Revision N°	Release Date	Description	QR Validation	CEO Approval
04	08/10/24	General review of the process	Silvia Desdouits	
03	08/02/21	General review of the process	Silvia Desdouits	
01	31/01/20	Integration with audit procedure (17021)	Silvia Desdouits	
0	10/01/19	First Release	Silvia Desdouits	

Introduction to Audit Procedures

An audit may be required for a few reasons: an initial application for Type Approval, lack of accredited quality system certification, required by the relevant legislation (mandatory audit) or monitoring visit.

The signed offer or work order uploaded to the "Delfi" software determines a review of the contract that involves the opening of the Job Number by introducing the data of the "Request Data for Offer" MDCOPE30.
In "Delfi" software it's recorded the registration of the job number and the accounting opening of the job. Depending on the closure of the communicated project phases, the "Avanzamento" tab on " Delfi" software is updated. The form MDSGQE30 is a summary of the information necessary for the activities to be performed and the relative timing: this form is provided to the Technical Manager for review and subsequent planning. This constitutes the startup of the project.
The Technical Manager carries out a timing plan according to IAF MD5 and an analysis and definition of internal and external resources to be involved in the project according to their competencies and preferentially to the place of residence with respect to the customer's location: based on it determines the auditors in charge of the order.
The Technical Manager enters the Customer's data in the "Certification Manager" used for the management of the deadlines: expected date of the audits, type, duration, assigned auditor and after the verification the effective audit date.
In the case of monitoring, the CoP Manager shall set up an alert before the scheduled date so as to leave a safety margin that allows to take into account the organization's particular needs / requests for scheduling the date of effective audit.
The Technical Manager shall send a communication to the auditors with the assignment of the task to carry out on the indicated Organization all the activities for the clearance requested, which ratifies and validates what is shared in a specific framework agreement and which contains the details of the audit.
Within five days of receipt, the appointed auditors must send the Technical Manager acceptance of the assignment.

Note 1. Technical Manager must observe the turnover of the appointed auditors: each auditor will not be assigned more than 3 consecutive times for the verification of the same Customer to guarantee the impartiality of his / her work. In the assignment at least the following data must be contained:

- the scheduled date: or the deadline by which the visit must be performed.
- the scheduled duration of the audit.
- the type of audit.
- indications on the audit team.
- customer information: the company name - the certified operational headquarters (i.e. the main office) - the contact person of the company - telephone and / or email - and the list of all branches that may be certified.
- certificate information: reference standard - subject and state of validity of the certificate.

The auditors are required to:

- respect professional secrecy and maintain the commitment to confidentiality and the absence of conflicts of interest.
- promptly inform CETOC TS of any changes in their professional situation, which could affect incompatibility, independence and impartiality.
- explain the regulatory requirements during the performance of the audits without providing operational indications aimed at applying the requirement itself or overcoming the non-compliant situations, in order not to condition the customer organization in any way.
- carry out the audit verification activity in compliance with this procedure.

The composition of the audit team may include:

- Observers. They work alongside TEAM LEADER or auditors without intervening in any way in the audit activities; they can request clarifications from TEAM LEADER or from the auditors, without stopping or disturbing the performance of the audit. They can be observers from CETOC TS or sent by third parties, such as the Authority to verify the CETOC TS.
- Technical experts (ESP). They work alongside TEAM LEADER or auditors to integrate and support the audit action, providing interpretations, clarifications and giving indications on the aspects to be explored. They deal directly with the organization, always alongside the TEAM LEADER or auditors, only at the request of TEAM LEADER;
- auditor in training. He works actively alongside TEAM LEADER or auditors, under the direct responsibility and guidance of TEAM LEADER, in the role assigned to him.

Observers, Experts and Auditors in Training can access the information normally available for the audit team and must comply with the confidentiality constraints of the audit team.
Their participation in the audit must be notified by the team leader to the audited Organization by communicating its presence in the Scheduling.
The team leader must illustrate roles, objectives and management rules of the various members of the audit team which will have to be communicated during the Initial Meeting.
Audit visits are carried out on a mutually agreed date and to a pre-arranged program. Audits will vary in length and factors that will be taken into consideration include company size, location, employee numbers and products manufactured, but usually range from 1 to 5 days.
It is the Team leader auditor's duty to contact organizations adequately in advance to agree on the dates of the audits to inquire about any specific organizational needs for carrying out the audit (e.g. Activities carried out exclusively in certain shifts ...) and special conditions of health and safety in the workplace (eg particular access restrictions, use of PPE ...) and / or information security (eg data accessible only with particular authorizations, restricted areas ..) to be observed on the sites of certification that may affect the verification activity. If the audit team provides for the presence of auditors and / or experts, the TEAM LEADER shall check their availability in advance. The dates shall be communicated to the Technical Manager.
As regards the planning of monitoring audits, the TEAM LEADER shall take into consideration:

a) Monitoring audit: The date of execution of the visit shall be prior to the expiry date of the clearance. The advance against this deadline shall be such as allowing the conclusion of the monitoring process (including the sending of any corrective actions, and the validation of the practice by the Technical Manager; it is recommended to perform the audit at least a month before.
b) Organization shall be contacted to define the dates for carrying out the audits at least three months before the expiry date of the clearance.
c) any movements of the audits beyond the scheduled deadlines shall be requested and motivated in writing by the Organization at CETOC TS. The requests for movement will in any case be subject to all the limitations / conditions foreseen by the certification regulation.
d) For requests to move up to 6 months from the scheduled date (the theoretical date), the clearance will not be suspended while for longer durations; the validity of the certificate will be confirmed only after having

carried out a check that verifies the conformity of the management system, otherwise if not, the certificate shall be withdrawn.

Once the audit planning has been defined, TEAM LEADER shall send the audit notification to the organization through the related audit plan with details on the execution of the same and the composition of audit team at least a week before.

A copy of Audit plan shall also be saved in the customer's folder on the CETOC TS sharepoint by CoP Manager (ISO17021 Filing System/COP/COP Operation/Organization folder/year).

Before the start of the audit, the auditors shall make sure they have suitable personal protective equipment (PPE), (safety shoes, safety goggles and earplugs ...) according to Customer's risk assessment in order to carry out the activity in a safe way.

The TEAM LEADER assigns part of the activities to the other members of the audit team while maintaining responsibility for all parts of the audit. During the audit, he can modify the tasks assigned to achieve the audit objectives.

All information collected during the audit visit shall be reported correctly, accurately and clearly by CETOC TS auditors in the audit report.

If the audit group consists of several members, at the end of the audit activity, it meets. Each auditor exposes and motivates his assessment. It is the responsibility of the TEAM LEADER to summarize and decide the conclusions of the visit, recording them on the audit report, in which it expresses its opinion on the compliance of the management system.

Auditors shall not retain copies of corporate documents; the only exception is allowed in case of a dispute of a non-compliance detected by the organization. In this case, the documentation can be attached to the NC as evidence to support the survey.

A visit will usually involve:

- A brief opening meeting to clarify requirements and program details
- A tour of appropriate areas of the manufacturing site(s)
- Examination of the control plan (see 'Guide to Control Plans') and audit of the controls defined in that plan to ensure compliance to legislation
- Examination of how change control is handled
- Daily closing meetings to discuss and agree findings for that day
- Final closing meeting to review and agree all findings

A report of the visit is prepared and either left at the time of audit or sent within 15 days after the completion of the audit. Any non-conformances (NCs) will be identified during the audit and a summary of the NCs will be left during the closing meeting.

The closure time scales will be agreed at the end of the audit, and the auditor and technical team will be available to review your closure evidence and discuss suitability.

An audit can be stopped:

- for reasons of force majeure that prevent the correct execution of the audit and make direct observation and verification of ongoing operational activities impossible (production, service delivery);
- in the event of an irremediable conflict between the parties (customer Organization and audit team);
- if the auditor detects safety-related problems that cannot carry out the verification

In such cases, TEAM LEADER shall contact the Technical Manager to communicate these events, which shall then be recorded on the audit documentation.

An audit can be suspended:

- if there is temporary unavailability from one of the two parties (Company and auditor);
- should the need arise to manage conflicts between the parties (customer organization and audit team) that emerged during the audit.

Once these situations have been resolved, the verification shall resume, and the time of suspension shall then be recovered. The TEAM LEADER shall contact the Technical Manager to report these events.

If, during the audit, the results do not meet the required standard requirements, the auditor shall constantly keep the representative of the organization updated.

AUDIT TEAM shall send the audit report with any attachments to CoP Manager within 3 working days from the end of audit and CoP Manager shall upload audit report on Sharepoint in the job order folder at the folder path "ISO 17021 FILING SYSTEM/COP/COP Operation /ORGANIZATION/YEAR/AUDITOR NAME", naming it according to the following encoding: name of the customer organization, followed by the day / month / year of the first day of the audit execution date.

In addition, the TEAM LEADER will have to communicate if there are any findings for which a response from the company is expected.

Non-conformances affect

In the case of an initial Assessment audit, serious NCs would prevent the issue of the Approval applied for until they were closed with reference to the root cause and may require a follow-up visit to verify rectification. Similarly NCs on a monitoring visit would be referred to CETOC TS's Technical Manager, would need to be rectified within an agreed timescale and could lead to an immediate request to cease production..

Observations would require closure within an agreed time scale. Failure to close these with effective identification of the root cause, and good corrective and preventative actions would lead to withdrawal of COP and ultimately withdrawal of Type Approval.

Non- compliance effect of CoP Test

We would expect to see if there would be a record of corrective action taken for all problems found on company CoP checks. In the more serious cases, we would expect a thorough investigation into the cause, including further tests to demonstrate that the problem had been rectified - sales release being suspended until fully satisfied.

Where the problem is found on one of the tests required to be performed at an approved laboratory (eg. seat belts), we should be informed immediately and will discuss and agree necessary action.

Standard to be achieved

The Type Approval Regulations do not specify a particular standard for the quality assurance element. However, the requirements of the specific clauses contained in some of the UNECE Regulations and EU Regulations must be met and general quality arrangements must be adequate. The principles of Conformity of Production control requirements that we apply are also set out in Annex VI of EU Regulation 2018/858, and in the case of ECE Regulations, Appendix 2 of E/ECE/324-E/ECE/TRANS/505/Rev.2

Small Business expectations

A small business will not be able to operate controls such as those in large global operations, and the CoP auditors will discuss each situation according to the circumstances. Nevertheless, the responsibility for quality must be clearly defined and appropriate systems seen operating.

Further advice

If you have any other questions in relation to Conformity of Production, our CoP Technical Manager is always prepared to discuss them with you. Please do not hesitate to contact CETOC TS to explain your requirements.