality Management System, must meet the requirements of the current version of ISO 9001 both initially and over time. It must also meet the additional requirements of the Accreditation Bodies (Example: Documents ACCREDIA RT-05, RT21, ...).
{text cancelled}

6.2 Audit procedure and audit programme

The contents of section 6.2 of the RGSG will apply.

6.3 Start of the certification procedure

The contents of section 6.3 of the RGSG will apply.

6.4 Pre-audit

The contents of section 6.4 of the RGSG will apply.

6.5 Stage 1 audit - (Initial review of documentation + initial audit)

The indications in section 6.5 of the RGSG apply; it should be noted that the stage 1 audit is conducted on-site at the organisation's site, possibly with a certain number of activities conducted remotely in accordance with Document IAF MD 4 and applicable accreditation rules.
In addition, at this stage of the audit, the organisation is required to provide the auditing team with the following documents:

- A copy of the obligatory documentation/documented information.
- A copy of the internal audit plans highlighting the progress and the summary of the results, showing any Non-conformities and the progress of any Corrective Actions
- List of Complaints received from Customers, showing how they have been managed.
- Summary of an analysis of customer satisfaction
- Summary of the company's data on process performance indicators
- Copy of the current improvement plans
- Copy of the last Management Review.
- A copy of the document of registration with the Chamber of Commerce and/or a copy of the valid By-laws, for associations or cooperatives etc.

6.6 Stage 2 audit (for an initial audit of the management system or certification audit)

The contents of section 6.6 of the RGSG will apply.

6.7 First issue of certification and renewals

The contents of section 6.7 of the RGSG will apply.
Issue of the certification automatically allows the organisation to use the certificate and the mark of TÜV Italia, in accordance with the conditions in section 8 of these Rules, together with the contents of section 8 of the RGSG.

6.8 Surveillance audit

The contents of section 6.9 of the RGSG will apply.

6.9 Renewal audit

The contents of section 6.9 of the RGSG will apply.

6.10 Special audits or unscheduled audits or a reduction in the scope of certification

The contents of section 6.10 of the RGSG will apply, with the following additions:
Accredia may ask for accompanied surveillance visits "Market Surveillance Visits" to be carried out with TÜV Italia on the premises of the certified organisation. These visits generally last for one day and are intended to determine the level of confidence in the management system's conformity to specific requirements, and the efficacy of the certification process.
These visits may be requested with at least 7 working days' notice. Accredia will send TÜV Italia the audit plan with at least 3 working days' notice of the Market Surveillance Visit, which it is required to send to the organisation.
This visit is not the same as a surveillance audit or certification renewal audit, but is a separate day.

7. Register of certified organisations

The contents of section 7 of the RGSG will apply.

8. Referencing the certification. Use of the certificate and mark

The contents of section 8 of the RGSG will apply.
For management systems that are only certified in accordance with ISO 9001, the following mark will apply, subject to updates:

Note: for further certifications of the management system obtained through TÜV Italia srl, a specific mark will be sent, if available. This will also refer to the other schemes for which certification was obtained.

9. Suspension of certification

The contents of section 9 of the RGSG will apply.

10. Withdrawal/cancellation of the certification

The contents of section 10 of the RGSG will apply.

11. Management of claims and reports by client organisations and by interested parties

The contents of section 11 of the RGSG will apply.

12. Documentation, or documented information of the management system and accessibility for TÜV Italia srl audits

The contents of section 12 of the RGSG will apply.

13. Changes to the management system

The contents of section 13 of the RGSG will apply.

14. Changes to the certification system rules

The contents of section 14 of the RGSG will apply.

15. Special requirements for organisations already certified by another body (transfer of a management system certification)

The contents of section 15 of the RGSG will apply.

16. Confidentiality

The contents of section 16 of the RGSG will apply.

17. Complaints (or Appeals)

The contents of section 17 of the RGSG will apply.

18. Complaints against TÜV Italia

The contents of section 18 of the RGSG will apply.

19. Disputes

The contents of section 19 of the RGSG will apply.

20. Financial conditions

The contents of section 20 of the RGSG will apply.