

Elaborazione e Verifica  
*Drafting and Review*

Approvazione ed Emissione  
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## 1. Purpose and scope of the Regulation

These Regulations establish the conditions that an organization must meet in order to obtain and maintain the certification of a Quality Management System (hereinafter referred to as the Management System or SG) **or to obtain the assessment of the Production Conformity Control System -CoP- (hereinafter also referred to as the Control System)**. The aim is to ensure that:

- Access to certification is open to all organizations that request it in compliance with these Regulations, without discriminatory policies or methods being applied to access certification. **For the certification of the quality management system**, CETOC TS applies tariffs and economic conditions defined in its "Price List" to avoid financial and economic discrimination or discrimination relating to the size of the organization or membership of particular associations/groups;
- the evaluation criteria of Quality Management Systems / **Conformity of Production** of the organizations used as a reference for comparison with the audit evidence include: the applicable standards – mandatory and non-mandatory -, these Certification Regulations, the applicable Technical Regulations and the sectoral provisions of the Accreditation Body.


CETOC TS does not provide organizations with assistance in implementing and maintaining compliance (including internal audits) of quality and quality management systems. Conformity of the Production, nor does it have any related structures that carry out this activity.

These Terms and Conditions are an integral part of the contractual agreements with the Client, unless otherwise agreed in writing or otherwise provided for by law.

This document is applicable unless the parties expressly agree on exceptions to be considered valid only if defined in writing between the Parties in advance. Any exceptions may not concern the conformity assessment procedures according to which CETOC Technical Service, hereinafter CETOC TS, operates as a Certification Body.

## 2. References

All the rules and regulatory documents indicated below are understood and applied in the current revision (in force), taking into account any periods of coexistence and/or transition between subsequent editions.

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## 2.1. Reference standards and documents for the Certification Body

- UNI CEI EN ISO/IEC 17021-1 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements
- UNI CEI EN ISO/IEC 17021-3 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems
- UNI EN ISO 19011 Guidelines for management system audits
- RG-01 - Regulation for the accreditation of Certification, Inspection, Validation and Verification Bodies - General Part
- RG-01-01 - Regulation for the accreditation of Management System Certification Bodies
- RG-09 - Regulation for the use of the ACCREDIA Mark
- IAF MD 1 The Audit and Certification of a management system operated by a multi-site organization
- IAF MD 2 Transfer of accredited certification of management systems
- IAF MD 5 Determination of audit time of quality, environmental, and occupational health & safety management systems
- IAF MD 10 Assessment of certification body management of competence in accordance with ISO/IEC 17021:2011
- Additional documents issued by the accreditation body ACCREDIA, by the EA and/or by the IAF applicable to the management system and/or specific sector to which the Certification Body is required to comply
- Additional documents issued by the Authorities applicable to the production conformity control system to which CETOC TS and its customers are required to comply
- [European Regulation 2007/46](#)
- [European Regulation 2018/858](#)
- [European Regulation 167/2013](#)
- [European Regulation 168/2013.](#)

## 2.2. Reference standards and documents for management systems

- UNI EN ISO 9001 - Quality management systems – requirements
- UNI EN ISO 9000 - Quality management systems - Fundamentals and vocabulary.
- UNI EN ISO 9004 - Quality management - Quality of an organization - Guidelines for achieving lasting success.

### 3. General Condition

#### 3.1. Conditions for obtaining and maintaining the Certification / Assessment of Conformity of Production (CoP)

The certification/**conformity assessment of production**, and its maintenance where applicable, are subject to:

- acceptance and compliance with these Regulations.
- the Organization's willingness to undergo routine and supplemental audits, documentary and at the Organization's premises and/or at other locations involved, such as the locations of the Organization's critical subcontractors and/or suppliers.
- the positive outcome of the conformity assessment activities carried out by CETOC TS.
- to the payment of the amounts defined in the economic offer.

Assessment activities are carried out by qualified auditors according to procedures in accordance with accreditation regulations. The audit team (hereinafter also referred to as the "Audit Team") may be composed of employees or external collaborators; an auditor belonging to the Audit Team is appointed Group Manager (or "Team Leader"). The Audit Team may include technical experts, who provide knowledge or expertise related to the specific scheme/sector.

#### 3.2. Confidentiality


CETOC TS undertakes to treat with the utmost confidentiality all information received from the Client and/or acquired during the activity related to the conformity assessment, such as, for example, audit documentation, the contract...

All CETOC TS staff and people involved in the certification process have signed a confidentiality statement. This obligation will continue even at the end of the services referred to in this contract. The Customer, at the time of signing the contract, gives his consent to the management of his personal data in accordance with the provisions of EU Reg. 2016/679.

The results of the conformity assessment activities required of CETOC TS, in the event of certification being issued, will be transmitted to the Accreditation Body. CETOC TS is obliged to provide information on the validity status of the certificates issued.

Any information concerning the client received by CETOC TS from sources other than the client itself (e.g. from authorities in the legislative field) will be treated as confidential by all CETOC TS staff.

If required by law or if authorized by contractual agreements to provide confidential information, CETOC TS will notify the customer of the information provided, unless prohibited by law following an order of the Judicial Authority.

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The data of all client companies are automatically entered in the CETOC TS Client Company Register, both nationally and internationally. The list of Client companies may be made public, subject to authorization, for the purpose of using as references of the activities carried out by CETOC TS.

### 3.3. Impartiality


CETOC TS ensures its impartiality in carrying out its conformity assessment activities. To ensure this principle, CETOC TS has set up a process of analysis, assessment and management of risks related to impartiality and independence.

CETOC TS undertakes to carry out the assessment of the Organization throughout the certification process with competence, responsibility, impartiality, confidentiality, transparency and attention to complaints, without providing any consulting service on Management Systems.

- CETOC TS also guarantees that the following conditions are met:
- CETOC TS staff are free from any commercial, financial or other pressure that may influence their judgment, in order to ensure that they do not influence the results of the inspections carried out
- CETOC TS guarantees to be an independent body with respect to the Client concerned
- CETOC TS declares that it is not and is not involved with the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the objects being tested, nor that it is the administrator or authorized representative of the Client Organization.
- CETOC TS declares that it is not engaged in activities that may conflict with independence of judgment and professional integrity in relation to certification activities.

If one or more of the above conditions is missing, CETOC TS will immediately replace the staff involved in the project or, if necessary, stop providing the service.

All decisions made about certification / **Conformity assessment of production** shall be based on objective evidence of conformity and not influenced by other interests. Compliance with the above principles is guaranteed by the Committee for the Safeguarding of CETOC TS in which the parties interested in the certification activity are represented.

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### **3.4. Requirements about the certification of a management system / **Production Conformity Assessment** release.**

#### **3.4.1. Requirements about certification of a management system release**

To obtain and maintain certification, the Management System of an Organization must initially meet and maintain compliance with the requirements of the reference standard over time.

Organizations that request certification of their Management System must indicate the applicable reference standard.

CETOC TS issues certification to Organizations whose Management System has been assessed as compliant with the applicable requirements established by the reference standard. When applying for certification, the Organization must indicate the purpose of certification, the activities and the sites it intends to certify. Confirmation of the scope of certification is subject to verification of the reported activities carried out during the period of validity of the certification.

Any exclusion from the scope of certification of activities carried out, sites, regulatory requirements, products or processes, will be evaluated and accepted or not in line with the provisions of the applicable reference standards or standards or other reference documents with which CETOC TS is required to comply.

Any sites to be excluded and the reasons for them must be submitted to CETOC TS for prior approval.


Audit activities carried out at the Organization's premises must be carried out during periods in which the activities subject to certification are in progress.

The contents of these Regulations and, consequently, the certification issued by CETOC TS is applicable to all activities and locations of the Organization.

- for the issue phase: indicated in the certification application submitted by the Organization.
- during the maintenance and renewal phases: indicated on the certificate issued by CETOC TS.

The certification can be issued with reference to:

- to offices/operating units duly registered with the Chamber of Commerce or regularly manned, only in cases where registration with the Chamber of Commerce is not required by current legislation.
- to the activities present in the certificate of registration with the Chamber of Commerce or in the corporate purpose (only in cases where registration with the Chamber of Commerce is not required by current legislation).

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### **3.4.2. Requirements for the release of the Conformity Assessment of a Production Control System (CoP) – specific part**

The assessment of the production control system must be carried out in accordance with the provisions of the framework directives and applicable regulatory documents (UNECE regulations...), the procedures of the Ministries of Transport by which CETOC TS is designated as a category C technical service (if issued) and the procedures of CETOC TS. For the Declaration of Conformity of a Production Control System (CoP), the Organization:

- will require CETOC TS to carry out an initial CoP audit in the event that:
  - o is not in possession of a valid ISO 9001 or TS 16949 certificate, issued by an accredited certification body.
  - o is provided for by a mandatory requirement of the Directives/Regulations (e.g. for helmets, seat belts, glass).
- may request an audit from CETOC TS (subject to the decision of the Technical Manager) if::
  - o Despite having a valid ISO 9001 or TS 16949 certificate, there are concerns about the control plans, their previous history.
  - o the manufacturer required a separate CoP audit.
  - o may not require an audit (subject to the decision of the Technical Manager and/or to the specific procedures of the European Ministries by which CETOC TS is designated) in the event that it is in possession of a valid ISO 9001 or TS 16949 certification, issued by an accredited certification body, and following the submission of documentation (e.g. control plans, Change Control Procedure, Assembly Plant Declarations, Access to Legislation, Test Results...) deemed adequate and compliant by the Technical Manager.

CETOC TS shall carry out an initial risk assessment for new CoP applicants in order to: assess the need to carry out an audit at the applicant's premises.

In exceptional circumstances, such as security reasons, the CoP (audit-based) conformity assessment may be extended for up to 6 months from the due date until the audit can be arranged. A 6-month re-assessment of CoP compliance must be completed; the decision for which the extension was granted must be clearly reasoned; it must also include a risk assessment.

In the case of the Production Conformity Assessment (CoP), CETOC TS, in the event of a positive outcome of the audit, issues a copy of the audit to the Organization, sends the documentation to the competent Authority, with a risk assessment of the outcome of the same by the Technical Manager attached, which the Authority will examine and, in case of approval, will issue the Certificate.

## 4. Certification process

### 4.1. Request for certification

The organization wishing to obtain certification of its Production Conformity Management System / **Assessment** contacts CETOC TS to request an offer. To this end, it is necessary for the organization to provide the necessary information contained in the "Request for quotation" form **for quality management systems or "Request data for quotation" for CoP evaluation activities** to the [quotets@cetoc.it](mailto:quotets@cetoc.it) email, duly completed in its entirety and signed by the legal representative or his/her representative. The correct and truthful completion of the form and the acknowledgment of these regulations are the responsibility of the organization and are necessary conditions for the correct formulation of the offer.

CETOC TS reserves the right to verify the adequacy of the data provided both during the drafting of the offer and during subsequent activities, such as the review of the offer and the contract, certification, surveillance and renewal audits.

CETOC TS may request at its discretion, for examination, documentation of the Management System / **Production Conformity Control System** (e.g. manual, procedures, other relevant documentation), deemed important for the purposes of the evaluation of the System.

By submitting the application for certification, CETOC TS undertakes towards the applicant organization to treat confidentially all the information and documentation it will come into possession of for the performance of the activity.

### 4.2. Assessment of the application for certification

Upon receipt of the "Request for Offer" / **"Request data for quotation"** and any documentation requested, CETOC TS carries out a review to verify its completeness and adequacy with respect to the information it has received and on the basis of which, having verified the ability to satisfy the request, it draws up the economic offer.

Once the verification has been carried out, CETOC TS sends the Organization in writing the acceptance of the application and the economic offer, in the event of a positive outcome, or, in the event of a negative outcome, sends the Organization a communication requesting the additional information deemed necessary or the impossibility, motivated, of carrying out the requested activities. The countersigned offer takes on contractual value.

## 4.3. Assessment of the management system at the organization

### 4.3.1. Quality Management System Assessment

The assessment of the Management System takes place at the Organization's headquarters through an audit, carried out in two separate phases: stage 1 and stage 2, in order to verify the compliance of the Management System with the requirements of the applicable standard and its correct application and effectiveness. The planning is communicated to the customer in advance.

The audit is carried out by an audit team, consisting of one or more auditors qualified according to the logic of competence by CETOC TS, whose composition is communicated in advance to the Organization which has the right to challenge one or more of the members of the audit team, within 3 (three) days of receipt of the communication, justifying the reasons in writing. The Audit Group will be considered tacitly accepted, if the Organization has not sent CETOC TS its disagreement in the terms set out above.

In the event of a request by the Organization to replace one or more of the members of the audit team, the additional costs resulting from such a request (e.g. travel costs) not provided for in the economic conditions will be borne by the Organization.

During the audit, the Organization must make available competent personnel with adequate autonomy (guides) who assist the auditors.

The Organization must allow auditors safe access to the areas where the activities covered by the certification are carried out, as well as the possibility of interviewing the personnel involved in the activities and, in general, making available all the information necessary for the conduct of the audit. The audit activity includes direct observation of ongoing operational activities (production, service delivery); the impossibility of verifying them during the initial audit phase and during the three-year certification period may result - as the case may be - in the non-issuance of the certification, or the suspension, revocation or reduction of the purpose indicated on the certificate.

#### 4.3.1.1. Stage 1

The Stage 1 Audit must provide an overview useful for the planning of Stage 2, allowing the understanding of the structure of the Management System, with reference to the context of the processes and the level of preparation of the organization that requested the assessment, also taking into consideration the awareness of human resources.

- The purposes of the stage 1 audit are:
- assess the suitability of the organisation's Management System documentation.
- evaluate the organization's website and any special conditions.
- determine the degree of preparation through stage 2 through dialogue with staff;
- review the identification and degree of understanding of regulatory requirements with particular reference to the performance of the activities carried out and the processes, objectives and operations of the Management System, and analysis and monitoring of the context and stakeholders, management leadership and risk-based approach;

- collect information regarding the purpose of the Management System, the processes, the Organization's website and the related applicable mandatory requirements, compliance with these and the possession of any required authorizations.
- check whether the composition and skills of the assigned audit team are adequate for the subsequent stage 2, or whether they need additional skills.
- provide the fundamental elements for planning the next stage 2.
- assess whether internal audits and management review have been planned and executed and that the level of implementation of the system provides evidence that the Organization is ready for Stage 2.

The Stage 1 audit report provides guidance on the timing for the execution of Stage 2, taking into account any shortcomings identified in Stage 1 and the time needed by the organisation to address them. The actions taken must be assessed as effective.

In the event of significant changes (e.g. in the organization, locations, context, corporate changes), between the conduct of Stage 1 and the subsequent Stage 2, which could have an impact on the Management System, CETOC TS reserves the right to repeat all or part of Stage 1, informing the customer of the decision taken and, if necessary, reissuing the economic offer.

For the correct conduct of the audit and effective collection of the required information, it is recommended that the organization's management be present at the salient moments of the audit.

Only in the event of a positive result of stage 1 can stage 2 be performed.

The Organization may request an exemption from this requirement but, in any case, the persistence of non-compliance at the end of stage 2 will prevent the issuance of the certificate until CETOC TS has verified the adequate resolution of the same.

Stage 1 and Stage 2 audits are performed with a sufficient interval (not exceeding 6 months) to allow the Organization to resolve any deficiencies detected in the internship


If more than 6 months old, a new stage 1 audit will be required.

The consecutiveness between the two internships is allowed only if no deficiencies have emerged during stage 1. The Organization has the right to request an exception to this principle by filling in the appropriate space on the audit document; the persistence of non-conformities at the end of stage 2 will prevent the issuance of the certification until CETOC TS has had evidence of their resolution.

For reasons of optimising audit planning, the consecutiveness of stage 1 and stage 2 audits are accepted in the event that:

- the organization is small (up to 10 equivalent employees calculated);
- the entire audit team designated for the initial audit is present on the site;
- the Stage 1 audit has been completed without critical issues such as to compromise the continuation of the certification audit.

If, during stage 1, conditions are found that require a change in the audit times of stage 2, CETOC TS will update the economic offer and send it to the Organization; the stage 2 audit can only be carried out upon acceptance by the Organization of the new offer. Failure to

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accept will be equivalent to the renunciation by the Organization of the continuation of the certification process.

#### 4.3.1.2. Stage 2

The purpose of the stage 2 audit is to assess the implementation, effectiveness and compliance of the Organization's Management System with respect to applicable requirements and concerns:

- information and evidence of the compliance of the Management System with the applicable requirements of the reference standard or other applicable regulatory documents.
- monitoring, measuring, reporting and reviewing performance with reference to key objectives and performance.
- performance of the Organization's Management System with respect to the applicable mandatory requirements.
- leadership, management responsibility for the Organization's policy.
- operational control of the organization's processes.
- internal audits and management review.
- links between regulatory requirements, performance policy and objectives, applicable mandatory requirements, responsibilities, staff skills, activities, procedures, performance data, internal audit findings and conclusions.
- the continuous improvement of the organization's management system.
- All company areas will be audited.

The overall results of the two assessment phases and any deficiencies found are recorded in audit reports that are delivered in copy to the Organization.

The organisation has the opportunity to express reservations about the results of the audit. The audit reports are considered confirmed unless otherwise communicated by CETOC TS within 30 (thirty) days.

In the event that Non-Conformities (NC) or Observations (OSS) are detected at the end of stage 2, the Organization must notify CETOC TS within 10 (ten) working days from the date of the audit of the corrective actions it intends to take (possibly attaching supporting documentation to evidence of what has been implemented).

At the end of the Stage 2 audit, the audit team will analyse the findings of Stage 1 and Stage 2 to formulate an overall opinion on the audit conclusions.

If Non-Conformities (NCs) are found in stage 2 and these are not positively closed by the Organization within 6 months from the last day of stage 2, it will be necessary to perform a new stage 2 before recommending the issuance of the certification.

### 4.3.2. Production Conformity Assessment (CoP)

The assessment of production conformity is carried out at the Organization's headquarters through an audit in order to verify the compliance of the Management System with the requirements of the applicable standard and its correct application and effectiveness. The planning is communicated to the customer in advance.

The audit is carried out by an audit team, consisting of one or more auditors qualified according to the logic of competence by CETOC TS, whose composition is communicated in advance to the Organization which has the right to challenge one or more of the members of the audit team, within 3 (three) days of receipt of the communication, justifying the reasons in writing. The Audit Group will be considered tacitly accepted, if the Organization has not sent CETOC TS its disagreement in the terms set out above.

In the event of a request by the Organization to replace one or more of the members of the audit team, the additional costs resulting from such a request (e.g. travel costs) not provided for in the economic conditions will be borne by the Organization.


During the audit, the Organization must make available competent personnel with adequate autonomy (guides) who assist the auditors.

The Organization must allow auditors safe access to the areas where the activities covered by the certification are carried out, as well as the possibility of interviewing the personnel involved in the activities and, in general, making available all the information necessary for the conduct of the audit. The audit activity includes direct observation of ongoing operational activities (production); the impossibility of verifying them may result - depending on the case - in the failure to issue the declaration of conformity, or the suspension, revocation or reduction of the subject matter of the declaration.

The purpose of the audit is to assess the implementation, effectiveness and compliance of the structure of the System

of Production Control, with respect to applicable requirements and concerns:

- the suitability of the documentation of the organization's Control System.
- The organization's website and any special conditions.
- Information and evidence of the compliance of the production with the applicable requirements of the reference standard or other applicable regulatory documents.
- monitoring, measuring, reporting and reviewing performance with reference to key objectives and performance.
- performance of the Organization's Management System with respect to the applicable mandatory requirements.
- leadership, management responsibility for the Organization's policy;
- operational control of the organization's processes.
- internal audits and management review.
- links between regulatory requirements, performance policy and objectives, applicable mandatory requirements, responsibilities, staff skills, activities, procedures, performance data, internal audit findings and conclusions.
- All business areas involved will be audited.

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For the correct conduct of the audit and effective collection of the required information, it is recommended that the organization's management be present at the salient moments of the audit.

The overall results and any deficiencies found are recorded in audit reports that are delivered in copy to the Organization.

The organisation has the opportunity to express reservations about the results of the audit. The audit reports are confirmed unless otherwise communicated by CETOC TS within 15 (fifteen) working days.

In the event that Non-Conformities (NCs) or Observations (OSS) are detected at the end of the audit, the Organization must notify CETOC TS within 10 (ten) working days from the date of the audit of the corrective actions it intends to take (possibly attaching supporting documentation to evidence of what has been implemented).

If the Non-Conformities (NCs) found are not positively closed by the Organization within 6 months from the last day of the audit, the Organization will be notified of the opening of the procedure for the revocation of the audited type certificates in the event that the Organization does not resolve the open Non-Conformities (NCs). To verify the resolution of Non-Conformities, an audit will be carried out before recommending the issuance of the certification.

## **4.4. Granting and Registering Certification**

### **4.4.1. Issue of the Certification management systems**


The release function of CETOC TS, after having read the audit documentation (including the opinion of the assessor), decides whether or not to issue the certification.

The outcome of the resolution is communicated in writing by CETOC TS to the organization together with any actions required by the deliberative function. If the information available is insufficient to express an opinion, the deliberative function may order an additional investigation to supplement the aforementioned information.

The organization is informed by an official communication explaining the further activities to be carried out. When certification is not granted, CETOC TS shall notify the organisation in writing of the reasons for this decision. The Organization that does not accept the decision taken by CETOC TS may appeal, explaining the reasons for its dissent, in accordance with the provisions of these Regulations.

In this case, CETOC TS will review and confirm or modify the decision taken, possibly arranging for further investigations and visits for which it may use a different evaluation team from the one that carried out the previous visit.

In the event of certification being issued, the organization receives a certificate of conformity in electronic format with the references of the certification issued including the certificate number (unique identification code), the addresses of the sites covered, the reference standard, IAF sector, the scope of application of the certification, the date of first issue, the start date of the current cycle, the expiry date - referring to the current certification cycle. The certificate bears the signature of the Legal Representative of CETOC TS.

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The certificate shall indicate the date of first issue and the date of renewal, to provide evidence of the status of the certificate in the event of renewal after expiry.

The certificate issued to the organization bears the ACCREDIA mark only for the sectors in which CETOC TS is accredited. In the event of acquisition of a new accreditation, CETOC TS will re-issue the certificate. The certification is valid for three years.

The certification is issued and registered against payment of the required fee.

#### **4.4.2. Issue of the declaration of conformity for CoP (conformity assessment of the Production)**

The decision on the issuance of the declaration of conformity with regard to the type-approval certificates subject to the audit is the responsibility of the competent Authority, to which CETOC TS will send the results of the audits performed and validated by the Technical Manager.

Referral to the Authority takes place only on condition that the overall result of the evaluation at the Organization is positive; or:

- The corrective action plan prepared by the Organization for any non-conformities (NC) and observations (OSS) detected is accepted by CETOC TS.
- If non-conformities have been detected, CETOC TS has had evidence of their effective resolution, either through adequate documentation provided by the Organization itself or through an additional verification at the Organization.

The decision is communicated to the Organization.

In the event of a positive decision, the declaration of conformity of production is issued and registered by the Authority.

Its validity and renewal are established by the Authority on the basis of the results of the audit.

If the declaration is not issued by the Authority, CETOC TS will communicate to the organization the procedures for continuing the process.

If the Organization does not agree with the results of the audit, it may make a complaint/appeal, or a report as provided for in paragraph 10.

In response to this request for appeal, CETOC TS reviews and confirms or modifies what pertains to it, possibly arranging for further investigations and visits for which it may use an evaluation team different from the one that carried out the previous visit.

The declaration of conformity is issued and registered against payment of the required fee.

A copy of the documentation examined and approved by CETOC TS must be:

- sent in electronic format to CETOC TS after the audit.
- kept by the Organization in a controlled form and kept available to CETOC TS for possible verifications.

If the Organization does not agree with the decisions taken by the Authority, it must contact the Authority directly.

## 4.5. Use of Certificate and Certification Mark (QMS)

As regards the use of the mark and the certificate, please refer to the contents of the "Regulations for the use of the mark and certificate" RGSGQ02.

The certified organization is included in the list of certified companies of CETOC TS, which is transmitted to the Accreditation Body.

## 4.6. Classification of deficiencies identified during audits

During the conformity assessment audits, any deficiencies in the Management System under consideration are classified as follows:

### Major Non-conformities (NC):

- In the event that a failure to meet an applicable requirement or partial fulfilment of a requirement is found that:
  - has, or reasonably suggests (or provides significant doubts) that it will result in the non-compliance with a requirement (mandatory or expected, or contractually requested or agreed with the customer) applicable to the product/service provided as part of the activities included in the scope of certification; and/or
  - has, or reasonably suggests (or provides significant doubts) that it will result in the inability of the Management System to ensure compliance with both mandatory and voluntary compliance, contractually agreed with customers and/or interested parties.
- A number of observations relating to the same requirement or aspect that gives or reasonably suggest that it has a systemic criticality.

### Minor observations (OSS) or non-conformities:


in the event that a partial non-fulfilment of a requirement is found:

- does not have, or reasonably suggests (or provides significant doubts) that it does not result in the failure to comply with a requirement (mandatory or expected, or contractually requested or agreed with the customer) applicable to the product supplied as part of the activities included in the scope of certification; and/or
- does not have, or reasonably suggests (or provides significant doubts) that it does not have therefore the inability of the Management System to ensure compliance with both mandatory and voluntary compliance, contractually agreed with customers and/or interested parties.

### Comments (COMM):

indications relating to actions aimed at improving the Management System.

They presuppose compliance with the applicable requirement.

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The Organization must undertake to manage any Non-Conformities and Observations detected during the audit, through the adoption and implementation of appropriate Corrections and Corrective Actions.

In the event that deficiencies in the management system classified as non-conformities or observations have emerged, RGA requires the customer to manage them, analyze the causes and take corrective actions to be implemented. RGA issues the customer with the "management of findings" form (analysis, corrective actions, responsibilities and implementation timelines) which must be sent by the representative of the Organization to RGA within 10 working days from the date of the audit. RGA is responsible for reviewing the Organization's submissions. Within 30 days from the date of receipt of the same, RGA shall send the Organization notice of acceptance of the corrective actions or send a specific request for integration or modification.

The verification of the implementation of corrections and corrective actions aimed at resolving (major) Non-Conformities is carried out through an additional audit, or on the basis of documentary evidence **to be produced within 3 months of the closure of the audit**; the obtaining/maintenance of the certification is in any case subject to the positive outcome of this verification.

The verification of the implementation of corrections and corrective actions relating to the Observations is generally carried out during the subsequent audit.

CETOC TS may decide to organise an extraordinary surveillance audit to verify the correct implementation of the actions defined to resolve the findings (non-compliance or in the event of a number of relevant observations that may have consequences on the effectiveness of the management system).

In the event that the Organization fails to send CETOC TS an adequate plan of corrections and corrective actions or, where required, evidence of implementation of the latter, or in the event that it is not available to undergo additional/extraordinary verifications, CETOC TS may take measures such as the suspension of certification **and, in the case of production control systems, notify the Authority to suspend/revoke the audited approvals.**

For Comments, it is not necessary to transmit corrective actions to CETOC TS; during the subsequent audit, the Organization is asked to provide evidence of the acceptance of these reports, or to justify any decision not to implement any action.

## 4.7. Accompanying visits

During the activities carried out by CETOC TS at the organizations for the evaluation of the Management System (issuance, maintenance, renewal, supplementary) the audit teams in charge may be supported by **observers**:

- appointed by the accreditation body in order to monitor the compliance of the service provided by CETOC TS;
- appointed by CETOC TS in order to monitor the activity of its auditors
- **Appointed by the Authority in order to monitor the compliance of the service provided by CETOC TS.**

The presence of observers will be communicated in advance by CETOC TS to the Organization. The refusal of their presence will result in the non-granting of the certification, or the suspension or **withdrawal** of the certification already granted.


Any damage to the Organization attributable to these measures cannot be attributed to CETOC TS.

## 5. Maintaining certification

### 5.1. Maintaining certification for Management Systems

During the validity period of the certificate, the Organization must:

- Maintain active and comply with the applicable requirements of its Management System.
- Communicate to CETOC TS any changes to the Management System relating to the activities falling within the scope of the certification that must be submitted for approval to the Decision-making Function.
- Notify CETOC TS of the corporate changes undertaken by the Organization, such as, for example, changes in company name, changes in the corporate composition or ownership, sales or acquisitions of activities and/or business units falling within those covered by the certification. CETOC TS will assess the need to carry out unscheduled audits and update the issued certificate accordingly. The amendments are submitted for approval to the Deliberative Function of CETOC TS.
- Promptly notify CETOC TS of any action taken against it by the competent authority for violation of legal requirements applicable to products and the adoption of procedures for the recall from the market of products found to be non-compliant with the requirements, providing all the information relating to the event so that CETOC TS can define the situation, its influence on the certification and implement the appropriate checks or actions.
- Promptly notify CETOC TS of changes in legal, organizational, commercial aspects and changes in site addresses or contacts. CETOC TS will assess the need to carry out unscheduled audits and/or update of the certificate issued

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Failure to communicate as per the previous points may result in the suspension of the certification referred to in art. 8.2.

During the period of validity of the CETOC TS certificate, it carries out a surveillance visit within 12 (calendar) months calculated from the date of the certification resolution (stage 2) or renewal (in the case of takeovers).

In the scheduling of audits, a tolerance of a maximum of three months from the date of the last day of Stage 2 is allowed, although exceptions can be agreed with CETOC TS, against justified justifications provided by the Organization, provided that a surveillance audit is guaranteed to be conducted at least once a (calendar) year, except in the years of Certification Renewal.

In the first certification cycle, the first surveillance visit must be conducted no later than 12 months calculated from the date of the certification decision. The surveillance visits will be scheduled in such a way as to make it possible to verify, over the three years of validity of the certificate, at least once, each applicable requirement of the reference standard according to which the Management System has been certified. Any additional close surveillance checks may be ordered by CETOC TS in relation to the results of the certification or surveillance visits carried out.


Carrying out surveillance audits beyond the indicated deadlines will result in the suspension of certification. During the surveillance visits, CETOC TS will also verify the correct use of the certification mark by the certified Organization.

CETOC TS, if it deems it necessary, may arrange for unscheduled surveillance visits, the cost of which is borne by CETOC TS in the event that no non-conformities are detected.

The surveillance visits, scheduled and unscheduled, are carried out in the same way as for the certification visit, both in terms of carrying out and compiling the related audit reports and for any non-conformities detected.

CETOC TS reserves the right to verify the maintenance of the state of conformity of the certifications issued also through:

- surveys and/or questionnaires addressed to certified organizations with reference to aspects concerning certification.
- the evaluation of documentation and/or declarations of certified organizations in relation to the activities subject to certification and disseminated in any form to the market (e.g. advertising material, websites, etc.);
- the request to certified organizations for documentation and/or registrations (in whatever form they are available);
- other performance monitoring systems of certified organisations;
- audits at short notice (minimum of 5 days) or without notice to investigate complaints, in response to changes or as verification activities for clients with suspended certification; the latter are paid free of charge for the customer only if the audit is successful. For further details, see art. 8.5.

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If, during maintenance audits or following specific communications from the Organization, conditions are found that require a change in the audit times (such as, for example, changes in the number of employees, the number of offices/sites, changes in operating locations, changes in the number of activities subject to certification or changes in the scope of certification, etc.). CETOC TS will update the economic offer and send it to the Organization; subsequent audits can only be carried out upon acceptance by the Organization of the new offer. Failure to accept will be equivalent to renunciation by the Organization and will result in the consequent actions referred to in art. 8.1) Waiver.


At the end of the verification activities of the maintenance of the state of conformity of the certifications issued, the individual surveillance reports are reviewed by the proposing function and then by the deliberative function for the resolution following which CETOC TS communicates the results to the Organization confirming whether or not the certification is maintained.

In addition, Accredia, the Accreditation Body, as part of the market surveillance activity, can carry out Market Surveillance audits or mystery audit activities, conducted directly by Accredia Inspectors at CETOC TS client organizations in order to assess the level of confidence in the compliance of the management system and the effectiveness of the accredited certification process through direct observations. For Market Surveillance activities, please refer to par. 8.6.

These audits can be ordered both following the identification of critical situations detected directly by Accredia or inadequate situations of which it becomes aware, and in the face of reports and/or complaints received by it.

It is not possible for the client organization to refuse the presence of Accredia inspectors, under penalty of suspension (par. 8.2) and subsequently revocation (par. 8.3).

Should CETOC TS make changes to these Regulations, they must be communicated in writing to all certified organizations or organizations under evaluation, specifying the timing for adapting their Management System to the new provisions.

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## 5.2. Monitoring the Production Declaration of Conformity (CoP)

During the period of validity of the declaration of conformity, the Organization must:

- maintain active and comply with the applicable requirements its Production Control System.
- communicate to CETOC TS any changes to the Management System relating to the falling activity within the scope of the declaration that must be submitted to the Authority for approval.
- notify CETOC TS of corporate changes undertaken by the Organization, such as, for example, changes in company name, changes in the corporate composition or ownership; sales or acquisitions of activities and/or business units falling within those covered by the declaration of conformity. CETOC TS will assess the need to carry out unscheduled audits and update the issued statement accordingly. The amendments are submitted to the Authority for approval.
- promptly notify CETOC TS of any action taken against it by the competent authority for violation of legal requirements applicable to products and the adoption of procedures for the recall from the market of products found not to comply with the requirements, providing all the information relating to the event so that CETOC TS can define the situation, its influence on the declaration of conformity and implement the appropriate checks or actions.
- Promptly notify CETOC TS of changes in legal, organizational, commercial aspects and changes in site addresses or contacts. CETOC TS, following communication to the Authority, will assess the need to carry out unscheduled audits and/or update the declaration of conformity issued.

Failure to communicate may result in the suspension of the declaration referred to in art. 8.2)

CETOC TS, during the period of validity of the declaration, carries out a surveillance visit according to the timing established by the production control plan shared during the first assessment audit, by legal provisions or by the specific provisions of the reference Authority. In this case, therefore, the timing can vary from six months to three years.

The surveillance visits, scheduled and unscheduled, are carried out in the same way as for the first assessment audits, both in terms of carrying out and compiling the related audit reports and for any non-conformities detected.

If, during the surveillance audits or following specific communications from the Organization, conditions are found that require a change in the audit times, CETOC TS will update the economic offer and send it to the Organization; subsequent audits can only be carried out upon acceptance by the Organization of the new offer.

Failure to accept will be equivalent to renunciation by the Organization and will result in the consequent actions referred to in art. 8.1) which follows.

## 6. QMS certification renewal

The renewal of the certification is subject to the positive outcome of the renewal audit which must be performed by the expiry date of the certificate in order to assess the continuous compliance with the applicable regulatory and legislative requirements.

The renewal audit (or "recertification") is a general review of the certified Management System and includes the verification of all regulatory requirements and the review of the audit reports of the previous cycle. In particular, it is evaluated:

- The effectiveness of the Management System as a whole, in the light of internal and external changes, and its continued relevance and applicability to the purpose of the Certification.
- The effectiveness of the Management System with reference to the achievement of the Organization's objectives and the expected results.
- The commitment demonstrated to maintain the effectiveness and improvement of the management system in order to improve the performance of them.

If the Management System or the operating context of the Organization have undergone significant changes (e.g., changes in applicable legal, commercial, organizational, ownership aspects, etc.), the procedures for renewing the validity of the Certification will be the same as those implemented for the initial assessment (Stage 1 and Stage 2), otherwise the Stage 1 and Stage 2 audits will coincide.

With respect to the expiry date of the certificate, the renewal audit must be carried out sufficiently in advance for the decision-making function to decide on the renewal of the certificate before the expiry of the certificate.

To this end, the renewal audit at the Organization and all the actions resulting from it (e.g. sending documentation, corrective action plan, carrying out additional field checks, etc.) must be completed before the certificate expires.

If, for reasons of force majeure, the Organization is unable to carry out the renewal audit within the established timeframe, it may request a postponement by written communication justifying the request, which will be managed according to the following cases:

- Case 1) the renewal activity started before or after the certification expiration date and is successfully completed within 6 months of the expiration date. The renewal audit will be performed without any change in the expected time and/or additional burden on the organization. In this case, the renewed certificate will keep both the numbering and the date of first issue unchanged and will have the expiry date of the previous certificate + 3 years; the certificate will indicate the period of non-validity, indicating the "Previous Three-Year Expiration Date" and the date of issue of the renewal after expiry.
- Case 2): the renewal activity started before or after the expiration date of the certification but is completed after 6 months but no later than 1 year from the expiration date: the duration of the audit will be the same as that provided for an initial stage 2 audit (and at least not less than the duration of a renewal) with a consequent increase in costs for the organization that will be communicated in advance by

CETOC TS. In this case, the historicity of the certificate can be maintained by reissuing the certificate with the numbering of the previous one and a new date of first issue and will have the expiry date of the previous certificate + 3 years; the certificate will also indicate the period of non-validity, reporting the "Previous Three-Year Expiration Date".

- Case 3): the Renewal process (verification and resolution) is completed more than one year from the date of expiry of the certificate: A new certification process will be initiated and an initial audit will be carried out including stage 1 and stage 2. In this case, a new certificate will be issued with a new numbering and a new date for the first issue.

Force majeure is considered to be all those situations that prevent the assessment of the performance of the activities/processes for which the Organization is certified (e.g. staff on layoffs; company restructuring; natural disasters). When the audit activity is started and/or completed after the expiration of the certificate, CETOC TS in concert with the Organization can always decide to carry out an initial audit (Stage 1 and Stage 2), issuing a new certificate without maintaining the historicity of the previous certificate.


CETOC TS must also keep records relating to the application for authorisation and the related resolution, available to the accreditation body. In any case in which, for reasons not attributable to CETOC TS, the renewal of the certificate can only take place after the date of expiry of the same, CETOC TS cannot be held responsible for any damage that the organization may suffer during the period in which the certificate will expire. Each certificate subsequent to the first is valid for 3 (three) years, calculated from the expiry of the first certificate issued.

## 7. Extension and reduction of certification

The Organization has the right to request changes to the certification in order to:

- extend it, or
  - o introduce additional applicable requirements
  - o Include new tasks
  - o include new corporate headquarters, sites, or subsidiaries
- reduce it, i.e. exclude
  - o applicable requirements already certified (provided that this is allowed by the reference standard)
  - o activities already certified (provided that this is allowed by the reference standard)
  - o company headquarters, sites or branches already certified (in cases where this is allowed or required by the documents issued by the Accreditation Body)

To start the process, the Organization must submit a formal request by sending the appropriate "Offer Request Form" to the [quotets@cetoc.it](mailto:quotets@cetoc.it) email, indicating the extension or reduction of the field of validity of the certification.

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Based on the request received, CETOC TS shall carry out all necessary verification activities, such as an examination of the management system documentation or an additional field audit, by communicating them to the organization; these activities may lead to a revision of the existing economic offer.

Once the checks carried out have been successfully completed, CETOC TS reissues the certification document suitably modified.

The Organization is required to appropriately adapt any reference to the certification that may be reported on the company documents or in any case disseminated to the market.

In the case of production compliance control systems, once the checks carried out have been successfully completed, CETOC TS sends the documentation required by the Authority for the issuance and consequent reissue of the suitably amended certification document; for its part, the Organization is required to appropriately adapt any reference to the declaration of conformity that may be disseminated to the market.

## **8. Waiver, suspension and Withdrawal of certification and takeover**

### **8.1. Waiver**


The Organization may withdraw the certification in the following cases:

- a) upon expiry of the Certificate, giving at least 3 (three) months' written notice;
  - does not accept any changes to these Regulations **or to the conditions of the Authority in charge where applicable.**
  - you do not accept any changes to the economic conditions.
  - changes to the applicable requirements set out in the standards or reference documents.
  - **In the case of Conformity of Production, when the production line relating to specific approval is terminated.**

In cases b), c), d) and e) the Organization must give written notice of its decision within thirty (30) days from the date of notification of the changes by CETOC TS and in any case before the performance of any activities provided for by these regulations (e.g. already scheduled surveillance).

The waiver entails the Organization's:

- the return of the original of the Certificate.
- the non-use of the certification declaration and the removal from all products and documents of any reference or symbol relating to the certification.
- the immediate cessation of the use of the Trademark and references to certification (distribution of material that reproduces it).
- **In the case of Production Compliance with the cancellation by the Authorities of the relevant approval certificates.**

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In the event of renunciation, CETOC TS shall remove the Organization from the register of certifications and apply the penalties provided for in these regulations, except in cases a) and b) mentioned above. In addition, any application for certification by the same Organization before one year from the date of renunciation is not admissible, except for exceptions evaluated by the Management of CETOC TS.

In the event of withdrawal, the certification of conformity of the Management System / **Production Conformity Assessment System** (for the activities included in the scope of certification indicated on the certificate) remains valid until the date of execution of the last audit following which it was confirmed.


If the organization wishes to have a certificate confirming the compliance of the Management System up to the date on which it communicated the withdrawal, it must make an explicit written request to CETOC TS which will perform, for this purpose, an additional audit whose duration and cost will be communicated in advance to the organization. The attestation of compliance that can only be issued in the event of a positive outcome of the audit, or in the event that non-conformities (NC) and observations (OSS) have been detected, the corrective action plan proposed by the organization is accepted by the RGA and that the organization has provided evidence of their effective resolution (through adequate documentation provided by the organization itself or through an additional verification at the organization).

The waiver must be communicated by PEC [cetoc.ts@legalmail.it](mailto:cetoc.ts@legalmail.it), registered letter with return receipt, cetoc Technical Service Srl – Via della Bufalotta 374 – Rome.

## 8.2. Suspension

The validity of the certification of management systems may be suspended for a limited period (maximum 6 months) by CETOC TS in the following cases:

- non-compliance with one or more applicable requirements of the reference standard of the certified Management System.
- finding deficiencies in the Management System such as having doubts or evidence on the conformity of the product/service provided by the Organization and on compliance with mandatory product/service requirements.
- Continued non-compliance with applicable requirements as a result of corrective actions/treatments approved by CETOC TS that have not been implemented or are not effective.
- failure to comply with the conditions defined for maintaining the certification (see art. 5);
- incorrect or improper use of the certificate, for which the organization has not taken the actions required by CETOC TS.
- non-acceptance by CETOC TS of changes made by the Organization to its Management System.

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- failure to carry out, for reasons not attributable to CETOC TS, the activities envisaged for maintaining the certification within the established deadlines.
- impediment in allowing the performance of additional audits or audits with short or no notice or Market surveillance visits carried out by the Accreditation Body, ACCREDIA.
- permanence of the state of insolvency after the first reminder.
- voluntary and motivated request by the Organization (allowed only once in the three-year certification period);
- failure to adapt the Management System to the new editions of the standards, beyond the transitional period granted.

The suspension measure is communicated in writing to the Organization by certified email or registered letter, within 10 (ten) working days of the decision, defining the conditions for the restoration of the certification and the deadline within which they must be implemented. In the case of the aforementioned p.to 8), the suspension of the certification may also be requested by the organization itself following a written request to CETOC TS specifying the reasons and the time within which it is expected that this situation of arrears can be regularized in order to revoke the suspension. In this case, the payment of a fee equal to 30% of the amount relating to maintenance activities not yet carried out will be required which, if carried out within one year from the scheduled date, will be considered as an advance on the amount due, otherwise it will be withheld as a penalty for lack of activity.

The suspension can have a maximum duration of 6 (six) months; in the event that the causes that led to the suspension measure are not removed within 6 (six) months, CETOC TS will decide, as the case may be, whether to extend the term of the suspension measure by a maximum of another 6 (six) months or to revoke the certification. In any case, the duration of the suspension period cannot go beyond the expiry of the certificate.


During the period of suspension, the Organization is still required to pay the amounts for the maintenance of the certification and may not use the certificate(s) obtained unless otherwise indicated by CETOC TS, nor qualify as a Certified Organization.

During the suspension period, CETOC TS:

- may suspend the surveillance activity referred to in art. 5, except as contained in paragraph 8.3 below.
- provides, where necessary, registering the state of suspension on the database of certified organizations.
- communicates, where required, the suspension measure to the Authorities and/or Bodies concerned.

The suspension is lifted only after CETOC TS has verified the restoration of compliance with the requirements or the resolution of the causes that led to the measure.

Before proceeding with the restoration of the certification, CETOC TS may carry out documentary and/or organizational checks in order to ascertain the effective resolution of the problems previously encountered; all expenses related to these additional checks are borne by the certified Organization.

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### 8.3. Withdrawal

The withdrawal of certification can be decided by CETOC TS **or by the Authority in charge of production conformity assessment systems**. It shall be communicated in writing to the Organization in the following cases:


- failure to eliminate the causes that led to the suspension within the terms decided by CETOC TS;
- detection of non-conformities considered particularly serious;
- failure to comply with the provisions of this Regulation as a result of gross negligence;
- frequent non-compliance with the commitments undertaken, even in a non-serious form;
- bankruptcy or liquidation of the Organization;
- suspension of the supply of the product or service;
- refusal or obstacle to verification visits;
- inappropriate use of certification;
- persistence of arrears in payments for CETOC TS services;
- for any other serious reason in the opinion of CETOC TS;
- after a maximum period of three months of suspension, the Organization refuses to carry out Market surveillance visits carried out by the Accreditation Body, Accredia;

Following the withdrawal, the Organization undertakes to:

- return the original Certificate within fifteen (15) days of such notification;
- not to use the certification declaration and to remove from the letterhead and from all documents the marks and any reference to the certification;
- settle all amounts due to CETOC TS.

The withdrawal entails by CETOC TS:

- the communication to the Customer of the decision taken regarding the validity of the certificate.
- the cancellation of the Organization from the register of certifications.
- **the communication of the revocation measure to the Authorities and/or Bodies concerned which, in the case of the assessment of the conformity of production, will cancel the relevant approval certificates.**
- the interruption of the control activity provided for in paragraphs 5 and 6 above.
- the application of the penalties provided for in these Regulations.
- the non-admission to the examination of any application for certification of the same Organization before one year has passed from the date of withdrawal, except for exceptions evaluated by the Management of CETOC TS.

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In situations for which it is necessary to intervene urgently in relation to the possible social danger of the event, CETOC TS, on the initiative of the Management or the deliberative function, has the right to take decisions to revoke the certification.

Any decision of CETOC TS, as well as any urgent measures taken, will be communicated in writing to the Organization by certified email or registered letter, within 10 (ten) working days of the decision.

## **8.4. Takeover (transfer of certification from another Certification Body)**

An organization in possession of certification of its Management System by an ACCREDIA accredited Certification Body or recognized in the MLA (Multi Lateral Agreement) field can request CETOC TS to take over the relevant certification.

That organisation shall submit the following documents to CETOC TS:

- Manual of your Management System, where required
- Copy of the certificate of your valid Management System
- Signed application and contract
- Copy of the audit reports relating to the last issue/renewal verification and the subsequent surveillance carried out with any Corrective Actions proposed/implemented following the findings highlighted
- Any complaints received with the Corrective Actions taken
- Declaration of the existence of any legal proceedings
- Reasons for requesting the transfer of audit activities for certification purposes.

Only valid certificates can be subject to transfer: if it becomes known that the certificate has been suspended or that the transfer has declared that it has not been possible, the transfer process will not be possible.

The documentation will be reviewed by the deliberative function of CETOC TS which may deliberate among the following options:

- Issuance of the certificate for the same certified activities/sites and with the same expiry date
- Pre-transfer visit to investigate the critical areas that emerged (number of non-conformities and/or type of suspension measures in place)
- Non-issuance of certification in case of certificate expired or withdrawn by the previous certification body.

When the first audit after taking over, the Technical Manager will ask RGA to prepare an audit plan detailing the processes/requirements/activities to be verified.

At the end of the transfer process, CETOC TS will inform the transferring entity of the issuance of the certificate.

## 8.5. Audits at short notice or without notice

CETOC TS may also carry out audits at short notice – carried out within five (5) working days from the date of notification – or without prior notice, to investigate complaints received, violations of the Regulation or applicable legislation, following changes in the Organization or as consequential action against the Organization whose certification has been suspended.

On such occasions, the right of recusal will be considered inapplicable. CETOC TS undertakes to choose the audit team in such a way as to reduce the potential risks associated with the Organization's inability to exercise this power.

Accredia may conduct unannounced audits of CETOC TS in accompaniment to CETOC TS's customers. On such occasions, the Organization cannot refuse the presence of inspectors from the Accreditation Body, ACCREDIA.

## 8.6. Market Surveillance and Mystery audit

ACCREDIA, the Accreditation Body, as part of the market surveillance activity, can carry out, in addition to traditional audits, Market Surveillance Audit or Mystery Audit activities.

The Market Surveillance Audit is an audit conducted directly by Accredia Inspectors at CETOC TS client organizations in order to assess the level of confidence in the compliance of the management system and the effectiveness of the accredited certification process through direct observations.

The visit takes place at the client Organization in the presence of personnel of the Organization and CETOC TS and lasts one day.


It is not the same as surveillance or renewal audits conducted by CETOC TS.

Contact with the audited organization is managed directly by CETOC TS.

The Organization will have to make available to Accredia the documentation that the CETOC TS auditors have taken as a reference during previous audits.

The audit plan will be prepared by the Accredia Verification Group and will be communicated by CETOC TS to the Organization within three working days before the Market Surveillance Audit is carried out. The methods for carrying out this verification follow the contents of the IAF ID 04 document.

If the Organization does not grant its approval, except for exceptional reasons of force majeure, the validity of the certificate is suspended until approval is granted for verification, for a maximum period of three months. After the three months have expired, in the absence of approval for the verification, the certification is revoked.

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## **8.7. Transferability of the Certification - Changes in the organizational structure**

The use of the CETOC TS Certifications is strictly reserved to the Organization and is not transferable, except in cases of transfer, transformation, merger, demerger, contribution, lease of a company or a business unit of the company concerned.

In these cases, the Organization must send a communication to CETOC TS in a timely manner, in any case no later than fifteen (15) days from the registration of the relevant registration in the Register of Companies, where applicable; Failure to comply with this deadline may result in the application of the measure of suspension or revocation of the certification.

In the cases described above, the Organization must also send CETOC TS a written request for the maintenance of the certification by the subject resulting from the modification of the organizational structure, accompanied by a copy of the relevant certificate of registration with the Chamber of Commerce and any additional documents, if deemed necessary. CETOC TS will then ascertain, possibly also through an additional check, that the Management System has not undergone changes, or in any case complies with the requirements of the reference standard.

The transfer of the certification is subject to the positive outcome of the assessments carried out, as well as to the settlement of all amounts due by the transferring organization. The costs of updating the certification and any additional verification (documentary and/or at the Organization) are borne by the subject resulting from the modification.

## **8.8. Variazioni Legislative, Normative, Regolamenti**


Should changes be made to the reference standards for certification, CETOC TS will promptly notify the certified Organization, which will have the right to adapt to the new requirements within the deadline that will be indicated, or to renounce the certification.

In the event that the Organization decides to maintain the certification, CETOC TS will verify the Organization's compliance with the new regulatory requirements.

The costs for any related verification activities and the reissue of the certificate are borne by the certified organization.

CETOC TS also reserves the right to make changes and additions to these Regulations without the prior consent of the certified Organization; in this case, CETOC TS will communicate the amendment to the Regulations by informing the Clients or, in the event that such changes do not affect the activity carried out at the Organization, by publication on its website [www.cetoc.ts.com](http://www.cetoc.ts.com).

If such changes have an influence on the activity carried out at the Organization, resulting in significant impacts (e.g. change in the frequency or duration of visits, etc.), CETOC TS will inform the latter, formulating, if necessary, a new offer; the Organization will have the

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right to renounce the certification within thirty (30) days following the relevant communication (see art.8.1).

Any costs for documentary and/or field evaluation activities, deriving from the aforementioned legislative or regulatory changes, are in any case borne by the Organization.

## **9. Certification Limits and Liability**

### **9.1. Liability of the organization - indemnification**

The Organization undertakes to comply with and maintain compliance with mandatory requirements, such as laws, regulations, etc., of an international, national or local nature, with particular regard to products, processes and services that fall within the scope of certification.

The issuance and maintenance of the certification do not constitute attestation or guarantee by CETOC TS of compliance with all the mandatory requirements incumbent on the Organization and, in general, of the latter's legislative compliance.

Therefore, the Organization is and remains solely responsible both to itself and to third parties for the proper performance of its activities and the compliance of the same, and of its products/services, with the applicable regulations, as well as with the expectations of customers and third parties in general.

The Organization also undertakes to indemnify CETOC TS and its employees, auxiliaries and collaborators from any complaint, action and/or claim of third parties related to the execution of CETOC TS's activities under these Regulations.

### **9.2. Breach of CETOC TS – limits to liability**

Except in cases of wilful misconduct or gross negligence, the liability of CETOC TS towards the Organization for any damage resulting from the execution or non-fulfilment, total or partial, of its obligations under the certification contract, shall be limited to the maximum amount of three (3) times the compensation due for the assessment activity carried out at the time of the error or omission that caused the damage.

### **9.3. Forfeiture clause**

Any claim or claim against CETOC TS must be made by the Organization, under penalty of forfeiture, no later than one (1) year after the event giving rise to the claim or claim.

## 9.4. Exclusion of liability of CETOC TS

Except in cases of wilful misconduct or gross negligence, even in cases of ascertained non-compliance by CETOC TS, compensation to the Organization for any loss of profit, such as, for example, interruption of business activity, loss of profit, commercial opportunities, turnover, goodwill or expected profits is excluded.

## 10. Complaints, appeals and reports

For any problem relating to the service provided, up to 15 days from the notification of the decision, it is possible to make a written complaint about the service provided or an appeal on the results of the conformity assessment using the following methods:

- Registered mail with return receipt to the address: Via della Bufalotta 374, 00139 Rome
- e-mail to: [cetocets@legalmail.it](mailto:cetocets@legalmail.it)

CETOC TS will analyze the causes and respond promptly to any corrective actions taken through its Quality Manager, following a recheck of the certification file by personnel independent of the CETOC TS technical staff who worked on it.

### 10.1. Complaints

Complaints can be received by CETOC TS from private individuals, from the client and from the applicants/licensees of the certification and in general from anyone who has an interest in it (e.g. customer of an organization certified by CETOC TS).

The Organization or the interested Party may submit a complaint to CETOC TS, in writing, if it believes that the quality of the certification service offered does not meet what is stated in these Regulations (e.g. decisions taken, behaviors adopted by CETOC TS or its staff/collaborators during the activities carried out, reports relating to the work of a certified organization) reporting the complainant's references and providing details on the object of the complaint.

CETOC TS guarantees maximum confidentiality both with respect to those who presented it and with respect to the content and maximum independence in their treatment.

CETOC TS analyzes and assesses the validity of the same and sends communication to the organization of the acceptance of the complaint within 15 working days. CETOC TS examines the complaint, possibly hearing the representatives of the Organization. CETOC TS keeps the complainant updated during the handling of the complaint and its results, providing a response to the organization within 3 (three) months of the submission of the complaint. If CETOC TS assesses that the reasons for the complaint are unfounded, it will proceed to communicate the reasons to the complainant in writing.

## 10.2. Recourse

The Organization and interested parties in general may appeal to CETOC TS in writing, for the protection of their interest, against the decisions of CETOC TS itself, setting out the reasons for the dissent, within 15 days from the date of notification of the decision. All appeals are handled with maximum independence in their handling.

CETOC TS analyzes and assesses the merits of the same and sends communication to the organization of the acceptance of the appeal within 15 working days. In the event that the appeal is considered unfounded, CETOC TS must send a written communication to the complainant explaining the reasons within 15 working days. For the analysis of the merits, causes and treatment of the appeal, the team in charge will be composed of staff not directly involved in the activity in question.

CETOC TS will communicate the composition of the analysis team and will keep the complainant updated on the progress of the management of the appeal; finally, it provides a response to the applicant organization within 3 (three) months of the submission of the appeal. The complainant may raise objections to the composition of the team.

The costs relating to the appeal are borne by the Organization, except in cases of recognized validity.

## 11. Duration of the contract – penalties - withdrawal


### 11.1. Duration

The Certification Agreement, of which these Regulations constitute an integral and substantial part, shall start from the acceptance of the offer of CETOC TS and shall remain in force for the entire duration of validity of the certification, unless terminated by the Organization or CETOC TS by registered letter with return receipt or certified e-mail at least 90 (ninety) days before the date of termination of the Certification Agreement.

### 11.2. Penalties

Fatte salve le condizioni di rinuncia alla certificazione previste al par. 8.1 che precede, l'Organizzazione certificata o certificanda che recede dal contratto, oltre agli importi previsti per le attività già eseguite, è tenuta al pagamento delle seguenti penali:

- after the acceptance of the offer and before the execution of Stage 1 or the agreed Renewal/Takeover activities: an amount equal to 30 (thirty) % of that provided for the Certification (phase 1 + phase 2) or Renewal/Takeover;
- in the period between the initial visit of Stage 1 and Stage 2: an amount equal to 30 (thirty) % of that provided for Phase 2;
- between the 1st and 12th month of validity of the certificate: the entire amount relating to the maintenance activities planned and not yet carried out for the reference period (1st surveillance), excluding the activities already carried out and therefore still due;

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- between the 13th and 24th month of validity of the certificate: the entire amount relating to maintenance activities not yet carried out and planned for the remaining period of validity of the certificate, excluding activities already carried out and therefore still due.
- beyond the deadlines (see 8.1 a): the full amount of the planned renewal activities.

### **11.3. Withdrawal**

Each Contracting Party has the right to withdraw from the contract at any time, by communicating the withdrawal by certified email or registered mail with return receipt signed by the Legal Representative. Withdrawal by the Organization entails the renunciation of certification.

CETOC TS has the right to withdraw from the Certification Agreement in the event that the Organization has been the subject of measures or convictions for facts concerning the failure to comply with the mandatory requirements pertaining to the Management System subject to certification or for failure to communicate such measures or convictions to CETOC TS. Withdrawal by CETOC TS entails the revocation of the certification, which remains in force until the date scheduled for the next periodic visit.

### **11.4. Mutual recognition of certifications with another certification body**

In order to be able to protect certified organizations in the event that a dispute related to the "defective service" leads to the bankruptcy, liquidation or dissolution of CETOC TS or in the event of loss of accreditation in one or more sectors, CETOC TS guarantees the continuity of the certifications issued, through a process of transfer of the same, establishing if necessary a special mutual recognition agreement with another certification body. It is understood that this process will be initiated only with the written consent of the CETOC TS certified organization which, alternatively, has the right to renounce the certification. This transfer will take place in compliance with the requirements defined by the IAF MD2 document "Transfer of accredited certification of Management Systems".

## 12. Treatment of personal data

Pursuant to Regulation (EU) No. 2016/679 on the protection of natural persons with regard to the treatment of personal data ("General Data Protection Regulation") and Legislative Decree No. 196/2003 as amended ("Privacy Code"), the personal data directly provided by the Organization or through third parties, are and will be processed by CETOC TS - and in particular recorded and stored in a database - in order to ensure the proper performance of contractual relations with the organization.

The treatment of requested data is carried out using computerized, manual and telematic tools, with logics strictly related to the purposes themselves and, in any case, in such a way as to guarantee the security and confidentiality of the data. It is necessary for the performance of contractual relations with CETOC TS, with the consequence that any refusal to provide them will make it impossible for CETOC TS to comply with the agreements.

The Data will be treated for the time strictly necessary for the performance of contractual relations with the Organization, without prejudice to the storage of data for a further period of 10 years (variable in the case of particular EU regulations and directives that require a further retention period) from the expiry of the last service performed, to comply with the legal and regulatory obligations provided.

The Data may be communicated by CETOC TS, as far as their respective and specific competence is concerned, to Accreditation Bodies, Certification Bodies, Administrations, Institutions, Associations, Judicial Authorities and Public Security Authorities as well as to any other competent Authority in the field and, in general, to any public and private entity whose communication is mandatory by law. These subjects will process the Data in their capacity as independent data controllers.

The dissemination of the Data is aimed exclusively at guaranteeing institutions and consumers about the issue, existence, renunciation, suspension or revocation of the certification.

### Data Controller

The "Data Controller" is CETOC TS Srl, with registered office in Rome, Via della Bufalotta 374.

Pursuant to Articles 15-21 of the General Data Protection Regulation and Article 7 of the Privacy Code (Rights of the Data Subject), the Organization may at any time exercise the rights of access, rectification or cancellation (so-called "right to be forgotten"), limitation of processing, as well as the portability of their data by sending a specific request to the address: [infots@cetoc.it](mailto:infots@cetoc.it).

The Data may be communicated and treated by third-party companies or by other parties (by way of example IT service providers, credit institutions, professional firms, consultants) who carry out outsourced activities on behalf of the Data Controller, in their capacity as external data processors.

The list of specifically appointed external data processors who process the Data is available from the Data Controller.

### **13. Applicable law and jurisdiction**

The contractual documentation, of which these Regulations form an integral part, is governed by Italian law. In the event of disputes arising between CETOC TS and the Client in relation to the interpretation and execution of this contract and for any legal actions for the management of appeals approved by the Legal Representative of CETOC TS, the exclusive competent court will be the Court of Rome.