



CONTENTS

1. Purpose and effective date of this document	2
2. Field of application	2
3. Terms and definitions	2
4. Responsibilities	3
5. Control of the rules	3
6. Certification procedure	3
6.1. General information	3
6.2. Audit procedure	4
6.2.1. Parties involved in the audit	4
6.3. Start of the certification procedure	4
6.4. Pre-audit	5
6.5. Stage 1 audit (Initial review of documentation + initial audit)	5
6.6. Stage 2 audit - for the initial audit of the OH&SMS system or certification audit)	6
6.7. First issue of certification and renewals	6
6.8. Surveillance audit	6
6.9. Renewal audit	7
6.10. Unscheduled audits	7
7. Register of certified organisations	7
8. Referencing the certification - Use of the certificate and mark	7
9. Suspension of certification	7
10. Withdrawal/cancellation of the certification	7
11. Management of claims and reports by client organisations and by interested parties	7
12. Checking of OH&SMS documentation and of TÜV Italia srl audit reports	8
13. Changes to the management system	8
14. Changes to the certification system rules	8
15. Special requirements for organisations already certified by another body	8
16. Confidentiality	9
17. Complaints (or Appeals)	10
18. Complaints against TÜV Italia	10
19. Disputes	10
20. Incidents or failure to comply with legal requirements	10

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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) with the specific requirements necessary for the certification of occupational health and safety management systems. These rules will come into effect on the date indicated in the heading.

In order to provide evidence of the utmost fairness and transparency in carrying out management systems certification activities in accordance with these Rules, in addition to the contents of the RGSG it should be noted that TÜV Italia does not provide advisory services in the following areas:

1. Performing health and safety coordination roles
2. Producing safety reports
3. Carrying out risk assessments
4. Carrying out health and safety inspections, and internal audits,
5. Communicating with the regulators on behalf of the client, vi) assistance in producing the organisation's occupational health and safety management system
6. Carrying out accident and/or incident investigations

2. Field of application

These rules apply to activities for the certification of occupational health and safety management systems (OH&SMS) carried out with ACCREDIA certification in accordance with document MD22, and also without ACCREDIA certification; TÜV Italia operates in all 39 of the EA classification sectors.

TÜV Italia applies these rules impartially and in exactly the same way, for all organisations utilising its certification services; in particular, no financial conditions or other undue conditions are ever imposed; access to the certification is not conditional on the size of the organisation or its membership of a particular associational group, nor on the number of previously certified organisations.

It does not prejudice the application of any other regulations on additional certification schemes for which the organisation may be certified by TÜV Italia and/or by other Certification Bodies.

The following standards and regulations are applicable to OH&SMS:

- ISO 45001:2018 - Occupational health and safety management systems - Requirements with guidance for use

Obligatory reference is also made to the documents issued by the certification body Accredia, available at www.accredia.it:

- MD 22 - Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)
- MD 21:2018 - Requirements for the Migration to ISO 45001:2018 from OHSAS 18001:2007
- ISO 17021-10 - Competence requirements for auditing and certification of occupational health and safety management systems
- MD 1:2018 - IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organisation
- MD 2:2017 - IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

3. Terms and definitions

The terminology used in these regulations corresponds to the following standards:

- ISO 45001:2018 - Occupational health and safety management systems - Requirements with guidance for use
- UNI EN ISO 9000:2015: "Quality management systems - Fundamentals and vocabulary";
- UNI CEI EN 45020:2007: "Standardization and related activities - General vocabulary".
- ISO/IEC 17000:2004 "Conformity assessment- Vocabulary and general principles"

For the definition of:

- Deficiency (CA)
- Nonconformity (NC) or otherwise called a Major Nonconformity (mNC)
- Observation (OBS) or otherwise called a Minor Nonconformity (mNC)
- Comment (COM)

see the RGSG.



4. Responsibilities

These rules set out in detail the responsibilities of the organisation and TÜV Italia during the contract pertaining to certification activities in accordance with ISO 45001:2018.

The client organisations of TÜV Italia may create a link to the homepage of the TÜV Italia website which is www.tuvsud.com/it

5. Control of the rules

These rules are available to interested parties at www.tuvsud.com/it.

Organisations may request a copy in printed format.

If the rules are revised, any organisation that has an existing certification contract will be informed of the new version.

Any changes made to the subsequent versions of the rules (following revisions) will be highlighted as follows:

- the revised and/or additional text will be written in italics
- any cancelled text that has not been substituted will be indicated with {text cancelled}

In the case of new additions, as the changes are significant, the changes will not be highlighted, but the full contents of the document must be relied on

6. Certification procedure

6.1. General information

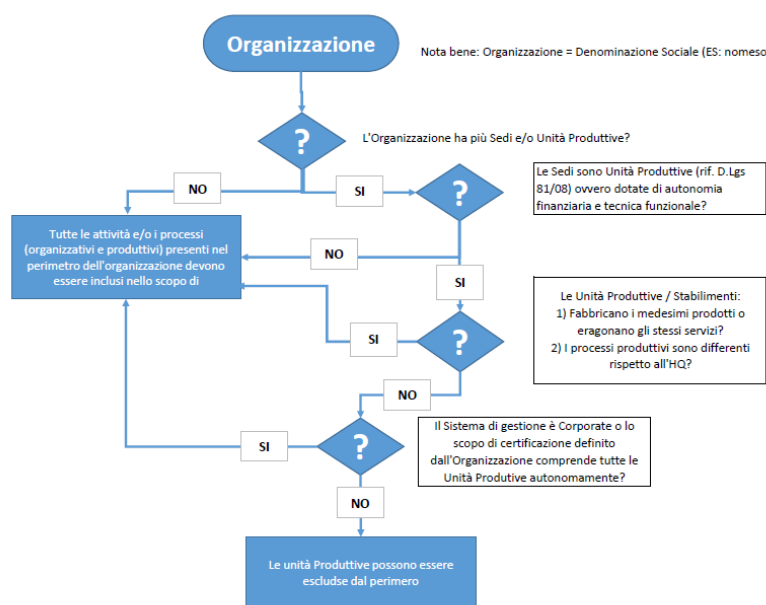
The procedure for certifying management systems, as adopted by TÜV Italia, is described in the RGSG.

During the certification procedure, the following considerations and special requirements pertaining to the following aspects, must be taken into account:

Organisations with multiple sites (multi-site certification)

Organisations with multiple local branches shall include, within their certification perimeter, any units that are not financially and technically or functionally independent, or those which are dependent on an Employer who has responsibility for the OH&S management system. All the processes of these sites, as they are conducted, must be assessed. For sites classified as Production Units, as defined in Italian Legislative Decree 81/08 as amended, which therefore have their own financial and technical-functional autonomy, for example their own Employer and/or their own risk assessment documents, etc., if they produce and/or provide various services and carry out various operational processes, may be excluded from the scope of the OH&SMS.

Below is a flowchart indicating the criteria used to decide whether or not a site can be excluded.



Partial certification of a site

Partial certification of a Site is NOT permitted. Partial certification refers to the certification of some of the processes, or of the processes in certain areas. The certification of part of a process is not permitted. If an organisation requests the certification of its OH&SMS, the



system shall include all the processes and areas of the organisation, without any exclusions. To indicate compliance with this requirement, the organisation shall identify and analyse all the processes, including them in a cycle of continual improvement of the OH&SMS.

Compliance with legal requirements (laws, decrees, regulations, etc.)

As regards compliance with legal requirements, the organisation shall declare and sign for conformity, completing the form "DECLARATION OF CONFORMITY TO LEGAL REQUIREMENTS" (see section 6.5 a); the general principle is that the maintenance and assessment of conformity to legal requirements falls under the responsibility of the organisation that manages the OH&SMS. TÜV Italia merely carries out random audits to obtain assurance that the OH&SMS is effective from this point of view and that – in the eventuality of nonconformity to requirements – the organisation will take appropriate corrective actions.

This general principle takes the form of the following detailed requirements:

- At the start of the stage 1 audit, the organisation must provide evidence of its compliance with legal requirements, including the obtaining, or application for, the necessary approvals from the authorities; at this stage of the audit, failure to provide evidence of legal compliance will be documented as a "deficiency" in the audit report and shall be dealt with and managed as defined in the RGSG.
- However (during the stage 2 audit, surveillance and renewal audits), TÜV Italia may detect one or more instances of the organisation's failure to comply with mandatory requirements; in this case, the audit team will issue one or more nonconformities; the nonconformities will only be considered to be successfully resolved if, at the next audit, the organisation can demonstrate that:
 - it has completed a new, global reassessment of its OH&SMS, with a particular focus on compliance with applicable mandatory requirements
 - it has taken appropriate corrective actions in respect of the specific findings of the TÜV Italia audit team, or of the organisation's own findings, during the global reassessment;
 - it has already obtained, or at least requested the corresponding approvals from the authorities.
- Regardless of the findings of the TÜV Italia audit team, the organisation itself may detect breaches of the legal requirements, after it has submitted the evidence referred to above; in such situations the organisation must itself put in place appropriate corrective actions, and take appropriate measures to mitigate and control the risks, particularly by demonstrating that it has obtained or requested the necessary approvals from the authorities; the TÜV Italia audit team will check all these aspects during the next audit, and if necessary will issue non-conformities, which will be dealt with as described in the second paragraph.
- Continued violation of mandatory requirements may result in the suspension and/or withdrawal of the certificate

Management of risks

It is the responsibility of the organisation that manages the OH&SMS to define procedures for risk management (identification of risks + assessment of risks + identification of appropriate health and safety measures to mitigate risks and/or keep them under control). TÜV Italia will assess not only that the relevant requirements have been respected and implemented, but also that they are effective.

Continual improvement

It is the responsibility of the organisation that manages the OH&SMS to define the methods and tools through which the commitment to continual improvement, as contained in the health and safety policy, is implemented, and how the improvements are actually measured.

TÜV Italia assesses not only that the requirements have been respected and implemented but also that they are consistent with the policy, objectives and goals of the organisation, and that they are effective.

6.2. Audit procedure

The audit procedure as described in the RGSG.

6.2.1. Parties involved in the audit

The organisation must guarantee the availability of the key roles in the OH&SMS (Employer, health and safety officer, company physician, workers' safety representative, etc.) at all relevant stages of the audit in accordance with the audit plan, which TÜV Italia will provide, ahead of the audit.

Top Management must be available, in accordance with the audit plan, and must also attend the opening and closing meetings.

The closing meeting must be attended by management legally responsible for health and safety at work (DL), the company physician (MC), the workers' safety representative(s) (RLS). Any absences shall be justified.

6.3. Start of the certification procedure

The certification procedure will be started when TÜV Italia issues the order confirmation.

The contents of the RGSG will apply



6.4. Pre-audit

The contents of the RGSG will apply.

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

The contents of the RGSG will apply.

The following has also been added

Stage 1 audit includes:

- checking of the OH&SMS documentation;
- the initial audit.

In general these two activities will be carried out at the same time, at the actual site (or sites) of the organisation. The outcomes will be contained in a single report.

Only in special cases may TÜV Italia and the client agree, in the contract, for these two activities to be done separately; in any case they will usually be done within a period of 4 weeks, and will conclude with reports; in these particular cases, the documents can also be examined at the offices of TÜV Italia instead of on the organisation's premises.

a) Checking OH&SMS documentation

The OH&SMS documentation will always be checked.

In general, OH&SMS documentation refers to the following:

- the documented information required by the standard, and by the OH&SMS;
- a description of the processes and their interactions
- the risk assessment document
- the emergency management plan
- a description of the processes to be assessed, including the laws and regulations they are governed by
- the organisation's Chamber of Commerce record, and information about the technical and logistics staff
- a declaration confirming whether or not there have been any previous convictions or penalties in respect of particular organisational and/or technical aspects, in relation to the OH&SMS
- the legal representative's declaration confirming legal compliance, which must refer to a list of the applicable legal requirements. The declaration must state that the legal representative of the certified organisation is aware that a requirement for obtaining and maintaining ISO 45001:2018 certification is compliance with the legal requirements – this compliance is the responsibility of the organisation).

b) Initial audit (stage 1)

The initial audit will always take place. It consists of an on-site visit (at the site or sites of the organisation) and the purposes are indicated below.

The initial audit enables TÜV Italia to better understand:

- the size and nature of the organisation's activities;
- the main issues facing the organisation in terms of occupational health and safety;
- the applicable legal requirements;
- the extent to which the organisation is able to undergo the certification audit;
- the type of experience necessary for the audit team who will be carrying out the certification audit;
- the number of people who will be needed for the certification audit.

The initial audit also enables the organisation to:

- obtain clarification about the details of the certification process
- make a more accurate forecast of the time needed to obtain certification, and to produce the certification programme;
- identify any deficiencies in the implementation of the OH&SMS in accordance with the applicable laws, these rules, the manual, the procedures and the legal requirements etc.

To fulfil these objectives, during the initial audit, the audit team will assess the degree to which the ISO 45001:2018 standard has been met, considering at least the following basic elements:

- The requirements (where applicable) stated in document MD22
- Policy (point 5.2)
- Leadership and worker engagement (point 5)
- Planning (point 6 – all sub-points)
- Competence (point 7.2)
- Awareness (point 7.3)
- Communication (point 7.4)



- Planning and operational controls (point 8.1)
- Preparation for and response to emergencies (point 8.2)
- Monitoring, measurement, analysis and assessment of performance (point 9.1)
- Internal audit (point 9.2)
- Management review (point 9.3)
- Incidents, non-conformities and corrective actions (point 10.2)
- Continual improvement (point 10.3)

For each of these requirements, the OH&SMS must have been implemented, and the corresponding records must be available.

The organisation must also provide the documents about legal compliance; this includes but is not limited to: fitness for use, fire prevention certificate if applicable, permits, assessments of specific risks, declarations of conformity of installations and/or equipment.

The outcome of the initial audit shall be included together with the results of the documentation examination, in an assessment report which will be issued after completion of the stage 1 audit.

If the implementation of the OH&SMS is defective, the client will be informed in that report.

If documentation review highlights any Deficiencies, the organisation shall correct them before the on-site audit is conducted; however, the stage 2 audit may be carried out, and will include an examination of corrections of the Deficiencies; if any Deficiencies in the documentation still exist when the Stage 2 audit is carried out, the certificate cannot be issued and a post-audit will be necessary. If the documentation examination highlights any Deficiencies that, in the opinion of the lead auditor, require another documentation examination, that opinion will be formalised in the Stage 1 report; obviously in this situation, another documentation examination will have to be carried out, after the organisation has remedied the reported Deficiencies

In the light of findings from the stage 1 audit, when TÜV Italia has had an opportunity to learn about the organisation's situation, TÜV Italia may consider whether it needs to change its quote.

- 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 the initial audit of the OH&SMS system or certification audit)

The contents of the RGSG will apply.

In addition, please note that:

The certification audit is always conducted on-site (on the site or sites of the organisation) within 6 months from the start of the stage 1 audit.

It will be done on the basis of an audit plan, which is designed to take into account the results of the activities already done (stage 1 audit), and special importance is given to the aspects of the OH&SMS found to be most significant; in general, the plan will include all the requirements of the applicable standard, but it may also not include any requirements that were found to be fully satisfactory during the course of the stage 1 audit. The plan will also include the following mandatory activities, for which no variations are allowed:

- Interview with Top Management/Employer, by the audit team
- Interview with the Health and Safety Officer, by the audit team
- Interview with the Company Physician, by the audit team
- Interview with the workers' safety representatives, by the audit team,
- Interview with the Employees, by the audit team
- audit activities carried out during work shifts not included in the normal working day, for example night shifts (if existing).
These activities will include interviews with workers, who must be available

The organisation will be informed of the plan in advance.

The purpose of the certification audit is to check that the OH&SMS is implemented in accordance with the relevant documentation (manual, procedures, instructions, legal requirements, any other applicable requirements, programmes, etc.), in an efficient manner, and that it meets the requirements of the reference standard.

6.7. First issue of certification and renewals

The contents 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 the RGSG.

6.8. Surveillance audit

The contents of the RGSG will apply.

Each surveillance audit relates to a part of the OH&SMS: the audit always covers, in principle, some "fixed" elements of the OH&SMS (requirements in points 4.1, 4.2, 4.3, 4.4,5.3, 6.1, 6.2, 9.1, 9.2, 9.3, 10.2, 10.3 of UNI ISO 45001:2018) plus additional elements.

However, in general, three-year surveillance audits cover the entire OH&SMS at least once.



The plan includes the mandatory activities mentioned in section 6.6 above.

6.9. Renewal audit

The contents of the RGSG will apply.

The plan includes the mandatory activities mentioned in section 6.6 above.

6.10. Unscheduled audits

The contents of the RGSG will apply.

For organisations operating in specific EA sectors (examples: 31a, 36, 37, 38, 39) TÜV Italia may participate as an observer of the emergency management drills; the procedure for the participation of TÜV Italia observers will be agreed with the certified organisations.

7. Register of certified organisations

The contents of the RGSG will apply.

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

The contents of the RGSG will apply.

Detailed indications of how to use the certificates and the certification mark are contained in the Guide to Certification Marks – Rules and Referencing of Certifications – Use of Certificate and Mark, which is available at www.tuvsud.com/it

9. Suspension of certification

In general, the contents of the RGSG and specifically the rules on the suspension of certification, may apply in one of the following cases:

- the organisation fails to respect the applicable requirements regarding health and safety in the workplace;
- the organisation does not promptly report to TÜV Italia all the nonconformity situations identified by the regulatory authorities;
- the surveillance or renewal audits identify nonconformities that are not closed in the next post-audit;
- the organisation does not take the corrective actions requested in the previous audit to resolve nonconformities, by the specified time limit and according to the specified conditions; the organisation references the OH&SMS certification in a way that does not conform to the rules (see section 8);
- the organisation does not keep records of the reports of deficiencies related to the OH&SMS, and of the related corrective actions taken (see section 11);
- the organisation makes significant changes to its OH&SMS without informing TÜV Italia (see section 13);
- the organisation is not up to date with the payments for work already done.

If the certification is suspended, TÜV Italia will officially notify the organisation, giving details of the conditions that the organisation has to meet – within a specified period of time – in order for the certificate to regain validity, and to avoid it being definitively cancelled.

TÜV Italia will inform ACCREDIA of the suspension (for certificates issued in connection with sectors of activity accredited by ACCREDIA).

Should the organisation, after the suspension of the certification, continue to refer to it in any way, TÜV Italia may take legal action.

If the organisation meets the conditions set by TÜV Italia, TÜV Italia will revoke the suspension of the certification, and will immediately notify the organisation and Accredia (only for certifications accredited by Accredia); otherwise, TÜV Italia will withdraw the certificate (see section 10).

Within TÜV Italia, all decisions connected to suspension of the certification (and lifting of the suspension) will be taken by the approval committee.

Sole responsibility for informing the public authorities and customers lies with the organisation whose certification was suspended. This is subject to any requirements deriving from applicable regulations or national laws

10. Withdrawal/cancellation of the certification

The contents of the RGSG will apply. The announcement of withdrawal of certification to the public authorities or clients is also the sole responsibility of the organisation whose certification was withdrawn. This is subject to any requirements deriving from applicable regulations or national laws

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

The organisation (already certified by TÜV Italia or not yet certified, but which nevertheless uses TÜV Italia's certification services) shall have prepared and implemented a documented procedure for managing reported deficiencies which can assure:

- the registration of all reported deficiencies received from "interested parties" (as defined in the standard UNI ISO 45001:2018, for example supervisory authorities, associations, employees, customers, suppliers, visitors, etc.) connected to the operation of the OH&SMS;



- the carrying out and registration of appropriate investigations of the reported information;
- the formal reply to any complaint received (replies must be received within 20 working days, and if reports are made by the supervisory authorities, they must be received by the deadline indicated in the relevant letter)
- the adoption, where necessary, of corrective actions and their registration.

The organisation must make the records available to TÜV Italia for examination at each audit.

If the certification refers to EA sectors for which TÜV Italia is accredited by ACCREDIA, the records shall be kept available for verification by ACCREDIA representatives.

12. Checking of OH&SMS documentation and of TÜV Italia srl audit reports

The certified organisation shall allocate a controlled copy of its OH&SMS documentation to TÜV Italia and must keep it on behalf of TÜV Italia, in its own records, and keep it up to date; an updated copy on disk of the updated documentation must also be provided to TÜV Italia on request, if it is required by the Approval and Certification Committees of TÜV Italia or by the representatives of ACCREDIA. This documentation is the reference for the audit team, during the surveillance and renewal audits.

Any industry standard is acceptable, for the disk copy.

The organisation is also required to keep a copy of the TÜV Italia audit reports for 3 years after the date of each report

13. Changes to the management system

The certified organisation must inform the relevant office of TÜV Italia of any major changes it intends making its management system, the related scope (for example, the inclusion of other certification standards and/or requirements excluded as they are considered not to apply, changes to the type of products, processes or services mentioned in the certificate, extension to include another site etc.), or to the related controlled documentation (see section 12).

TÜV Italia will consider whether there is a need to carry out an additional unscheduled audit, based on those changes (see section 6.10). This may be accompanied by a revision of the certification, or a completely new certification process.

Failure to observe these conditions may result in suspension of the certification (see section 9).

The certified organisation itself may ask TÜV Italia to review its certification, if one or more of the situations described above, should occur.

Also in this case, TÜV Italia will assess whether or not there is a real need to carry out an additional unscheduled audit as a result of the changes (see section 6.10) or whether to start a brand new certification procedure. The new audit, and the activities and processes for which the extension is required, shall cover all the points of the applicable standard.

In all cases, the revised certifications will be issued with the favourable opinion of the approval committee.

14. Changes to the certification system rules

TÜV Italia may make changes to the certification system as described in these rules and/or in the RGSG. If it does, TÜV Italia will allow the already-certified organisations to make observations on the proposed changes.

Once the changes have been decided, TÜV Italia will specify the date on which they will come into force, and will give details of the corrective actions required from the organisations, allowing them a reasonable period of time to fulfil the requirements.

If an organisation cannot or does not want to adapt to the new rules, TÜV Italia will decide on necessary actions, in accordance with the general rules.

15. Special requirements for organisations already certified by another body

An organisation whose management system is already certified according to UNI ISO 45001:2018 by another certifying body accredited for the organisation's industry, may also request certification from TÜV Italia in accordance with the certification model described below.

TÜV Italia may assess whether or not this model applies, also based on the results of a preliminary investigation to verify the following:

- the reasons for the organisation's request;
- confirmation of the validity of the existing certification (in terms of authenticity, appropriateness for the scope, the actual existence of the accreditation of the certifying body for the sector of activity in question, the timing of issue and expiry, the absence of any suspensions etc.).

The model cannot be applied if the existing certification is subject to a suspension order, due to technical reasons.

The model provides for the application of the general rules described in the other sections of this document, but with the special requirements listed below, which are distinguished according to two different potential situations (for any cases not covered below, the transfer of certification is not possible and the organisation requesting certification must start a new certification procedure)

- a) the originating certifying body is accredited by Accredia and the certification to be transferred is an accredited certification;
- b) the original certifying body is a body within the group of the German parent company.



In any event, in both these situations, before being authorised each certification will be submitted for approval by the approval committee.

Situation (a)

At the time of first examination of the management system documentation, the audit reports completed by the previous certifying body in the past three years will also be taken into consideration.

Furthermore, if TÜV Italia takes over during the period in which the certification of the previous body is still valid, an audit will be scheduled. During the TÜV Italia audit, all the elements of the management system will be audited (with reference to points of the reference standard) together with the additional requirements of the RGSG, document MD22 and the other accreditation requirements of Accredia.

In addition:

- any pre-existing nonconformities must be closed;
- complaints must be handled properly (see section 11);

If the audit is positive, and the Approval Committee authorises the certification, the certification expiry date will be the same as for the original certification. The surveillance programme will be the same as for the original certification.

However, if TÜV Italia takes over at the same time as the renewal of the previous certification, the TÜV Italia audit will check all the elements of the management system and any additional requirements stipulated in the RGSG and any Accredia requirements that apply to the specific case.

In addition:

- any pre-existing nonconformities must be closed;
- complaints must be handled properly (see section 11);

In such a case, the date of issue of the certification (and therefore of the decision by the TÜV Italia approval committee) must precede the date of expiry of the previous certification. Therefore, the date of expiry of the TÜV Italia certification is three years after the date on which the certification is authorised.

In both these situations (TÜV Italia takes over during the validity of the previous certification or at the same time), any non-conformities or observations will be dealt with in the standard way, and any extensions of the scope of the certification will require specific audits; the scope of the certification will also be defined in the standard way.

Situation (b)

If the organisation has a valid, active, non-suspended UNI ISO 45001:2018 certification from a certifying body in the TÜV SÜD Group and intends starting a certification process in accordance with the Accredia model described in MD22, the organisation must make an express application to TÜV Italia. In relation to the application, TÜV Italia will issue a new set of contractual documents (offer and order confirmation), which will be based not only on these rules but also on the following procedure:

In the first instance, an audit will be done on the basis of documents (full assessment of the certification file lodged with TÜV Italia on behalf of the previous certifying body) in order to check:

- that there are no pre-existing nonconformities;
- that there are no complaints or reports that have been incorrectly handled;

An on-site certification audit will be planned, with a duration of 2/3 (equivalent to a renewal) of the time indicated on the tables determined by Accredia for a new UNI ISO 45001:2018 certification.

If the audit is positive and the approval committee authorises the certification, the certification will have the same date of issue as that of the decision, and will expire three years after the date of issue. In such a case, the surveillance plan will continue in the same way as for a new certification cycle, in other words 2 surveillance audits: 12 and 24 months after the date on which the on-site certification audit was completed.

16. Confidentiality

TÜV Italia will ensure that all the information acquired during the activities connected to the certification of management systems will be dealt with in the strictest confidence, subject to any requirements of:

- provisions of law;
- instructions of accrediting bodies.

In these exceptional cases, the client will be informed *in writing* about the information disclosed to third parties.



The TÜV Italia personnel involved in the certification process will sign a formal undertaking to observe confidentiality. A copy will be provided to the organisation on request; the audit reports will only be sent to the organisation, with a copy to be kept in the TÜV Italia archives, and a copy for the members of the audit team.

17. Complaints (or Appeals)

The contents of the RGSG will apply.

18. Complaints against TÜV Italia

The contents of the RGSG will apply.

19. Disputes

In the event of any dispute with TÜV Italia srl, the Court of Milan has jurisdiction.

20. Incidents or failure to comply with legal requirements

The organisation must immediately inform TÜV Italia of any incident that may have caused serious harm to the safety or health of employees and/or where there has been a significant breach of legal requirements, regardless of the number of communications from the supervisory authorities